## UNITED STATES DISTRICT COURT DISTRICT OF SOUTH CAROLINA

THE UNITED STATES OF AMERICA, ET AL.

\* versus Case No. 9:14-cv-230

BLUEWAVE HEALTHCARE

January 23, 2018 CONSULTANTS, INC., ET AL.

\* \* \* \* \* \* \* \* \* \* \* \* \* \* \* \*

REPORTER'S OFFICIAL TRANSCRIPT OF THE JURY TRIAL - DAY SIX HELD BEFORE THE HONORABLE RICHARD M. GERGEL UNITED STATES DISTRICT JUDGE January 23, 2018

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(Call to order of the Court.) 1 9:04AM 2 THE COURT: Good morning. Please be seated. 9:04AM 3 From the government, any matters you need Okay. 9:04AM 4 to address with me? 9:04AM 5 MS. SHORT: Yes, Your Honor. We do plan to play two 9:04AM videos this morning. 6 9:04AM 7 THE COURT: Uh-huh. 9:04AM One is of defendant Johnson. We've, 8 MS. SHORT: 9:04AM 9 overnight, cut way back on both videos. So Mr. Johnson's video 9:04AM 10 is now 13 minutes long -- oh, I'm sorry -- 23 minutes long. Ι 9:04AM 11 can't read my own handwriting -- 23 minutes long. 9:04AM There are three U.S. trial exhibits that are 12 9:04AM 13 coming in through this video deposition clip. 9:04AM understanding that they are not opposed. 14 9:05AM 15 What are they? THE COURT: 9:05AM They are U.S. Trial Exhibit 1295, 1612, 16 MS. SHORT: 9:05AM 17 and 1001. 9:05AM 18 Is there -- the government's offered THE COURT: 9:05AM 19 1295, 1612, and 1001. 9:05AM 20 Any opposition from the defense? 9:05AM 21 MR. COOKE: No objection to those. 9:05AM 22 MR. ASHMORE: Over here, Your Honor. No objection. 9:05AM 23 Very good. Plaintiffs' Exhibits 1295, THE COURT: 9:05AM 24 1612, 1001 are admitted without objection. 9:05AM 25 Yes? 9:05AM

In terms --

MS. SHORT: And then the video deposition of 1 9:05AM defendant Dent we have condensed down to a 13-minute clip. 2 9:05AM there's just one trial exhibit that is being introduced through 3 9:05AM 4 this video clip. It's U.S. Trial Exhibit 1540. 9:05AM 5 Is there any objection to Plaintiffs' THE COURT: 9:05AM Exhibit 1540? 6 9:05AM 7 MR. COOKE: No objection. 9:05AM No, sir. 8 MR. ASHMORE: 9:06AM Plaintiffs' Exhibit 1540 is admitted 9 THE COURT: 9:06AM without objection. 10 9:06AM 11 Yes, ma'am. Anything else? 9:06AM 12 That is all. MS. SHORT: 9:06AM 13 Defense counsel, anything you need to THE COURT: 9:06AM address with me? 14 9:06AM 15 MR. COOKE: Nothing, Your Honor. 9:06AM 16 MR. ASHMORE: No. sir. 9:06AM 17 THE COURT: Y'all, let me just say this: 9:06AM 18 obviously after this, I take it the government will rest; is 9:06AM that correct? 19 9:06AM 20 MR. LEVENTIS: Yes, Your Honor. 9:06AM 21 **THE COURT:** I'd -- I suggested this before. 9:06AM 22 know, obviously, I have addressed exhaustively legal issues in 9:06AM 23 The only other case I have addressed as this case. 9:06AM 24 exhaustively would be my 5,000-case MDL and the Roof case. 9:06AM 25 Okay? This is where it ranks at. 9:06AM

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9:07AM

I am very familiar with this. I'm thinking almost 200 pages of notes. I'm very familiar with the facts and the law here. I do not require exhaustive argument.

If there's something, you know -- obviously, I want you to protect your record, listing out your issues. And if there's something in particular you feel like that you think is really important, if I have questions, I'll ask you.

But, you know, I've tried to tell you, I've listened to this case. And the bar at the directed verdict stage is pretty low. We all know that.

So -- and, you know, unless something changes in these two depositions, I will just forecast for you is that the -- it is unlikely to be a successful motion, but I don't want to tie the Court up unnecessarily.

I've heard your arguments on these legal issues.

I'm fully aware of them. I want you to protect your record on appeal, but I don't want to spend a lot of time on it because I don't think it would be particularly useful to the Court.

Let's bring in the jury.

MR. COOKE: So we shouldn't have sent all our witnesses home?

THE COURT: That's exactly right. That was a mistake.

MS. SHORT: Your Honor, if I may, these are the exhibits that were just admitted.

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THE COURT: Thank you. Give them to Miss Eunice.

THE DEPUTY CLERK: Thank you so much.

THE COURT: Remember, at the end of each day, you need to check in with Ms. Ravenel.

THE DEPUTY CLERK: They've been doing that, Judge.

THE COURT: Good.

(Whereupon the jury entered the courtroom.)

THE COURT: Please be seated. Good morning.

JURY: Good morning.

THE COURT: We're going to -- the next witnesses will be again offered by deposition. And I will remind you that it's just as if these individuals were sitting on the witness stand.

The government may proceed.

(Starting video.)

THE VIDEOGRAPHER: We are now on the record. Today's date is May the 30th, 2017. The time is approximately 9:38 a.m. This is the video deposition of Brad Johnson taken by counsel for the plaintiff. The location is 288 Meeting Street, Suite 200, Charleston, South Carolina.

My name is Christopher Mills, legal videographer, representing A. Williams Roberts, Jr. & Associates.

This deposition is taken in the matter of United States of America, et al., versus Berkeley HeartLab, Inc., et

9:10AM	1	al., Case Number 9:14-cv-00230-RMG.
9:10AM	2	DIRECT EXAMINATION
9:10AM	3	OF MR. JOHNSON:
9:10AM	4	Q. Good morning, Mr. Johnson.
9:10AM	5	Will you please state your name for the record?
9:10AM	6	A. My name is Robert Bradford Johnson. I go by Brad Johnson,
9:10AM	7	and sometimes business cards state R. Brad Johnson.
9:10AM	8	Q. Thank you, Mr. Johnson.
9:10AM	9	Now, there is an additional party today in the room
9:10AM	10	besides yourself.
9:10AM	11	Is Mr. Dent here as well?
9:10AM	12	A. Yes, ma'am. Mr. Calhoun Dent, III, is in the corner.
9:10AM	13	Q. When did you start with Berkeley HeartLab?
9:10AM	14	A. 2002, I believe.
9:11AM	15	Q. When you were at Berkeley HeartLab, did you receive any
9:11AM	16	training on the how to present to doctors and what kind of
9:11AM	17	gifts and other remuneration you could give to doctors?
9:11AM	18	A. Yeah. You couldn't give anything.
9:11AM	19	Q. Did you receive any training on the Anti-Kickback Statute?
9:11AM	20	A. We did.
9:11AM	21	Q. And what about the False Claims Act?
9:11AM	22	A. We did.
9:11AM	23	Q. Well, when did you first meet Tonya Mallory? Is that
9:11AM	24	better?
9:11AM	25	A. August or October or September 2009, I believe. Somewhere

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in there.

- **Q.** Had you had any communications with her before that point?
- A. No, ma'am.
- **Q.** Did you understand that Ms. Mallory had previously worked at Berkeley HeartLab?
- A. I learned that after I met her, yes.
- **Q.** So how did you first learn about Tonya Mallory's laboratory?
- **A.** As I said, we had a meeting sometime in '09. First time --
- **Q.** How did that meeting come to be?
- A. Casey Boyd had reached out to Cal. As I said, Cal reached out to me. And he said, What do you think? You want to meet with them?

And I said, "Why not? Let's try them. Let's see what they got."

- Q. What did Ms. Mallory and Mr. Warnick want from you?
- A. Well, they actually at first wanted us as employees. And we had mentioned to them "Would you come to be interested?"

And we said due to the fact what we'd experienced at Berkeley, we said we didn't want that. Berkeley was -- had notoriously -- basically, every time they could stick us, they stuck us.

So we was like we don't -- no offense to them about it. We said we just didn't want to go that route again. And

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They did.

Α.

so -- and they said, "Well, what would you want?" And we said, "We want these sales in these states." So ultimately did it come to pass that every HDL test that Q. was not sold in the states of Virginia or Maryland -- and ultimately it sounds like Maryland became a BlueWave territory? It did. Ultimately, were all the tests sold outside of the state Q. of Virginia sold by BlueWave? Α. We started taking over more states. would having independent contractors reduce any other of BlueWave's liabilities beyond just its tax liabilities? Yes, it does. It would actually reduce our -- if an individual decided to go out and do something unethical, then it would reduce our liability there as well. So is it true that you insisted that the 18 to \$21 appear Q. in the contract? I would say it was all of us insisted on it. No. Α. Did Ms. Mallory insist upon it? Q. Okay. We all insisted upon it. We wanted everything in writing so there would be no situations going where, well, we thought she was in charge of the electronic medical records. We wanted everything put down so everybody knew their job responsibilities and the duties in the contract. Did HDL perform on Section 3(b) of the contract? Q.

Clause 3(e) of the contract, it says, "Provide zero 1 0. 9:14AM 2 balance billing." 9:14AM What does that mean? 3 9:14AM 4 Α. Zero balance billing, again, is a statement made that we 9:14AM 5 will take whatever insurance pays and write off the difference 9:14AM in that situation. 6 9:14AM 7 Did anyone else sell with you? Q. 9:14AM 8 Α. Yes. 9:14AM 9 Who? 0. 9:14AM 10 Actually RB Lively Consulting and Medgroup out of Atlanta. 9:14AM Now, how did the relationship work between RB Lively 11 0. 9:14AM Consulting and Medgroup out of Atlanta? 12 9:14AM 13 Burt Lively was RB Lively -- or RB Lively Consulting, and 9:14AM 14 Richard Yunger was Medgroup. We were just, all three, sales 9:14AM 15 representatives. 9:15AM And how did you divvy up the territory? 16 Q. 9:15AM 17 We didn't. Α. 9:15AM So, for instance, if a sale was made in Mississippi by 18 Q. 9:15AM 19 Mr. Yunger, how would the commission be split? 9:15AM 20 we took our overall and did a 2, 2, and 2. 9:15AM So according to this contract, it says, "Compensation. 21 Q. 9:15AM 22 The contractor should be paid a commission equal to 2 percent 9:15AM of collected revenue." 23 9:15AM 24 Uh-huh. Α. 9:15AM 25 And that was collected -- HDL's collected revenue or Q. 9:15AM

- BlueWave's collected revenue? 1 9:15AM
  - That was HDL -- that was HDL's collected revenue in those Α. assigned territories. That was paid to BlueWave.
  - Q. All right. And so each other company, RB Lively and Medgroup, also had a similar contract with BlueWave?
  - Yes. Α.
  - All right. For a cumulative of 6 percent of these Q. respective territories, Mississippi, Georgia, Tennessee, and Florida, parts of them?
  - Α. Yes.
  - All right. Now, did y'all -- is it true that Mr. Lively Ο. and Mr. Yunger also operated in Alabama?
  - Yes, they -- their contracts would be the same states. Α.
  - How much did Royal Blue earn in commissions on behalf Q. of -- for sales of HDL and Singulex tests?
  - I do not recall. Α.
  - Okay. Would \$5.9 million be consistent with your 0. recollection?
  - Again, I would not even have a clue.
  - Why? Q.
  - It's not something I look at on a daily basis. Α.
  - You don't remember making \$6 million? Ο.
  - No, ma'am. Α.
  - Q. So, Mr. Johnson, was HDL successful?
  - That's a double-edged sword to the question. Α.

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How do you define a successful company?

- Did it grow financially? Q.
- It did grow financially. Α.
- And how would you describe its growth within the first Q. four to five years?
- Well, at the end of five years, it was gone. But, I mean, first --
- Well, cut it off at 4.5 then. How about that? 0.
- I mean, I would say actually after five years is when it bit it. It was hypergrowth. Business was growing extremely fast. It was a lot of moving parts, a lot of employees, a lot of jumping through hoops. And it was beyond successful of what I think anybody imagined.

I know somebody had asked me did I ever think it was going to be this big. Actually, my accountant did. And I told her three years ago, I said, no, I had no clue we would -- I had no clue the business would be this way.

- How did it compare growthwise? Q.
- If you take -- growthwise, actually, Takada the first year did a billion-plus, 1.3 billion. So I have to say it grew fast.
- Okay. 0.
- If you take Berkeley, the first year growthwise that I was at Berkeley, I felt like it grew rapid hypergrowth too, we did. we started adding so many employees. I think the first year,

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there was about 100 and something employees almost added. it was just --

So if we were to look at, for instance, Berkeley's claims for Medicare during its beginning years and compare them to HDL's claims during the first few years, how would you -- what do you believe that would show about their respective business sizes?

I would think they would be probably 100 percent Α. identical.

Okay. Q.

I think the industry is pretty much standard. You got any average physician office practice. So what -- what you've seen from all the companies is about 30 percent Medicare in this business market.

So all of the monies earned by BlueWave were remitted Q. pursuant to the contracts with HDL and Singulex?

I would -- I would say that that's probably an accurate Α. statement.

All right. And so how much money did HDL pay BlueWave 0. pursuant to the contract that you entered into with HDL?

I do not know off the top of my head.

Well, if bank records show that HDL paid BlueWave 0. \$220.3 million between 2010 and 2014, is there any reason that you think that that is an inaccurate number?

If the bank statements show that those checks were sent to

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BlueWave for those amounts, that makes sense.

- **Q.** And is that consistent with how much money you made -- you remember Bluewave making from HDL?
- A. Again, I don't remember how much was done there.
- **Q.** Do you recall earning approximately \$24.6 million from Singulex?
- A. No, I do not recall the specific number.
- Q. Okay. But if Bluewave's bank records show that \$24.6 million came into Bluewave's account between 2010 and 2015, would that be pursuant to the contract you entered into with Singulex?
- A. Yes.
- **Q.** What did BlueWave do with the \$244.6 million that it earned?
- A. Well, what did BlueWave do with the money it earned?

  Obviously, it paid our contractors. So paid massive numbers in attorney fees, stuff like that, and distributed K-1s.
- Q. All right. And so did you earn K-1s from BlueWave?
- A. Yes, I did.
- Q. And did you earn approximately \$53.2 million?
- A. Again, I would not know the specific number.
- Q. Why don't you know the specific number?
- A. You don't realize this. I've got a lot of different businesses, a lot of different companies. And you're talking about -- what are we in? 2017 now?

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- Q. So do you have any other business that earns you \$50 million?
- A. No, I do not.
- **Q.** Do you have any other business that earns you anywhere close to \$50 million?
- A. No, I do not. But why would I sit here and know the exact number that I got paid?
- Q. Well, I'm asking because it's \$53.2 million, Mr. Johnson.

  Is it fair to say that every dollar that left

BlueWave flowed out to expenses in terms of sales representatives only, legal fees, or distributions?

- A. Expenses, sales, contractors, K-1s. I would think that's probably close.
- Q. Did you reinvest a penny back into BlueWave?
- A. I don't think we reinvested a lot back into Bluewave. We had money in the account, though.
- Q. What kind of doctors did you target, Mr. Johnson?
- A. Target?
- Q. Yes.
- **A.** Family practice, internal medicine, endocrinologists, some cardiologists.
- Q. Did you have any criteria that you used?
- A. I did use some targeting criteria.
- Q. What were those criteria?
- A. Let's see here. Let me think about it for a second. It's

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been three years.

Small groups of physicians, number 1. Number 2 would be you have to draw your own blood. That would be a -- very much of an asset. You would have to be an early adopter, a very smart physician, cutting-edge physicians, small groups. I think I said that one.

- **Q.** Anything else?
- A. Let me think. I'm trying to think. Access to those physicians as well. And I think I said on one of my target criteria is money hungry.
- **Q.** So just to be clear, what is your relationship with Mr. Lively?
- A. Best friends since college. Met him my sophomore year, his freshman year. So that's -- I don't know how many years that is.
- Q. And what is your relationship with Mr. Yunger?
- A. Same thing. He has been one of my best friends forever. Met him the first day at Merck Pharmaceuticals. And he's actually Burt's brother-in-law, correct. And we've worked together for years.

Berkeley actually brought Burt and Richard on while I was at Berkeley to keep me from leaving Berkeley.

- **Q.** Did you review this document prior to your testimony here today?
- A. I glanced at it, but I don't think I reviewed it. No,

ma'am. 1 9:23AM

- 2 So at this point, this email -- what is the date of this Q. 9:23AM email? 3
  - Α. September the 23rd, 2010.
  - Okay. At this point, are you selling for BlueWave? 0.
  - Α. I am.
  - Are you still selling for H -- for Berkeley? Q.
  - No, ma'am, I'm not. Α.
  - Okay. And it indicates here that Mr. Lively states that 0. you asked to provide this lipid clinic pro forma to
  - lmallory@kcim.com?
  - Uh-huh. Α.
  - Who is Ms. Lori Mallory? Q.
  - Α. It says the CEO of Kansas City Internal Medicine at the top.
  - Do you recollect talking or meeting with Ms. Mallory? Q.
  - That's 2010. No, ma'am. Α.
  - Do you recollect asking Mr. Lively to do this pro forma? Q.
  - Α. I do not.
  - What did you talk to Mr. Lively about with regard to this 0. email?
  - I asked him, "Can you refresh my memory about this? Α. happened?" Stuff like this.
  - Q. Okay. And what --
  - His statement was -- he said, "Hey, you call me," because Α.

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the officer manager there wanted to know why people were doing 1 9:24AM 2 lipid clinics across the country and you said, "Hey, listen, 9:24AM put in these numbers for her again and let her look at it." 3 9:24AM 4 And that's it, so -- period. 9:24AM All right. At the end it says -- well, we can go through 5 9:24AM It says, "Your processing and handling fees based upon 200 6 9:24AM 7 specimens per week would be \$4,000." 9:24AM 8 Do you see that? 9:24AM 9 Yes. Α. 9:24AM 10 All right. "And that's a conservative estimate, 200 9:24AM 11 lipids per week." 9:24AM 12 Do you see that? 9:24AM 13 I do. Α. 9:24AM 14 Now, I understand that to be based upon a \$20 processing Q. 9:24AM 15 and handling fee, 20 times 200. 9:25AM Yes, I think that's --16 Α. 9:25AM 17 Because that's the processing and handling fee that HDL 0. 9:25AM offered? 18 9:25AM 19 Α. I'm sure, 17 plus 3. 9:25AM 20 Okay. And not the processing and handling that Berkeley 9:25AM 21 offered? 9:25AM 22 Α. Correct. 9:25AM And then it says, "I have based my estimations on a 23 9:25AM 0. 24 Level 3 follow-up visit from the 2010 Medicare fee schedule." 9:25AM 25 Okay. Α. 9:25AM

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- **Q.** Is that what you mentioned previously in your testimony?
- A. I mentioned that there was Level 3 and Level 4 follow-up visits, yes.
- **Q.** Right. So that a physician could earn money off of having a follow-up office visit?
- A. Yeah. More information equals more follow-ups or equals more things wrong with a patient, correct.
- **Q.** So at that -- "after that point, you should have a steady stream of follow-up visits which should equal your weekly volume."

Do you see that statement?

- A. I do.
- Q. All right. The weekly follow-up total would be \$12,200?
- A. Uh-huh.
- **Q.** Well, what is that \$12,200?
- A. I'm not sure I'm following.
- **Q.** Well, how much is a Level 3 office visit reimbursed for by Medicare?
- A. I have no idea.
- Q. It's approximately \$61?
- A. I have no idea. That's why I'm asking you.
- **Q.** Well, that's what's plugged into this table on the next page which I will represent to you is the attachment.
- A. Okay.
- Q. Did Mr. Lively indicate to you that you had given him

these numbers? 1 9:26AM

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- 2 That I had given him these numbers? Α.
  - Q. Yes.
  - Α. I think the only numbers that I gave Mr. Lively -- as I said, they said they would do this many lipids. There's 25 physicians in it. That's all I gave him.
  - So you did not instruct him about what the office-level Q. visits were?
  - No, ma'am, I did not.
  - So as a result, if a physician had 200 lipids per week, he would make -- he or she could make \$4,000 for processing and handling and then could make \$12,200 off of follow-up office visits for what looks like a total of \$16,200?
  - Α. Is that on a weekly basis or what?
  - well, it looks to me that, if they run this lipid clinic Q. for 48 of 52 weeks, a gross income of \$777,600.
  - Okay. Α.
  - Q. So --
  - Α. Okay.
  - And there's a net revenue indicated to the practice of \$547,600?
  - Uh-huh. I see that. Α.
  - would this be an example of a sales rep using -- selling Q. HDL using P&H as a sales tool?
  - No, ma'am, I do not believe so. It's got the numbers in Α.

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there, but it does not show anything about the net. 9:27AM 1 2 the same time, when you start figuring it up, you're going to 9:27AM

need seven phlebotomists.

- Q. So I'm going to hand you what I'll have marked as Government's Exhibit Number 8. This document, I will represent to you, was handed to me by your lawyer this morning, and so it doesn't have a Bates number on it, Mr. Johnson.
- Yes, ma'am. Α.
- If you could just describe for the record what the cover sheet of this document looks like, just to make sure that we have a record about what the document looks like.
- Okay. Α.
- In the upper left-hand corner, whose name is that? Q.
- Brad Banias. Α.
- And who is that? Q.
- That's an attorney here at the office, I think. Α.
- Okay. And there's an email address "from" at the top. Q.
- Brett King. Α.
- 0. And who is Brett King?
- He's a local attorney we use on -- or I use on some things.
- Why did Brett King hire Maynard Cooper? 0.
- I asked Brett would he take a look at our copy of our Α. legal test that we've been giving.
- Why did you ask Brett to do that? Q.

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- I thought it would be a good thing to look at and get an Α. opinion.
- Whose legal opinion test? Q.
- Α. It was the one that we created at BlueWave.
- What was the impetus for asking Mr. King about it? 0.
- I just asked him could he give us an opinion off of it. Does it look good? Everything fine with it?
- What experience does Mr. King have that would be germane 0. to this legal compliance test?
- It doesn't. I asked him. He ended up forwarding it to Α. someone, I guess, to look at it.
- why did he forward it to somebody else to look at when 0. you --
- Α. Because I asked him to tell us was our legal test okay.
- From Ms. DeMoss to you -- to Brett King, cc Edward Sledge, Q. one page was marked 5. "Please find attached the compliance questionnaire and the 11th Circuit opinion in the Medfusion case. Once you have had a chance to review, I'm happy to discuss."
- Uh-huh.
- Did Mr. King provide you with the compliance questionnaire in the 11th Circuit opinion in the Medfusion case?
- Yes, he sent me the compliance conference test and their Α. answers, and he sent the Medfusion stuff. I think I knew something about the Medfusion people.

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- **Q.** Let's look at the compliance test. Did you review the answers provided by Ms. DeMoss?
- A. Yes, ma'am, I looked at them.
- **Q.** How did you get them?
- A. Via email, should be.
- Q. I'm going to turn to Question 17. "How much is the P&H fee? Can you pay any amount?"

"Medicare" -- I'm going to turn to the second paragraph. "Medicare generally considers the expenses of handling of specimens to be in its calculation of the bundled payment. Many private payers take the same approach. When a physician accepts a handling fee from a lab, this may not only be a double payment, but the government may view the fee as intended to induce the physician to refer to the laboratory."

- A. Okay. What's your question?
- Q. When you read this statement, did you have concerns about HDL's payment of processing and handling fees?
- A. No, I did not, because we already had an opinion from a 600-man firmed called LeClairRyan by Michael Ruggio which was done by Exponent, which is a \$1.2 billion company, which is one of the largest health care companies in the entire world. And I had already seen Greg Root's legal opinion out there.

And I also knew -- now I knew Atherotech had a legal opinion and had read their time and motion study and showed fair market value. I knew Singulex had a fair market value

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study as well done from late -- as a lawyer as well. So no.

- Q. Did you show this opinion from Ms. DeMoss to Mr. Ruggio?
- A. No, I don't know Mr. Ruggio personally.
- **Q.** Did you show this opinion to Mr. Root?
- A. No. I did not talk to Mr. Root.
- **Q.** Did you talk -- did you ask anyone after you got this opinion from Ms. DeMoss about whether or not your continued payment of processing and handling fees was legal?
- A. No, I did not, because we already had legal opinions saying it was legal, and it was below fair market value, period.
- Q. So was Ms. DeMoss the only person who ever indicated that this payment might be illegal or unlawful?
- A. No. We saw other physicians who said, "Hey, we want to know more about it." But, again, in that situation where a physician would ask us about it, we either gave Tonya's legal opinion or we gave the actual studies if we needed to do it in that same situation. Or at the same time, when I was at Berkeley, we used the Greg Root legal opinion letter or we referred them to HDL, which either Tonya took care of the phone call or LeClairRyan took care of the phone call or Tonya utilized in-house counsel to take care of the phone call.
- Q. Did you share this information from Ms. DeMoss about the legal compliance answers with Mr. Dent?
- A. I believe Cal and I looked at this together.

9:32AM	1	Q. And why do you believe that to be the case?
9:32AM	2	A. We typically shared everything together.
9:32AM	3	(Video ends.)
9:32AM	4	MS. SHORT: Your Honor, that's the end of this video.
9:32AM	5	THE COURT: Very good.
9:32AM	6	MS. SHORT: And at this time, by stipulation of the
9:32AM	7	parties, the United States presents the testimony of defendant
9:32AM	8	Cal Dent.
9:33AM	9	(Video played.)
9:33AM	10	DIRECT EXAMINATION
9:33AM	11	OF FLOYD CALHOUN DENT, III:
9:33AM	12	Q. Could you please state your name for the record.
9:33AM	13	A. Floyd Calhoun Dent, III.
9:33AM	14	Q. Mr. Dent, do you go by any nicknames?
9:33AM	15	What do you recollect about the Anti-Kickback Statute
9:33AM	16	training?
9:33AM	17	A. Specific training at Pfizer?
9:33AM	18	Q. Yes.
9:33AM	19	A. I thought I answered the question. Let me we're going
9:33AM	20	way back in time.
9:33AM	21	Q. Well, what did you understand after your time at Pfizer
9:33AM	22	about what you could and couldn't do under the Anti-Kickback
9:33AM	23	Statute? What did it mean?
9:33AM	24	A. You're forcing me to give you Anti-Kickback Statute. In a
9:34AM	25	nutshell, you can't go pay and bribe physicians to prescribe

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your product.

- **Q.** Why not?
- A. Could you be more specific in your question?
- Q. Well, what's the reason?
- A. Well, it's inappropriate activity. I mean, I can't go buy business from a physician. There were a lot of abuses in the pharmaceutical industry prior to me coming into that industry. You would run into physicians that would tell you, "I'll write your product if you send me on a hunting or a fishing trip," or "I'll prescribe your medicine if you send my wife and family on a cruise."

And Pfizer was probably the most conservative company in that arena -- along with Merck, which is where Brad worked -- to make sure that everybody was extremely compliant and not breaking any rules. You know, they had very strict guidelines on how much money could be spent per head on individuals at dinner. You know, those things would change, but those were internal policies over time.

I think a lot of the conservativeness that Brad and I instituted in our business was due to the background that we had with our previous pharmaceutical employers.

- **Q.** And, ultimately, what transpired with your book of business?
- A. Well, January 4, 2010, we had -- were putting the final polishes on a sales contract agreement, but timing was of the

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essence. You know, we were going into this new business venture. We were now independent contractors and had our own company. And we went out with an absolute vengeance to get as much business as we absolutely could as quickly as we could to establish our business.

And, frankly, it was very easy picking. And the reason it was easy picking was because the customers had had such bad experiences not only with Berkeley but with LipoScience in the past, with VAP in the past, changing billing programs, sending out retail bills, et cetera. Their faith was in their rep.

So we got shut down in 30 days. You know, I don't -that doesn't seem to get highlighted in a lot of these
discussions, but the business that we brought to HDL came in
the first 30 days from five people working from before sunrise
to well after sunset every single day. And it was a very
well-executed attack. I'll use a military term.

You know, we knew our customers. We had relationships with our customers. And we went out to give them a better product and better service and a better company, and certainly to help our company grow and HDL grow.

- Q. Now, Mr. Dent, just so we have a clear record about what this document is, because there's no Bates number on it, can you describe what's in the upper left-hand corner on page 1.
- A. It is an email from Brett King dated Friday, May the 26th

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of 2017, at 11:40 a.m., to Brad Banias, Banias. I always mispronounce his name. I apologize. He's not in the room, but he's our attorney. And it says "Subject: Forward Brett/BlueWave."

- **Q.** At any point in time, were you aware that Mr. Johnson had sought review of your compliance review test from BlueWave by any outside counsel?
- A. I am aware that Brad had forwarded our compliance test to Brett King.
- **Q.** For what purpose?
- A. The timeline on this is in 2013. And it was kind of in the midst again of this investigation and people asking a lot of questions about P&H. And I remember him calling me and telling me, "Hey, I called Brett about it too, and I thought it would just be a good idea to have another attorney look at our compliance test, see if they had any concerns about it, and kind of consult with us on that." And I said I think that's a great idea.
- **Q.** So what happened?
- A. I remember receiving a phone call sometime thereafter, and Brad had received answers from an attorney who I didn't know. I didn't know what law firm they came from. But, apparently, Brett had forwarded that on to somebody that was more knowledgeable of health care law than himself. And he kind of read through the questions with me and went over the answers

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and we talked about it, and that was kind of it.

- Do you recollect any concerns on the part of the 0. health care attorney related to Bluewave's business model?
- I'd have to read through it, you know, and look and see if there's any specific concerns about it. But I don't recall there being anything that was contrary to stuff that, you know, we were hearing at the time and the chatter at the time of what was going on about concerns with processing and handling fees. I mean, it's in the --
- what did they say about processing and handling?
- Which one? Number 9? Number 9 is what you asked me. says, "Can you emphasize in your presentations how much the physician will make? Presentations should not emphasize how much a physician will make as it relates to the provision of lab services and tests sent to the lab. The government would likely view such a presentation as intending to induce referrals and would use the presentation as evidence of intent."
- Did you -- upon receipt of this advice from the lawyer, 0. did you do anything?
- Ma'am, I don't think it's advice. I think somebody is reviewing a test because we have asked them to look at the test and respond without any input what their thoughts are on these.

I don't disagree with that answer, especially this This is at the end of 2013, when there is newspaper time.

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articles in The Wall Street Journal, there's stuff in The New York Times, there's stuff in Forbes, there's stuff in the National Lipid Association questioning a practice that has been undergoing for decades, decades. So these are questions pertaining to that, and people have new information that is resulting in their answer.

"Question: How much is the P&H fee? How can you -can you pay any amount?"

well, are we talking about Singulex? Are we talking about HDL? What are -- what are the amounts?

- I'm going to direct your attention to the lawyer's 0. advice --
- Α. Okay.
- Q. -- on the second paragraph.
- The lawyer's answer. "The P&H fee is intended to Α. represent a fair market value fee to compensate the physician" --

First of all, I would disagree with her there. It's not to compensate the physician; it's to compensate the business entity that employs the individuals that perform the blood. That might be a lab. That might be the physician So I say she's wrong. I would mark that part of her practice. answer wrong.

-- "for handling and processing the laboratory specimens collected at a physician's office that are sent to

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the lab. Medicare generally considers the expenses of handling of specimens to be in its calculation of the bundled payment."

I don't even know what she's talking about with a bundled payment. We've heard --

- Q. Did you ask her?
- A. I haven't spoken with her. I don't know who she is.
- Q. Okay. Keep reading.
- A. Okay.

"Many private payers take the same approach. When a physician accepts a handling fee from a lab, this may not only be a double payment" -- I agree. If you overlap and double-pay for a draw fee, that's a double payment. That would be absolutely inappropriate.

-- "but the government may view the fees as intended to induce the physician to refer to the laboratory."

That's exactly what the government is doing at this time, coming back, looking at a practice that's been going on for decades and now say saying, "Aha. We believe processing and handling fees are used to induce physicians."

- Q. So in 2013, November of 2013, or -- is that -- yeah, November 13th, 2013, BlueWave received advice from a health care attorney, according to your testimony here today, that the government may view the fee as a kickback?
- A. Can I comment on how ironic that is?

  Because in one instance you tell me I've hired an

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attorney, I paid them money to review a contract from A to Z, but I can't rely on them to tell me that everything in there is legal. I have to have them append something on a particular paragraph and sentence.

But, here, you're taking a test that we're seeking more clarification from other people, that I have to rely on this as a legal opinion and that her single opinion is the only opinion? We are talking about many law firms to this point.

Q. Okay. And it says, "CYP2C19 script for all of Dr. Martin's existing patients." I'm going to flip over to the back page and show you the attachment, which appears to be a prescription.

"To HDL, add CYP2C19 to my assessment panel and retroactively run CYP2C19 on" -- I can't -- "whole specimens" maybe?

- A. It says "in-house specimens."
- Q. "In-house specimens dated 7/8/2010."

In your experience, is this what other physicians would do to order this CYP2C19 test on stored blood?

- A. I think I've testified multiple times that writing a prescription was a very formal way for a physician to communicate what they wanted the laboratory to do.
- **Q.** Did you ask for other physicians to similarly write such scripts for your physician clients, and did you see such prescriptions written?

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- A. I have seen many prescriptions --
- **Q.** For the CYP2C19 test?
- A. I have seen many prescriptions for CYP2C19 tests where physicians are communicating their desires for the laboratory to run tests on certain patients.
- Q. This doesn't appear to pertain to a particular patient,
  Mr. Dent.
- A. Ma'am, this is another way. It's actually a more formal way than a new account form, because if I took a new account form that a physician had already signed, you could possibly just add verbiage to it and make changes. So by having a completely stand-alone piece of paper -- most physicians guard their prescription pads pretty closely because they fear staff in particular filling out prescriptions for pain medication.
- Q. Mr. Dent, I need to stop you. Because we just need to get through this, I please need to ask to answer my question today.
- A. I'm trying to answer your question, ma'am.
- **Q.** Did you see other physicians similarly write such prescriptions for the CYP2C19 test that did not refer to specific patients?
- A. I already told you, I saw many prescriptions that physicians had written requesting CYP2C19 for in-house specimens. And he's also asking, "Would you please add this test to my assessment panel?" He's asking for two things.
- Q. Okay. All right. So you saw other documents like this?

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- A. Absolutely.
  Q. Okay. Whose writing?
  A. Mine. I wrote this. I met with Dr. Martin. And he said, "I would like for you to add CYP2C19 to my assessment panel and run it on the in-house specimens." I wrote that and handed his prescription back to him and said, "You sign it." And he signed it. That's my handwriting.
  Q. So I just want to be clear. You wrote -- which part of this did you write?
  A. This "to HDL" is not my handwriting. That date is not my handwriting. This verbiage "add CYP2C19 to my assessment panel
- A. This "to HDL" is not my handwriting. That date is not my handwriting. This verbiage "add CYP2C19 to my assessment panel and retroactively run CYP2C19 on the in-house specimens," that's my handwriting, just like I would have written on a new account form or addendum when I fill it out, "Hey, Doc, what custom panels do you want?" And then I would give that to them to sign. And then they would sign, and they'd hand it back to me and I'd fax it in.
- **Q.** Did you similarly write on other prescription pads for other physicians and then have them sign it?
- A. I would not deny that I would write that. I'm not asking for medication or anything like that. And they're signing it, not me. They have nurses write stuff on prescription pads they sign all the time.

(Video ends.)

MR. LEVENTIS: Your Honor, that concludes the video.

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And, Your Honor, the United States rests its case in chief.

THE COURT: Very good.

Ladies and gentlemen, we're going to -- I'm going to send you back to the jury room. I need to take some matters up outside your presence.

(Whereupon the jury was excused from the courtroom.)

THE COURT: Please be seated.

Government is resting. Any motions from the defendants?

MR. ASHMORE: Your Honor, can we take this down?

THE COURT: Please. I think that would be helpful.

MR. ASHMORE: I would offer to help --

THE COURT: Thank you.

Mr. Cooke?

MR. COOKE: Thank you, Your Honor. The defendants, BlueWave and Dent and Johnson, would move for directed verdict as to all claims. And heeding the Court's prelude this morning, we would incorporate by reference our motions for summary judgment and all the arguments that we've made up to this point.

But I would, with the Court's indulgence, like to address a few things that I think are -- have come up because of the actual case that the government has put on.

THE COURT: Very good.

MR. COOKE: And I'll begin with the government -- you

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remember there were motions in limine about the expert witnesses who were going to testify as to fair market value, and the government has not put up any evidence as to -- to demonstrate that the process and handling fees that were paid were not commercially reasonable or a fair market value.

So what that means is that they cannot be taking the position that process and handling fees are all per se violations of the Anti-Kickback Statute because the linchpin of Anti-Kickback Statute is the intent. Was it intended to induce referrals?

So --

THE COURT: Which, by the way, I think everybody has kind of gotten off the beam here a little bit. The AKS is an intent to induce.

MR. COOKE: Right.

THE COURT: And the -- the government may take, in its own prosecutorial view, that certain act -- conduct might infer or suggest or raise questions about or a flag about certain practices, but the gravamen of the claim must be it is done to induce a referral. That is the bottom line. I intend to make that clear in my charge to the jury.

And so a lot of this talk about -- you know, about -- and I've heard it from the defense about, well, you didn't tell us exactly it was wrong. It doesn't lend itself.

That's not the nature of the statute. It is because it goes to

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the defendants' intent.

And so the question is, is there evidence, in my view, to support a claim of an FCA and AKS -- most of the case is an AKS violation, not all, but most of it? Do they meet those standards, particularly under the AKS, for -- for intending willfully -- knowingly and willfully intending ever to induce a referral?

No, I had a motion for summary judgment by the government saying at least after a certain date there was, like, no debate. No, no, no. It's -- they've got to prove the intent of the defendants. And that's a jury question, not a court question; that's a jury question. And -- and so whether or not they put in evidence about fair market value, if you're doing it to induce a referral, it's unlawful.

> MR. COOKE: That's right.

Even if -- even if it was fair market THE COURT: value, it would be unlawful. If you were -- I mean, to be honest with you, I think some of the most damaging testimony here is the pro formas, because it appears directly at what an AKS violation is, which is to induce a referral.

So I don't know -- whether the government offers or doesn't offer fair market value, the fact if it's not fair market value, it may cast a greater inference of inducing, but you can't induce someone by a reimbursement. That would be -you can't do something to induce them to make a referral to

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you.

MR. COOKE: With the intent to induce referral.

That's it. THE COURT:

MR. COOKE: So far --

THE COURT: You and I are on the same page.

MR. COOKE: We're exactly on the same page, but this is what has happened now.

We believe that their argument about -- about the fair market value is intended to taint all processing and handling fees, every one, because they were paying \$17 rather than \$3 or \$4 or whatever.

They haven't done that. So, instead, they have to show subjectively -- subjective intent on a case-by-case basis.

I fundamentally disagree with you. THE COURT: know, there's evidence here from several sources that the -that the -- that it's a bundled -- we just heard reference about it -- it's all within the office visit and that any additional payment, it's already been paid for. It's a double That's not a necessary finding, but there's evidence payment. of that.

Dr. Mayes testified that his office determined what it costs them to process it and that some of his partners were then getting 3 to \$5,000 a month additional and taking it as additional compensation.

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That's just all evidence. Whether it's credible or not, y'all raised questions about his motivation and credibility, that's all for the jury to decide. But I've got to view the evidence in the light most favorable to the nonmoving party here.

MR. COOKE: Bear with me, if you would, because I do think it's important to show whether the government has connected the damages to the violations, because I think it's unquestionable that you have to look at a -- you don't agree with my term -- case-by-case basis, but the question of intent obviously can be an individualized thing.

We saw a videotape of Mr. Blasko --

THE COURT: Let me say this: It could do that, but if you have a marketing plan, a scheme, that is a marketing strategy to do this -- and that's part of this evidence on these pro formas, that they were teaching that, they were instructing, Ms. Mallory instructed her people in Virginia about it -- then you would have a -- you have evidence of a -- of a -- you know, I told y'all before this, there's a debate about macro versus micro. And I can see the argument on both sides of this thing.

But to the issue of whether the government has carried its burden at this stage to -- taking it in a light most favorable to the nonmoving party here, I don't think there's any question that they put up sufficient evidence to

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require the -- to deny the motion for directed verdict and to require the defense to put up a case.

MR. COOKE: Can I get to my next point?

THE COURT: Go right ahead.

MR. COOKE: And I really am going to go fast, but I feel it's important to bring some of these things to the Court's attention.

established that all the Bluewave sales reps are independent contractors. Every single element that you look at to determine whether somebody is a servant or an independent contractor has weighed in favor of them being independent contractors. And, in fact, the government specifically alleges that they're independent contractors. That's an element of their claim for the -- for the unlawful commissions.

so what we've seen is we've seen isolated events. We've heard from -- from Boomer. We've heard from Mr. Blasko. We've heard from two or three isolated situations. Mr. Martel, who pleaded the Fifth, those are all independent contractors. They're -- their deviations from what they were trained to do are not imputed to BlueWave. And, in addition -- I say this in addition -- they are not imputed to these two individuals.

So --

THE COURT: Who are officers of Bluewave and -- you

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know, this whole issue is -- and one of the defendants mentioned it. You know, we set up these guys as independent contractors so we wouldn't get blamed for what they did.

Anti-Kickback Statute and use corporate forms to deny your culpability by claiming that everybody downstream isn't you. There is ample evidence in the record that this was a top-to-bottom scheme. One of the allegations is a conspiracy. I believe there's ample evidence here to cast an inference that these salespersons were part of the conspiracy.

So I would respectfully disagree with you there's not ample evidence and that these are isolated. I don't know if they're isolated or not. I've sat here and listened to this evidence just like you have, Mr. Cooke. And none of us were out in the field monitoring what everybody was doing.

But there's ample evidence that says, yes, this was a company-wide scheme and plan, a marketing strategy, from the top down. Whether that's persuasive, whether they can -- the government has carried -- will persuade a jury is a determination. But there is -- taking it in a light most favorable to the nonmoving party, there's sufficient evidence to survive a motion for a directed verdict.

MR. COOKE: We would then -- we would then -- and I'm -- really, I'm going to go through them quickly.

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There's no evidence that any -- that any specific claim resulted from a violation of the Anti-Kickback Statute. In addition, the government lumped their damages in Virginia and the District of Columbia with the rest of the nation. And BlueWave did not even work in Virginia and the District of Columbia.

So their damages proof is fatally flawed.

There's no evidence -- as to the commission agreement, I've got several points I'd like to make on that.

There's no evidence that there was a -- that there was a knowing violation of the -- of the False Claims Act or a knowing and willful violation of the Anti-Kickback Statute in having a commission agreement. Even the special fraud alert that came out in June of 2014 didn't mention that. Even the letter from Ms. Strawn to their attorneys that came out shortly before that didn't mention that as even something that they were looking at.

And I would add to that that we -- we contend that the Anti-Kickback Statute is not intended to reach a salesperson unless -- unless they try to induce a physician or a health care provider. The operative language is "one who recommends or ... arranges for testing."

And we would submit that a reasonable person in the position of these defendants would not know, and I don't think it's the case that the Congress's intent in passing the

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Anti-Kickback Statute was to keep people from selling.

THE COURT: It would not be a violation, a commission per se, but if it was used to induce or cause to present to the government of the United States a fraudulent or false claim, then there's a potential problem. And I want to -- I do want to hear from the government, on the issue of commissions, about how the payment of a commission would be a violation of the FCA and the AKS.

Who wants to address that from the government?

MR. COOKE: Could I add one more thing before --

THE COURT: Yes. Go right ahead.

MR. COOKE: And we would argue additionally that, if what they're saying is that the violation is that BlueWave pays Kyle Martel a commission to go out and recommend and arrange for tests and he is a person, that that would violate the First Amendment protection of commercial -- of nondeceptive commercial speech.

THE COURT: Well, let me ask you this: Does the government assert that the payment to the Bluewave salesman is a -- is a payment by Bluewave of remuneration to these individuals? Is that the theory that the -- that the commissions are unlawful?

MR. SHAHEEN: Well, there's two theories. There's two sets of kickbacks there.

There's one, the commission that HDL paid to

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BlueWave. That, in and of itself, is a set of kickbacks.

Separately, there's a kickback from BlueWave to their independent contractors.

THE COURT: To induce them to make --

MR. SHAHEEN: Yes, Your Honor, it's remuneration. It was done to induce them to arrange for or recommend referrals. Those referrals resulted in federal claims. And defendants did know.

We entered into evidence proof from Derek Kung saying that this was a practice that needed to be terminated.

We entered into evidence --

THE COURT: Save your argument.

MR. SHAHEEN: That's fine.

THE COURT: I think there's sufficient evidence. I thought that was the theory. I just wanted to confirm.

Go ahead, Mr. Cooke.

Let me just say, I have a seriatim that addressed all these issues. I think I have, frankly, almost every one of them addressed in a prior order, but I don't want to take my silence as being any kind of agreement on these.

But keep going.

MR. COOKE: No, I understand. And I was sort of
implying that --

THE COURT: But I did want to hear the government confirm my understanding of the --

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But I wanted to make it clear that, in MR. COOKE: addition to our position that a reasonable person in their position and them specifically would not have known that it was a violation of the law to pay commissions, I don't believe that the -- we contend that the Anti-Kickback Statute should not be interpreted that way.

It was obviously enacted to prevent people from paying off doctors, not salesmen. And there's a fundamental difference, which I don't think I need to explain, between having a doctor have his judgment tainted verses a salesman who obviously is trying to sell a product. It's not insidious in the way that paying off a doctor --

THE COURT: It's also alleged under the broad umbrella of conspiracy in that they were all conspirators.

But go ahead.

MR. COOKE: All right. We would additionally move for a directed verdict as to any claims based on waiver of copays or deductibles for TRICARE.

Most of the evidence that the government put in related to waiver of copays and deductibles in general. Because that's an issue with private insurance companies, some states don't allow waiver of copays and deductibles. And in -sometimes in the past, the government has taken the position that, if you waive copays and deductibles on nongovernment patients, you're ingratiating yourself to the doctor, which

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encourages him to --

THE COURT: See, this is the thing. It need not be under Medicare, for instance, unlawful. But if you're using the device to induce referrals --

> MR. COOKE: Right.

-- then it becomes an AKS problem --THE COURT:

MR. COOKE: Right.

-- because you're inducing referrals on THE COURT: the basis of -- I mean, I can understand how that is very attractive to physicians. These tests were not inexpensive. And if suddenly there's a copay that is significant, the patients are going to kick back and then the doctors won't want to order them.

So taking away a -- what was called no-balance billing eliminated a cost by -- eliminated under TRICARE potentially a -- a cost -- cost limitation -- a limitation on ordering practices, and that's a potential problem.

I suspect you're getting ready to tell me they didn't put much evidence in about damages. There is very limited damages, but it's -- I raised this before with Mr. Shaheen. There's some. There's some evidence, and even one claim would be unlawful.

MR. COOKE: Well, except -- let me address a couple of things. One is all that stuff about waiving copay for private patients and so forth, that's not in the complaint.

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The only complaint -- the only thing in the complaint about waiving copay and deductibles was waiving it as to TRICARE.

Now, first of all, there is not a shred of evidence that they knew until their interview with the Justice Department that there was even a question about TRICARE. You can't waive deductible. There's no deductible to waive for Medicare and most governmental programs. In fact, in a fair amount of the TRICARE, you can't waive -- there's no deductible.

Right. Because active-duty service THE COURT: people don't --

MR. COOKE: Active duty and maybe some other. mean, we tried to figure it out, and even the government's expert couldn't tell you specifically which one did and didn't.

But they put up no evidence. Their expert, Mr. Hines, testified that we didn't even try to put up evidence or to calculate evidence of damages on TRICARE.

THE COURT: Yeah, but I view it as elements of state I mean, they're being told -- I mean, I just think of mind. there's a fair amount of evidence -- substantial amount of evidence here that there were a variety of devices in a scheme to induce doctors to act. That's just one of them.

And it goes to the state of mind. Even though itself may not be a source of damages, it's part of the entire

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scheme to induce. The government has a right to argue that.

And, Mr. Cooke, I suspect you'll argue to the contrary. And that's what we call closing argument.

MR. COOKE: It is. We would now -- would now move to dismiss the claims for -- based on medical necessity.

The testimony in the case has been that the physicians order the tests that they want. The physicians aren't required to order any particular test, and they didn't put in any evidence of any specific test that any physician ordered which was medically unnecessary.

And, in any event, it would not be the responsibility of HDL or Ms. Mallory or BlueWave if a physician did order a test that was medically unnecessary.

THE COURT: Well, what I viewed as medical necessity was -- of course, you had Dr. Trost testify that many of these tests were completely inappropriate for -- for routine patient populations. Many of them, if you ordered them, you would do a baseline; you wouldn't do it every quarter.

There was evidence of inducing bundling, though there's a claim that the doctors were, of course, free to check what they wanted. They were also told there was evidence, if they didn't order a certain numbers of tests, they wouldn't get the process and handling fee. Pretty suspicious, frankly. Even if they did one, they ought to get their process and handling fee.

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Then they were sending four vials. So what's that all about? I mean, it's clear that the bundling thing here is an issue, and how the jury takes all of that -- is there sufficient evidence to show that -- about medical necessity? Yeah, there's sufficient evidence. It's not as direct evidence as some of these other things. But is there evidence a jury could reach a conclusion? Sure, there is.

And it's, again, the micro versus the macro.

And I believe they can prove that there was a scheme to

order -- bundle unnecessary tests to run up the cost and to

have these doctors induce them with these large referral fees.

So there's potentially both an AKS, and there's a straight-up FCA violation. So I would respectfully deny that on that basis as well.

MR. COOKE: And our next -- and I'm getting near the end. But the government offered no evidence of damages based on medical necessity. That truly would have to be a case-by-case analysis, and they didn't put in any testimony -- all they said was these were all the claims we paid during this quarter, this quarter, this quarter. And they made no effort to link any part of that to medically unnecessary tests that were ordered.

THE COURT: I think the jury can make reasonable -I'll charge them on damages and how they meet that. They can't
speculate.

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But I think there's reasonable evidence.

There's some argument that all of it is medically unnecessary in the way it was packaged. So the jury could reach that conclusion. So I deny the motion on that basis.

MR. COOKE: We would move for directed verdict on the fourth and fifth causes of action. That's the -- those are the equitable claims and --

THE COURT: I'm not addressing equitable claims at this point.

MR. COOKE: All right.

THE COURT: I've taken those under advisement. I will address those. I've told y'all, if necessary -- you know, one of the elements -- I've told you this, Mr. Cooke. You obviously know it. There's a remedy at law there need not be equitable issues, and I'm not going to address equity at this point.

MR. COOKE: May I have just a second to look at my notes to see if I left anything out?

THE COURT: Absolutely.

(Pause.)

MR. COOKE: Your Honor, I would just incorporate by reference any other good arguments that I've overlooked. How about that?

MR. SHAHEEN: Your Honor, Mr. Kass --

THE COURT: I have some trouble imagining there was

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any arguments you overlooked, good or bad. I feel like I ruled on everything.

Let me just say that I am -- I have obviously attended the entire trial and dealt with these issues, many of them pretrial. And I do find, under the standards for a directed verdict, that the -- there is sufficient evidence in the record to support the government's claims. And the motion for a directed verdict by Bluewave is denied.

Okay. Mr. Ashmore?

MR. ASHMORE: Thank you, Your Honor. Your Honor, I understand your rulings. I would simply, for the record, also move for directed verdict. I do want to -- Mr. Cooke's many fine points incorporate all of the --

THE COURT: Even the ones that are no good, you don't?

MR. ASHMORE: To the extent they apply to Mallory, Your Honor, I would join in those particular points, incorporate all of my many pleadings in this case in support of the motion for directed verdict.

We take the position that a jury -- that there's not enough evidence -- sufficient legal evidence in the record for the jury to -- a reasonable jury to find for the government, and therefore move for a directed verdict.

THE COURT: Very good. I have -- for the same response, I have taken the evidence in light of the view most

favorable to the nonmoving party. And the motion for a 1 10:10AM directed verdict is denied. There is sufficient evidence in 2 10:10AM the record to support each of the government's claims. 3 10:10AM 4 Okay. Are we -- do we need a break before we 10:10AM start with the defendants' case? 5 10:10AM I wouldn't mind just a quick restroom 6 MR. COOKE: 10:10AM 7 break. 10:10AM THE COURT: Let's do it. 10 minutes. 8 10:10AM 9 (Recess.) 10:10AM 10 Please be seated. Any matters the THE COURT: 10:23AM 11 parties need to address before we bring in the jury? 10:23AM 12 MR. LEVENTIS: Not from the United States, Your 10:24AM 13 Honor. 10:24AM 14 THE COURT: From the defense? 10:24AM 15 MR. COOKE: None, Your Honor. Thank you. 10:24AM 16 Bring in the jury. THE COURT: 10:24AM 17 (whereupon the jury entered the courtroom.) 10:25AM Please be seated. 18 THE COURT: 10:25AM 19 Ladies and gentlemen, the government has rested. 10:26AM It's now time for the defense to put up its case. 20 10:26AM 21 BlueWave, you may proceed. 10:26AM 22 MR. COOKE: Thank you, Your Honor. The defendants 10:26AM 23 BlueWave, Dent, and Johnson would call Floyd Calhoun Dent, III. 10:26AM 24 THE DEPUTY CLERK: Please place your left hand on the 10:26AM 25 Bible, raise your right. State your full name for the record, 10:26AM

10:26AM	1	please.					
10:26AM	2	THE WITNESS: Floyd Calhoun Dent, III.					
10:26AM	3	THE DEPUTY CLERK: Thank you.					
10:26AM	4	(Witness sworn.)					
10:26AM	5	THE CLERK: Thank you. You may be seated.					
10:26AM	6	FLOYD CALHOUN DENT, III,					
10:26AM	7	one of the defendants herein, called as a witness on his own					
10:26AM	8	behalf, being first duly sworn, was examined and testified as					
10:26AM	9	follows:					
10:26AM	10	DIRECT EXAMINATION					
10:26AM	11	BY MR. COOKE:					
10:26AM	12	Q. Would you state your full name for the record, please?					
10:26AM	13	A. Floyd Calhoun Dent, III.					
10:26AM	14	Q. Mr. Dent, you've been here for the duration of this trial.					
10:26AM	15	You've been involved in this case for quite some time. It's					
10:27AM	16	been suggested that you made too much money, and so we're going					
10:27AM	17	to spend a little time talking about how you got to that point.					
10:27AM	18	Is that all right with you?					
10:27AM	19	A. Yes, sir.					
10:27AM	20	Q. How old are you?					
10:27AM	21	A. I'm 48.					
10:27AM	22	Q. Where were you born?					
10:27AM	23	A. I was born in Columbia, South Carolina.					
10:27AM	24	Q. What family do you have?					
10:27AM	25	A. I have a wife, three children. My oldest son is 23, my					

daughter is 21, and my youngest son is 7. 1 10:27AM Do you have any of your family here? 2 Q. 10:27AM I do. 3 Α. 10:27AM 4 Q. Who are they? 10:27AM 5 My wife is here. My mother-in-law is here. 10:27AM father-in-law is here. My pastor is here. My best friend is 6 10:27AM 7 here -- two of my best friends are here. My mother and father 10:27AM 8 were here earlier. 10:27AM 9 You need a glass of water? 10:27AM Q. 10 I'm good. Α. 10:27AM 11 Where did you go to school? 0. 10:28AM College or high school or --12 Α. 10:28AM 13 Start with high school. Q. 10:28AM 14 I went to Dreher High School in Columbia, South Carolina. Α. 10:28AM 15 Q. When did you graduate? 10:28AM 16 1988. Α. 10:28AM what kind of things did you do in high school? 17 Q. 10:28AM I was pretty much a -- I was in National Honor Society. 18 Ι 10:28AM Α. 19 played football. I wrestled. I was president of the 10:28AM 20 Lettermen's Club. I was in Key Club. I was a solid student. 10:28AM 21 All right. Where did you go to college? Q. 10:28AM 22 I received an appointment to the United States Naval Α. 10:28AM 23 Academy. 10:28AM 24 Q. How did you do that? 10:28AM

It's an interviewing process. You have to get a

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senatorial, congressional, presidential, vice presidential nomination. I was blessed to have a principal nomination by Fritz Hollings and also Floyd Spence, and I accepted the appointment.

On what made you decide you wanted to go to the Naval

- **Q.** What made you decide you wanted to go to the Naval Academy?
- A. I have a strong family history of military service, and it was a challenge. My father actually made a bet with me that I couldn't get in. I did.
- **Q.** Did you graduate from there?
- A. I did.
- Q. What did you do while you were at the Naval Academy?
- A. Well, my first year, I wasn't the best student.

  Plebe-year indoctrination can be tough. But by graduation, I made the Dean's List, graduated with a 2.83 average, but I certainly had over 3.9 my senior year. I played rugby while I was there. I was a member of the Society of Automotive Engineers. I was an engineering student. I graduated with an engineering degree.
- **Q.** Now, I'm going to try to get you to brag on yourself a little bit.

But did you consider yourself a hard worker?

- A. I've been a hard worker my entire life.
- **Q.** What did your father do for a living?
- A. My father was professional sales for Trane Heating & Air

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Conditioning for 38 years.

- Did you ever follow him around while he was doing his job? Q.
- I did. As a child, he would take me on sales calls.
- Tell me -- tell the jury, before we get into your life Q. after the Naval Academy, some of your early experiences with work.
- I started working at a very young age. My father had always instilled in me do excellence in whatever you do. And at 9, I started a lawn company. I remember him giving me a hand-crank push mower that I'd go around the neighborhood and cut yards, usually get paid \$10 a yard. And sometimes I'd get paid 15, which was more than what I was asking.

Later I worked at a farm -- Variety Farms. I picked okra. I picked strawberries. I was compensated by the weight of the bushel.

- I was going to ask, did you get commissions on those? 0.
- Got certainly paid by the volume of what you picked. Α.
- All right. Q.
- I worked for a South Carolina knife maker named Alvin Poston when I was 12. I cut the blade stock out of steel on a band saw and got paid a dollar a blade. He's no longer with He's deceased. us.

I worked for W.O. Blackstone in high school ripping out heating and air conditioning, ductwork, insulation, running ductwork. Got paid by the hour there.

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I always had summer jobs, you know, in and out.

And -- but my primary responsibility was school and

extracurricular activities there.

- **Q.** Did you serve in the Navy after you got out of the Naval Academy?
- A. I did. I was commissioned by George Bush, Sr., as an ensign in the United States Navy.
- Q. How long did you serve?
- A. My commitment was five years. I served almost six.
- **Q.** What was your -- do they call it MOS in the Navy?
- **A.** In the enlisted ranks, you'll have a military occupation specialty.
- Q. So what did you do while you were in the Navy?
- A. First assignment was auxiliary electrical and repair, division officer on the U.S.S. Richmond K. Turner, a CG-20 here in Charleston, South Carolina. I later moved on to become the communications officer on board that same ship. So I had a top-secret clearance and was responsible for the communications and the encryption on board the ship.

Transferred to the U.S.S. Nicholson, DD-982, which was a guided missile destroyer. We were primarily responsible for antisubmarine warfare, and we run the shipyard. When they shut down the shipyard, we were the last ship there and had to complete everything with the ship's force.

We installed a vertical launching system on the ship.

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I got trained as a Tomahawk watch officer, a combat information center officer. I later became the damage control assistant on there, which was responsible for training all the shipboard firefighters to combat what was called the helo crash and smash So if a helicopter, you know, crashed, you had to send a guy in with a proximity suit.

Operationally --

THE COURT: Mr. Cooke, let's move this on a little bit. We don't need to go quite as much --

## BY MR. COOKE:

- I guess we don't need to know every single thing you did Q. in the Navy.
- That's fine.
- Did you receive any commendations while you were in the Q. Navy?
- I received one Navy Commendation Medal and three Navy Achievement Medals.
- And when did you get out of the Navy? Q.
- I resigned my commission in 1997. Α.
- What did you do after that?
- I went to work for Pfizer Pharmaceuticals. Α.
- How did you decide to go to work for Pfizer? Q.
- There's recruiting companies that are primarily responsible for placing commissioned officers in the corporate arena.

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- **Q.** And did you have several opportunities to go to work for -- were you given offers at more than one company?
- A. You interview with companies like Military Recruiting Institute or Lucas was another one.

And MRI selected me and represented me, and they take you to big hiring conferences. And there's companies that have preselected you by your résumé, and you interview with those at those hiring conferences.

- Q. How did you decide on Pfizer?
- A. I wanted nothing to do with the medical industry at that time. I have an engineering background. My father was engineering sales, and that's what I wanted to do.

Unfortunately, there was only one company that even remotely fit that description. I did interview with them. They offered me a job. They wanted you to open up your own distributorship, but everybody else pretty much were pharmaceutical companies.

I interviewed with three out of the eight that had selected my package, and I had a job offer from all of them.

- **Q.** Did you -- once you got to Pfizer, did you take an interest in learning the technical details about the products that you were selling?
- A. Very much so. You have very intense training on the various disease states and the products and the competitive products.

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- What did you sell at Pfizer? 0.
- I sold a lot of different medications. Sold Norvasc, which is amlodipine for hypertension. Launched Lipitor, which is atorvastatin for lipid management. Sold Glucotrol XL for Sold Zoloft for depression. I launched a drug diabetes. called Viagra, which some people may be familiar with. zithromax.

The list is long. I covered a lot of different disease states.

- Were you successful at Pfizer?
- I won rookie of the year my first year, and I was always in the top of their sales force every year I was there.
- And how long was that? Q.
- That would have been from 1997 until roughly 2000, 2001.
- we've heard the phrase "compliance" a lot in the last week Q. or so.

Did you receive any of what they call compliance training while you were at Pfizer?

- Annually. Α.
- Take a moment to just explain to the jury what that meant and why it was important.
- well, it's certainly important to make sure you're compliant with all the laws, whether they're state laws, federal laws. They primarily focus on HIPAA, you know, which is protecting patient confidential information, the

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Anti-Kickback Statute, the False Claims Act.

Generally it's focused to make sure there's nothing there to impede a physician's judgment when they're ordering a particular diagnostic or prescribing a particular medication.

- In what form did your training come?
- Conference calls, in-class sessions. Sometimes they would be as corporations, sometimes they'd just be as a district. Various different forms.
- So you were familiar with the Anti-Kickback Statute, False Claims Act, HIPAA, other laws as early as 1997?
- That's correct. Α.
- Is that -- did you come to find that that's pretty much commonplace in the pharmaceutical industry and in the health care field generally, that is, compliance training?
- That's correct. Α.
- Well, why did Pfizer not want you to cross the line and -or push the line on inducements to physicians?
- well, there's substantial penalties on the back end for that, to include prison time and financial penalties.
- In your videotape, you commented that Pfizer was conservative.

What did you mean by that?

Pfizer and Merck both were -- Pfizer became the number one pharmaceutical company in the world at that particular time, and compliance was at the forefront of everything that they

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did.

I mean, that was kind of a transitional phase in the pharmaceutical industry. There apparently had been a lot of things going on in that industry for years that they were trying to clean up. Sending providers on hunting, fishing trips, cruises, having elaborate presentations, you know, a Fantasy Island kind of thing.

- **Q.** Uh-huh. And so you learned that you can't do those kind of things?
- A. Absolutely. You can't do those kind of things.
- **Q.** And Pfizer was pretty serious about that?
- A. Very serious about it.
- Q. When did you leave Pfizer? 2001?
- A. That -- around that time, 2001.
- Q. Where did you go from there?
- A. I went to Aventis Pharmaceuticals. A gentleman by the name of John Monash, he had been the assistant to the regional manager at Pfizer, primarily responsible for my training. Got promoted from a sales rep to a hospital representative. And he had contacted me and asked me if I'd like to come work for him at Aventis, and I said yes.
- Q. What did they sell?
- A. I primarily sold Lovenox, enoxaparin sodium, which is an injectable that's used in the cath lab. So I spent a lot of time in the cath lab. It's primarily designed to prevent

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patients from clotting and ultimately suffering a pulmonary embolism.

- Q. Were you successful in your job there?
- A. I won rookie of the year there, and I was at the top of the sales force every year I was there.
- Q. How many salespeople did they have?
- A. Aventis was bought by Sanofi or Sanofi -- there's different pronunciations -- and was later named Sanofi-Aventis. There were thousands of sales reps.
- Q. How long were you there?
- A. I left Sanofi-Aventis in 2005 to pursue an opportunity with Berkeley HeartLab.
- **Q.** Tell the jury a little bit about Berkeley HeartLab and also why that was attractive to you.
- A. Well, Berkeley HeartLab was founded by Frank Ruderman, who was the CEO, and also a gentleman by the name of Robert Superko, which was a cult leader in the cardiovascular industry that had come out of Lawrence Berkeley National Laboratory. He had discovered a technology called segment and gradiant gel electrophoresis. I know that's a big fancy name, SGGE.

But essentially they could subfractionate LDL into different subclasses and HDL into different subclasses.

while that was important, having sold lipid-lowering medications out in the industry, you would frequently hear providers talk about patients that they had treated the best

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they could, get them to goal, and still go on to have heart attack and stroke, and they didn't understand why.

So it fascinated me that there was something else above and beyond what not only the industry knew but what I So I thought it was a good fit. knew.

- And when did you start work there? Q.
- In 2005. Α.
- Did you get assigned to somebody to train you? 0.
- I did.
- Who was that? Q.
- Brad Johnson. Α.
- He was there before you? Q.
- Α. He was.
- What did they tell you about him? Q.
- I heard a lot of positive things about Brad. Α. about his financial success, which directly correlated to his success in the field in selling physicians on their product.
- How did you become trained at Berkeley? Q.
- Similar to what I experienced in the pharmaceutical I mean, you had compliance training. You had "you sells" introductory training. You'd go over the clinical trials, the support -- you know, the evidence behind what they do. You got to meet the experts, you know, that discovered the technology. They would train you. Physicians would come in and train you. Compliance officers would train you.

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similar to what I'd experienced in the pharmaceutical industry.

- **Q.** So can you tell us what a -- sort of a day in the life of a Berkeley HeartLabs salesman was like. How did you actually do what you did?
- A. Once you were certified and went out to train -- or training process is complete and actually sell, I divvied my days up into three different slots: breakfast, lunch, and dinner. You'd have to have access to the physicians. Those were the timelines that I felt that I could best gain access.

I'd divvy my sales call up into an initial sales presentation, an in-service, and a test review. So you got to move the doctor from understanding there's something better and wanting to use your product. And you need to make sure that the staff understands how to collect the specimens and send it in. And then you want to make sure the physician knows how to interpret the test results on the back end and apply treatments. Because if they don't believe in your product, they're not going to continue to use it.

So I think all three of those steps were necessary.

- Q. Did you find that it was pretty much a 9-to-5 job?
- A. No. I would get up 3:30, 4:30 in the morning routinely, and I wouldn't get back until after 11:00 at night. I averaged 85,000 miles a year on an automobile.
- Q. Did that put any wear and tear on your personal life?
- A. It can create some struggles. You have to balance.

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- Q. Were you successful at Berkeley?
- A. Very. Won rookie of the year there. And I was -- Brad and I constantly competed for the number 1 and 2 spots.
- **Q.** How long were you there?
- A. Left Berkeley in 2010 when we started BlueWave Healthcare Consultants. End of 2009, beginning of 2010.
- Q. We will talk about that in a few minutes.
  Did you receive compliance training at Berkeley?
- A. Yes.
- Q. Can you specify what you did?
- A. With regards to compliance training?
- Q. Yes.
- A. The first compliance training I was given was by an attorney named Jonathan Wolin. In fact, processing and handling fees came up then. And coming out of the pharmaceutical industry, I questioned how you can pay a processing and handling fee and that be appropriate and legal.

And we were given time and motion studies to support what was fair market value, and we were read the legal opinions that they had on that and told how the -- it was made legal. It was an appropriate practice.

- Q. Why did -- let's stop on that for just a moment. Why did it seem strange to you that they could pay process and handling fees to physicians?
- A. Well, in the pharmaceutical arena, it had come under -- I

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would call it tremendous scrutiny, where you couldn't even give a pen anymore that had your product name on it. And so the regulation there was -- I could say it was excessive. understood the reasoning behind it. And so when I saw the laboratory business had this fee, just -- it naturally sparked the question "Help me understand. I'm sure it's appropriate, but help me understand why it is appropriate."

And at that point, when I went out in the field, there were basically only two competitors at that time. It was a company called LipoScience and a company called Atherotech. And the customers you would encounter that had used those products, they also had processing and handling fees that they had been collecting as well. So I had no reason to believe anything was illegal or inappropriate.

- I mean, what's the whole idea behind a process and Q. handling fee? What problem is the laboratory trying to solve with that?
- well, I think Tonya did a good job explaining it. you have to get the blood from a physician practice to the lab in order to perform the tests. And there's several different ways that you could do that. It could be with phlebotomists, whether they're mobile phlebotomists, part-time phlebotomists, full-time phlebotomists, with courier services. oftentimes, the provider practices were willing to let their staff do the work on behalf of the lab.

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So it was simply to offset the time and energy that their employees took to process the specimens, package them up and -- so they could get to the lab and the tests could be performed.

- **Q.** Well, why is it the laboratory's responsibility rather than the physician's responsibility to get your specimens to your lab?
- A. Well, the laboratory bills for the test. So the laboratory is the one that's reaping the benefit of the reimbursement for that test. So it's no different than LabCorp or Quest, they place phlebotomists in practices and offer the couriering service. I'm sure you've seen vans running around that say "LabCorp" and "Quest."

Our courier service was FedEx. So the providers would be given prepaid FedEx billable stamps that went directly on the kits that held the specimens to get them in.

- **Q.** Were there any alternatives to processing and handling fees as far as ways of getting the blood to the labs?
- A. I think I mentioned them.

I mean, one, if a physician was willing to let their staff draw the blood and didn't want a processing and handling fee, they could do that. And there were several provider practices that were like that. In fact, something I think that needs to come out and hasn't come out in trial, only 40 percent of the ordering providers at Health Diagnostic Laboratories

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even collected processing and handling fees.

- We're still talking about Berkeley. But that's a good point that you make, that not all doctors even asked for the process and handling fees?
- No, they did not. But the ones that were familiar with it -- and let's say, for example, I demonstrated the benefit of my product versus another product they were already using. love finding a customer that had already done advanced testing because I didn't have to convince them of the need to do advanced testing; I just needed to differentiate my product from them at that point.

And if they were already getting a processing and handling fee, they would inquire, "Does your laboratory pay a processing and handling fee?" And I'd answer correctly, yes.

- While you were at Berkeley, did they ever tell you that Q. process and handling fees would be a good inducement for referrals?
- Never. Α.
- why -- why -- why didn't they teach you that?
- well, I think I mentioned earlier, you should never provide a provider anything that would cloud their judgment in ordering an appropriate diagnostic for a patient.
- Other ways of getting blood. Could you -- could you just 0. have your own service centers on every corner?
- You could. That's an expensive venture. I heard somebody

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testify that those would average a million dollars a pop to build one of those centers. But it's not as much the cost of the center; the center would have to be in a geographic location where you have enough patients to support it or eventually it's going to go away anyway.

You'll see those with LabCorp and Quest out there They're usually in close proximity to a hospital. today too.

- Is it primarily the big companies, LabCorp and Quest, that have their own draw centers?
- Those are billion-dollar corporations, publicly traded, that have those, yes.
- Did you ever encounter any concerns that if the patients don't get the blood drawn right in the doctor's office, that sometimes there's some leakage there and they don't make it to the draw centers?
- Oh -- you talking about the patients going to the draw center?
- Q. The patients, right.
- Yeah, we were involved in an analysis to assess just that while I was at Berkeley HeartLab. And two-thirds of the patients, which surprised me, if you sent them out the door to go get their blood drawn somewhere else, they never even made it. And that was also true for one of the test sites where the draw center was right across the mall in a big medical building.

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And I kind of had to think why that was the case. And it does make sense if you think about it. patients have waited a long time before they see the physician. By the time they are seen and they're leaving the practice, they're late picking their kids up from school. The last thing on their mind is to go somewhere else and get their blood work done.

So you certainly have a higher capture rate if you're getting the specimen collected in the physician practice.

- So even though the physician may have ordered the test, you found that the patients sometimes didn't follow through and get them?
- Oh, absolutely.
- well, what about hiring other laboratories to draw the blood? Could you do that?
- Yeah, that was a common practice. In fact, HDL had lab-to-lab agreements with Quest and LabCorp. Quest and LabCorp would actually draw specimens on behalf of the laboratory. They got more and more resistant to that over time, and I think it's because HDL was making such an impact in the marketplace.

And HDL was a highly complex laboratory that not only did the advanced testings, but they could run general lab testing if that's what they wanted to do. So LabCorp and Quest certainly viewed --

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- I've got to cut you off for a second. We're still talking Q. about Berkeley. I don't want to get too far ahead of ourselves.
- Okay. I'm sorry. Α.
- That's all right.
- Well, that same thing applied to Berkeley too. one of the reasons I left Berkeley, they were bought by Quest. So Berkeley had actually been bought by Celera, and then Celera was later purchased by Quest. So the big laboratories saw that as an opportunity and also a way to minimize a potential threat of one of these smaller labs and advanced companies to take their business away.
- But using the lab-to-lab agreements, did you find that that was an economical way for Berkeley, and later for HDL, to proceed?
- well, it's an economic model that works. Lab-to-lab agreements cost more than physician-to-laboratory agreement.
- Can you elaborate on that a little bit? I've heard that mentioned several times. That -- why is it that you would have to pay a laboratory more to draw your blood and handle your specimens than you'd have to pay a physician's office?
- I think the labs were more knowledgeable of what it actually cost to get the specimen. So when you would negotiate into an agreement with the lab to get a fair market value fee, they knew what fair market value was. And they would tell you

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how much it was, and that's what you'd have to pay.

- Q. What did they range dollarwise?
- A. I've seen them range anywhere from \$25 all the way up to \$50.
- Q. Per specimen?
- A. Per specimen.
- **Q.** Is that -- does that depend on how many tubes that they would have to handle?
- A. It could on the front end, you know, when you're negotiating it. I mean, a lot of laboratories offer an advanced test and requires one tube to get it processed. Other laboratories can have two, three, four, five tubes.

The processing and handling is different for the type of specimen. I mean, whether you're collecting hair, whether you're collecting semen, whether you're collecting saliva, skin cells, blood, plasma, that's -- they're all different. So the processing that goes into them is different, which is why there needs to be a fair market value assessment.

- **Q.** What about hospitals? Could you just send them down to the local hospital to have blood drawn?
- A. We had some lab-to-lab agreements with local hospitals all over the country.
- **Q.** So what about -- we kept hearing about phlebotomists. What's a phlebotomist?
- A. A phlebotomist is somebody that's trained and certified to

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collect a blood specimen from a patient.

- **Q.** Would they process and handle them as well as just physically draw it?
- A. They do.
- **Q.** Explain the process of a laboratory providing a phlebotomist for a physician's office.
- A. Well, from an industry standpoint, I think that's more of a slippery slope than a processing and handling fee that's calculated by specimen.
- Q. Well, I'm going to ask you about that in a minute. But before -- tell me what that means. When you were at Berkeley HeartLab, and based on your knowledge of the industry, how would a laboratory go about providing a phlebotomist to get their blood specimens out of a physician's office?
- A. I'm not sure I understand the question, but there's a number of different ways. I mean, if they had a body that was already trained, they could certainly place that individual into the physician practice. It's not as easy as it sounds because it depends on the geographic area. I mean, there's some very rural areas, there's nobody that lives out there that's certified to draw blood. So you have a difficult time finding employees to do that.

They may be operating out of limited space. They might have a medical assistant in there that's trained, but even the medical assistant in the practice doesn't have time

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because they're tasked to do so many other things within the I've seen examples where there's an employee in the practice that's pretty much already dedicated to drawing blood, and those big laboratories will go in and hire that individual to become their phlebotomist to draw blood.

- So if I walked into my doctor's office, and he had -- he or she had a phlebotomist that was supplied by a laboratory, would their white coat say -- have the doctor's office name on it, or would it have the laboratory, or something else?
- Yes and no. I can think of examples where an employee was hired by LabCorp and they would wear their LabCorp coat when they were coming to get inspected by somebody from LabCorp, but, any other time, they wouldn't wear their coat. they're clearly a LabCorp employee. I've seen other practices where they're wearing Quest jackets or LabCorp jackets. seen both.
- If you could find -- assuming you could find a phlebotomist to work in a doctor's office, what were the -what did you perceive when you were at Berkeley HeartLab as the downside of doing that?
- Oh, there's many. You have to have the right personality, you know, to fit that practice. I've seen phlebotomists get placed in a practice and then the practice manager calls up and says this isn't a good fit, you need to get them out of here. It could be legitimate concerns; it could just be unjustified

10:56AM	1	personality concerns. But, in that situation, you try to
10:56AM	2	please the customer.
10:56AM	3	Q. How how did Berkeley go about sorting all of this out
10:56AM	4	to figure out what you could do and what you couldn't do in
10:56AM	5	terms of getting your your blood delivered.
10:57AM	6	A. I'm not sure I understand your question.
10:57AM	7	Q. Did they tell you that they had lawyers?
10:57AM	8	A. Yes.
10:57AM	9	Q. Did you ever see a compliance bulletin? Did you have a
10:57AM	10	manual to work from at Berkeley?
10:57AM	11	A. Yes.
10:57AM	12	MR. COOKE: 135. Do you have 135? BlueWave 135.
10:57AM	13	MR. SHAHEEN: Are you asking us to pull it up?
10:57AM	14	MR. COOKE: I've got it to put up. I don't think
10:57AM	15	it's in evidence yet.
10:58AM	16	Here you go.
10:58AM	17	MS. SHORT: No objection.
10:58AM	18	MR. COOKE: Go ahead and put 135 up, please. I'd
10:58AM	19	like to offer into evidence BlueWave Exhibit 135.
10:58AM	20	THE COURT: Is there an objection?
10:58AM	21	MS. SHORT: No, Your Honor.
10:58AM	22	THE COURT: Mr. Ashmore?
10:58AM	23	MR. ASHMORE: Could I see that, please?
10:58AM	24	No objection, Your Honor.
10:58AM	25	THE COURT: Very good. BlueWave 135 admitted without

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objection.

## BY MR. COOKE:

- Q. Do you recognize this?
- A. That's the Berkeley HeartLab Compliance Bulletin Number 3.
- **Q.** Have you seen it before?
- A. I have.
- **Q.** Did they use this while you were at Berkeley?
- A. Yes, they did.
- Q. Okay. Now, you see that they talk about what their process and handling fee would be. It says, "In order to ensure compliance with Stark 1 and 2" -- by the way, you didn't mention Stark before, but is that one of the laws that you were trained on as well?
- A. It was.
- **Q.** Is that similar to Anti-Kickback Statute?
- A. It's similar.
- **Q.** All right.
- -- "and the Medicare and Medicaid anti-kickback laws, BHL has established the following guidelines with respect to processing and handling fees."

And you see there that they were changing their fee. It had been \$10, and then it was going to go to \$11.50. Do you know whether it was ever more than that?

- A. Yes.
- Q. Can you tell us about how much Berkeley HeartLabs paid in

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process and handling fees?

A. When I first went to Berkeley, it was a \$20 processing and handling fee. \$17 of it was processing and handling, and the \$3 was the draw fee. I know there's a lot of terms being thrown out, and I'd be confused because I'm confused sitting out there.

The draw fee is commonly called a collection fee, a venipuncture fee, or a draw fee. Those three names are used interchangeably. That's the \$3 fee.

The processing and handling fee is separate and distinct. And that was \$17, which is interesting, because I had to destroy all of the materials that I had at Berkeley HeartLab, because, when I left Berkeley and went to HDL, I was sued twice by Berkeley for a noncompete because myself and Brad carried roughly 70 to 80 percent of the business of Berkeley HeartLab and the majority of that business followed us to HDL.

So virtually every one of the processing and handling agreements that I was involved in getting established for Berkeley HeartLab in the state of South Carolina was \$20, 17 and 3. I know in the production request from Quest, who had bought Berkeley, not a single one was produced, and we couldn't find them. They only produced ones that were for 10 and 11.50.

There was a blessing that happened, because we found one that actually happened. It came up in production for \$20 before I even worked at Berkeley. So while I was at Berkeley,

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they reduced it to 10. And that was primarily to cut their overhead because they were selling to Celera. So they wanted to show that it was less money going out. They cut it in half. And then they built in a 15 percent annual increase, which is why it jumped up to 11.50.

- Q. And how many tubes did that include?
- A. Most of the time, it was just two tubes of blood. And I heard the question asked, why does the number of tubes matter? It certainly affects the time and energy of the staff that it's utilizing to process what's necessary for what tests are ordered.

There's different tests that are performed off different tubes. So you have to make sure you collect the right tube for the tests that have been ordered.

- **Q.** I'm not going to get you to go into that in any detail until we get to HDL.
- A. Okay.

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MR. COOKE: Could we have Mallory Exhibit 42, which is already in evidence. And you can scroll down -- I want to get down to the Root opinion letter.

# BY MR. COOKE:

- **Q.** Have you ever seen this before?
- A. I have.
- **Q.** What is that?
- A. Can you zoom in on it a little bit?

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- Q. Yes.
- A. That is the legal opinion letter that we were given when I worked at Berkeley HeartLab that was done by an attorney named Greg Root and Jonathan Wolin as the general counsel and chief compliance officer at Berkeley HeartLab.
- **Q.** Were you informed about this opinion while you worked there?
- A. Yes. We were given a hard copy of this opinion, which --I think it's important to explain something.

This is 2007. When I first went to work for Berkeley in 2005, we were told about a legal opinion and that they had it on file, but they were hesitant to give it to the sales reps. They would train you on it, but they wouldn't give it to you. And I asked why we couldn't have a copy of it. And it was a new term for me, but attorney-client privilege that they didn't want it to be distributed out there in the field for other people to have it.

But it's interesting, I never paid attention to the law firm that drafted it. But I learned in this discovery process Ropes & Gray is the law firm that drafted the original legal opinion for Berkeley HeartLab in 2005. That's that same firm that HDL was working with later that they're trying to determine if it's appropriate or inappropriate, and they later determine that it is, and then they decide it's not once the fraud alert comes out.

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MR. COOKE: I'm not going to offer it. I'm just going to show it to him to refresh his memory.

MS. SHORT: I object.

MR. COOKE: Your Honor, I'm not going to introduce this into evidence, but I would like to show it to the witness.

THE COURT: You need to ask -- is it to refresh his recollection under Rule 612?

MR. COOKE: Yes, Your Honor.

THE COURT: You need to ask him the question. If he doesn't remember it, then you can ask him if it refreshes his recollection.

#### BY MR. COOKE:

- Q. Have -- have you actually seen the -- since you left -- since you left Berkeley, have you seen the memorandum from Ropes & Gray that they wrote back in 2005?
- A. Yes. The version I saw is different than what we were trained on, because most of it is blacked out and redacted.
- Q. All right. I think that's all I need to do with that one. Thank you.

I'm going to go back to the previous exhibit, Mallory 42. This one is the one you said you actually were given?

- A. We had hard copies of this, yes.
- Q. All right. Let's scroll down so we can see what he says. Can you give me kind of the first paragraph there?

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- A. You want me to read it?
- **Q.** Read it to yourself, and then I'm going to ask you to summarize what it meant to you. And then let us know when you're ready to go to the next section.
- A. We can go to the next section.
- **Q.** Okay.
- A. They're referencing the October 2005 legal opinion from Ropes & Gray here.
- Q. All right. Scan down.

Do you see a reference to an OIG advisory opinion?

- A. I do. They're referencing the advisory opinion 05-08 that was brought into testimony earlier.
- **Q.** I was going to ask you that. Is this the same advisory opinion that we heard about yesterday?
- A. I believe that it is. Apparently, they have a unique numbering system.
- Q. Did you actually read that advisory opinion yourself?
- A. I have read that opinion, yes.
- **Q.** Okay. So could you read out loud what Mr. Root says about that advisory opinion?
- A. "As a way of review, the HHS, Health and Human Service Office of the Inspector General, issued an advisory opinion concerning a laboratory compensating an ordering physician for the collection of specimens on June 6th, 2005. OIG Advisory Opinion Number 05-08. In that advisory opinion, the OIG states

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that if a laboratory pays a referring physician more than the Medicare reimbursement amount of \$3 for specimen collection, the payment could be considered a violation of the federal Anti-Kickback Statute."

And then it goes on to the Social Security Act.

- Q. Okay. Scan down.
- "In addition, the advisory opinion states that the practice might also violate the civil False Claims Act if the physician submits claims to Medicare for the specimen collection services paid for by the laboratory. The OIG opined that the physician practice would be inappropriately double billing Medicare."
- That might be opined; is that right? Q.
- Opined, opined. Yes, sir.

THE COURT: Only lawyers use the word "opined."

### BY MR. COOKE:

I guess that's true. Q.

Go ahead and move to the last paragraph.

But before you read it, is this where the \$3 for the draw fee came from?

We were trained in great detail by the attorneys at Berkeley HeartLab the difference between a draw fee and the difference between a processing and handling fee. And that's where there was an email by my business partner, Brad Johnson, that was referenced. One word makes it legal; one word --

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- Q. We're going to get to that.
- A. Oh, okay. But the draw fee, there was a \$3 cap on that. And that was for sticking a needle in the vein, getting the blood out of the patient. And, I mean, I could walk through all the individual steps, but I'm paraphrasing.
- **Q.** But the drawing of the blood is different than the processing and handling of the specimen?
- A. Yes, they are different.
- Q. Let's a go ahead and scroll down to the next paragraph.

All right. Go ahead and read that, if you would.

A. "Berkeley HeartLab's response: In response to that advisory opinion, Berkeley HeartLab revised its practice of compensating physicians for the collection and processing and handling of specimens. First Berkeley HeartLab conducted a time and motion study along with a fair market value compensation analysis to determine the cost of performing the unique and labor-intensive specimen processing and handling associated with Berkeley HeartLab's testing.

"The specimen processing and handling is a distinct function from the venipuncture or specimen collection.

Berkeley HeartLab's specimen processing and handling involves the following steps."

Do you want me to read through all of those?

- Q. No. We'll talk about that later.
- A. Okay.

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Q. Just read it to yourself.

Is that a pretty accurate statement of what the steps were?

- Α. That's accurate.
- Okay. Let's go to the next section. 0.

All right. Read that, please.

Berkeley HeartLab then revised its arrangements with ordering physicians to the collection, processing and handling of specimens. Instead of paying one sum for these services, Berkeley HeartLab began compensating the physician practice \$3 for the venipuncture collection and \$7 for the processing and handling of the specimen described above."

So that's the total of 10.

"In addition, Berkeley HeartLab began requiring the physician practice to agree that it will not submit claims to Medicare for any specimen collections paid by Berkeley HeartLab."

That last sentence there, "In addition, BHL began requiring the physician practice to agree that it will not submit claims to Medicare for any specimen collections paid for by BHL."

How did they accomplish that?

well, they accomplished it with the processing and Α. handling letter of agreement, you know, putting verbiage in there that basically told the physician that, if you're billing

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somebody else for this service, the lab can't pay for the service either.

That would be double billing, and you would be receiving double the compensation for a service. You can only be paid for the service once.

So the general practice is most people would set the processing and handling letter of agreements up at the practices minus the draw fee in the first place so that there's not even that potential of it happening.

- Does the laboratory really have any way of knowing what Q. compensation the doctor is applying for --
- Α. No.
- -- whether it be Medicare, Medicaid, TRICARE, private insurance, billing the patient directly?

Are you -- are you -- is the laboratory -- to use a legal term, are you privy to that? Does the laboratory even know what is -- what the doctor is billing for?

- No. You're -- there's no way the lab could determine I mean, you don't know what the billing practices are of that practice when you leave. But you have faith and confidence and hope that the practice is going to do what's appropriate, just like I have faith and confidence and hope that my attorneys are going to tell me correctly what to do and not to do.
- All right. But in any event, they put that in their

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agreement, telling them you can't double dip, you have to get one or the other; is that right?

- That is correct. Α.
- Let's go to the next section. Q.

Go ahead. What advice did Mr. Root give to Berkeley HeartLab?

"Analysis of Berkeley HeartLab's specimen collection processing and handling arrangements. Berkeley HeartLab should continue to structure its specimen collection processing and handling arrangements so that they comply with the personal services and management safe harbor to federal anti-kickback provisions."

You want me to read the number?

- Skip that. Q. No.
- "The safeguards implemented by Berkeley HeartLab should Α. allow it to easily comply with the safe harbor. The most crucial requirement of the safe harbor is that compensation is consistent with fair market value."
- All right. You read that kind of fast. Could you read that sentence again more slowly.
- "The most crucial requirement of the safe harbor is that compensation is consistent with fair market value."
- Did -- is that what you understood when you went to 0. Okay. work with Berkeley HeartLab?
- Yes. Α.

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- Q. Go ahead and continue, please.
- A. "In 2005, Berkeley HeartLab conducted a thorough analysis to determine the fair market value compensation for performing the processing and handling services required by Berkeley HeartLab testing.

"In 2005, I reviewed" -- that's the attorney speaking -- "the documentation of Berkeley HeartLab's time and motion study as well as the accompanying market value compensation for the involved process described earlier in this letter.

"As for specimen collection, by not paying more than the Medicare reimbursement of \$3, Berkeley HeartLab should avoid the risks contemplated by the OIG advisory opinion."

- Q. Go to the next section.
- A. "In addition, Berkeley HeartLab requires any physician practice that enters into an arrangement for the performance of specimen collection processing and handling to agree not to bill Medicare for specimen collections paid for by Berkeley HeartLab.

"This aspect of the arrangement removes the danger of violating the civil False Claims Act contemplated in the OIG's advisory opinion."

- **Q.** By avoiding allowing them to be double paid?
- A. Correct.

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Q. Go to the next section, please.

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"In late 2007, Berkeley HeartLab polled all its phlebotomists, either Berkeley HeartLab employees or under contract with Berkeley HeartLab through third-party employment agencies, concerning the time and labor requirements of its specimen processing and handle. This analysis sought input from 14 phlebotomists working in six states.

"Berkeley HeartLab specifically asked the phlebotomists how much time was necessary for each of the tasks described above that comprise Berkeley HeartLab's unique specimen processing and handling. Twelve phlebotomists responded with the requested information.

"Berkeley HeartLab did not consider the time requirements submitted by one of the phlebotomists because her responses were significantly higher than the other 11 responding phlebotomists. On average, the remaining 11 phlebotomists indicated that Berkeley HeartLab's specimen processing and handling require 32 minutes to complete.

"The time and motion study performed by Berkeley HeartLab in 2005 determined that its specialized specimen processing and handling required a phlebotomist 26.2 minutes to complete."

- when you were in the field while you were working for Berkeley, did you ever observe the processing and handling process?
- Daily. Α.

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- So did you have an idea as to whether this seemed Q. Okay. to be a reasonable calculation of the amount of time that it took?
- I think it's reasonable. One of the tubes for Berkeley has to clot for 30 minutes before you can spin it down. when you spin it down, that's 15 minutes at 3,000 rpm's.

It wouldn't be fair to include all of those minutes in totality. So that's why you have people that are familiar with the process to evaluate it.

- The phlebotomists can be doing something else Right. while it's sitting and while it's spinning, so you don't count all the time; is that right?
- Correct, but --
- How long does it take to actually just draw the blood, the part that you get paid \$3 for?
- well, you've heard testimony that it takes roughly a I heard somebody say a little less than a minute. minute. And I think that's fair, you know.
- All right. Go ahead to the next section, please. ahead and read that.
- "Assuming 30 percent additional cost for benefits and utilizing the newly developed time of 32 minutes needed for task completion, Berkeley HeartLab's analysis determines that on average its specimen processing and handling costs BHL to be \$9.47.

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"Berkeley HeartLab is employing the same hourly rate of \$13.67 per hour that it used in its 2005 time and motion So they're being conservative. study.

"Berkeley HeartLab is now proposing to compensate physician practices \$8.50 for specimen processing and handling. This amount is approximately 11 percent less than the amount determined by Berkeley HeartLab's analysis. Berkeley HeartLab will continue to compensate the practices \$3 for the specimen collection."

- So that was for, you said, two tubes?
- Two tubes. 98 percent of the specimens that came in were Α. one or two tubes, but I'm saying two.
- And that was in 2007? Q.
- That's correct. Α.
- Go to the next section. Q.
- "I have reviewed Berkeley HeartLab's revised compensation analysis for the specimen processing and handling and concur that the proposed compensation should not exceed fair market value. Berkeley HeartLab polled every phlebotomist working for the organization and carefully considered their responses. addition, Berkeley HeartLab is proposing to compensate physician practices only \$8.50, an amount approximately 11 percent below their revised analysis.

"Finally, Berkeley HeartLab is using the same hourly rate employed in its 2005 study and not upwardly adjusting the

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rate to take into account inflation. Berkeley HeartLab also plans to continue to require physician practices to enter into written agreements which state that the practice will not bill Medicare for any specimen collection services performed for and compensated by Berkeley HeartLab.

"Once again, this practice adequately mitigates the risk that either Berkeley HeartLab or the physician practice will violate the civil False Claims Act by double billing Medicare."

- **Q.** And that \$8.50, is that in addition to the \$3 for the draw?
- A. That's correct.
- **Q.** So this is purely the processing and handling?
- A. Yeah. So you add the 3 in there, and that's where you're getting the 11.50.
- **Q.** Go to the next section.
- A. "This is specific to New York providers."
- Q. Okay. Let's skip New York.

Was that because there was some different law in New York?

- A. That's my understanding.
- Q. Okay. Let's go to the conclusion.
- A. "Conclusion. As previously stated, the safeguards implemented by Berkeley HeartLab in 2005 should minimize the risks that either Berkeley HeartLab or an ordering provider

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that enters into an arrangement to collect process and handle specimens will violate either the federal anti-kickback provisions or the civil False Claims Act.

"Neither should Berkeley HeartLab's proposed plan to adjust compensation to physician practices to a slightly higher rate implicate these provisions of federal law.

"Berkeley HeartLab has performed adequate research and analysis to determine the fair market value of the time and resources needed to perform its unique specimen processing and handling and set the revised compensation safely below its own fair market valuation.

"However, Berkeley HeartLab must remember that fair market value determinations are open to interpretation. While I believe its assessments are reasonable, an investigator or regulator might draw different conclusions. I strongly recommend that Berkeley HeartLab maintain thorough documentation of its investigations and analysis concerning the fair market value of its specimen processing and handling. Contact me if you have any further questions."

- Q. Just finish it off.
- A. "Sincerely, Gregory Root" -- I think that's "Esquire."
- **Q.** Okay. What was your understanding about who he was and what his specialty was?
- A. He's an attorney, an outside attorney that Berkeley HeartLab contracted with to give them this legal opinion.

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- Q. So does that fairly summarize what you were taught at Berkeley HeartLab about the legality of processing and handling fees and what you had to do to protect your company?
- A. It completely substantiates my testimony but doesn't address the \$20. But it references the other legal opinions and the other time and motion studies that we have talked about and have referenced in there, yes.
- **Q.** What -- did you know Tonya Mallory when you were working for Berkeley HeartLab?
- A. No, I did not.
- Q. Did you find that the advanced lipid studies that were being marketed and done by Berkeley were well received in the medical communication?
- A. Well, very much so by some and not by others.
- Q. What do you mean by that?
- A. Just like you have varying opinions in law, you have varying opinions in physicians that practice medicine. And I remember when I first got into the medical field -- and I don't say this to be condescending if there's a medical doctor in the room -- but I started calling on 10 to 20 of them a day. And I quickly realized I had them on a pedestal as being the authorities to treat me, and I wouldn't want some of them to treat me.
- **Q.** Did you find that not all of them were as interested in the latest and greatest thing as others were?

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- A. Many were not interested in changing their current practices.
- Q. How did you -- how did you figure out which doctors to prioritize, which ones that you would really want to focus on?
- A. Berkeley, as part of their training process, gave us very specific targeting criteria that my business partner Brad was instrumental in drafting and working with them at Berkeley to create.
- **Q.** And can you summarize for the jury what -- what you look for in a physician.
- A. Well, me personally, you're looking for cutting-edge physician practices, typically practices that are not hospital-owned. And I say that because it's not that we didn't have hospital-owned practices. But based off my experience, when you had a physician that was owned by a hospital that wanted to do your tests, the next step of getting that approved, you went through all these different committees to the hospital. And it could take months sometimes before you get an answer.

But we got answers, and we had many hospital practices come on board.

But as a salesperson, the sooner you can get business on board, the better. So it was easier to look for smaller practices with one or two medical providers where the doctors are the decision makers and you don't have to go through a

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bunch of committees.

One of the most important things was they had a system in place to get the blood. We're selling blood diagnostics. If they don't have somebody there to draw the blood, then you're never going to get the specimen. would target practices that had blood-drawing capability.

- I think you covered that on your videotape deposition that Q. was played earlier this morning.
- I think so. Α.
- So I don't need to go through it in excruciating detail.

But you remember that there was one line on there that said look for money-hungry doctor or something like -- or that want to be money hungry.

What did that mean?

I remember the verbiage. And we only saw that document, again, that I recall as part of this discovery process. was an email produced. I was copied in on it. I never denied that. And it was the same document that we had at our previous employer, Berkeley HeartLab.

I've always taken "money hungry" to be a business-savvy physician, somebody that when -- x-rays -- they want to bring an x-ray machine in their practice for a couple of reasons. One, it's more convenient for their patient to get the x-ray right there on the spot.

And the other reason, it generates revenue for their

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practice that they had been relinquishing somewhere else. That's a business-savvy physician.

Same with bone density scanning. That same personality is the first one to prescribe a new medication by Crestor when it comes out. They're anxious for the new products.

It seems like everybody wants to forget that physicians are running a business. And if they don't run a business, they will go out of business.

- **Q.** Did that -- did that mean to you, though, that by "money hungry," you were looking for doctors that would be attracted to the processing and handling fees?
- A. No, it did not.
- Q. Well, why not? Why wouldn't somebody who sees that document that says "money-hungry doctors," why wouldn't they just rightfully go right to the conclusion that, ah, they must be looking for people that want our process and handling fees?
- A. Well, that's a big leap that somebody has made in this case to try to prove their point. But you have to remember only 40 percent of physicians collected processing and handling fees. That means 60 percent of physicians did not.

You actually heard testimony from the single best witnesses of contractors that work for BlueWave say that I spoke about a processing and handling fee briefly only at the request of physicians asking me to clarify it. It wasn't a

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part of the sales pitch to get them to move.

Now, with that being said, if they are willing to devote their employee to do the work, I think it's absolutely 100 percent unreasonable for them to pay for an employee that's working for a lab without fair market value compensation. They should be compensated for the work that their employees are performing.

And the other point that needs to be made, this practice has been going on in this industry since Cal Dent was 12 years old -- 12 years old.

- Q. Okay. How did BlueWave come to be born?
- A. Brad Johnson and I formed Bluewave at the very end of 2009, very beginning of 2010. We were very dissatisfied at Berkeley HeartLab for a number of different reasons.

They had been bought by Celera. Not a single member of the executive committee that was there when we started was there any longer. It was a major cultural change.

Our commission structures -- you would be promised a certain commission structure plan, and it would change every quarter. And imagine you're a salesperson, it takes months sometimes to get a practice up and running. You may lose a practice. You're competing against all your business from that previous quarter that you have to sell for and then above that to get compensated.

So we were going to form our own lab, Brad and I did.

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And thank God we're self-aware men; we're not lab people.

That's not my expertise. I'm a sales guy. That's what I do.

I'm very methodical. You've heard a lot of testimony about

that. I pay a tremendous amount of attention to detail. I

think those are good qualities to have. And we were going to

do that. We were looking at opportunities. And I was called

by Russell Warnick one day when I was out in the field working

for Berkeley HeartLab. Russ was the chief scientific officer

at Berkeley. I did know Russ very well when I worked at

Berkeley. He had left Berkeley, just like many of us with the

mass exodus were leaving Berkeley. And he had been consulting

with a bunch of different laboratories.

And at the time, he told me he had been consulting with a lab called HDL, but he didn't tell me he was a founder of it or he worked for it or any of the above. But he was inquiring about my satisfaction or dissatisfaction at Berkeley HeartLab.

And I confirmed his suspicions that I was very unsatisfied and I wanted to leave. And he said, Well, there may be some opportunities for you out there. I later got a phone call from Casey Boyd.

Casey Boyd, if you'll recall, somebody had testified earlier he was a sales representative that worked directly for Health Diagnostic Laboratories. And he and I talked for a while. I met Casey once or twice before just out in field. He

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was a manager with Kos Pharmaceuticals, and he managed one of the reps in my territory.

And he arranged for Tonya and I to have a phone call, which later resulted in the Atlanta airport Marriott meeting.

- **Q.** Were you making good money at Berkeley?
- A. I made really good money at Berkeley.
- **Q.** How much were you making?
- A. I made millions of dollars at Berkeley HeartLab.
- **Q.** Did you really?
- A. Yes.
- **Q.** How were you able to do that?
- A. Well, it was tough when your commission plan changed every time and -- but we'd go out and sell based off a 15 percent commission plan or a 20 percent commission plan. And then when they'd calculate the numbers, we'd hear things like "You made too much money. You made more than the CEO of the company."

well, hold on a second. You sent me a commission structure on the front end. I expect to be compensated the way that you told me that you were going to compensate me. And they wouldn't do it, and they always had excuses.

And to quote my father, he said --

- Q. We're not going to complain about Berkeley any more than that.
- A. Okay.

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Q. But I just want to get an idea of -- what was your

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structure? You were paid on a commission?

- Yes. Α.
- And what was the range of percentages that you agreed on?
- There were compensations as high as 20 percent of collected revenue for specimens generated in the geographic area of responsibility. And it got as low as 5 percent revenue.

There's tricks in commission plans that people can play, and it really boils down to what do you establish is your baseline? Are you competing against your previous year? Are you competing against your previous six months, quarter, et cetera?

- In all the time that you were working for Berkeley or any of the pharmaceutical companies, did anybody ever suggest to you that it could be illegal to have commissions based on volume of your sales?
- No. Α.
- Q. Did you ever hear that?
- I've never heard that until this investigation and Mark white, who represented us at White Arnold & Dowd, said to me quote, Cal, that's the only way they're going to drag you guys into this thing, end quote.
- we'll get to that in a minute -- in a little while. Ο.

Okay. So you had the meeting at the -- in Atlanta, right, with Tonya?

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we did. Α.

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- And then again you did not have a business association Q. with her while she was at Berkeley, I understand?
- I did not. Α.
- But you were both expatriates of Berkeley?
- We both worked for Berkeley HeartLab.
- Tell us about that meeting. Q.
- We decided to meet at the Atlanta airport Marriott because it was convenient for everybody. I mean, it's an airport hub. You can fly in the airport, go straight to the hotel, don't have to get car transportation.

The people present at that meeting were myself and Brad Johnson, Tonya Mallory, Russ Warnick, and Joe McConnell.

- What did you talk about? Q.
- we talked -- it was a meet-and-greet, first of all. Α. Everybody introduced themself, kind of went over their background and credentials.

I was extremely impressed with Joe McConnell, that I didn't know about before. He was coming from the Mayo Clinic. And I was familiar with his name because he had authored many of the clinical trials that were the support behind different tests that we had offered even at Berkeley.

Russ Warnick, I would say there's probably no one -his knowledge is second to none. And he's written lipid manuals on lipid testing. I've seen, you know, descriptions

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this thick. That manual is that thick. I got a copy of it somewhere.

In fact, he had autographed one one time and gave it to me and said, Cal, you're probably the only person that will read it.

I used to joke with him frequently. I said, Yeah, when I want to go to bed, that's what I read, because it'll knock you to sleep.

- But you did read it?
- I've read parts of it.
- Okay. Was this in the fall of 2009? 0.
- I've heard different dates in here from September, October, November. I think there's a document that will pinpoint the exact date. I believe it to be October of 2009.
- All right. Can we have Exhibit 1293? Q.

Can we get the witness a cough drop? You THE COURT: got something here?

> MR. COOKE: Yes.

THE COURT: Oh, you got one?

THE WITNESS: Thank you. I've one. Thank you. apologize.

THE COURT: No problem.

## BY MR. COOKE:

Does this Exhibit 1293, plaintiffs' exhibit, does this refresh your memory about that?

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- A. This is an email from Brad Johnson to Tonya Mallory, Russ, and myself dated October 16th, 2009. Tonya attached the notes to the meeting. Yes, that would be the meeting I was referencing.
- **Q.** Are the notes attached to that or is this -- go ahead and scroll down. Just -- tell you what. We're not going to go line by line through this. Just give me the whole text.

All right. Can you just briefly tell the jury what this -- what this is and what's highlighted and what's not.

- A. Well, it's a summary of the discussions that we had at the meeting at the Atlanta airport Marriott talking about a business opportunity between HDL and whatever company Brad and I formed. I don't think we had BlueWave at that point.
- Q. Okay. Is -- the bold stuff, is that your writing or is that somebody else's?
- A. I think, from earlier testimony, somebody was suggesting that those were changes. And I think they said Brad made the changes, but I would say that Brad and I both made the changes.
- **Q.** Okay. Scroll down to paragraph 9 there relating to P&H fees.

Go ahead and blow that one up for us.

This has been shown previously in the trial, but there's a section there that says "P&H fees will be paid to physicians. Target amount is \$15 to \$21 per patient. This cost will be paid by HDL." And then it says, "Agree. Prefer

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18 to 21."

Is that your proposed change?

- A. I would not disagree with it, no.
- **Q.** Okay. Just explain to the jury why you made that suggested change.
- A. Well, I'll own the statement. And I don't even think we talked about processing and handling fees at the meeting. And when we got this proposal, they're saying 15 to 21. We're responding back 18 to 21 because we know that's consistent with what's in the market.
- **Q.** Do you happen to know whether -- or remember whether that included the draw fee?
- A. It doesn't delineate that here.
- **Q.** Okay. How did you know what the market was bearing at that time?
- A. Well, at this point in time, I've been in the market since 2005. So 2005, '6, '7, '8 -- this was '9; right? So five years. And I'd competed against LipoScience, Atherotech. There was some new companies trying to made headway out there. And you were familiar with the market. We were probably more familiar with the market than anybody because we're the face of the company going into the practices and you know what they're getting paid.

MR. COOKE: Can I see 1228, please, Plaintiffs' Exhibit 1228.

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If I could add to that, we actually had THE WITNESS: sales representatives that worked at Berkeley HeartLab that had already left Berkeley HeartLab and were working at some of the other advanced companies like Boston Heart, for example. we were being recruited by them to come and work for them as regional managers of these companies. And I had trained most of them and Brad had trained most of them.

> Blow this up. MR. COOKE:

# BY MR. COOKE:

- This is an email dated -- it says to Christina Dent, but that's because you were using your wife's email account at that time?
- I would never deny that. In fact, my wife had to produce all of her emails as part of this discovery.
- Q. All right.
- The only time that I used my wife's email was when I was still an employee at Berkeley HeartLab negotiating an opportunity to leave Berkeley HeartLab. And I didn't think it appropriate to use Berkeley HeartLab's email address to conduct personal business.
- That's all right. I wasn't asking you to apologize for it; I just wanted to confirm that that was you and not Christina sending this email.
- No, that's me. That's not my wife sending that. Α.
- Okay. December 15, 2009, and down there right below that, Q.

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you said, "Hey, Tonya, attached are the updated P&H letters for a laboratory and practice."

was that the proposed P&H agreement?

- Yes. Α.
- And "I'm not sure why you changed the amount to Okay. 15.50 for a practice. I've been using \$20 for a practice and \$25 for a laboratory based on our previous discussions. advise if something changed. Thanks in advance for clarification."

Can you explain why you pointed that out to her?

- well, again, we're transitioning from Berkeley to another Α. And I had testified earlier that we had used \$20 processing and handling fees at Berkeley for physician practices and 25 for lab-to-lab agreements.
- But you were not using \$20 at Berkeley when you left Q. Berkeley, though, were you?
- It was 11.50. No, I was not. Α.
- Did Tonya know what you actually were paying at Berkeley?
- I feel confident we probably discussed that. we're discussing it here.
- So the fact that you were suggesting \$20, was that a reflection of the fact that you felt at that point that Berkeley had lowered theirs for reasons other than what the fair market value was?
- well, I testified earlier Berkeley absolutely lowered

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their amount for a business purpose. And that was relayed to us by Clark Robinson, my manager, when the fee dropped.

You have to imagine, we're salespeople that have made a commitment and a promise to a physician practice to pay a certain amount for the services that they're going to provide. Many physicians had gone out and hired additional employees to perform this work for them. Now, imagine I had worked for a dollar amount, committed that to you, and then I got to go back in and tell you it dropped 50 percent, you know, with no real explanation.

So it was a sensitive topic for sure, but we knew at HDL as well Berkeley was collecting one and two tubes of blood for that 11.50. Again, we took a very conservative business approach in everything that we did. It's been suggested that we offered the highest fee of anybody in the industry. If you actually broke it down and you saw the slides on that, we paid the less amount per tubes. And the \$20 -- and this is an area that was including the \$3 venipuncture fee, so it's 17 processing and handling, \$3 venipuncture.

- **Q.** And what was ultimately agreed to? Was there a range in your contract?
- A. I'm pretty sure the range that was agreed to in the contract was 18 to 21, which, again, a testament to our state of mind, we paid 17. And I'm hesitant to even say the word "we." I'm not sure people understand that BlueWave is a sales

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contract organization. The laboratories that we represented paid processing and handling fees, not Bluewave. Cal Dent, Brad Johnson, BlueWave have never paid a single processing and handling fee in my life.

Labs that we represented did. They always had. But a way to pull me into this now is to say I had a conspiracy with them to do this. Again, it's a practice that's been going on since I was 12 years old.

well, was -- your suggestion to go from what you had been paying at Berkeley up to \$20 per practice and \$25 for laboratory, was that to give you another tool to help lure customers away from Berkeley?

No, that's to represent what I knew was fair market value in the geography.

And then where did you come up with the \$25 for a Q. laboratory?

That's the same amount that Berkeley HeartLab paid for lab-to-lab agreements.

Now, is a laboratory in the position to give you 0. referrals?

Is the laboratory in a position to give referrals? Α.

Right. Q.

Α. No.

Q. They're not your customers, are they?

Α. No.

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- **Q.** Okay. So would you have any reason to pay a laboratory any kind of an inducement to draw your blood for you?
- A. No.
- Q. Did you think that you could convince laboratories to draw your blood for you for less than \$25?
- A. There may be lab-to-lab agreements out there for less than \$25. I don't know. But I think if you're negotiating a fee down lower, it may not be representative of fair market value.
- Q. Let me see Exhibit 1288, please. Is this the -- does this represent the final stages of negotiating the agreement?
- A. March 16, 2010. "Did you guys look at the contract before I got it from Gene's office? I have attached what I got and the original term sheet. Brad, you said the attorneys ripped it apart, but we really need to put it back together. This is terrible."
- Q. Okay. What was that about?
- A. I think Brad's probably expressing some frustration, and I would have shared his frustration. It seems like anytime you give a document to an attorney to review, they change something.
- Q. Okay. But this is actually Tonya saying, "Brad, you said the attorneys ripped it apart, but we really need to put it back together. This is terrible." That's Tonya --
- A. That's Tonya speaking to Brad.
- Q. Okay. The reason I wanted to show you this is to ask you

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this question: Was the sales agreement between BlueWave and HDL negotiated at arm's length? Do you know what I mean by that phrase, "at arm's length"?

- I've heard different definitions of it, but if you'd give me your definition, I'll tell you whether I agree with it or not.
- well, assume that by it, I mean that each side was trying Q. to negotiate to get the best deal for themselves.
- That's correct.
- It was not a wink and a pat on the back or anything like that. You were trying to get the best deal you could get; HDL was trying to get the best deal they could get.
- That's correct.
- was there negotiation over the amount of your commissions? Q.
- Α. Yes.
- And your commission structure? 0.
- we ended up landing at 16.8 percent; later, with the 18-month reduction, to 13.8 percent, with a later increase to 19.8 percent and then back down to 16.8 percent, keeping in mind that, based off my knowledge of the business, your sales and marketing teams usually get 25 percent. That's how much money is devoted to that. And our contract with Singulex was 24 percent, which would confirm that.
- Is it just coincidental that that happened to be in Q. the same range of the commissions you were getting at Berkeley?

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- A. Well, generally speaking, we were 15 percent for the majority of the time I was there, but I've already testified to numerous commission changes there.
- **Q.** At the time that you entered into this contract, had HDL had occasion to do a time and motion study or get a specific legal opinion about P&H fees?
- A. At which point in time? March 2010?
- Q. Yes.
- A. My understanding -- and Tonya had relayed this to us even as early as the October 2009 meeting -- that she had done an internal time and motion study that wasn't extremely comprehensive, but she had also been involved in the internal time and motion study when she was at Berkeley. And we suggested, and she agreed, that it would be best to get an outside company to do it so nobody could ever interpret and say it was biased.
- **Q.** Well, we'll come back to that later because we're actually talking about a little farther down the road.

When you were talking about the difference between a lab-to-lab specimen processing versus a physician's office, is the actual process of processing and handling any different in the laboratory than it would be in the doctor's office?

A. No.

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Q. So for that \$25 for the laboratory, you're paying for the same service that you'd be paying whatever you're paying for

the doctor? 1 11:47AM 2 Correct. Α. 11:47AM MS. SHORT: Your Honor, I'm going to object to this 3 11:47AM 4 line of questioning about lab-to-lab agreements. It's not part 11:47AM of the case. 5 11:47AM Overruled. 6 THE COURT: 11:47AM 7 BY MR. COOKE: 11:47AM This thing about the lawyers tearing the agreement apart, 8 11:47AM 9 what lawyers were involved in this process? 11:47AM 10 2010, it would have been Gene Sellers representing 11:47AM 11 BlueWave and it was LeClairRyan representing HDL. And Charles 11:47AM Sims, I believe, was involved in that. I met with Charles. 12 11:47AM 13 The reason I remember him is he was also a graduate of the 11:47AM 14 Naval academy, and he had boxed while at the Naval academy. 11:47AM 15 And then Dennis Ryan, who was one of the founding partners of 11:48AM LeClairRyan, was involved in this. 16 11:48AM was LeClair -- did you understand LeClairRyan to be a big 17 Q. 11:48AM law firm? 18 11:48AM 19 Α. Huge. 11:48AM And Gene Sellers is not a huge law firm? 20 11:48AM 21 Α. No. 11:48AM 22 And who is Gene Sellers? 0. 11:48AM 23 Gene Sellers is a personal friend, I believe -- I think 11:48AM that's a fair classification -- of Brad's. He's an elderly 24 11:48AM gentleman. And I think it's Birmingham, Alabama, or a small 25 11:48AM

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town outside of Birmingham. And it's my understanding that he's certified as an accountant, heavily involved in contract negotiation, and he's also an attorney. And I believe he taught law at one of the major colleges in Alabama.

- Q. He's not a health care attorney, though?
- A. He's not a health care attorney; never claimed to be.
- **Q.** Was it your understanding that LeClairRyan had health care attorneys?
- A. Absolutely. One of the biggest in the world.
- **Q.** Are they involved in the formation of the contract?
- A. Yes. They drafted the original draft of it.
- **Q.** Was it your expectation that, if you were about to enter into a contract that was illegal, that the lawyers who were drafting the contract might say something to you about that?
- A. I would have never entered into a contract that I thought any portion thereof was illegal, never.
- Q. Well, did anybody involved in this negotiation on either side ever say, you know, this is kind of dangerous, doing a commission-based agreement; this might violate the Anti-Kickback Statute?
- A. No. And, at that time, processing and handling fees were under zero scrutiny. I mean, this was routine practice, standard in the industry. All these other labs had time and motion studies and legal opinions. I mean, it's -- only now was is it being considered an inappropriate activity.

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- You mean now like in this courthouse? Q. All right.
- Well, now in this courthouse. Not now in 2010. Α. you.
- Did anybody tell you that, "Cal, when you were at Q. Berkeley, you were an employee, a W-2 employee. Here, you're going to be an independent contractor. That makes a big difference under the Anti-Kickback Statute"?

Were you ever told that?

- I was never told that.
- Did anybody hint at that? Did they say that it was a Q. potential risk or even a potential issue?
- I don't ever recall anybody saying that.
- So you wound up entering into an agreement; correct? Q.
- Α. That's correct.
- Q. Let's just look at the --

Put that full thing. And then is there another page to it? Just scroll down. I don't want to read the whole thing. I just want to see what they talked about.

Did you ultimately resolve these issues and enter into a sales agreement?

There weren't issues between Tonya and Brad and Cal; it was just the attorneys going back and forth. And I guess everybody was hypersensitive to that, making sure that everything was correct. But I don't view negotiations of a contract as being anything inappropriate. People are asking

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questions and we're trying to do everything that is appropriate. So we -- after the attorneys said it was good to go, we all signed it and executed it.

MR. COOKE: I'm going to put you to the test. Do we know which exhibit is the sales agreement, final sales agreement? You don't remember?

MR. GRIFFITH: 56.

MR. COOKE: 56?

May I have 56? There it is.

# BY MR. COOKE:

- Q. Is this -- does this look like the final agreement?
- A. It does.
- **Q.** Okay.

Can we scroll to the next page. Can you blow that up a little bit?

Is this the final provision that you entered into about the processing and handling?

- A. It is.
- Q. It says, "Provide process and handling fees to physicians in the range of 18 to \$21 and process and handling fees to outside labs in the range of 18 to \$25 provided that any fee change shall be mutually agreed upon by the parties unless required by any state or federal laws or regulations."
- A. That's correct.
- Q. Did any of the attorneys who looked at this agreement or

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helped draft this agreement suggest to you that there was a risk involved in this?

- A. None.
- **Q.** Did this seem any different to you than what you had been taught was legal and appropriate at Berkeley --
- A. It was consistent not only what I had been taught but what I knew to be the standard of practice in the industry with all labs.
- **Q.** There's also a provision down here, "e. provide zero-balance billing in the territory for Medicare, PPOs, POSs, and Medicaid except as otherwise mutually agreed to by the company and contractor."
- A. That's correct.
- **Q.** Do you see that?

would you mind translating that for us?

- A. Well, I think we've heard ad nauseam what zero-balance billing is, but if you want my definition of it, it's --
- **Q.** No, I get that part. The PPOs, POSs?
- A. That's preferred provider organizations or point-of-service organizations. Those are commercial insurance subsidiaries.
- Q. All right. And, again, zero-balance billing meant that you were not going to bill the patient any more than the insurance company would pay?
- A. That's correct. And, again, I don't think this point has

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been made, and people understand this.

It is forbidden by law to balance-bill Medicare patients and Medicaid patients for laboratory services. Forbidden my law. Nobody has disputed that. The reason being, just like an annual health and wellness physical, that is a preventative health care service. They didn't want a copay and deductible in place to deter the patient from getting their annual health and wellness physical.

Laboratory services are also deemed as preventative health care services. So this waiving the copay and deductible -- I know there's been a ton of talk about that -it's forbidden by law for Medicare and Medicaid. We only learned in this investigation that someone wants to interpret TRICARE differently. We've always been trained that TRICARE is another federally funded insurance subsidiary, and we handled it the same way as Medicare and Medicaid.

The irony is if it's forbidden by law for one, why wouldn't it be forbidden by law for the other? So the labs that ran the billing program -- again, BlueWave had nothing to do with the billing, nothing to do with setting the policies, nothing to do with filing the claims. Forbidden by law.

- Cal, as time went on, did you discover that certain states 0. and some insurance companies have rules about zero-balance billing?
- we did. And you have to push those discussions to

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commercial insurance subsidiaries. So your UnitedHealthcares, Cignas, Aetnas, Humanas, et cetera, the commercial insurance is the way we had always been trained -- and it's still my understanding today -- that there's a difference between being in network and out of network. You know, if the laboratory is in network with a particular insurance company, call it Blue Cross Blue Shield, there may be a contractual obligation that requires that laboratory to make an attempt to collect copay and deductible.

Here's the other thing I want to make sure people understand: If the lab collected that copay and deductible, they keep it. That's revenue for the laboratory. They keep it. If it's revenue for the laboratory, Bluewave would have been compensated a percent of any copay and deductible. I commend what Tonya was doing and these advanced laboratories were doing. They were trying to make these tests available to everybody, irregardless of what their economic status was.

You'll hear testimony -- or you already have -- that there's -- these labs like Berkeley only catered to people in Beverly Hills originally. These are life-saving diagnostics, and they need to be made available to everybody. That was the whole waiver of copay and deductible. And, again, with Medicare and TRICARE -- which, Medicaid has been thrown out in this case. There were more Medicaid specimens than TRICARE.

Q. In this paragraph e, it says "provide zero-balance billing

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for the territory" -- that's the territory that you'd be serving; right?

- A. That is correct.
- Q. -- "for Medicare, PPOs, POSs, and Medicaid, except as otherwise mutually agreed by the company and contractor." Did you mention TRICARE in there?

A. TRICARE is not mentioned in there. And this is another point. TRICARE was hardly any of our business, which -- there's been testimony about maybe 16 claims. I heard a TRICARE expert say there were 2 million TRICARE claims.

TRICARE equated for .078 percent of HDL's business, not even 1 percent. .078 percent. That's it.

- Q. Did any of the lawyers that reviewed this contract tell you that you need to be careful because there are certain TRICARE plans that have copays and deductibles and there may be some legal issue about waiving that?
- A. No.

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- Q. Never?
- A. Never.
- **Q.** When did you -- when did you first learn that there could be some TRICARE plans that do have a patient responsibility component?
- A. When Elizabeth Strawn -- I don't know if she's in here anymore -- for the Department of Justice interviewed me in Washington, D.C.

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- Q. And that was in what year?
- 2013. Α.

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- And did she tell you it was illegal? Q.
- Α. She didn't know.
- What she did ask you? 0.
- She asked me why the labs were waiving copay and deductible for Medicare patients. And I said, "Ma'am, you do understand there isn't such a thing as a copay and deductible for Medicare patients?" And I got a dumbfounded look and people started writing things down on paper.
- Did you believe in any way, shape, or form that it could be a violation of the Anti-Kickback Statute or the False Claims Act for the laboratories to waive deductibles and copays for TRICARE?
- We were always trained that TRICARE was another federally funded insurance subsidiary, and it was handled just like Medicare and Medicaid. And the commonsense gut check tells you that that's the case; right? If it's forbidden by law in one, why in the world would it not be for the other? it was handled just like Medicare by the laboratories.
- Now, I want to digress for just a second. I think you testified earlier that the people in the laboratories aren't in the doctor's office when the doctor submits his application for reimbursement for insurance or Medicare or TRICARE; correct?
- No, they're not in the office.

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- Q. And you're not either, are you?
- A. No, I'm not.
- **Q.** And you're not at HDL when they submit their claims for reimbursement, are you?
- A. That would be their billing department's responsibility or their contract billing department's responsibility.
- **Q.** So when you're actually out there making your sales calls, you're making your presentation to the doctor, do you even know whether he has any TRICARE patients?
- A. You could possibly know. If it came up -- you know, if a doctor described to you their payer mix -- you know, I think you heard testimony from Dr. Mayes, for example, that 60 to 70 percent of his patients were Medicare.
- Q. Uh-huh.
- A. And he's an internist. I would argue that most internists are 80 to 90 percent Medicare, but that's not always the case. They were trying over the last 5 to 10 years to incorporate more commercial insurance into their practice and start bringing in younger patients because the reimbursements were higher on the commercial side than on the federal side.
- Q. Sure. But you're not -- you don't -- you don't actually get to go in and look through their patient charts and see what their diagnoses are and do this kind of thing?
- A. Not with relation to ordering. From time to time, on a test review, it would not be uncommon for a physician to break

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out their patient chart to look at a test report.

MR. COOKE: May I see Exhibit 1136, please.

### BY MR. COOKE:

Q. This is what we've been referring to as the HDL position statement on process and handling fees paid to physicians and partner laboratories. It says, "The purpose of this document is to provide support and due diligence in consideration of the current practices of providing a fee to physicians to reimburse the costs associated with the extensive processing and handling of samples collected at an independent location for testing by Health Diagnostic Laboratory, Inc., in Richmond, Virginia. This reimbursement is not specific to the costs associated with performing venipuncture."

Was that, again, to distinguish it between the --**A.** Yes. Yes, sir. It's differentiating between the draw fee and the processing and handling fee.

- **Q.** What was the origin of this position statement? Why was there considered to be a need for a position statement?
- A. From time to time, the customers will ask you. I mean, you heard testimony to that. They'll ask you what legal opinions you have to support the practices of these labs that you represent do.

So this was HDL's position statement, no different than having a Berkeley HeartLab position statement or legal opinion.

Did you participate in drafting that statement? 1 Q. 12:02PM I did not. 2 Α. 12:02PM MR. COOKE: Can we look at exhibit -- Mallory 3 12:02PM 4 Exhibit 5. 12:02PM BY MR. COOKE: 5 12:02PM Do you remember seeing this exhibit when it was introduced 6 12:02PM earlier last week? 7 12:02PM There's been a lot. You'll have to show me the body of 8 Α. 12:02PM 9 it. 12:02PM 10 MR. COOKE: Show the whole thing. 12:02PM 11 BY MR. COOKE: 12:02PM You see this? This is the email that Tonya Mallory talked 12 12:02PM 13 about in her testimony dated January 17th, 2012, to Mr. Ruggio 12:03PM 14 asking him to review the guidelines. 12:03PM 15 Α. Correct. 12:03PM 16 So my question to you is, was it your understanding or 12:03PM 17 your belief that HDL was getting legal advice and drafting its 12:03PM policies regarding process and handling fees? 18 12:03PM 19 Yes. Α. 12:03PM 20 And who did you believe that they were getting advice 12:03PM 21 from? 12:03PM 22 LeClairRyan and, more specifically now, Michael Ruggio, 12:03PM 23 which is -- my understanding, he was a senior counsel for the 12:03PM 24 Department of Justice who had no longer worked for the 12:03PM 25 government but was now working for LeClairRyan. 12:03PM

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- **Q.** And did you believe that he was an expert in health care law?
- A. Yes.
- **Q.** And compliance matters?
- A. Yes.
- Q. And as we've gone through this case, has it been confirmed to you that, in fact, HDL was in very regular and constant contact with their legal consultants about processing and handling fees and all other areas of compliance?
- A. We've always known that.

THE COURT: Mr. Cooke. We've gone about an hour and a half. I didn't know if this was a good time to break. We can go a few more minutes. I'm going to leave it to you.

MR. COOKE: This would be a good time.

THE COURT: Very good.

Ladies and gentlemen, let's break for lunch.

We'll be back in about an hour.

(Whereupon the jury was excused from the courtroom.)

THE COURT: Please be seated.

I know you offered, Mr. Cooke, a document, BlueWave 56, which was the final contract between BlueWave and HDL. I believe the government had it already in under another exhibit, but I don't believe you've offered it. I don't mind it being duplicative, but you need to move to --

MR. COOKE: I'm happy to borrow the government's

number if that would be acceptable. 1 12:05PM THE COURT: what's the final contract number, 2 12:05PM Ms. Short? Do you know that number? 3 12:05PM 4 MS. SHORT: Let us check. 12:05PM I've got it somewhere in these notes. 5 MR. COOKE: 12:05PM It's certainly in. I've seen it. 6 THE COURT: 12:05PM 7 MS. SHORT: Yes, Your Honor. It's U.S. Trial 12:05PM Exhibit 1047. 8 12:05PM 9 THE COURT: Okay. We're just going to -- when you 12:05PM 10 reference Bluewave 56, that is actually Plaintiffs' 1047. It's 12:05PM in evidence. 11 12:05PM 12 All right. Thank you. MR. COOKE: 12:05PM 13 Okay. Anything we need to take up before THE COURT: 12:06PM 14 we break? 12:06PM 15 MR. LEVENTIS: No, thank you, Your Honor. 12:06PM 16 THE COURT: From defense? 12:06PM 17 MR. ASHMORE: No, sir. 12:06PM 18 MR. COOKE: Nothing. Thank you. 12:06PM 19 THE COURT: Very good. 12:06PM 20 And, Mr. Cooke, you'll advise the witness that 12:06PM 21 you aren't being unfriendly; now that he's on the witness 12:06PM 22 stand, you can't really confer with him. 12:06PM 23 MR. COOKE: I'll advise him and everybody else in the 12:06PM 24 courtroom, Your Honor. 12:06PM 25 (Recess.) 12:06PM

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THE COURT: Please be seated.

Any matters we need to address before we bring in the jury from the government?

MR. LEVENTIS: No, Your Honor. Thank you.

THE COURT: From the defense?

MR. COOKE: Just that Mr. Griffith is meeting with the witness.

Is it all right if he's out of the courtroom?

THE COURT: Yes, absolutely. Please bring in the jury.

(Whereupon the jury entered the courtroom.)

THE COURT: Please be seated.

Mr. Cooke, please continue your direct examination.

MR. COOKE: Thank you, Your Honor.

### BY MR. COOKE:

**Q.** Good afternoon. I want to take you quickly through some of the other things that you did to get BlueWave up and organized.

We've been talking a lot about HDL, but you also entered into a contract with a company called Singulex; is that right?

- A. That's correct.
- Q. Would you tell us who Singulex is.
- A. Singulex is another advanced diagnostic company

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headquartered in California. What do they do that's different than HDL? Q. They did a lot of things that were similar, but the tests that we promoted for them that were different than the offering at HDL was a high-sensitivity cardiac troponin I. I've been cautioned to speak slower. High-sensitivity cardiac troponin I and some inflammatory markers, interleukin-6, interleukin-7A. To those of us who aren't and don't want to be doctors, 0. what does that do for you? They're very specific inflammatory markers and then a very Α. specific cardiac marker. And is that something that doctors sometimes like to use? 0. Α. Yes. And is it different than what HDL offered? Q. It was different than what HDL offered. would Singulex be considered a competitor of HDL? Q. In some states, they would be considered a competitor. Α. But in the states where BlueWave marketed for them, no. And did they each agree that you could market for both of Q. them? They both agreed that we could market for both of them. Α. who did you deal with primarily at Singulex? 0.

we had what was called an RMC, regional management

committee meeting. And that meeting was typically held

And Phillipe Goix was the CEO of Singulex. 1 1:28PM Gary Tom was the representative there. I don't recall his 2 1:28PM He was primarily responsible for billing. And then 3 1:28PM 4 myself and Brad Johnson. 1:28PM MR. COOKE: Can you bring up 1049. 5 1:28PM BY MR. COOKE: 6 1:28PM 7 I'm going to ask you to look at this -- it's an exhibit 1:28PM that's already in evidence, Plaintiffs' Exhibit 1049 -- and get 8 1:28PM you to tell me if this is the Singulex agreement. 9 1:28PM 10 Α. Yes. 1:28PM 11 was that modeled after the HDL agreement? 0. okav. 1:28PM 12 Yes. 1:28PM 13 Did Singulex have lawyers? Q. 1:28PM 14 Α. Yes. 1:28PM 15 Who were their lawyers? Q. 1:28PM I don't recall the names of the law firms that represented 16 Α. 1:29PM 17 them. 1:29PM 18 were they substantial law firms? Q. 1:29PM 19 Α. To my knowledge, yes. 1:29PM 20 Did they review the agreements? 0. 1:29PM 21 Yes. 1:29PM 22 Did they make any changes to the agreements? 0. 1:29PM 23 Α. 1:29PM Yes. 24 Did they add, for example, a provision that they could Q. 1:29PM audit you -- do a compliance audit every year? 25 1:29PM

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- A. Yes.
- **Q.** Did they bring up any potential problems with the agreement, such as that it called for commissions being paid to independent contractors?
- A. No.
- **Q.** Did they bring up any problems about waivers of copay and deductibles?
- A. No.
- **Q.** Did they bring up any problems about payment of process and handling fees?
- A. No.
- **Q.** How much was the process and handling fee under their agreement?
- A. When we first started with them, it was \$20, 17 P&H and 3 venipuncture.
- **Q.** And then what did you do?
- A. At my request, we lowered it down to 10 processing and handling and 3 draw fee for a \$13 combined fee.
- Q. Why that? I mean, why a lower fee for them than HDL?
- A. When we originally started with them, there was the hope that they would bring some additional biomarkers on that would be sold that would need to be run off an additional tube.

And it's not uncommon when a lab is starting to commercialize itself, especially when you're sending specimens across country, they do what's called validation within the

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laboratories. So they like to have more blood.

I used to joke and call them vampires. The more blood they had, they liked it.

But when I learned that the validation processes had been completed and we weren't going to be adding the additional biomarkers and there was one tube in there, I told them the \$20 processing and handling fee, in my opinion, was excessive.

- **Q.** Did both HDL and Singulex develop a laboratory service agreement to use with their -- with the physicians?
- **A.** Talking about a processing and handling letter of agreement?
- Q. Yes.
- A. Yes. There was a processing and handling letter of agreement for provider practices, and there was a separate one for lab to lab.
- Q. I'm going to show you 2626 -- Government 2626. Can you scroll down? Hopefully I've got the right number. Is that it?

  No. I thought that was the right number. Try 1144.

All right. Does that look like the process and handling agreement?

- A. That's an HDL processing and handling agreement.
- **Q.** Right. I want to call your attention to several provisions. Can you go to paragraph 5. Can you read that out loud.
- A. Yes, sir. "Number 5: Physician will not bill, receive,

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nor collect any reimbursement from any third-party payer, including commercial insurers and governmental programs such as Medicare and Medicaid for any processing and handling services or collection fees for which physician receives any fees from Health Diagnostic Laboratory."

- **Q.** And whose idea was that to put that in the agreement?
- A. That's been standard verbiage in every agreement -processing and handling letter of agreement I've ever seen, so
  I'm sure the attorneys put that verbiage in there.
- **Q.** Is that similar to the provision that was in the Berkeley agreement that Mr. Root opined on in his letter?
- A. They are virtually the same.
- Q. Can you look at paragraphs 7 and 8, please.

You said that -- it says there, "Each of the parties to this agreement shall comply with all applicable laws, and specifically physicians shall provide the processing and handling services and the collection services in accordance with all applicable laws, rules, and regulations."

And then what is the last provision there?

A. "Number 8: Nothing in this agreement or in any other written or oral agreement between HDL and physician with respect to the subject matter hereof nor any consideration offered or paid in connection with this agreement is intended to be an inducement to the referral of any item or service to HDL.

"Any consideration paid by HDL to physician as 1 1:33PM 2 compensation for the processing and handling services and the 1:33PM collection services provided hereunder is consistent with what 3 1:33PM the parties reasonably believe to be fair market value." 4 1:34 P M And was there a similar agreement entered into with --5 1:34 P M with Singulex and its physicians? 6 1:34 P M 7 Α. Yes. 1:34 P M were physicians required to accept process and handling 8 0. 1:34 P M fees? 9 1:34 P M 10 Α. No. 1:34 P M 11 But if they did accept processing and handling fees, did 0. 1:34 P M 12 they have to sign this agreement? 1:34 P M 13 Α. Yes. 1:34 P M I want to show you a document that's been marked as BW46. 14 Q. 1:34 P M 15 May I approach, Your Honor? MR. COOKE: 1:34 P M 16 THE COURT: You may. 1:34 P M 17 BY MR. COOKE: 1:34 P M 18 Do you recognize that? Q. 1:34 P M 19 I do. Α. 1:34 P M 20 And what is it? 1:34 P M 21 This is a "Processing and Handling Do's and Don't Test." Α. 1:35PM 22 And who developed this test? 0. 1:35PM Myself and Brad. 23 Α. 1:35PM 24 MR. COOKE: I would offer this into evidence, Your 1:35PM 25 Honor. 1:35PM

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Is there an objection to BlueWave 46? THE COURT: MS. SHORT: No, Your Honor. MR. ASHMORE: No, sir. THE COURT: Very good. BlueWave 46 is admitted without objection. Can we go ahead and bring that up. MR. COOKE: BY MR. COOKE: Tell the jury what this is. This is an assessment test that we would administer to our contractors upon completion of legal training addressing processing and handling fees. Why did you do that? From our experience, it was important to do legal training and make sure that everybody was reading off the same sheet of music and complying with all the laws. And did you also require that they take tests? Yes, we did. we'll cover that a little bit later. So, Mr. Dent, did you or did you not, while you were at BlueWave, use process and handling fees as an inducement to physicians to refer patients or to order tests? No, we did not. Why didn't you do that? As I stated before, when you're looking at the

Anti-Kickback Statute and the laws, you shouldn't do anything

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that -- these are my words -- corrupt the physician's mind when it comes to choosing an appropriate diagnostic, medication, imaging study, or anything else for their patients.

**Q.** But, Mr. Dent, you're paying money -- excuse me -- the laboratories are paying money to doctors.

why didn't that just hit you over the head as this
is -- there's got to be something wrong with this?

- A. Well, when I heard that originally, as I stated before, at Berkeley HeartLab, I asked the question. And then it was explained to me and clearly documented that it was appropriate because the staff of that physician practice, they're doing the work on behalf of the laboratory. So this was a way to ensure that they were compensated. And it was completely legal as long as it was within the fair market value assessments.
- Q. I'm going to -- we've heard an awful lot about what is said about processing and handling fees and what is said about the economics of advanced lipid testing, but I don't think this jury has really heard how Cal Dent sold these tests and how you trained the people that worked under you to sell these tests. So I want you to act like I'm a doctor and you're coming to see me for the first time.

First of all, how did you get into my office?

A. Well, access is difficult in some practices, which is why you would develop relationships with other people in a geographic area that might already have a relationship with

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that physician practice.

Primarily, those are pharmaceutical representatives that are calling on the practice. But you have to remember we were contracting with individuals that worked in the territory and knew the provider practices anyway. So they've already had established relationships that they've had for years.

But you can set up appointments. Sometimes you can't get an appointment at a physician practice unless you schedule it a year in advance. But primarily breakfast, lunch, dinner, and oftentimes they'll have a lunch calendar. just have to ask the questions and -- you know, with the staff to find out if they will perhaps entertain doing a breakfast, which would be earlier in the morning.

They don't like to typically do things that would disrupt seeing their patients in the middle of the day. that's why we'd work early morning and late evening, go to dinner a lot of times.

- How long -- once you got into the physician's office, I Q. guess you'd have to tell them what it is you're selling; right?
- Correct.
- And this would be a physician who's not currently a customer or a client of either HDL or Singulex?
- Correct. Α.
- So once you get in there, typically how long would you 0. spend with the doctor?

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- My average sales call went anywhere from an hour and Α. 45 minutes to two and a half hours.
- We're not doing that here. Q.

Is that all right with you?

- No, I perfectly agree with you. Everybody would go to Α. sleep.
- But I do -- and I'm being partly facetious because 0. obviously this is important.

So I would like for you to tell this jury in a condensed form what you would tell the doctor to get him to become a customer of HDL or Singulex.

I think you heard some testimony earlier from contractors that the government was calling to testify against us that said we would present them with knowledge of each of the individual tests and said that we would go over case studies with the providers and that we would also go over clinical studies to support any claim that had been made about a particular diagnostic. And that's exactly what we would do.

In fact, if I couldn't convince the doctor at that point that they wanted to do my testing, there's no sense in talking about processing and handling or training the staff on how to draw the blood anyway. If they don't want to do it, they don't want to do it. We're moving on to another customer.

which I want to pause on that, because that's extremely important when comes to the targeting criteria.

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time is valuable. I don't want to waste time and money traveling three different states to go and meet with a physician that's not going to be interested in our product.

That's where working with other sales representatives in the industry can help you identify the appropriate type of practice or doctor that would be interested in your test, which is why that priority criteria says somebody that's already doing advanced testing would be a great candidate because I don't have to convince them of the need to do advanced testing.

You heard testimony from an expert witness. It was a cardiologist that essentially said, in his opinion, none of these tests are medically appropriate. Well, I can assure you there's just as many cardiologists out there that would say, if you're not providing these tests for your patients, you're committing malpractice. So it's important to target the right physician.

But I would always lead with an opening statement that came right out of the JUPITER trial. And I would argue that the JUPITER trial is by far the single best statin monotherapy trial that has ever been done to date. double-blinded, randomized, placebo-controlled, large number of patients. In fact, there's 8,901 patients in the placebo group, 8,901 patients in the treatment group.

And it looks at men, women, all different ethnic It basically covers all comers of healthy backgrounds.

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patients.

But there's an opening statement in there after they had reviewed all the clinical literature that says 50 percent, half, of all patients that go on to have a heart attack or a stroke have normal LDL values according to the guidelines. That's sad.

And what I mean by that, if you got a 50 percent on your exam on law school, I assure you you probably wouldn't be standing here today. So 50 percent diagnostic is a failure.

And then I would assess, am I getting buy-in or not?

Am I getting disagreement with that? Would I get challenged on that?

If they want to challenge me, I'd give them a proof source. It wasn't me saying this. In fact, these are the lead doctors at Harvard, Cornell, Brigham and Women's Hospital that are making these statements, not me. So I'd support it with that.

Most physicians would agree right out the gate that there's a lot of patients that go on to have a vascular event -- whether it's here, whether it's here is irrelevant -- that they have treated the goal. In fact, they refer to them in doctor talk as mystery patients. The patient that had an event, they had treated aggressively, they had them to goal, and they really don't understand why they had an event and they want to know why.

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And I would explain that there's really three reasons for that, and I would go straight into a case study of a real patient that we're familiar with the ordering provider. So we know all the background. And I would go over that case study with them. I have it. I think you have it. It's been admitted into evidence.

Q. I think I've got three of them. They've been marked as BW494, 495, and 496.

MR. COOKE: May I approach to make sure I've got the right ones?

THE COURT: You may.

#### BY MR. COOKE:

- Q. These look familiar?
- A. These are all case studies. The one that I used probably 95 percent of the time is the 64-year-old male patient right here.
- **Q.** All right. Before you go into that, I'd like to offer into evidence all three of these.

THE COURT: Any objection?

MS. SHORT: No, Your Honor.

MR. ASHMORE: No objection.

THE COURT: Very good. BlueWave --

### BY MR. COOKE:

- Q. Do you have a copy of this with you?
- A. I do.

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THE COURT: Hold on just a minute.

BlueWave 494, 495, 496 admitted without objection.

MR. COOKE: Thank you.

And can we bring up 496.

# BY MR. COOKE:

- Q. Is that the one you wanted, Case Study Number 2?
- A. That's correct.
- Q. Okay. Bring that up.

Now, what is this that you're looking at?

- A. This is a real patient that had received Health Diagnostic Laboratory testing that was converted into a case study by the laboratory.
- Q. Okay. Show us the whole page.

And is this what a lab result report would look like?

A. Yeah, this is a lab report. And I'd usually tell the doc

- too on the front end, I don't want to oversimplify it, but red is bad, green is good, yellow is borderline, and the goal is green. You want to shift everything over to green either with lifestyle modifications and/or pharmacological intervention.
- Q. All right. So what would be the point of this particular case study?
- A. Well, can you zoom in just on that top block, the patient demographics. That one. Stop it at the bottom of the lipid block. Right there.

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This is where I would open because this is what over 95 percent of physicians out there are looking at when they're trying to manage lipid disorders in a particular patient. And I'll draw you a type.

You're looking at a 64-year-old male with a BMI of 23. He's only 5 foot 5, 139 pounds. So on physical appearance, most people would say this patient is healthy. You know, they don't have the -- and I would tell them they don't have the metabolic belly like me. They're probably not diabetic. They're not running around with that risk factor of obesity. You're not looking at this patient and determining risk.

Then I go to the lipid panel. Now, in all fairness -- and I was always very transparent with providers. I don't want to mislead anybody. This patient is already on treatment.

So this patient had hypertension. They were treated with 5 milligrams of Norvasc, amlodipine. They were treated to goal. Their blood pressures were in the 120/80 range, which is optimal blood pressure. And it had been that way for a while.

The patient was also on 10 milligrams of atorvastatin or Lipitor. I like this case study because I was familiar with those medications. I had sold them, so I was very familiar with them. And the lipids look absolutely phenomenal.

One you're probably most familiar with is that LDL of

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67. You heard earlier somebody saying, well, you really don't even need LDLs in a not-at-risk patient population less than 130.

Look at HDL. It's really high. It's 51. In fact, the total cholesterol is way below 200. It's only 133.

And I'd pause on that, and I would say, "Doc, if you saw this patient today knowing what I described, would you do anything differently?"

And I intentionally left that as kind of a broad question. "Well, they might be coming in and complaining with leg pain or something else."

And I'm like, "Of course. But aside from that, looking at their cardiovascular risk, would you do anything different?"

"Absolutely not. I'd pat him on the back and send him on his way and say, 'You look good. See you next year.'"

Here's what happened with this patient. He was home in the morning, woke up. When you have a catecholamine surge, you get crushing chest pain. And he reported numbness in his left arm and a tingling sensation in the fingers of his left hand.

His wife was a nurse, which is important because she called 911 first. Then she crushed up a 325-milligram aspirin and put it in a glass of water and asked him to drink it.

MS. SHORT: Your Honor, I'm going to enter an

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objection. All of this testimony is hearsay. There's no foundation --

THE COURT: He's not offering it for the truth of the matter. He's presenting his sales presentation.

Overruled.

THE WITNESS: And I would say these are case studies, that we do know the -- I have knowledge of the patient and the case study. It was trained to me what it was.

So the patient has crushing chest pain, wife called 911. Then she gave him the aspirin. That's important. Oftentimes, especially medical professionals will try to render help to the patient before they call for additional backup, but she did it right.

The patient made it to the hospital in a little over 20 minutes, which that may sound like a record time, but when you live in a metropolitan area and you have three heart hospitals from you, that's not superfast.

On presentation, he had an elevated CK-MB. And I don't want to get into too much of the science, but that's creatine Kinase-myocardial --

THE COURT: Let's keep it moving in terms of what the sales presentation is.

# BY MR. COOKE:

Q. Right.

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A. He had a heart attack. All right. So he goes on the

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cath. And he had single-vessel disease. It was in the left interior descending artery. That's commonly referred to as the widow-maker. Patient got a stent, loaded up on the medications that he's supposed to. It's a 1A recommendation for Plavix and aspirin. Most doctors will leave them on that indefinitely. I think the guideline is for one year. And the patient comes back six weeks later for a follow-up visit.

- **Q.** So let's just get -- can we get kind of to the punch line of what it is that you then tell the doctor on why he should be using these HDL tests?
- A. Well, the question at that point is to go back. Why did this patient have an event? And I would argue there's probably three reasons that could discuss it.

One, either the guidelines that are out there aren't setting the numbers low enough that you're treating to.

Perhaps the diagnostic that you're using has inaccuracies itself and is not measuring the parameter that you're treating.

And then, thirdly, what other residual risk factors are out there that you never even thought to look at?

There was an article just the other day on the front page of The New York Times about a gentleman that coach -- Q. Skip that part, please.

THE COURT: We want to talk about what was presented to the doctor.

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THE WITNESS: Okay. I'm presenting to the doctor there's a problem, and they're acknowledging there's a problem. They're telling me there's a problem.

And now I'm going to offer them a solution to the problem, advanced diagnostics that reveal residual risk. That's when I open the rest of the report up.

### BY MR. COOKE:

- Q. And you see all these red things; right?
- A. In this patient, you see a whole bunch of red things. And there's a lot of different things going on with the patient but -- and I'm more than happy to discuss all of those as in great or as little detail as you would like.
- Q. Well, I think the -- I do want to move on.

And I think the point that you're making to the doctor is that these tests would have picked up things that the tests that he was normally doing would not pick up; is that right?

A. That's correct. And I'll give you an example that you can relate to, and I'm only giving it because it was in testimony from an expert.

There's a high-sensitivity C-reactive protein in the inflammatory marker section, and you'll see it's in yellow. And there was a primary care doc that was being referenced that it was inappropriate for them to send this patient to me with an elevation at hsCRP and even remotely insinuate they might be

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at an increased cardiovascular risk.

That same testimony went on to say it's normal for people in their 70s to die of a heart attack. Well, my mother and father were in the room at that point, and they're both in their 70s and had heart surgery --

THE COURT: Mr. Cooke, I'm allowing the testimony for his sales presentation.

MR. COOKE: For the sales, right.

### BY MR. COOKE:

- **Q.** Don't talk about things that you've read or heard recently. My question to you is to go back on what you were telling in your sales presentation.
- A. So if a physician had zeroed in on hsCRP, which they would ask about that, I would go back to the JUPITER trial. And I would go straight to page 2196 of the JUPITER trial, and I would read to them measurement of the high-sensitivity C-reactive protein. It's an inflammatory biomarker that independently predicts future vascular events and improves global classification of risk regardless of LDL cholesterol level.

That one marker right out of a trial --

MS. SHORT: Your Honor --

THE WITNESS: -- from Harvard.

MS. SHORT: Your Honor, I'm not sure what he's reading from. It's not an exhibit in evidence.

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THE COURT: Yeah, I think what we need to do is he gets to present his sales presentation, but we're deviating off of that, basically making an argument for the test.

MR. COOKE: Okay. I appreciate that. You can appreciate that there's some overlap, obviously.

THE COURT: I understand.

MR. COOKE: But let me move ahead, because we really aren't going to do this for an hour and a half.

### BY MR. COOKE:

- Q. What if a doctor then says, "Well, Cal, you were telling me all that stuff back when you were selling me tests from Berkeley. I've been using Berkeley. Why should I switch to HDL?"
- A. "Well, Doc, there's a number of different reasons. You know, one of the problems that you complained of when you were with the Berkeley test is, gosh, this stuff can be really complicated and I have to go to all these different journals to find the treatment suggestions. So, Doc, that's one of the beautiful things about Health Diagnostic Laboratory. They have worked with Joseph McConnell from the Mayo Clinic to actually create treatment suggestions that come along with the report."

And that would get them excited. And then I could show them the report and then I could go to the treatment suggestions. And I would remind them these are treatment suggestions. They know in their own clinical judgment they're

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the only ones that can make the treatment, but it's nice to have something they can reference immediately.

If they wanted further clinical information, we had what was referred to as the physician reference manual, which I believe has been admitted as evidence. And you could pull one test, for example, APOE genotyping. Many physicians would question the clinical utility of APOE genotyping. And they'd say, "There's never been a clinical trial out there to support any use of that."

I said, "Really?"

And they'd say, "Yeah."

And I'd say, "Well, what are your favorite journals?" "Well, the American Heart Journal, Circulation, New England journal, Lancet."

There's 189 clinical trials referenced in the physician reference manual on that one diagnostic alone.

- How many trials would you say are referenced in that 0. entire manual?
- Α. Thousands.
- And these are all -- these aren't just things that the folks over at HDL cooked up; these are actually --
- Peer-reviewed clinical journals. And the beautiful thing about HDL's website, they could go to the physician reference manual and anywhere where there was a footnote about a claim, they could go right to the clinical trial and read it.

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was a resource for them that they valued tremendously. I guess you could argue that would induce a doctor to use us. Q. Did you ever tell a doctor that another good reason to use HDL is because we've got higher processing and handling fees than Berkeley? Never. Α. Never. Did you ever train anybody to do that? 0. Did not train anybody to do that. Did you train people by taking them around with you and Q. watching how you sell the doctors? I had many field rides where people rode with me in my own territory. And I traveled across the entire country to ride with people. Did you and -- and I cut you off. But, at some point in Q. your presentation, do you tell the doctor that -- how you're going to get the blood? We were never -- well, yes, absolutely how to get the Α. blood. well, in other words, is he -- are you going to provide a phlebotomist? Are you going to pay P&H fees? Would you explain to him what the options were for getting the blood delivered to the lab? Sure. Well, again, if you go back to the targeting

criteria, we're looking for physician practices that already

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have a means to draw blood in their office, preferably it being their employee. It could also be a Quest phlebotomist. It could be a LabCorp phlebotomist. It could be a draw site down the road, across the street. There's numerous ways for them to get blood.

That's what I was referencing earlier. 60 percent of practices didn't even collect the processing and handling fee. But if it's one that was familiar with it, you gave an example of a prior Berkeley customer, I could say a LipoScience customer, an Atherotech customer, any other customer that had processing and handling fees, they would usually initiate the question, does the laboratory pay a processing and handling fee if my staff performs the work? And, absolutely, I tell them yes.

"How much is it?"

"Well, the HDL pays a \$17 processing and handling fee."

- **Q.** About how much -- percentage of the time would a physician ask you about process and handling fees?
- A. I could best correlate that with the number of physicians that actually collected a processing and handling fee. So I would say, in my best estimate, it's 40 percent.
- **Q.** Can you think of even one time when you ever told or hinted to a doctor that one of the reasons that he ought to order more tests is because he could get more process and

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handling fees?

- A. I can't think of a single time that I said that. But I will tell you there will come into evidence something that is being referred to as a pro forma, which we'll explain when we get to it, insinuating that that is what I did.
- **Q.** Well, you were here, weren't you, when we saw the videotape of Mr. Blasko?
- A. Yes.
- Q. And did you train him?
- A. No.
- **Q.** Well, who trained him?
- A. I'm not sure if he was -- he obviously was trained from the video. My best guess is Charles Maimone, one of the BlueWave contractors, trained him.
- **Q.** And how did you feel the first time you saw that presentation? You remember Mr. Blasko kind of leaning in and saying, "Doc, there's an economic aspect to this"?

Do you remember that?

- A. I do. I believe the jury saw that same video, and then they also saw a video of me describing it. And my conclusion was it looked like a "Saturday Night Live" skit.
- **Q.** In what way?
- A. Well, in my video, I said, "Hey, Doc, you can get \$20 per test." And I just -- that was inappropriate and not the way we would train anybody.

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- **Q.** Why is it inappropriate?
- A. Again, there's no -- it's improper to offer a doctor something that would cloud their judgment. And I think the way that he was promoting that could potentially be interpreted as clouding a physician's judgment. And I'm right in that or we wouldn't be in this room today.
- **Q.** I want to take you through -- and we're not going to spend a lot of time on any one thing, but I want to do a chronological trip through some of the documents that the jury has already seen. Is that all right with you?
- A. Yes, sir.
- **Q.** Can we start with Plaintiffs' 1136. I'm sorry. Skip that.
- 1162. Do you remember seeing this? This is an email dated June 16, 2010. And this involves correspondence with Kyle Martel. Do you remember him?
- A. I know who Kyle Martel is, yes.
- **Q.** He was the guy that came up here and pleaded the Fifth Amendment to everything; right?
- A. Yes, that was Kyle Martel that pleaded the Fifth Amendment.
- Q. All right. Did you encourage him to plead the Fifth?
- A. Absolutely not.
- Q. Did you want him to testify?
- A. I would have loved for Kyle to testify, but he was scared

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to death to testify.

Q. Don't --

THE COURT: Sustain that objection.

MR. LEVENTIS: Objection, Your Honor.

THE COURT: Mr. Cooke?

## BY MR. COOKE:

Q. Don't talk about what Kyle said. All right?

But you've seen this document that's in evidence.

And go ahead and put it down to the whole thing. Can you come down to that section down there.

This is dated June 16, 2010. It says, "Thanks so much for taking the time to meet with me yesterday. Per our discussion, I have an opportunity to make more clinical and business sense to your practice than your current in-office lab services provided by Premier Laboratories.

"The new advanced lipid panel I represent includes NMR LipoProfile test" -- so on and so on.

Read that to yourself. Do you see where he's talking about the financial aspects of this program?

- A. Can you direct me towards a particular sentence?
- **Q.** Well, he just refers to it as a business opportunity. Do you see that?
- A. I do.
- **Q.** Did you ever encourage your contractors to approach a potential client that way?

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- A. I did not. In fact, we trained them not to do any kind of marketing claims or create your own marketing materials on your own. And I would consider an email doing that to be inappropriate. That's most likely why I'm not copied on it.
- **Q.** And I was going to ask you that before I went to the next one. Were you aware of this, or were you copied on it in any way?
- A. I've never been made aware of this until this investigation.
- Q. And you're not copied on this email?
- A. I'm not copied on this email.
- Q. All right. Let's look at 1194. Going down to the bottom, if you would.

You see here this question was being asked to -- of you. It says, "I'm not sure why the reps would want the doctor to send samples to LipoScience when we carry the same test and can provide the full LipoScience report to any doctor that wants it, as we do with Fillingane."

And then -- see the one right up above that? It says

I am -- Steve Norris. Do you know who Steve Norris is?

- A. I see that.
- **Q.** Who is Steve Norris?
- A. Steve Norris, I don't know his official title, but I would have classified him as manager over client services at HDL when we first started. This is in 2010.

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Q. Okay. He says, "I am pretty sure it is to receive both P&H fees."

Do you see that?

- A. Yes, I do.
- **Q.** Then scroll up. And Tonya says, "I understand but was politely asking Cal and Brad to fix it."

Do you remember that?

- A. I do.
- **Q.** And then up to the top, going to the top. And then he says, "Understood."

What was that all about?

- A. Can you go down to the bottom and see if it references the territory that it's coming out of?
- Q. Don't see it.
- A. I don't either, but I can explain why he would ask that.

Several of the initial BlueWave contractors that we were bringing on board had also sold for LipoScience. And LipoScience proprietary technology was NMR, which is nuclear magnetic resonance. One of the beautiful things about Health Diagnostic Laboratories is they had acquired the best of the best diagnostics from all these other labs. In other words, they had myeloperoxidase from Cleveland HeartLab. They had cholesterol absorption markers, which Boston was offering to try to differentiate itself. And they also included the NMR test with their offering.

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At Berkeley, NMR was a primary competitor or target for mine to switch over because SGGE, segmented gradient gel electrophoresis. So I thought this is wonderful, you got a lab that offers both technologies, not just one. So it's even better for the physician. They can choose which one they want. If they want both, they can have them both.

The problem with the initial report that HDL was doing is many of the physicians that had done NMR testing before through LipoScience, they didn't like the fact that HDL only reported LDLP and HDLP. Those were just two of the tests from the LipoScience report. Tonya had all the other values, but to try to consolidate and put all the values on the one sheet of paper, she wasn't giving the whole report.

So the reason doctors were sending it to NMR, they still wanted to get the full report. Eventually, that stopped happening because Tonya created, in my opinion, an NMR report that looked better than the one LipoScience had originally.

- **Q.** But, here, the comment says, "I'm pretty sure it's to receive both P&H fees." Is that something that you would encourage to --
- A. No. And I can't speak to Steve Norris and where he came up with that conclusion or who he got that from.
- **Q.** But weren't you doing that with Singulex? We've heard testimony that suggested that people were encouraged to order both from HDL and Singulex so they could get both process and

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handling fees.

A. Well, there's nothing inappropriate for a doctor to send specimens to multiple labs. Again, that's one of the benefits of HDL, is it consolidated things that they were already sending to other labs because they could get them at a one-stop shop, a Walmart, if you will, but a highly -- a high-end Walmart. So they could get it all at one place.

So you're absolutely correct. If a physician wanted the Singulex test and HDL, they still had to send blood to two different locations. In fact, we were trying to get some sort of agreement between HDL and Singulex so that didn't have to happen because it made the sales reps' job a lot easier.

Because this -- probably -- here's another point to make.

One of the hardest parts of our job is convincing the phlebotomist to do two and three times the amount of work. They're drawing more tubes, filling out more requisitions, packing up more boxes when they have to send things out to multiple labs. It's easier for them to send it to one lab.

- Q. But with this Singulex thing, it's true -- is it true, like they said, that if the doctor ordered both an HDL set of tests and then Singulex at the same time, that they could get process and handling fees from both?
- A. They could get processing and handling fees for both because they're performing the work required for both labs.

  They could not get the draw fee twice. If they were collecting

the draw fee, for example, with HDL, and they happen to fill a 1 2:06PM 2 tube up for Singulex off that one draw, then they could only 2:06PM get the processing and handling from Singulex, which would have 3 2:06PM been the \$10. 4 2:06PM Is that because they're only sticking the patient one 5 2:06PM time? 6 2:06PM

- A. That is correct.
- Q. So was it ever part of your sales presentation that you could encourage a doctor to order more specimens, get more P&H fees, and then even increase it more by doubling up and ordering from Singulex at the same time?
- A. No, it was not.
- **Q.** Did all of the doctors that you worked with order from both HDL and Singulex?
- A. No.
- **Q.** About what percentage would you say? Is there way of guessing?
- A. Less than 10 percent of the physicians that order HDL specimens ordered Singulex with an HDL specimen.
- **Q.** And when they did order a Singulex specimen, why would they order?
- A. First of all, selling Singulex is a very technical sale.

  And most physicians, when they hear troponin I, they think ER,

  they think going in to rule in or rule out a heart attack. And
  that's true going back in time, because it was once believed

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that you only had elevations in troponin I when you had acute myocardial death or necrosis of the myocardial cells.

Singulex had developed a technology that was a thousand times more sensitive than the historical cardiac troponin I marker, which now you had a test that would give you prognostic utility, not just diagnostic utility.

And I'm trying to speak in layman terms, but what we learned from that is, as you and I -- all of us who are sitting in this room, you actually have troponin I circulating in your blood. It's just there's never been a diagnostic sensitive enough to pick it up. But most of that, hopefully, in this room is due to apoptosis, which is a normal dying off of cells.

So if you can establish a baseline of cardiac -- THE COURT: Mr. Cooke.

#### BY MR. COOKE:

- Q. I think we got --
- A. Okay. Sorry.
- Q. So anyway --
- A. This is how I sold.
- Q. I know, but we just don't have time.

So there would be different clinical reasons to order a Singulex test in addition to an HDL test? Is that what you're telling us?

A. Yes.

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Q. All right. I'm going to move on now. We talked about pro

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formas, a pro forma being some sort of a financial model or financial calculation. Do you recall that?

- A. I do.
- Q. I'm going to show you what's been introduced as Plaintiffs' Exhibit 1099. And this is dated September 23, 2010. I'm not going to get you to read the whole thing, but it starts out -- it's to Lori Mallory, not to be confused with Tonya Mallory, but it's Lori Mallory at Kansas City Internal Medicine.

And she starts out, "My name is Burt Lively. I am a colleague of Brad Johnson. He asked me to provide you with a lipid clinic pro forma based on our discussion."

Do you remember seeing that?

- A. I remember seeing this in the course of this investigation, yes.
- **Q.** All right. And do you -- can you explain to the jury what Mr. Lively was doing there?
- **A.** Well --
- **Q.** Obviously, you're not the one that told him to send it, because Brad Johnson -- it says Brad Johnson did, but --
- A. Right.
- **Q.** -- who was Kansas City Internal Medicine? Why did they want a pro forma?
- A. I'm not best to speak to this. I don't know who Kansas
  City Internal Medicine is. I didn't call on them. But I can

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speak to what the pro forma is from Burt's perspective.

**Q.** Yeah, that's -- I think that's what I really wanted to ask.

MS. SHORT: Your Honor, objection. Hearsay. Testifying as to what somebody else's perspective is?

THE COURT: Yeah, he can testify -- I'll sustain that objection.

You asked him, though, a different question, which was, there's this pro forma, and you were asking him. He can certainly address whether he promoted that or whatever.

## BY MR. COOKE:

- Q. Right. And can you explain -- and you've read this before, so I'm not going to ask you to do it again for the jury.
- A. Right.
- Q. But can you explain what the purpose of that communication with that particular potential customer was?
- A. I don't think I'm in the best position to explain the purpose of it.

THE COURT: I sustain the objection.

MR. COOKE: All right. We'll move on.

# BY MR. COOKE:

Q. Let me ask you this: Was it permissible to use a proforma when requested by -- or to provide a proforma when requested by a client or a potential client who was trying to

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consider different options?

- A. My first formal training on pro forma occurred when I was at Berkeley HeartLab. And a lady by the name of Jennifer Mason, whose husband was a cardiologist, that worked at Berkeley HeartLab, she later went to Atherotech, she was a cardiac nurse, and she had written a pro forma with Frank Ruderman and Michael Mercer, who were the CEO and the COO at Berkeley HeartLab --
- Q. Okay. Needs to be a little bit shorter than that.
- A. Okay.
- Q. Just get to the bottom of --

THE COURT: The question was proper; the answer wasn't responsive. So why don't you ask the question?

BY MR. COOKE:

- **Q.** It was buried in there somewhere. When, if ever, would it be appropriate to send a pro forma to a client or a potential client?
- A. There's nothing that forbid anybody from sending pro forma, about we never trained anybody to use a pro forma as a methodology to induce the referral of patients.
- Q. Let's -- let's clear the air about one thing. Were you ever in all of your career taught that it was somehow illegal to answer questions about the financial aspects of the products that you were selling?
- A. Never.

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- **Q.** And were you trained to understand that physicians run a business and have to pay their expenses like everybody else?
- A. I believe that's common sense.
- Q. So we're going to talk about some specific ways that different people have talked about the financial arrangements.

But, in your own words, can you describe -- where's the -- where's the line that you taught people not to cross between answering questions and addressing the financial aspects of your product versus using that as an inducement for referrals?

A. If you can't sell the test off clinical utility, you're not going to sell the test, period, in my opinion. In fact, at Berkeley, there was an initiative one quarter to sell what were referred to as lipid clinics.

And a lipid clinic was essentially -- it's really verbiage. It was to have a medical doctor do the initial visit with the patient, the initial test interpretation, and then they would send them to a mid level, whether that be a nurse practitioner, PA, to do the follow-up visits.

So the pro forma that Jennifer Mason had put together addressed that model within a business presence.

- **Q.** And do you know whether this company that's referred to here ever became a client of HDL?
- A. It's my understanding in the course of this investigation that they did not, but I don't have personal knowledge of the

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customer.

- Q. All right. Let me show you Exhibit 1230. Now, this is the one that the jury was shown. And it says -- it's not from you, but you're copied on this. And it says, "FYI to all, I want to refocus that this is a PH fee, not a draw fee. One word makes it legal; the other illegal."
- A. I agree with that statement.
- **Q.** So that's not an admission that we're trying to skirt the law here?
- A. Absolutely not.
- **Q.** Can you explain to the jury what that means?
- A. I think I had testified earlier that at Berkeley, we had very formal training, and always have, to differentiate what a draw fee is versus a processing and handling fee. There's federal guidelines guidance that you cannot exceed \$3 for the draw fee.

when it came to the processing and handling, that was a fair market value question because what are you processing and what are the handling? what type of specimen? how many tubes? does it go in a cooler? does it have to be on ice? et cetera.

- Q. And so that goes back in -- I think you read that out of Mr. Root's letter back at Berkeley HeartLab; correct?
- A. That's correct. And what happened is some of the contractors we had hired from other companies, we would notice

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in conversation with them in the field, they would say "the draw fee, the draw fee." And we'd have to stop them and differentiate, say, "Hold on a second. It's the processing and handling fee; it's not a draw fee."

So Brad's clarifying that.

Understood.

Let me show you Exhibit 1075. And can you tell what this is?

- A. That's the training booklet for a new hire.
- **Q.** All right. And is that one that you used at BlueWave?
- A. Yes.
- Q. I want to take you into -- let's go down to page 18026, if we can.

All right. First of all, "Things you should learn," down here at the bottom.

Do you see where it says "Targeting" and so forth?

- A. I do.
- **Q.** Did you typically tell your folks to go out and get all those money-hungry doctors that wanted processing and handling fees?
- A. I don't think I ever used that verbiage.
- **Q.** Okay. Did you tell them to go look for doctors that wanted process and handling fees?
- A. No.

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Q. Well, right down here, see at the bottom, it says "Most

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Common Obstacles"?

- A. Yes.
- Q. P&H, the very first one.
- A. Yes.
- Q. Does that mean that a common obstacle is that you have to offer the doctor --

MS. SHORT: Objection, Your Honor. Can he ask a non-leading question?

THE COURT: Yeah, let the witness testify.

MR. COOKE: All right.

THE COURT: Sustain the objection.

MR. COOKE: Thank you. And I apologize.

### BY MR. COOKE:

- **Q.** What does that phrase mean?
- A. That one of the most common obstacles is processing and handling. I think I testified to that earlier.

One of our -- hardest part of our job is convincing the phlebotomist to process and handle that blood. I mean, you're asking them -- the example of switching from Berkeley to HDL, I'm asking them to process four tubes instead of two tubes. Never mind. That's twice as much work.

I'd argue it's not twice as much work. There's only one requisition, but it certainly adds to their workload.

**Q.** So this phrase in your manual, does that even refer to P&H fees?

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- It's referring to the function of processing It does not. and handling the blood.
- There was some testimony about a communication from a Q. Mr. Perling.

Do you remember that?

- I remember the name. Α.
- All right. Let me show you 1266. Q.

And Florida was not your territory, was it?

- It was not. There were three contractors in Florida.
- So I'm not going to spend a lot of time on this, but do Q. you remember seeing this exhibit shown to the jury?
- I do. Α.
- And it's a communication from a Mr. -- go to bottom of this, if you would. And this is -- it looks like a customer is writing and saying, "Please see below for comments from our health care attorney regarding the HDL contract. forward this to HDL's legal department for review to see what they can do to work this out."

Scroll to the top, and I just want to see what BlueWave did with that.

Anytime, if we had a question of legality or appropriateness or inappropriateness of something, we would forward that to the CEO of the lab and have them have their attorneys review it.

It's my understanding that Lester Perling was the

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attorney representing a doctor down in Florida that had a question about the legality of P&H. And Lester Perling, in turn, was linked up with the attorneys at HDL. They had a phone conversation and exchanged emails, and the problem was resolved. And that physician became a customer of HDL.

Q. All right. Let's look at 1266. This is dated December 13, 2010. And it says, "I have spoken with Cal about this already, and we definitely have to address this very soon as they have a hefty amount of specimens that are already ready to ship today."

In other words -- I'm sorry. What is he referring to there?

A. It says, "I have spoken with Cal about this already, and we definitely have to address this very soon as they have a hefty amount of specimens that are already ready to ship."

I always, when I trained on an in-service, fresh blood is good blood and cold blood is good blood. You don't want the blood sitting out at room temp for more than an hour, and you want to ship it out overnight the same day in which it was drawn.

I assume he's referencing that they need to get this resolved quick or these specimens are going to go bad, which in turn means the patient would have to come back and get stuck again. So that's not a good thing.

MR. COOKE: To close the loop, may I approach, Your

Honor? 1 2:20PM 2 THE COURT: You may. 2:20PM BY MR. COOKE: 3 2:20PM 4 Q. I'll show you what's been marked as BW Exhibit 68. 2:20PM 5 Do you recognize that? 2:20PM This appears to be the continuance of this. 6 Α. 2:20PM 7 Thank you. Q. 2:20PM 8 Yeah. Α. 2:20PM And we would offer BlueWave 68, and I 9 MR. COOKE: 2:20PM 10 believe there's no objection. 2:20PM 11 Any objection? THE COURT: 2:20PM No objection. 12 MS. SHORT: 2:20PM 13 MR. ASHMORE: No objection. 2:20PM BlueWave 68 admitted without objection. 14 THE COURT: 2:20PM 15 Please continue. 2:20PM 16 MR. COOKE: Can you go ahead and bring that up. 2:20PM 17 BY MR. COOKE: 2:20PM 18 All right. Does this appear to be an email from Tonya to Q. 2:20PM Kyle Martel? 19 2:21PM Kyle was one of the contractors --20 2:21PM 21 Florida contractor. 2:21PM -- in Florida. 22 Ο. 2:21PM And she says right there in the middle, "I wanted to 23 2:21PM 24 give you an update on the discussions that our attorney has had 2:21PM 25 with Dr. Reddy's attorney, Lester Perling." 2:21PM

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Does that appear to confirm that, in fact, HDL's attorney did have discussions with Mr. Perling?

- A. That's the email I was referencing that confirmed my testimony was true and accurate.
- **Q.** Is that the way that you would normally deal with any questions about legality of processing and handling fees?
- A. Any legal matter would be forwarded to the CEO of the lab in question so that they could handle that with their legal team.

MR. COOKE: Let's move forward to 2011. Could we have Mallory Exhibit 3, please.

#### BY MR. COOKE:

- **Q.** All right. Do you recall seeing this? Is this another instance in which Tonya Mallory referred a matter to Patrick Hurd at LeClairRyan?
- A. I'm not copied on this one.
- Q. Do you remember that?
- A. Can I read it first?
- Q. Yes.

### (Pause.)

THE WITNESS: I don't recall that, but I have complete faith and confidence that Tonya sent everything to her attorneys for review.

## BY MR. COOKE:

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Q. Let's move forward. I'm going to show you another Kyle

Martel email, 1257. It's already in evidence. Have you seen 1 2:23PM 2 this one before? 2:23PM You don't need to read it out loud, but if I could 3 2:23PM 4 just give you a moment to look at it yourself and tell this 2:23PM jury whether you ever saw it prior to this litigation. 5 2:23PM I don't recall seeing this even in the course of this 6 2:23PM 7 investigation. 2:23PM Do you -- is this the -- is this a presentation 8 Okay. 0. 2:23PM 9 that you would have endorsed had it been presented to you for 2:23PM 10 approval? 2:23PM 11 I'll have to read it to --Α. 2:23PM 12 Go ahead and read --0. 2:23PM 13 Objection, Your Honor. MS. SHORT: 2:23PM 14 THE COURT: Sustained. 2:23PM 15 I just don't understand why you would do that, 2:23PM 16 I mean he's not familiar with the document. Mr. Cooke. 2:24 P M 17 MR. COOKE: Okay. 2:24 P M 18 BY MR. COOKE: 2:24 P M 19 would you have ever approved a sales presentation or an 2:24PM email to a potential customer which emphasizes the financial 20 2:24PM 21 aspects of testing? 2:24 P M 22 Α. No. 2:24PM 23 That's a proper question. THE COURT: 2:24 P M 24 MR. COOKE: Thank you. 2:24 P M 25 BY MR. COOKE: 2:24PM

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- **Q.** Did you guys give yourselves tests on whether you were staying up with -- with the -- with the technology of compliance training?
- A. Yes.

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- **Q.** Did you take tests yourself?
- A. I did.
- Q. I'm going to come to some of the specific tests in a few minutes, but first I want to show you -- if I can find my page of notes on it.

May I have a moment, Your Honor? I'm missing a page of my notes.

THE COURT: Take your time.

MR. COOKE: Do you have my 2012 -- oh, you got it. Thank you.

### BY MR. COOKE:

Q. Can we look at the Exhibit 1004, please. This is one that is copied to you, and this is Plaintiffs' Exhibit 1004. And it's to a Dr. Netter.

"I hope all is well. Cal asked me to forward the attached pro forma and the most current contract with Quest Diagnostics. Please don't hesitate to call if you have any questions."

Do you remember that?

- A. Yes.
- Q. Why did you ask that that material be sent to Dr. Netter?

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A. Dr. Netter and Dr. Phillips had recently joined up to practice out of the same office. And it's important to note at this point in time, both of them were what are commonly referred to as MD VIP physicians. So they're primarily operating off of a cash reimbursement-type model.

Nancy Netter had had several problems with phlebotomists when they -- originally, she had LabCorp.

LabCorp was drawing the specimens for HDL and Singulex. They later came in and said, "We're not going to draw these specimens anymore." That was for competitive reasons. And they pulled their phlebotomist out, and she had a Quest phlebotomist come in.

The Quest phlebotomist, in turn, was drawing HDL and Singulex specimens, and she had the same thing happen. And so she asked if we could take a look at what her specimens were with HDL. It was easy for Singulex; she didn't order Singulex.

But also Dr. Phillips, because he was now in the same office building with her, Dr. Phillips authorized that as well. He did order HDL and Singulex to see what their ordering patterns were, look at the P&H fees, and see if it made sense for her to hire that Quest phlebotomist as her own employee and would it make more sense to have her as a part-time phlebotomist, a full-time phlebotomist, and would the P&H fee offset her expense to do that.

Q. Were you using that to induce her to order more tests?

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- A. Absolutely not.
- **Q.** Let's look at Exhibit 1122. This is going to relate to a question that somebody raised about process and handling fees, I think.

This was on March 27, and it's from you to Tonya Mallory. It says, "Attachment for your records. Can you please send me the form letter you use to address matters like this?"

And I'm going to ask you to assume that the attachment was a question that related to process and handling fees.

But what was the letter that you would send to address matters like that?

- A. I need a little more background to -- zoom in on this.
- Q. You want me to read the whole page?
  Is there another page to it? Is that all?
  Okay. There you go.
- A. So this is the attachment?
- Q. This is the attachment from Pathology Laboratories. It says, "Pathology Laboratories has recently been made aware that there is a laboratory offering payment to physicians for the collection of samples sent to that laboratory for testing. As a result, PathLabs wants to make you aware that payment for collected referrals has potential legal consequences to both the laboratory and the physicians."

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Was it usual to see other laboratories out there saying things about you to customers?

A. No. I mean, from time to time, you'd have questions about processing and handling fees. Once we left Berkeley and started promoting for HDL, there was an influx of questions about the legality and illegality of it because -- you heard testimony about Frank Ruderman, the ex-CEO of Berkeley HeartLab, going out and actively going into accounts himself and distributing a McDonald Hopkins legal letter saying that all the practices at HDL were doing were illegal.

So competitors were equipping doctors. Tonya's attorneys conducted that law firm with a cease and desist. They adhered to it. And so getting a letter like this became more commonplace at this time.

- **Q.** Did it occur to you that it would be beneficial to have a new formal legal opinion for HDL?
- A. HDL reviewed their legal opinions annually. It said that at the bottom of the position statement in 2010 that they routinely did actual reviews and such.
- **Q.** And let me show you Exhibit 1253. We've seen this. This is what we call the LeClairRyan letter from April 27, 2012.

Do you know how that came into existence?

A. Well, Tonya had always been seeking to get a formal legal opinion, and she wanted to complete the time and motion study by an outside vendor. We all agreed that the internal one

2:31PM	1	could be presumed to have bias, even with our knowledge of the
2:31PM	2	industry. Again, I compliment her for seeking an outside
2:31PM	3	company to do one, a formal one.
2:31PM	4	Q. Who did she get to do it?
2:31PM	5	A. Exponent was the name of the company, and I believe it was
2:31PM	6	recommended by Michael Ruggio.
2:31PM	7	Q. And who is Exponent?
2:31PM	8	A. They're a company that specializes in doing time and
2:31PM	9	motion studies. They have engineers that throw value
2:31PM	10	assignments for space and equipment. They specialize in doing
2:31PM	11	these type of studies.
2:31PM	12	Q. Did you ever see the study that they performed for HDL?
2:31PM	13	A. I did.
2:31PM	14	MR. COOKE: May I approach, Your Honor?
2:31PM	15	THE COURT: You may.
2:31PM	16	BY MR. COOKE:
2:31PM	17	Q. Does that look like the report that you saw?
2:32PM	18	A. That looks like the report that I saw. I seem to recall
2:32PM	19	it being thicker than that.
2:32PM	20	Q. There are a lot of attachments that I'm not including.
2:32PM	21	This is just the
2:32PM	22	A. Okay.
2:32PM	23	MR. COOKE: I would offer this as BlueWave
2:32PM	24	Exhibit 157.
2:32PM	25	THE COURT: Any objection?

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MS. SHORT: No, Your Honor.

MR. ASHMORE: No, sir.

THE COURT: BlueWave 157 admitted without objection.

#### BY MR. COOKE:

**Q.** I'm not going to ask you to go through the report, but the jury will have it to look at. And let's go back to the LeClairRyan letter.

This is the one that Mr. Ruggio wrote?

- A. Yes, sir.
- **Q.** Were you given a copy of this letter?
- A. The LeClairRyan letter?
- Q. Yes.
- A. Yes.
- Q. Why was it -- while we're waiting for this, why was it important for you to have a letter like that?
- A. Again, it's nice to have the legal opinion in hand to reference in the event that a potential client ever asks a question about the legality or appropriateness of P&H fees. But it's also reassuring to me to know that the lab we're representing has done their homework and got things approved appropriately.
- **Q.** All right. Let's go through the aspects of this letter, then.

Can you highlight the first couple of paragraphs.

Can you just make it big enough so that he can read it.

1 2:34PM 2 2:34PM 3 2:34PM 4 2:34PM 5 2:35PM 6 2:35PM 7 2:35PM 8 2:35PM 9 2:35PM 10 2:35PM 11 2:35PM 12 2:35PM 13 2:35PM 14 2:35PM 15 2:35PM 16 2:35PM 17 2:35PM 18 2:35PM 19 2:35PM 20 2:35PM 21 2:35PM 22 2:35PM 23 2:35PM 24 2:35PM

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2:36PM

Okay. You see that? "Allowance fee to physicians to reimburse the costs associated with the extensive process and handling of samples collected at independent locations for testing by HDL need to be reviewed in accord with the applicable federal law."

Did that strike you as being similar to what Mr. Root had analyzed at Berkeley?

- A. Very similar.
- **Q.** I'm going to ask you to skip to the second paragraph -- third paragraph and ask you if you could read that out loud, please.
- A. Starting with "historically"?
- **Q.** Yes.
- A. "Historically, HDL has expended great time, effort, and resources to conduct a time and motion study to determine fair market value associated with these services. In 2010, HDL's analysis revealed a fair market value of approximately \$34.83, including blood collection supplies, \$7.90; processing and handling, \$25.44; space cost of 85 cents; and equipment costs of" -- it looks like -- ".64. However, this estimate did not include the costs associated with follow-up on the call center, involving nurses. So a new time and motion study was conducted in early 2012."
- Q. Go ahead and read the next paragraph.
- A. "This review was conducted by Exponent and based first on

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identifying the time estimates using the costing model and, second, assigning the cost to professional time and related supplies and materials that would be required for process and handling.

"Finally, this primary analysis was used in that phase, which involved including the data and process manager at HDL; identifying the call center as a source of this retrospective data; providing information on rate, type, and duration of follow-up activities conducted by the site personnel."

Q. Go to the next page. And I'm not going to get you to read the whole thing. I want you to go to the conclusion.

Can you read the last paragraph.

A. "Based on our recent analysis of the report prepared by Exponent of HDL's staff and resources involved and that HDL has defined this as a typical site, a fair market value of up to but not to exceed \$36.03 per specimen for processing and handling tasks is appropriate and justifiable.

"HDL's current agreements with physicians in this regard are well below that amount. Based on this careful study, this arm's length, fixed-in-advance fair market value fee will fall into the safe harbor exceptions under the Anti-kickback Statutes and the civil False Claims Act to alleviate any issue in that regard.

"The safe harbor requires that the aggregate

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compensation pay for the services of said advance and be consistent with fair market value and based on Exponent's detailed review and our analysis of applicable laws. HDL is acting within applicable statutory laws to pay this fair market fee for processing and handling services.

- **Q.** Let me ask you this: Did a physician get a higher process and handling fee for a specimen if he ordered in bulk or if he ordered more tests?
- A. No.
- **Q.** Was there anything he could do to get the amount of that processing fee to increase?
- A. No.
- Q. If they asked for more fees, what would the answer be?
- A. No.
- Q. Well, what if they said, "But even though it's not an inducement, well, we'll order more tests. We're just planning on our own to order hundreds of tests. Could we get a higher process and handling fee for doing that?"

What's the answer?

- A. No.
- Q. Why?
- A. It's fixed in advance and aggregate. The fee is set for that total amount, and it's not going to change.

And there was testimony earlier that the practice had asked for a higher fee, and they were told no.

6 2:39PM 7 2:39PM 8 2:39PM 9 2:39PM 10 2:39PM 11 2:39PM 12 2:39PM 13 2:39PM 14 2:39PM 15 2:39PM 16 2:39PM 17 2:39PM 18 2:39PM 19 2:39PM 20 2:39PM 21 2:40PM 22 2:40PM 23 2:40PM 24 2:40PM

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- **Q.** And, in fact, is that what you told anybody who asked for a higher fee?
- A. I actually don't recall anybody in my geography asking me for a higher fee.
- **Q.** I'm going to move quickly through a couple of other things that just chronologically fall into place. Let's look at 1166. This is a reference to another pro forma.

Do you remember this, "MD VIP Doc," and you're writing to -- looks like to Tonya?

Do you see that?

- A. I see it.
- **Q.** Can you say briefly in, like, a minute or so what this related to? Do you remember it?
- A. Can you go to the initiating email?
- Q. Yeah, go to the -- sorry. Thought we were there.
- A. So this is the email here?
- **Q.** Yes. Do you see that there? He's asking the questions about getting a phlebotomist and then putting other --
- A. I remember this.
- Q. Okay. What was the outcome of that?
- A. I'd have to read the entirety to get all the specifics down, but Anna McKean was an employee at HDL. And she had a family member, I believe it was an uncle, that was in North Carolina that was an MD VIP doc, one of those concierge physician practices.

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And at this time in 2012, there had been discussions about having draw centers in different areas where it made sense. If there was enough patients under management in a particular area, they were contemplating doing that. So this was, I believe, discussions surrounding that.

MR. COOKE: And go ahead and scroll to the top of that, please.

## BY MR. COOKE:

- **Q.** So do you know what, if anything, was done about putting a phlebotomist in that office?
- A. I don't know. I don't remember, but if -- I mean, I'm sure there would be follow-up emails. I'm asking a question of Jerry Carroll, who was the responsible contractor for this geographic area. And I'm asking, "Hey, is this the MD VIP doc that you visited before?"

Because I remember there was an MD VIP doc that he had talked about before he was going to do a draw center.

Q. Let's look at 1203. This is an email that we spent some time with last week when Mr. Cornwell was on the stand.

Do you remember that?

A. I do.

24

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- **Q.** Have you seen this email?
- A. I saw it last week.
- Q. All right. Were you copied on this email?
- A. I was not.

- 1 2:41PM 2 2:41PM 3 2:41PM 4 2:41PM 5 2:41PM 6 2:41PM 7 2:41PM 8 2:41PM 9 2:41PM 10 2:41PM 11 2:41PM 12 2:42PM 13 2:42PM 14 2:42PM 15 2:42PM 16 2:42PM 17 2:42PM 18 2:42PM 19 2:42PM 20 2:42PM 21 2:42PM 22 2:42PM 23 2:42PM 24 2:42PM 25 2:42PM
- Q. Did he run it by you beforehand?
- A. He did not.
- Q. How did you like it when you saw it?
- A. I didn't like it.
- Q. Why?
- A. Well, there's a lot of claims and inaccuracies, and he doesn't even know who people are, and he's promoting stuff in a fashion that I believe to be inappropriate.
- Q. And what did you think was inappropriate about it?
- A. Well, from what I remember last week, he was talking about processing and handling fees and talking about the -- really kind of position he is in an inducement. I would have thought that would be very inappropriate.

And they weren't supposed to create any marketing materials themselves. This is obviously a marketing email that would fall into that category.

- **Q.** Did he take your tests?
- A. He did.
- **Q.** And did he pass?
- A. He passed the tests.
- **Q.** Let's look at 1126. This is August 26, 2012.

You remember this?

Go all the way to the bottom of this. There's an attachment, I think.

Do you remember somebody sending a statement from the

```
NLA?
                     Is that the National Lipid Association?
          1
2:42PM
          2
                    I do.
              Α.
2:42PM
                   Do you remember seeing that?
          3
              Q.
2:42PM
          4
              Α.
                   Yes.
2:42PM
          5
                         MR. COOKE:
                                     Go ahead and scroll forward so we can
2:42PM
              follow chronologically.
          6
2:43PM
          7
              BY MR. COOKE:
2:43PM
          8
                   That was forwarded by Dr. Pokrywka to Tonya Mallory;
2:43PM
          9
              correct?
2:43PM
         10
              Α.
                   Correct.
2:43PM
         11
                                    And then go ahead and scroll forward.
                         MR. COOKE:
2:43PM
         12
              BY MR. COOKE:
2:43PM
         13
                                What was this about?
                   All right.
              Q.
2:43PM
                   Well, the National Lipid Association had put some verbiage
         14
2:43PM
         15
              on their website saying, hey, this processing and handling fee
2:43PM
              arrangement between laboratories and physician practices is
         16
2:43PM
         17
              getting some scrutiny. And, hey, docs, if you do this, you
2:43PM
         18
              need to check it out with your attorneys, and I want to make
2:43PM
         19
              everybody aware of this.
2:43PM
         20
                   And what was done with that when you got it?
2:43PM
         21
                    I would have forwarded that to Tonya and her legal team.
2:43PM
         22
                   And did you do that?
              Q.
2:43PM
         23
                   Do you have the email showing that I did?
2:44PM
         24
              Q.
                   Yeah.
2:44PM
         25
              Α.
                    Okay.
2:44PM
```

2 2:44PM 3 2:44PM 4 2:44PM 5 2:44PM 6 2:44PM 7 2:44PM 8 2:44PM 9 2:44PM 10 2:44PM 11 2:44PM 12 2:44PM 13 2:45PM 14 2:45PM 15 2:45PM 16 2:45PM 17 2:45PM 18 2:45PM 19 2:45PM 20 2:45PM 21 2:45PM 22 2:45PM 23 2:45PM

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- Q. Go ahead and scroll to the top.
- A. So it's sent from my Blackberry. I missed that. And what did I say? I just forwarded it to her with no comments, it looks like. I forwarded it to Brad.
- **Q.** And did you -- do you remember whatever came of that as far as the HDL attorneys reviewing it?
- A. I believe the HDL attorneys reviewed it.
- Q. Okay. Let's look at 1310. It's an email the same day.

This was the one that was referenced where Tonya writes to Boomer and said, "I'm sorry Scott Davis and Frank Ruderman are giving you a hard time down there."

Can we scroll to the bottom so we can see what she was talking about? I guess that's it.

Who were those two gentlemen?

- A. They both worked with me at Berkeley HeartLab. Frank Ruderman was the CEO of Berkeley, and Scott Davis was a sales rep quickly promoted to regional sales manager and then became Frank Ruderman's right-hand man.
- **Q.** Let me show you exhibit -- and they were still with Berkeley HeartLabs, and they were a competitor?
- A. I don't know if they were at Berkeley at this point. They had left and were trying to start another lab at one point, too.
- Q. Okay. Look at Exhibit 1244. This has been referred to a number of times as the Kung memo.

Did you come to learn who Derek Kung was? 1 2:45PM 2 Derek Kung was general counsel for Health Diagnostic Α. 2:45PM Laboratories. 3 2:45PM 4 Q. This is a memorandum that he addressed to the board of 2:45PM 5 directors at HDL on August 30, 2012, talking about HDL 2:45PM arrangements and anti-kickback and Stark. 6 2:46PM 7 Do you see that? 2:46PM 8 I do. Α. 2:46PM 9 Were you copied on that memo? 2:46PM 10 I only learned of the Kung memo as everybody is 2:46PM 11 referencing it in the midst of this investigation, in 2:46PM 12 discovery. 2:46PM 13 All right. Did anybody ever tell you what the Kung memo Q. 2:46PM said? 14 2:46PM 15 Not until this investigation. Α. 2:46PM 16 You were not on the board? 0. 2:46PM 17 No, I was not on HDL's board. Α. 2:46PM 18 Do you remember that, under the provisions of the Singulex Q. 2:46PM 19 contract, they were allowed to -- were they allowed to audit 2:46PM 20 you? 2:46PM 21 They were allowed to audit us, yes, sir. Α. 2:46PM 22 Did they do that? 0. 2:46PM 23 They did. They exercised that right twice. 2:46PM Α. 24 What company did they use? Q. 2:46PM 25 The first one was a company by the name of Navigant. Α. 2:46PM

1 MR. COOKE: And, Your Honor, may I approach? 2:46PM 2 THE COURT: You may. 2:46PM BY MR. COOKE: 3 2:46PM 4 Q. Does that appear it be a draft report, and were you 2:47PM provided with that? 5 2:47PM 6 Yes. 2:47PM 7 Your Honor, we would offer -- this is MR. COOKE: 2:47PM BlueWave Exhibit 142. 8 2:47PM 9 MS. SHORT: No objection. 2:47PM 10 MR. ASHMORE: No objection, Your Honor. 2:47PM 11 Bluewave 142 admitted without objection. THE COURT: 2:47PM Please proceed. 12 2:47PM 13 BY MR. COOKE: 2:47PM 14 So what did this company Navigant do? First of all, do 2:47PM you know anything about Navigant? 15 2:47PM Navigant is a very large consulting firm that does a lot 16 2:47PM 17 of different types of audits, including audits of sales teams 2:47PM 18 in the medical industry. 2:47PM And do they audit specifically for compliance with federal 19 2:47PM 20 health care laws? 2:47PM 21 That was a part of this audit. 2:47PM 22 0. Okay. 2:47PM 23 Could we go to page 3 of that report. 2:47PM 24 See the "Project Scope. Navigant Consulting, Inc., 2:47PM 25 served as Singulex's independent third-party auditor to perform 2:48PM

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a compliance audit of BlueWave's sales practices, with an emphasis on training, materials, client interaction, anti-kickback/Stark Laws, HIPAA, and other relevant federal and state regulatory compliance."

Do you recall being told that that's what they were going to do?

- A. That was absolutely the scope of this audit.
- Q. And were you interviewed by them?
- A. Yes, I was. I flew to Atlanta, stayed in the airport Marriott, and met with one of their lead auditors.
- **Q.** Did they look at your contracts?
- A. They looked at our sales contract agreement.
- Q. Did they look at the processing and handling fees?
- A. They looked at the processing and handling letter of agreements between both laboratories.
- Q. What else did they do?
- A. They interviewed us. They asked for a lot of different records. They wanted all of our training materials, our introductory packet, PowerPoint presentations, tests that had been administered. They also wanted to conduct field rides with our contractors, and we gave them a list of all the contractors and let them contact them on their own. And we had a conference call with the field contractors to let them know that they may be contacted by somebody from Navigant, that it was a real request, and please allow them and set up a timely

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6	М	Ρ	9	4	:	2
7	М	Ρ	9	4	:	2
8	М	Ρ	9	4	:	2
9	М	Ρ	9	4	:	2
10	М	Ρ	9	4	:	2
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13	М	Ρ	9	4	:	2
14	M	Ρ	9	4	:	2
15	M	Ρ	9	4	:	2
16	M	Ρ	9	4	:	2
17	М	Ρ	9	4	:	2
18	М	Ρ	9	4	:	2
19	М	Ρ	0	5	:	2
20	М	Ρ	0	5	:	2
21	М	Ρ	0	5	:	2
22	М	Ρ	0	5	:	2
23	М	Ρ	0	5	:	2
24	М	Ρ	0	5	:	2
25	М	Ρ	0	5	:	2

ride-along so that they can interview you and observe your selling.

- **Q.** Did they ever say anything to you about your contract possibly being illegal because it provided for commission payments --
- A. Never.
- Q. -- based on the volume of your sales?
- A. Never.
- **Q.** And did they even say, "Well, it's a gray area" or "it might be tricky" or anything like that?
- A. No, sir.
- **Q.** How about the process and handling fees? Did they ever tell you that those were illegal?
- A. They did not.
- **Q.** Or might be illegal?
- A. No, they did not say they might be illegal.
- Q. Look at page 5, please.

Back up one. Scroll down so I can see the -- there it is. That's what I wanted to see.

This one is not in color, but you see what they did?

Looks like they did the same thing that you guys did.

- A. Yeah, I thought it was actually pretty neat that their report was color-coded just like the lab reports.
- Q. Red, green, and yellow?
- A. Yep.

```
Let's look at page 6.
          1
              0.
2:50PM
          2
                         Your page number must be different than mine.
                                                                          Scroll.
2:50PM
          3
              up a bit. I'm sorry. I had the wrong page.
2:50PM
          4
                         Look at page 7. You see where they begin to talk
2:50PM
              about the individual elements? You see "oversight" was green?
          5
2:51PM
                   I do.
          6
              Α.
2:51PM
          7
                   Written standards --
              Q.
2:51PM
                   Well, I don't see the colors on this.
          8
              Α.
2:51PM
          9
                   well, it says green. See it right there?
              Q.
2:51PM
                   Oh, at the bottom. I thought you were talking about the
         10
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         11
              table. Yes.
2:51PM
         12
                   And then green was -- "written standards" was yellow?
              Q.
2:51PM
         13
              Α.
                   Yes.
2:51PM
                   Go to the next page. "Communications" was yellow?
         14
              Q.
2:51PM
         15
              Α.
                   Yes.
2:51PM
                    "Training" was green?
         16
              0.
2:51PM
         17
              Α.
                   Yes.
2:51PM
         18
                    "Auditing and monitoring" was yellow?
              Q.
2:51PM
         19
              Α.
                   Yes.
2:51PM
                    "Disciplinary guidelines," yellow?
         20
2:51PM
         21
              Α.
                   Yes.
2:51PM
                   "Investigatory policy guidelines" was green?
         22
              Q.
2:51PM
         23
                   That's correct.
2:51PM
              Α.
         24
                   And were they -- they were aware -- excuse me.
              Q.
2:51PM
         25
                         were they aware that you were independent
2:51PM
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## contractors?

- A. They were aware we were independent contractors.
- **Q.** Were they aware that you used independent contractors?
- A. They were aware that we used independent contractors.

They were given copies of the independent contractor agreements as well and reviewed those.

- **Q.** Did you take into consideration any of the recommendations that Navigant made?
- A. Yeah, we went through each one. In fact, I remember the disciplinary guidelines, and said no guidelines and no specific policy. And I said, "Well, can you give me example of what we need to do?"

And they said, "Our legal counsel recommends you initiate a retaliation policy."

And I said, "What's a retaliation policy?" I had never heard of such a thing.

And he said, "Well, if an employee does something or reports another employee for doing something inappropriate, there needs to be guidelines that you can't retaliate against them."

I said, "Well, you do realize" -- at that time, I said, "There's three employees: Me, Brad, and our executive administrative assistant."

And he said, "Yeah, I do." He goes, "Well" -- he says, "Everybody else is an independent contractor." He goes,

"Well, it's my recommendation. Whether you do it, I mean, it's 1 2:52PM 2 up to you, but as you grow and you get more employees, that's 2:52PM something you may want to consider." 3 2:53PM 4 Q. All right. Let me show you something related to one 2:53PM 5 aspect of training. 2:53PM May I approach again? 6 MR. COOKE: 2:53PM 7 THE COURT: You may. 2:53PM BY MR. COOKE: 8 2:53PM 9 Show you what's been marked as BlueWave 6. Do you 2:53PM 10 recognize what that is? 2:53PM 11 It looks like an agenda for training call on P&H fees. 2:53PM 12 MR. COOKE: I would offer this as an exhibit, Your 2:53PM 13 Honor. 2:53PM 14 MS. SHORT: No objection. 2:53PM 15 No objection. MR. ASHMORE: 2:53PM Bluewave 6 admitted without objection. 16 THE COURT: 2:53PM 17 BY MR. COOKE: 2:53PM 18 And it's pretty short. Q. 2:53PM 19 So can we bring that up. 2:53PM 20 This was dated November 1, 2012, and it's an email 2:53PM 21 from Sandra Tankersley. She was one of your -- she was your 2:53PM 22 employee? 2:53PM 23 Yes. 2:53PM Α. 24 To you and to Brad, and the subject was "Agenda for Q. 2:53PM 25 training call on P&Hs." 2:54PM

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2	:	5	4	Ρ	М	5
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2	:	5	4	Ρ	М	8
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2	:	5	4	Ρ	М	10
2	:	5	4	Ρ	M	11
2	:	5	4	Ρ	М	12
2	:	5	5	Ρ	М	13
2	:	5	5	Ρ	М	14
2	:	5	5	Ρ	M	15
2	:	5	5	Ρ	M	16
2	:	5	5	Ρ	M	17
2	:	5	5	Ρ	М	18
2	:	5	5	Ρ	М	19
2	:	5	5	Ρ	М	20
2	:	5	5	Ρ	М	21
2	:	5	5	Ρ	M	22
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2	:	5	5	Ρ	М	24
2	:	5	5	P	М	25

Attachment was a PPTX. Is that a PowerPoint?

- A. PowerPoint presentation.
- Q. "Kickbacks, gratuities, and conflicts of interest."

Do you happen to remember why you undertook that particular training at that particular time?

- A. We did training routinely. We tried to do, as I mentioned before, anti-kickback, Stark, False Claim Act training annually. I know HIPAA was done every six months.
- Q. Let's look at Exhibit 1096, please, plaintiffs' exhibit.

This is -- this is dated January 4, 2013. And who is taking that test?

- A. This is me taking the test.
- **Q.** Okay. Did you have to take the test yourself?
- A. From my military experience, I thought it was always the appropriate thing to do and set the example. If I'm asking them to take it, I should take it too.
- Q. How did you do on it?
- A. I think I passed.
- **Q.** Let's look at the first question. I'm just going to race you through it here.

Can you give gift cards to physicians and phlebotomists?

A. The answer is no. And I'd like to elaborate on that.

Again, we were hiring contractors -- or our contractors had worked for a lot of advanced laboratories. And

some of those laboratories allowed those individuals to give 1 2:55PM 2 gift cards to staff in an office but not to an ordering 2:55PM provider. And we believed that the best policy was no gift 3 2:55PM 4 cards at all to anybody. So we would continually stress that 2:55PM 5 to folks. You don't give gifts cards. That's probably the 2:55PM reason for the exclamation points. 6 2:55PM 7 Are you allowed to take a doctor out to eat at a 2:55PM 8

- conference where you see them?
- If you're at a conference somewhere, dinners are permitted for business discussions.
- "Can you supply a hotel and pay for travel for doctors to 0. attend a conference?"
- As a general rule, the answer is absolutely not.
- "Can you pay for referrals?" Q.
- Α. No, not.

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- Can you pay -- can you give anybody a finder's fee that's not a doctor --
- Α. Sure.
- -- if it's a pharmaceutical representative or something 0. like that?
- You could do that. Α. Sure.
- "Can you supply a lab with equipment not related to lab Q. services?"
- Α. No.
- "Can you supply your physician with a phlebotomist?" Q.

- 2:56PM 1 2:56PM 2
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- A. Yes. There are instances in which you could provide a phlebotomist.
- **Q.** "Can you persuade your doctor to perform unnecessary tests?"
- A. No.
- Q. Can you send the doctors on a cruise?
- A. No.
- **Q.** "Can you emphasize in your presentations how much the physician will make?"
- A. No.
- Q. "Can you go to prison for violating Stark and anti-kickback laws?"
- A. Yes.
- **Q.** Can you persuade your doctors to -- well, it looks like you asked that one twice.
- A. Well, it's to perform unnecessary tests, no. Yeah, it's the same as 7.
- Q. Number 12. "Do we balance-bill patients?"
- A. No.
- Q. Okay. And then you've got an explanation there.
- A. Yeah, it says, "We do not charge patients for non-covered tests. We will at least collect copays and deductibles as required by in-network contracts," which is referencing the commercial insurance companies. If you're in a network with one and you have a contractual obligation, the lab has to

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collect those copays and deductibles.

- Q. And that's what you explained earlier?
- A. Yes. There's also some states that had state statutes we learned about later. That needed to be done as well, and Tonya did that.
- Q. "Do we bill for copays and deductibles?"
- A. Which number are we on?
- **Q.** 13.
- A. Yes, for in-network contracts. That's kind of what I was explaining.
- **Q.** Number 14, "If a doctor tells you he'll do a hundred tests a week if you give him a registered dietician, what do you say?"
- A. The answer is no, because that's something that is linked to volume.
- **Q.** Is there another page?

"A doctor asks, 'Can I get \$25 draw fee?' Your answer?"

- A. That's kind of a trick question because it's for a physician practice, and the answer is no. But you could do -- the draw fee is \$3. Processing and handling fee is different. So there's a lot of different things that you could talk about there.
- **Q.** So that one was doubly wrong because it's \$25 and it refers to draw fee?

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A. That's correct.

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**Q.** Glad you explained it.

"Do we have a legal document for P&H?"

- A. The answer is yes.
- **Q.** And what was the legal document?
- A. I'd have to look at the date on this. There was several at that time. The LeClairRyan legal opinion letter is the primary one.
- Q. And then "What is the P&H fee?" You don't need to read that. I think we've heard that.

"How much is the P&H fee?" I think we've heard that one. And you broke it down for HDL and for Singulex.

"How many tests do you have to do to get a registered dietician? How do you answer?"

What do you tell them?

- A. You can't link a number of tests to having a registered dietician.
- **Q.** Okay. How much can you spend per year on a health care provider?
- A. That comes directly out of the laws addressing how much you can spend. \$360 is what we incorporated as our policy, but it actually has a built-in annual percent increase. So I wouldn't hit anybody if they said 372 at that point in time. It may be higher than that now.
- Q. And here's a good one. "How much per year does a doctor

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earn from P&H for performing 10 tests a week?"

- A. They don't earn anything. It's paid to the practices to offset the time and energy that their staff takes to perform a service.
- Q. Now, go back and let's look at the date of this. This was January 4th of 2013. Was this before you ever received a subpoena from the Justice Department?
- A. We certainly had this test before. I think you saw some that were admitted into evidence that go back to 2010. And we would tweak this from time to time. We received the subpoena early in 2013. Do you know the exact date?
- Q. I believe the testimony was it was in late January.
- A. Yeah. So this is before the subpoena was received. This was part of our course of training.
- Q. And let's look at 1221.

THE COURT: Mr. Cooke, are we -- we've been going a little over an hour and a half. Are you going to be much longer on this? Do you want to break now or you want to --

MR. COOKE: Could I just ask him one question about this and then we'll break?

THE COURT: Absolutely.

## BY MR. COOKE:

Q. And in honor of the looming break, we're not going to ask you to go through the whole test, but I am going to ask you, this one was dated September 19, 2013. And so, by this time,

you're well into the investigation. 1 3:00PM 2 Α. Correct. 3:01PM And let me ask you, did that change your answers to any of 3 Q. 3:01PM 4 the tests, the test questions? 3:01PM I don't believe so. 5 Α. 3:01PM MR. COOKE: Your Honor, this would be an 6 3:01PM 7 appropriate --3:01PM 8 THE COURT: Good. 3:01PM 9 Ladies and gentlemen, let's take our afternoon 3:01PM 10 break. 3:01PM 11 (Whereupon the jury was excused from the courtroom.) 3:01PM 12 THE COURT: Please be seated. Any matters we need to 3:01PM 13 address before the break from the government? 3:01PM 14 MR. LEVENTIS: No, Your Honor. 3:01PM 15 From the defense? THE COURT: 3:01PM 16 MR. COOKE: Nothing. Thank you. 3:02PM 17 Very good. Let's take about a 10-minute THE COURT: 3:02PM 18 break. 3:02PM (Recess.) 19 3:02PM 20 Please be seated. Any matters we need to THE COURT: 3:16PM 21 address before we bring back the jury? 3:16PM 22 MR. LEVENTIS: Yes, sir. 3:16PM Bring back the jury. 23 THE COURT: I'm sorry? 3:16PM 24 MS. SHORT: Just one quick question. Counsel were 3:16PM 25 wondering during the break what the order of cross-examination 3:16PM

will be. Do you want the United States to go first or 1 3:16PM 2 Mr. Beattie? 3:16PM I'm going to have the government cross 3 THE COURT: 3:16PM 4 first, and then the codefendant. 3:17PM 5 MS. SHORT: Okay. Thank you. 3:17PM Good. And I do that by the way of 6 THE COURT: Okay. 3:17PM 7 the order of the pleadings. That's the logic. You're the 3:17PM plaintiff. 8 3:17PM (Whereupon the jury entered the courtroom.) 9 3:18PM 10 THE COURT: Please be seated. 3:18PM 11 Direct examination, please continue. 3:18PM 12 MR. COOKE: Thank you. 3:18PM 13 BY MR. COOKE: 3:18PM 14 Mr. Dent, what would you do if somebody failed the test or 3:18PM didn't pass some parts of it? 15 3:18PM we'd call them up if there was a question that was missed 16 3:18PM 17 and just talk them through it and ask what they were thinking. 3:18PM 18 And, nine times out of ten, they misread the question. 3:18PM On the -- and on the training sessions, did you, from time 19 3:19PM 20 to time, have attorneys on calls where legal matters are being 3:19PM 21 discussed? 3:19PM 22 we had attorneys on calls when legal matters are being Α. 3:19PM 23 discussed. Not on the tests, but --3:19PM 24 Q. No, no. On the training -- on the training sessions? 3:19PM 25 Α. Yes. 3:19PM

3:19PM	1	<b>Q.</b> Did you have lawyers participate in that?
3:19PM	2	A. Yes.
3:19PM	3	Q. You started to tell me something. And I'm jumping around
3:19PM	4	a little bit here. But when you were at Berkeley, did they use
3:19PM	5	pro formas on occasion there?
3:19PM	6	A. Yes. There was a quarter that we were tasked to go out
3:19PM	7	and sell, quote/unquote, lipid clinics. That was their
3:19PM	8	strategy for that particular quarter. And it failed miserably.
3:19PM	9	And I thought it would on the front end.
3:19PM	10	<b>Q.</b> And that was the lipid clinic that you were describing
3:19PM	11	earlier in your testimony?
3:19PM	12	A. Yes, sir.
3:19PM	13	Q. Were you informed as to whether using the pro forma in
3:19PM	14	that setting was legal when you were at Berkeley?
3:20PM	15	A. I wasn't told it was illegal.
3:20PM	16	Q. Did they did the top management know that people were
3:20PM	17	using pro formas to try to promote these lipid clinics?
3:20PM	18	MR. LEVENTIS: Objection, Your Honor.
3:20PM	19	THE WITNESS: We were tasked to go out
3:20PM	20	THE COURT: Does he only if he has knowledge,
3:20PM	21	actual knowledge.
3:20PM	22	BY MR. COOKE:
3:20PM	23	Q. Do you know whether
3:20PM	24	THE COURT: Sustained.
3:20PM	25	BY MR. COOKE:

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  - Q. -- the people in the supervisory responsibility at Berkeley were aware that pro formas were being used to try to promote the lipid clinics?
  - A. Yes.
  - **Q.** Do you know of other laboratories that had used no-balance billing?
  - A. It's still in practice today.
  - **Q.** Where?
  - A. All over the country. I mean, as I stated before, you have to use a no-balance billing program for Medicare and Medicaid.
  - **Q.** What about for private insurers?
  - A. It depends on whether you're in network or out of network or if there's a state statute that forces you to make an attempt to collect copay and deductible.
  - **Q.** Are you aware of other laboratories who used essentially the same no-balance billing policy that HDL and Singulex used?
  - A. Yes.
  - Q. Did you think it was a unique or unusual practice?
  - A. No.
  - **Q.** You said something about trying to convince a phlebotomist to do extra work. Can you elaborate on that? Why was that difficult?
  - A. Well, I could give examples where you sell the physician on the test. They want to do it. They want to run it. And

3:21PM	1	you have a test review scheduled to come back in and go over
3:21PM	2	the test, and there's no test. And you go down and find out
3:21PM	3	that it was the phlebotomist didn't draw them.
3:21PM	4	Q. Did you find that sometimes phlebotomists or physician
3:21PM	5	staff was already pretty busy before they met you?
3:21PM	6	A. Physician practices are very busy.
3:22PM	7	Q. Did you often deal with the phlebotomists yourself?
3:22PM	8	A. Yes.
3:22PM	9	<b>Q.</b> The Singulex contract provided for the audit, and we've
3:22PM	10	looked at one of the reports. Were you audited another year?
3:22PM	11	A. We were.
3:22PM	12	Q. And were you advised of any deficiencies that required
3:22PM	13	remedial action?
3:22PM	14	A. We were not.
3:22PM	15	Q. As a result of any of the Singulex audits, were you
3:22PM	16	advised that an independent contractor arrangement was
3:22PM	17	impermissible?
3:22PM	18	A. No.
3:22PM	19	Q. That commission-based compensation was impermissible?
3:22PM	20	A. No.
3:22PM	21	Q. That waiver of copays and deductibles was impermissible?
3:22PM	22	A. No.
3:22PM	23	Q. That process and handling fees were illegal
3:22PM	24	A. No.
3:22PM	25	Q or risky?

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Α.
     No.
     Or that they were too high?
Q.
Α.
     No.
Q.
     Up until this lawsuit or the -- well, up until this -- up
until this lawsuit, did anybody ever tell you that it was
illegal to pay a process and handling fee as long as it was
fair market value?
     I was never told that paying a processing and handling
fee --
          MS. SHORT:
                      Objection.
                                   I couldn't follow the
question -- there seemed to be something embedded in that
question.
                      I don't think so.
          THE COURT:
               You want to repeat it just so she will hear it?
          MR. COOKE:
                      Sure.
          MS. SHORT:
                      Thank you.
BY MR. COOKE:
     Up until this litigation, were you ever advised or told
that it was illegal to use process and handling fees that were
fair market value?
Α.
     No.
     So let's talk a little bit about what happened in 2013.
0.
That was the year of the subpoena; correct?
Α.
     Correct.
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Could you tell us how that began for you?

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- well, we received a subpoena from -- from the federal I had never seen one before. So, immediately, we turned it over to Gene Sellers, who was our corporate counsel. And he acknowledged this is beyond the scope of what he can So he forwarded it over to Gene -- or not -- Gene forwarded it over to John Galese with Galese & Ingram, who had done litigation work for us in the past. And John was quick to say, "we need somebody that's more familiar with all the health care stuff." So both Gene and John Galese and Jeff Ingram accompanied us to be introduced to White Arnold & Dowd.
- Where is that firm located? 0.
- Birmingham, Alabama.
- And we heard from Linda Flippo. Is she a member of that Q. firm?
- She is. Α.
- who else did you meet with at the firm?
- Met with Mark White, Augusta Dowd, Hope Marshall, and Linda Flippo. And then Gene Sellers, John Galese, and Jeff Ingram were at that meeting.
- were you candid with them in telling them what your business practices were?
- I think I'm candid with everybody about everything. Α.
- You were candid with your lawyers? Ο.
- Absolutely. Α.
- At any time during their representation of you, did they Q.

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ever tell you that you're breaking the law and you need to stop what you're doing?

- A. No, they did not.
- **Q.** So what happened with the investigation?
- A. Well, we kind of turned it over to the attorneys, and then there was a request for documents. Linda Flippo was the one who was primarily responsible for the collection of documents. She made trips to the corporate office.

I flew back out to Birmingham again to bring my phone and my laptop so they could copy everything off of it. I mean, we cooperated with every request we were ever sent.

- Q. How did things progress from there?
- A. With regards to?
- **Q.** Do you recall a meeting in June?
- A. The one that's being referenced as a summit meeting?
- Q. Yes.
- A. Yes, I recall that meeting.
- Q. I'm trying not to lead you because this is an important part. So I'm just going to ask open-ended questions.

Did you go to Richmond and meet with other people?

A. We were asked by Tonya at HDL to come to Richmond for a strategy meeting, and we had to execute some documents related to another cancer laboratory that we were starting up. And we went up there for that purpose.

I remember when we went into the hallway, which led

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to the conference room, which I believe was attached to Russ Warnick's office, I round the corner and I saw Gene Sellers.

And he was wearing a suit, and I'd never seen Gene Sellers in a suit. And I saw Mark White and Linda Flippo. And I'm like, What are y'all doing here?

They're like, Well, we're coming here for a meeting.

I'm like, Who's paying you to be here? I didn't know you were here. What's this about?

They said, well -- and then Mark piped in and said, "Brad, remember I told you that we had to come to this meeting?"

Brad said, "No, I don't remember that." He said, "Well, what are we here for?"

I said, "They asked us to come up here. We said okay."

- **Q.** Were you aware by then that Ropes & Gray was representing HDL?
- A. I knew Ropes & Gray was representing HDL at that point, yes. I had never met Ropes & Gray, but I heard the name.
- Q. What did you know about Ropes & Gray?
- A. They were another massive health care law firm with 600-plus attorneys.
- **Q.** Up until the day that you walked into that meeting, had anybody told you about something called Project Twilight?
- A. No.

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- Q. Had you met a gentleman by the name of Nick Pace?
- A. No. I think -- I recall meeting Nick Pace one time in the hallway at HDL, and I think it was that same morning when we were being escorted up to that room.
- **Q.** Had anybody briefed you up to that point on what HDL was negotiating or talking to the government about?
- A. Me personally? No.
- **Q.** Well, how about -- well, did you hear about any negotiations that were going on?
- A. No.
- **Q.** Were you aware that -- that the HDL attorneys were, in fact, talking to the government?
- A. This is in June of '13, and the subpoenas were received in early '13. There had been lots of discussions about the document production, responding to the subpoenas, what are they looking at, are you guys a target.

I remember that was a legal term that was explained to Brad and I. They're like, "You don't want to be a target."

I'm like, "What's a target?" I don't know the legal description of it, but basically if you're target, somebody is going after you for criminal action.

- **Q.** And the Anti-Kickback Statute, did you understand that the Anti-Kickback Statute is a criminal statute?
- A. I've always understood it to be a criminal statute that

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resulted in prison time if you broke it.

- **Q.** So prior to your coming to that meeting, were you ever made aware that HDL had already decided to start moving away from processing and handling fees?
- A. No.
- **Q.** Is that a conversation that you would like to have been part of?
- A. It would have been nice to know, yes.
- **Q.** Did you ever tell anybody that you would not be willing to quit selling products that had processing and handling fees if the government said to stop?
- A. I remember at White Arnold & Dowd being asked the question, what's your stance on processing and handling fees? If they go away, will you still sell?

I'm like absolutely, I mean, but it needs to be an industry standard.

- **Q.** Have you ever knowingly broken the law in your -- in your work?
- A. No.
- Q. Would you ever do it?
- A. Not intentionally.
- **Q.** So what happened at that meeting?

The Ropes & Gray attorneys spoke, and we heard that Cal got revved up.

A. Yes.

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- Q. Can you tell us about that.
- A. Well, that "revved up" terminology came in Linda Flippo's minute notes when we -- they were required to produce attorney-client privileged information. That's the first --
- Q. We do know our case, so just tell me about how you got revved up.
- A. Okay. Well, I was surprised when I saw the term "revved up." I wouldn't deny getting revved up over something that I believed in. But I do remember the meeting, and those notes clearly helped refresh my memory of the meeting.
- **Q.** All right. So what did they tell you, and what did you say at the meeting?
- A. Well, we walked into the meeting. Tonya explained to us and introduced us to Brien O'Connor and Laura -- I believe it's pronounced Hoey -- and said they were with Ropes & Gray and representing HDL and were currently engaged in discussions with the Department of Justice, and they had questions of myself and Brad.

So we sit down, and they start asking questions about what other labs pay processing and handling fees. Do we have copies of the processing and handling letter of agreements? Do we have any of the time and motion studies that they -- had been conducted? Do we have their legal opinion letters, et cetera?

And we both responded -- because once before, we had

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produced sample processing and handling letter agreements for probably 80 percent of the advanced labs out there. Because they're readily available, they're in the practice, physicians are happy to give them to you.

And so we've turned that stuff over to Tonya. In fact, we've turned that stuff over even during audits. You know, so -- yeah, we'll get you that information. If there's something specific that you're lacking, let us know.

There was a point in that meeting where Brien O'Connor from Ropes & Gray took the position that we had relayed to the Department of Justice that HDL is moving away from processing and handling fees. And when I heard that, I said, "Whoa, hold on a second. What is this about?"

And Tonya immediately stood up and said, "That is not a position that I have taken at this point in time. And I told you that, if the laboratories -- all of them have to move away from processing and handling fees, we would lead the way in doing that."

So that kind of calmed that back down. I believe that's me getting revved up.

- **Q.** So what was your -- what was your position? What were you telling everybody?
- A. You know, my position was very simple. You know, we've got all these legal opinions. It's been going on for decades. There's time and motion studies to support it.

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And I asked the question, "What law has changed? What opinion has changed? What out there is resulting in this?"

And they're like, "Well, we're being investigated and we're trying to find out if it's appropriate or it's not appropriate."

I said, "Okay." I said, "So you said you were going to change the practice now without even having clarification."

They reassured us, "No, we're working to get clarification on that."

In fact, there were only two action items out of that meeting when we left.

Number one, they asked us to not distribute the LeClairRyan letter anymore, which I clarified and said, "Well, we don't routinely distribute the LeClairRyan letter anyway. We certainly use it if somebody inquires about it." I said, "Why are you taking that position?"

I didn't even get a position about the safe harbor at that point. What we were told is that it violated attorney-client privilege to do so.

I said, "Well, haven't you already done that?" I said, "HDL is giving it out." Tonya acknowledged that. I said, "We've given it out."

They said, "Well, well, well, yeah, but just don't give it out anymore."

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I said, Okay. We won't give it out anymore.

The next action item was follow up and give us any of these additional documents that you can get your hands on. And we said okay. Those were our marching orders at the end of that meeting.

- **Q.** Do you remember any specific discussion of whether the LeClairRyan letter, the original letter, was reliable? Was there any discussion about that at that meeting?
- A. I don't recall discussions about the LeClairRyan letter being legal or illegal.
- **Q.** Do you remember discussions about what positions the government might take with regard to --
- A. Yeah, there were discussions about the positions the government might take, yes.
- **Q.** Did anybody -- was anybody there able to open a law book and show you anywhere where it said that processing and handling fees either were illegal or you could only pay a certain amount in process and handling fees?
- A. No. And I asked for that, and I couldn't even get an opinion from Ropes & Gray.

I said, "Guys, I don't even know what your opinion is on this. Are you saying it's inappropriate or is it not?" And they wouldn't tell me.

They're like, "Well, we're still looking into this and trying to figure this whole thing out."

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And I said okay. In fact, it's interesting because that's June of 2013. You fast-forward to the fall of 2013, still paying processing and handling fees, that very law firm works with Derek Kung to redraft a new processing and handling letter of agreement, and they wrote a 38-page PowerPoint presentation supporting the legality of processing and handling fees.

That practice continued for another year from that meeting until June 25th, 2015, when the fraud alert came out.

MR. COOKE: Let's get Mallory Exhibit 29 up, please.

## BY MR. COOKE:

- Q. Is this what you're referring to?
- A. Yes, sir.
- Q. And this is an email from Tonya Mallory to you and to Brad dated October 25th, 2013. And it begins, "Cal and Brad: We have modified the P&H agreement to strengthen compliance documentation."

Can you scroll down to the bottom of that email.

You see right below that is an email from Tonya -- I'm sorry, to -- from Derek Kung.

That's the attorney; is that right?

- A. That's correct.
- Q. To Tonya Mallory, Joe Anastasia.

Who is he?

A. Joe Anastasia held a management position. I think it was

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over client relations.

- **Q.** Okay. Kathy Johnson?
- A. Chief compliance officer at HDL.
- **Q.** Tabitha Henley?
- A. She also had a management position over client services.
- Q. So he says, "I've attached the most recent draft of the revised P&H agreement. I don't think there is anything controversial. I asked Ropes to revise to account for situations where practices have ICs" --

Do you know what that is? Independent contractors?

- A. Correct.
- Q. -- "or other nonemployees assisting with services. Please let me know if you have any concerns.

"Tonya, if you're signed off, then sales support can start using this document."

was that shared with you?

- A. I'm not copied on that email until the next one. But, yes, that was all shared with me.
- **Q.** And did you adopt that revised agreement?
- A. Yes.
- **Q.** At any time, did anybody from Ropes & Gray tell you that you need to stop doing -- that you need to stop with process and handling fees?
- A. No, they did not.
- Q. What did you believe was going on between Ropes & Gray and

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the government?

A. It was referred to as negotiations. Tonya was seeking clarity on what their position was going to be. You know, and we would hear different stories from time to time, because there were three categories.

There was the processing and handling letter of agreements for the fees that were being paid. There was the zero-balance billing that was being discussed. Later, there was the position about our contract in and of itself, because we're paid a percent of collected revenue, it is a violation of the Anti-Kickback Statute.

And then a week or two later, we would hear, "well, the processing and handling fees is no longer a focus anymore. They've moved away from that. Now they're just focusing on zero-balance billing."

So we're just seeking clarification, you know, trying to find out do you -- can you do it or can you not do it?

- **Q.** Do you remember a time coming when Ropes & Gray put together a PowerPoint presentation on the legality of process and handling fees to present to the government?
- A. We were not presented the PowerPoint presentation, but we got our hands on the PowerPoint presentation during the discovery process in this investigation.

But I believe that coincides with what was relayed to us, that the position is the processing and handling fees are

legal by Ropes & Gray. And I've since read the PowerPoint 1 3:39PM 2 presentation, and that's the position --3:39PM MS. SHORT: Your Honor, is he testifying about a 3 3:39PM 4 document he says he hasn't seen? 3:39PM THE COURT: I'll sustain it as to something that you 5 3:39PM didn't see, you know, at the time. 6 3:39PM 7 I think you're asking his state of mind at the 3:39PM time, and he said he didn't see it. So I sustain that 8 3:39PM 9 objection. 3:39PM 10 MR. COOKE: All right. 3:39PM 11 BY MR. COOKE: 3:39PM were you -- did you become aware that Ropes & Gray was 12 3:39PM 13 going to make a presentation to the government? 3:39PM 14 Α. I heard that that was happening, yes. 3:39PM 15 Q. Do you know when that occurred? 3:39PM 16 I do know that occurred, yes. Α. 3:39PM 17 When did that occur? 0. 3:39PM 18 It was in 2014, I believe. Α. 3:39PM MR. COOKE: Could we just put up Mallory 87. 19 3:40PM 20 BY MR. COOKE: 3:40PM 21 Do you see a date on there? Q. 3:40PM 22 Yes. May 15th, 2014. Α. 3:40PM 23 MS. SHORT: Your Honor, may I point out I believe 3:40PM 24 that counsel is trying to now show him the PowerPoint 3:40PM 25 presentation that he's already testified he didn't see until 3:40PM

this litigation. 1 3:40PM 2 THE COURT: I'm not going to -- don't worry. 3:40PM see what he's going to do. 3 3:40PM 4 MR. COOKE: I'm moving on to something else. 3:40PM 5 THE COURT: I didn't think he was going to after I 3:40PM ruled already, so no need to address it. 6 3:40PM 7 MR. COOKE: Can we see Exhibit 1497, please. 3:40PM 8 BY MR. COOKE: 3:40PM 9 Is this a letter that you received from your -- an email 3:40PM 10 that you received from Linda Flippo on March 19, 2014? 3:41PM 11 Yes. Α. 3:41PM And it says, "Please find attached a letter that we 12 0. 3:41PM 13 received from Elizabeth Strawn." 3:41PM 14 Do you see that? 3:41PM 15 I do. Α. 3:41PM 16 Can you scroll down now to the letter MR. COOKE: 3:41PM 17 that was attached. 3:41PM 18 BY MR. COOKE: 3:41PM 19 You see this March 18, 2014? 3:41PM 20 Yes. 3:41PM 21 Did you receive that letter? Q. 3:41PM 22 Α. Yes. 3:41PM 23 MR. COOKE: Scroll down so we can see the whole 3:41PM 24 letter, please. 3:41PM 25 BY MR. COOKE: 3:41PM

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- **Q.** What, if anything, does this letter indicate about the state of the investigation?
- A. They were continuing investigating the facts surrounding the fees.
- **Q.** Where it says, "Dear Counsel: As we previously disclosed to you, the government is investigating your client's role in the practice by certain laboratories to pay fees to physicians who refer business to those laboratories."
- A. Correct.
- **Q.** And then can you read the next line.
- A. "Such fees violate the Anti-Kickback Statute if one purpose for their payment is to induce referrals. See HHS OIG Advisory Opinion 05-08."
- Q. Stop right there.

Was one purpose of the payment of processing and handling fees to induce referrals of patients or --

- A. No.
- **Q.** -- ordering of tests?
- A. No.
- **Q.** Not even one purpose?
- A. No.
- **Q.** The purpose of this letter is to give you a sense of the direction of the investigation?

"This is not an attempt to provide a full discussion of the issues or the allegations of the investigation to date."

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- A. That's what the letter says.
- **Q.** Did you believe, after you received this letter, that a final finding had been made as to the government's position on process and handling fees?
- A. No.
- **Q.** The next paragraph begins, "Based on our investigation to date, it appears to us that the laboratories' payments to referring providers raise an inference that one purpose of those payments was to induce referrals."

Do you -- did you -- did you understand what was meant by "raise an inference"?

- A. I mean, I think that's pretty clear that they believed that.
- **Q.** At this point, had you provided all the information that the government had asked you to provide?
- A. Yes.
- **Q.** Did they have your processing and handling fee agreements or the agreements between HDL and the physicians?
- A. Yes.
- Q. Did they have your marketing agreements --
- A. Yes.
- Q. -- with HDL and with Singulex?
- A. Not only through discovery from us but from HDL.
- **Q.** Had you actually been personally interviewed?
- **A.** By?

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- 0. By the Justice Department.
- March 18th, 2014? I mean, it's right around that same Α. time.
- Q. Okay.
- I think -- I think my interview was -- I don't know. Can you tell me the date of my interview?
- I don't -- I don't recall. Q.
- I was interviewed in 2014. Α.
- Even if I knew, I couldn't tell you. Never mind. Q.

"These payments exceed the amount Medicare pays for blood specimen collection and processing services, providing an obvious financial benefit to the referring providers, particularly when viewed in the aggregate. This raises an inference that one purpose of the payments is to induce referrals."

amount paid exceeded the amount that Medicaid -- Medicare pays for blood specimen and collection and processing services? There was discussion about this new terminology and the way it was being used in aggregate, because I asked for clarification on that.

So what about that statement? Did you agree that the

You have to remember, we had two legal opinions in hand, written ones, and multiple legal opinions, three in totality at Berkeley HeartLab, that referenced the "in aggregate" comment, said it fell into a safe harbor and met

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that.

We had been trained that the in aggregate was the fee is set, call it \$17. That fee doesn't go up as it relates to volume. It is set.

So they said, "Well, they're taking a position now that you have to set the total amount in aggregate for the year."

I said, "How can you do that?" And nobody knew the answer to it. And I said, "Well" -- I gave an example. I said, "Are you saying that you set aggregate as the amount of a full-time phlebotomist for a year?"

Nobody understood what they meant by "aggregate." That was later discussed again.

Q. So then she goes on in the next paragraph, "We are continuing to investigate the facts surrounding the payment of these fees, including Bluewave's conduct and representations to providers regarding these fees."

Do you see that?

A. I do.

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Q. And then it says, "If you would like us to consider additional evidence or if you wish to highlight evidence you have already produced on the subject, please let us know as soon as possible. In order to consider and fully evaluate that information, we must receive it no later than March 31, 2014."

Do you know whether you provided any additional

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information from BlueWave?

- A. I was under the impression all the information had been provided.
- **Q.** And we've seen that evidently Ropes & Gray prepared a presentation.
- A. Correct.

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- **Q.** Does this letter say anything about the independent contractor commission payments?
- A. No, it does not.
- **Q.** Does it say anything about waivers of copays and deductibles?
- A. No, it does not.
- **Q.** Did you believe at that time that it was a violation of any law to waive copays and deductibles?
- A. No, I did not.
- **Q.** Did you believe it was a violation of any law to receive commissions if you sell laboratory tests on a commission basis?
- A. No, I did not.
- **Q.** And did you believe it was a violation of the law to have a laboratory pay process and handling fees?
- A. No, I did not.

And one point of clarification again. BlueWave was being represented by counsel in this arena. And they were even telling us, "Guys, you ought to pay P&H fees."

"No, we do not. The labs pay P&H fees."

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Okay. "Guys, do you have anything to do with setting the billing programs at these laboratories?"

"No, we do not."

They said okay. "Let the big boys fight this out" was the quote that I had from Mark White.

- Q. What happened after this? What happened on March -- on June 25th, 2014?
- A. June 25th, 2014, a fraud alert was received.
- **Q.** Okay.
- A. Basically, it was the Department of Justice position on processing and handling fees.
- **Q.** Was that -- prior to that date, had you received any similar guidance from the government about the validity of process and handling fees?
- A. No, sir.
- **Q.** Did that special fraud alert say anything about the commission sales link?
- A. No, it did not.
- **Q.** Did it say anything about waiver of copays and deductibles?
- A. No, it did not. It was specifically focused on processing and handling fees.
- **Q.** Did you communicate with your lawyers about the effect of the special fraud alert?
- A. We did.

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- **Q.** What did you understand that it meant?
- A. There were a lot of phone calls and stuff exchanged very rapidly. It was quickly determined that we needed a conference call.

And we got on a conference call, and I remember this because it was kind of shocking to me. I had read the fraud alert. And Ropes & Gray was leading this conference call, and the quote was "This is great news. It 'strengthens' our defense."

And I asked the question, "What do you mean by that?" I said, "That's not how we're interpreting it. That's not how Mark White is interpreting it."

And they said this -- "The government has finally acknowledged there's a difference between a \$3 draw fee and a processing and handling fee. This is great news."

And I said, "Well, the point I'm focusing in on, it says that it cannot be calculated by patient encounter."

And there was kind of a pause.

And they said, "Well, let's get back in touch. We'll have another conference call in about an hour. Does that sound good?"

"Okay. Great."

We asked Mark to call Elizabeth Strawn directly and find out what her position was on it.

Q. Mark White?

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# A. Mark White, our attorney.

In the meantime, you have to remember we knew contractors that worked at other laboratories. I know my business partner contacted Jonathan Farrell at Boston Heart. They too were taking the exact same position that it was legal.

And I said, well -- because in their defense, I mean 90 percent of this thing is talking about how you can pay processing and handling fees. And then there's one sentence slipped in there that basically says you can't calculate it based upon patient encounter.

I didn't understand it because that's exactly how the \$3 venipuncture fee is paid. How else could you pay it? It's paid every time a needle goes into a vein. That's paid by a patient encounter. And with the definition I'm hearing in here now, it's certainly linked to volume.

So I'm like, "Well, they're doing the exact same thing. I don't understand that."

So Mark had conversations with Elizabeth. He relayed back what was discussed, and he said, "Elizabeth's interpretation is, 'How in the world can any laboratory be interpreting that fraud alert, that it's okay? They all the need to cease and desist immediately, and can you please provide me the names of other laboratories?'"

So at that point, Brad and I said, Well, Boston has interpreted it the same way. There were a couple of other labs

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we had confirmed. And that was the gist of that call. We had the follow-up call.

And then everybody said, "We're going to be a leader in the industry and move away from processing and handling fees."

- Q. Let me show you one more exhibit in that regard, 123.
  Did you receive this email?
- A. Yes.
- **Q.** And was this done in response to your request that there be a conversation with -- with the Justice Department attorneys?
- A. Yes.

MR. COOKE: And can you scroll up a little bit and scroll down a little bit.

#### BY MR. COOKE:

- Q. You see that? Laura and Brien, who are they?
- A. Those are the two lead attorneys for Ropes & Gray that were handling this matter for HDL.
- Q. It says "they spoke to Elizabeth for about 20 minutes. Elizabeth told R&G that they have never had a situation like this in the past where an advisory was written in the middle of the investigation and admitted that these are typically written when there are areas that are vague or not spoken that need to be clarified. Elizabeth clarified that the intention of this advisory was to state that there was no possible scenario in

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which P&H payments were okay, and to stop the practice in the market. R&G explained that there are many in the market that believe that it is" -- is there another page? -- "that it blesses the use of P&H and will continue to use them. Elizabeth repeated several times that the intention was to make it clear that there was no possible scenario in which P&H was okay. She was interested to hear more about those companies

"This concludes that we have to move forward with discontinuing" --

**THE COURT:** Is there a question in this?

MR. COOKE: Yes.

that will continue the practice.

### BY MR. COOKE:

- **Q.** Did you follow that advice?
- A. Yes. But, again, BlueWave didn't pay a P&H, but we represented a company that did, and we followed the advice.
- Q. So were -- to your knowledge, did BlueWave ever, after June 25th, 2014, sell any test or any laboratory that had a process and handling fee associated with it?
- A. No.
- **Q.** You heard some testimony earlier about an Emily Barron?
- A. Yes.
- Q. Was she in your territory?
- A. No.

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Q. Were you familiar with the conflict that arose with Emily

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Barron?

- A. Yes.
- **Q.** Can you describe your knowledge of that to the jury, please.
- A. It was early in 2013. I would say most likely February 2013. It might have been as early as January. I got a call from Tabitha Henley from HDL relaying to me that there were a bunch of clients down in Florida that were calling in and complaining that they had been trying to get in touch with Emily to get supplies and answer questions and they were unable to do so.

And she said, "Can you please address this?"

And I said, "Sure." So I called Brad. We discussed it. He's like, "Man, I've already talked to Kyle Martel and Kevin Carrier" -- who were the other two reps down there -- and said "Emily is not working anymore."

I said, "She's not working?"

He goes, "Yeah." He said, "I'm not sure what was going on."

I said, "Okay." I said, "Well, we're going to have to address this."

And we eventually addressed it. There was a lot going on down in Florida between the contractors.

- Q. Did you go down and try to mediate things between her?
- A. We did. We ultimately determined in discussions with all

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of them independently -- we tried to discuss it with them together, but there was a breakup between Kyle and Emily that was creating some issues. And I had asked all of them to write a proposal for territory divisions and who would be responsible for what accounts.

Ultimately, Brad and I had to go down there and meet with all three of them in a conference room and divvy up their territory, and that's what happened.

- Q. Was that before or after you heard from Mr. Dickerson?
- A. Before.
- Q. Did you eventually hear from Mr. Dickerson?
- A. We did.
- Q. What was your understanding about his role?
- A. Well, we pretty much just turned that over to the attorneys. You know, there were concerns that Emily might file a lawsuit. Of what nature, we had no idea. We had a verbal agreement from everybody on the territory split. It was pretty amenable for the most part until it got down to about five remaining accounts. You know, one person was claiming it was theirs; the other person was claiming it was theirs.

And I said, "Look, guys. It's kind of like divorce court. If y'all can't work it out amongst yourself, you're asking me to work it out for you. I'll make a decision.

Neither one of you are going to be happy with it, but I'm going to make a decision before we leave here today. We've flown

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down here."

So we divvied that up. We redrafted the contract agreements and sent those out. Kevin Carrier signed his. Kyle Martel signed his. And Emily's never came back in. So we reached out, BlueWave did, several times to try to get the new contract.

The only change in her contract was simply the territory. It was the same commission split that they had been doing amongst themselves; it was just changing the geographic area of responsibility that she was going to have, basically so she and Kyle wouldn't overlap anywhere is what it boiled down to.

- **Q.** Did she ever tell you that the reason she was not out calling on doctors or selling was because her lawyer had told her that your contract was illegal?
- A. No. And, in fact, we addressed that at the meeting. And Emily told me that she had a phobia of driving.
- Q. When you say you addressed that, you addressed what?
- A. When Brad and I went down and had that meeting to divvy up the territory. Remember, we had already been told she wasn't working anymore. And that was confirmed not only from her partners but also from client services at HDL. So I inquired of her, you know, "What's going on? Why aren't you working?"

And she told me she had a driving phobia. I said, "Explain that to me. You worked for LipoScience. You've been

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driving these accounts all over the state before." I didn't understand it.

And my takeaway from that, it was a -- it wasn't a truth. You know, it was an excuse. It wasn't a truth. And she continued not working. She did tell me that she has her grandmother and her mother drive her to accounts.

- **Q.** During any of those conversations, did she say anything about concern for the legality of what she was doing down there?
- A. No.

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- **Q.** Was the decision to terminate her related in any way to her being a whistle-blower or suggesting to you that her contract was illegal?
- A. Absolutely not.
- **Q.** Well, did you just ignore the lawyer who said that her prior lawyer had raised questions about the legality of the contract?
- A. No. We turned that over to our attorneys to address it and get a resolution on it. Gene did call me at one point. Remember, that meeting with her attorney occurred June of 2013. That corresponds with the summit meeting June 2013. One of our action items at that summit meeting was do not hand out the LeClairRyan letter any longer.

And we even had our attorneys on the conference call to tell all the contractors don't hand out the LeClairRyan

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Same questions came up. Attorney-client letter anymore. privilege has already been violated, but they said don't hand it out.

So this attorney is asking for documents. trying to get the documents. Gene first called me and asked "Cal, do you have this?" And I said, "Emily has it, Gene. She's had the LeClairRyan letter forever. They're not supposed to distribute the LeClairRyan letter anymore. That's a 2012 letter."

He goes, "Oh."

And I said, "Aside from that, it's not mine to give It's not BlueWave's to give anyway. That belongs to anyway. HDL. That needs to be an HDL attorney discussion, not a BlueWave attorney discussion."

And it's my understanding that Gene at that point referred him over to HDL, which I learned in the testimony yesterday that in fact did happen, although it wasn't part of the testimony until they dug it out of him.

- All right. And did you learn that he had a conversation 0. with Mr. Kung?
- Α. Yes.
- You were -- in your videotape, you were asked about -- one 0. of you was asked about Lauren DeMoss. I believe it was you.

Can we see Exhibit 1002.

This would take you to November of 2013. Do you

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remember being asked about this on your video deposition?

- I do. Α.
- And what was going on in your life in -- now that I can Q. put an arrow there -- November 2013?
- What was going on in my life? Α.
- Well, with regard to BlueWave and HDL. Q.
- Can you be more specific? Α.
- With regard to the investigation by the Justice Ο. Department.
- Well, November 2013, that's post the June 2013 meeting.
- Right. 0.
- That's -- also, LeClairRyan and Derek Kung had redrafted the processing and handling letter of agreement. And, in all fairness -- and this is why I'm exercising caution -- I want to make it clear, I did not have the Ropes & Gray PowerPoint presentation at this present time. I didn't have it. We were told about it. I didn't learn -- actually get it until this investigation.
- 0. All right.

Can we scroll down. I'm sorry. The other way.

Did you actually see at that time what her comments were about the different questions on the test?

- Whose comments about which test? Α.
- Q. I'm sorry. In your testimony, you -- it was related to you that Lauren DeMoss had been asked to review a draft of the

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test that you administered.

- A. Brad and I had a conference call and went over the answers to Ms. DeMoss's responses to the questions. I believe I had a copy of it, or Brad discussed it with me and read it if I didn't. I mean, sometimes I'd be in the car driving and not have something with me, but we absolutely went over her responses to those questions, yes.
- **Q.** Were you already aware at that time that the government was going to be -- was investigating the processing and handling fees?
- A. Yes.
- **Q.** Were you aware at that time that Ropes & Gray was in the process of negotiating with the government about process and handling fees?
- A. Yes. That's precisely why Brad sent the test to Brett King, which is an attorney who doesn't deal in health care, to just have a fresh eye look at it who's not involved in all this stuff because there was so many different opinions and things flying around.

Everybody just wanted an answer. And we wanted to see what an unbiased party, an untainted party, would say about it in the middle of the investigation and discussions.

Q. I'm going to ask you this in conclusion. I've got a couple of miscellaneous things that came up that I'd like to get you to comment on.

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The first is about preservation of emails. Do you remember Boomer testifying about a conference call in which you related the email preservation policy of BlueWave?

A. I do.

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- **Q.** Yeah. When did that call actually take place?
- A. Very, very early in our whole development, most likely 2011.
- **Q.** Was it before or after you received a subpoena from the Justice Department?
- A. Before.
- Q. It was before?
- A. Yes.
- **Q.** Had you ever advocated to anybody since receiving the subpoena that they delete emails?
- A. Absolutely not.
- **Q.** What in fact did you insist upon?
- A. To keep all their emails. And we had attorneys get on the call and tell them that. You know, when the production started, the subpoenas started, make sure that you don't delete anything.
- Q. And did you, in fact, preserve your emails?
- A. Yes.
- **Q.** Did you gather those and produce those to the government?
- A. Yes, we did.
- Q. And did they go back longer than the retention period that

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was supposed to be your standard policies?

A. Yes. What Boomer's referencing, after we were -- this is when we first went to HDL. And we got sued by Berkeley HeartLab not once but twice. And that was a new experience for myself and Brad. And we literally spent hundreds of thousands of dollars for document production on emails that were readily available off of a Berkeley HeartLab server.

And John Galese was involved in that litigation. And he suggested to Brad and I that, with our new company, we implement what he called a document retention policy. And he suggested that you keep your documents for 90 days, and you get with your serving -- the manager that handles your server and have everything fall off after 90 days. And if it's something you need to keep, print copies of it. It would certainly limit any problems with a gross expense like that in the future.

We talked about it. We actually agreed that we would do that. It never happened. So Greg, who oversaw the IT system, they were always there.

- **Q.** So long story short, you produced them and they're there?
- A. That's correct.
- Q. You ever make the statement that it's not what the law says; it's what it doesn't say?
- A. I don't ever recall making that statement, but I think that's a good statement.
- Q. And what does that statement mean to you?

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A. Well, I kind of like things black and white. And if you can't do it, then you can't do it. If you can do it, you can do it. You know, even the fraud alert that came out, there's so much ambiguity in that, even the attorneys that reviewed it were excited when it came out and said, "We can do this."

And not just HDL's attorneys; the attorneys representing other laboratories said the same thing. Make it black and white. It's kind of like tax law. You know, there's always a gray area that somebody wants to come after you.

Q. All right.

Let me see Exhibit 6042.

This is completely changing subjects. This is going to be the -- I hope it's going to turn out to be the UnitedHealthcare explanation of benefits that was discussed by one of the witnesses earlier. Do you remember seeing that --

- A. Yes, I do.
- Q. -- with Ms. Coleman?
- A. I do.
- **Q.** Which page did you want to go to to explain you're able to analyze this document?

MS. SHORT: Your Honor, has this witness seen this document outside the context of this litigation?

THE COURT: What's the purpose of offering this?

MR. COOKE: Ms. Coleman struggled with what's -- the meaning of some of the line items were, and he knows what they

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mean. And he'd like to explain it.

THE COURT: Well, is he offered as an expert on TRICARE? What is this --

MR. COOKE: I can qualify him on interpreting explanations of benefits.

THE COURT: I sustain that objection. If it's relevant as to state of mind, you could go to that but not for the purpose you're seeking.

MR. COOKE: Skip it.

## BY MR. COOKE:

- Q. Next subject. The -- you've seen lists, as we've been here over the last week or so, of the top 20 practices that received process and handling fees?
- A. I've seen that list here, yes.
- Q. I'd like to talk to you for a few minutes about your observations about the relationship between the amount of process and handling fees that a practice receives and the amount of work that they do, the amount of tests that they order?
- A. Sure.

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- **Q.** So tell me who Keowee Practice and Columbia Heart Clinic and Floyd Miller and Spartanburg Family Physicians are.
- A. All four of those are accounts that were under mine and Tony Carnaggio's direct responsibility. They're in South Carolina.

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- Q. Did they make a profit from processing and handling fees?
- A. No, they did not.

MS. SHORT: Your Honor, objection. Foundation. How does this witness know what a third party -- whether a third party made a profit?

THE COURT: Lay a foundation.

MR. COOKE: Well, I'm going to his state of mind.

THE COURT: Well, that wasn't a state-of-mind question; that was a fact question. I sustain the objection.

## BY MR. COOKE:

- Q. Did you believe that any of these practices were profiting off of processing and handling fees?
- A. No, I did not.
- Q. Why not? Let's start with Keowee. Tell us about Keowee.
- A. Well, I mean, I'm very familiar with those accounts and I'm very familiar with their volumes. And what I relayed to you when we first met, we've since gone back and verified those facts to be absolutely true and accurate. Keowee Primary Care and Internal Medicine --
- Q. I do want to focus on what your state of mind was at the time, so let's talk about what your knowledge of their practice was.
- A. Of Keowee Primary Care and Internal Medicine?
- Q. Yeah.

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A. It's a large internal medicine practice in Seneca, South

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Carolina. Dr. Tauqueer Alam is the lead internist in that practice. They have several -- five or six -- midlevel providers in that practice: Kelly McCormick, LeRoy Snead. There's several of them in there. They also own their own laboratory. They have five employees in that laboratory. He runs many blood diagnostics on his own analyzers. And he's been an advanced customer for years. He was a customer of mine at Berkeley.

- Q. What about Columbia Heart Clinic?
- A. Columbia Heart Clinic is arguably, in my opinion, the single best invasive cardiology group in the state of South Carolina. They're located in Columbia. They're associated with what used to be Palmetto Richland Memorial Hospital, which is part of the CommonWell Health Alliance now, and the -- they are an interventional cardiology group.

They own their own laboratory. They have four to six employees in there at any given time. They also run some in-house diagnostics. They have 12 to 15 cardiologists in that particular group. They have had registered dieticians in there that provide health care counseling to patients. And a lot of the docs not only do invasive procedures, but one in particular, Dr. Joe Hollins, is also a board-certified lipidologist.

- Q. Was Dr. Hollins on the advisory board for HDL?
- A. He is on the advisory board at HDL.

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- Q. or was?
- Was, yes. Α.
- And you knew him well? Q.
- Α. I knew him very well.
- We're going to come back to him. 0.

Lloyd Miller was an internist in Florence, South Carolina. Lloyd had changed his practice many times. He was with a large group, then he went out and he went independent. worked for a hospital. Then he went back out independent He had a lot of changes going on. again.

Lloyd Miller, what kind of practice did he have?

High-volume practice, Lloyd Miller only worked from -- he worked Monday through Thursday, which I thought was a little unusual, but he worked from 7 to 7. So he'd come in at 7 a.m. and leave at 7 p.m. And if you do the math for that, he's really putting in a 44-hour workweek instead of a 40-hour workweek, and he still has his hour lunch. And very in tune with advanced diagnostics. He was a customer of mine at Berkeley as well and then later switched over to use HDL.

- How about Spartanburg Family Physicians?
- Spartanburg Family Physicians is a very large family practice group. They have seven to eight medical providers in They have an in-house laboratory as well. And they also have six employees in there. Tony called on that account more than I did. They were a Berkeley account back in the day,

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but they had moved their practice and relocated. And then my responsibility was more traveling state to state, you know, working on a board for another company, et cetera. Tony kind of picked it up in its entirety. He set it back up with HDL.

- with regard to those four practices, were you in a position to observe how many employees and how much equipment that they had to maintain in order to draw and process and handle their test specimens?
- Yes. I'd been at all of those practices many times, in their laboratory, in the physician offices, in their break room.
- And can you -- without putting a dollar number on it, can 0. you say whether it was a substantial amount or a small amount or somewhere in between?
- A dollar amount on what? Α.
- what they had to spend within their practices to process and handle --

Same objection, Your Honor. MS. SHORT:

THE COURT: You have to lay a foundation for that. Sustain the objection.

### BY MR. COOKE:

- At Keowee, how many staff did they have dedicated to the 0. processing and handling of laboratory specimens?
- Well, I can testify to the staff in the laboratory. Α.
- Q. Yes.

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- A. You know. And everybody in the lab is qualified to draw blood. They would routinely have three people drawing blood at the same time, but you could interchange the employees to do that.
- **Q.** And Columbia Heart Clinic?
- A. Same thing. And, again, they owned their own laboratories.
- Q. Lloyd Miller?
- A. Lloyd didn't own his own laboratory. And he would have typically two -- one to two employees. But, as I testified earlier, he changed. There was a point in time where he had a LabCorp phlebotomist in there. There was another time that his wife and one of the nurses were drawing blood. His wife was a nurse in the practice.
- Q. And then Spartanburg Family Physicians?
- A. Big laboratory, five employees working in the lab, four of them could be drawing blood at any given time. They had multiple phlebotomy chairs.
- **Q.** Are you familiar with Heritage practice down at Hilton Head?
- A. I am.
- Q. Was that one of your accounts?
- A. It was in my territory of responsibility. I had called on the account before. Tony primarily managed it.
- Q. Do you remember speaking to them about HDL and advanced

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laboratory -- advanced lipid studies?

- A. A couple of times, I spoke with them about that.
- **Q.** Tell the jury what your contacts were in that regard. You recall the testimony that we heard from one of the physicians down there about -- about your involvement; correct?
- A. Well, I have to put it in context and timeline. Paul Long is the lead provider at Heritage Medical Group. The first time I called on him was after April of 2011. And the reason I remember that date, that group was on a no-see physician list that was part of our Berkeley HeartLab injunction, which was part of the settlement agreement we had with our prior employer, that we could not see this group of physicians for a year. And that was one of the groups.

Once that injunction was lifted, myself and Tony Carnaggio went down. We had a lunch appointment with Paul Long. Before you do the lunch appointment, you visit the lab, you visit the practice manager, kind of learn what their current situation is in there. And I learned that they had a Quest phlebotomist that was drawing their blood.

Went back to Dr. Miller and I kind of presented the HDL offering. And he told me that I could not offer him anything that Berkeley HeartLab had not already offered. And I said okay. I said, "Well, I used to work for Berkeley. In fact, I was their number one sales rep. And I beg to differ with you."

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And he goes, "What can y'all do?"

So I immediately started off with the test report. After my presentation, he made the decision that he did not want to switch over to HDL, which was fine.

And I said, "Dr. Miller, I do need to make you aware of something, though."

And he goes, "What's that?"

I said, "I respect the fact that you don't want to do HDL." I said, "But I uncovered something in your practice that you need to address."

He goes, "What's that?"

I said, "You've acknowledged that you have processing and handling fees that Berkeley is paying you."

He goes, "That's correct."

And I said, "You also have a Quest phlebotomist that I witnessed drawing the Berkeley specimens earlier."

And it was like a deer-in-the-headlight look. I said, "You can't have both." I said, "You know, that would be a double payment of services, and you need to get that addressed."

And he thanked me. He said, "Thanks so much. I didn't realize."

I believed him. I don't think there was any intent there. I don't think they -- he really picked up on the fact, because Quest had bought Celera which had bought Berkeley. And

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I believe that he was probably doing Berkeley before that.

- **Q.** When you made that presentation to him, did you use your higher process and handling fees as a selling point?
- A. No, he didn't even want to switch over. I wasn't going to get into that.
- Q. So you didn't even get into that?
- A. No.
- Q. What other contact did you have with them?
- A. The next time, the Heritage Medical Center practice manager had reached out to Tony Carnaggio. And Tony had called me. And he knew that they were doing Berkeley. The Berkeley rep that covered that account was a gentleman by the name of Mark Bemiller. Mark Bemiller was friends with Dr. Mayes. And he asked me about it. Do we want to go see this account?

And I said, "Tony, that's up to you, bud. If you want to go see the account, get them set up and get a shot at it, you're welcome to." I said, "I tried it once before with Paul Long. You remember it didn't go well. But if you want to, knock yourself out."

And, apparently, he met the practice manager at a trade show, went back in, got the offering. I remember him calling me. He was excited. They wanted to switch over to HDL. So they became an HDL customer.

Q. Did you use processing and handling fees as a -- one of your tools to persuade them?

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- A. No.
- **Q.** Do you remember attending any educational proceedings with them?
- A. I do. Once providers started ordering the tests out of Heritage Medical Center, Dr. Long had expressed that some of his partners didn't understand the tests, they didn't know how to interpret the tests, and he had asked could we please bring in specifically a cardiologist that could explain how to interpret these tests and why they are clinically necessary and viable.

I said sure. He said, "Who would you recommend?"

And I said, "Well, Joe Hollins is a board-certified lipidologist. He's also passed his sleep boards. And he's also an interventional cardiologist. I've worked with him for years. I don't think there's anybody more experienced in this arena. In fact, he's recently been qualified to present a CE lecture," which, CE lectures, to me, are very valuable tools because they're approved lectures by the American — this one was approved by the American Academy of Family Physicians.

- Q. Does that mean continuing education?
- A. Yes, sir. This particular lecture was approved for one hour of continuing medical education.
- **Q.** And are there certain rules about what exactly you're allowed to present at a CE?
- A. Very strict rules. You know, they have to stick to the

slide presentation. 1 4:20PM 2 variation in that. You have to register all the attendees of 4:20PM There has to be a representative from the lab that 3 4:20PM 4 actually is hosting it. You can't have marketing materials go 4:20PM

> And were any questions asked of -- was it Dr. Hollins who did that?

I think there's a percent allowance for

Dr. Joe Hollins presented the material, yes. Α.

inside where the lecture is being done, et cetera.

- And you were present?
- I was, which was a bit unusual because I was called and asked to come to that particular evening preparation. wasn't something I would normally do at this point. involved with executive management of the labs, starting other labs, and sat on the board of a genetic company in Toronto, Canada.
- Was this in early 2013? Ο.
- Α. Yes.
- Spring of 2013? Q.
- Α. That's correct.
- were -- was a question asked about the process and handling fees?
- Towards the very end of the lecture, questions were being Α. posed to Joe Hollins about processing and handling fees by one of the physicians in there. I think his last name is Lenns. I'd have to look at the structure to give you his exact name.

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He posed a question to Dr. Hollins about processing and handling fees, again, which I thought was unusual, especially at a CE lecture. I'd never attended a lecture, much less a CE lecture, where physicians inquired about processing and handling fees.

Dr. Hollins was a bit taken back and said, "I really don't deal with processing and handling fees. That's something our laboratory and management team does, but Cal is in the back of the room if you would like to ask him."

All eyes go to me.

- **Q.** Now, before you go into that, did you notice that this doctor was sitting next to Dr. Mayes?
- A. Yes.
- Q. Did you know Dr. Mayes?
- A. No.
- **Q.** Did you know at that time that he had filed a secret lawsuit?
- A. No. I know now, which sheds some light on that meeting, in my opinion.
- Q. Just go on and tell me what you said.
- A. So the same question by Dr. Lenns was posed to me about processing and handling fees. And I said, "Look, this is a continuing education lecture."

And you got to remember this is in the height of an investigation too; right? Right in the middle of it. So I'm

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even a little hypersensitive to questions like that, more so than I'd ever been before.

So I said, "First of all, you don't do testing and order these tests for processing and handling fees; you offered them off clinical utility." Then I immediately turned to the practice manager and Tony Carnaggio, and said, "I'm under the impression that Tony has already given your practice manager She has also received the the 2010 position statement. LeClairRyan opinion letter dated in 2012." I said, "The position statement addresses the Office of the Inspector General Opinion 05-08."

I think that's where somebody is coming up with this OIG opinion letter like --

- Q. Let me stop you there because you've anticipated the next question I was going to ask.
- Sorry. Α.
- Did you tell them that you had gotten an opinion from the Q. OIG as to the legality of processing and handling fees?
- Α. No.
- what specifically did you refer to?
- The 2010 position statement references in there the OIG opinion letter -- or opinion of 05-08.
- And that's the one we looked at this morning? Q.
- And it was not uncommon -- I've heard people refer to that document internally as the OIG opinion letter, and it's

1 not an opinion letter from the OIG.

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- Q. I'm going to -- the last thing that I want to do is talk about -- do you remember hearing Mr. Hines' testimony early last week about the dropoff of sales after processing and handling fees were discontinued?
- A. I do.
- **Q.** And what was your experience? Did you keep track of sales nationwide?
- A. Yes.
- **Q.** Did you keep them on a week-by-week basis?
- A. Yes.
- Q. Did you look for trends?
- A. Absolutely.
- **Q.** And did you find that, in fact, as Mr. Hines said, sales were increasing until the processing and handling fees were discontinued, then it dropped off precipitously?
- A. Well, there's a tremendous flaw with Mr. Hines' linear graph. He's plotting revenue; he's not plotting sample count.
- **Q.** All right. I'm going to ask you to take a look at that graph.
- A. Okay.
- Q. If we can bring that up. Is this the graph you're referring to?
- A. Yes, sir.
- Q. And this is -- this is by the top 20 physicians. And what

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was it that troubled you about his characterization of this graph?

- A. Well, if you look at it, I think the point in time that everybody really wants to focus on is June of 2014 when the fraud alert came out.
- Q. All right.
- A. You can see down at the bottom, where there's July 2014, and you can draw a line straight up.
- **Q.** Okay.
- A. From the --
- Q. We've actually done that for you.
  Can I -- can I have that line put on the graph.
- A. Okay.
- **Q.** Is that what you're referring to? And you're connecting it with the -- with the dots here?
- A. That's correct.
- **Q.** Okay.
- A. If you go over to the far left of the graph, you're looking at dollars. So that is revenue collected; right?
- Q. Yes.
- A. First of all, in the advanced diagnostic arena, there's a common terminology called diminished-return business model.

And, without getting technical, the simple way to explain that is if a physician orders a test, an initial test on a patient, oftentimes, that is going to include genetic

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tests. Genetic tests are reimbursed typically at higher dollar amounts than nongenetic tests. All the follow-up visits after that, you're not getting genetic tests anymore. So the dollar amount that comes in on the specimens is significantly less.

So if you're ramping up business in 2010, 2011, 2012, you're bringing on new customers. And when you're bringing on new customers, you're going to be getting a lot of V1s, visit 1s, that include genetic tests. Even if there was nothing that changed, you just stopped getting customers, this bell curve would absolutely result.

But there's many things going on. One -- and you heard testimony to this -- Medicare stopped paying for genetic tests. They stopped paying for APOE. They stopped paying for all of them. Several commercial insurance companies were doing the same thing. You heard testimony about Humana. But after Dr. McConnell went and visited Humana and they understood the clinical utility of the tests, they started paying for the tests again.

So drop in revenue is a very common curve when you're plotting revenue.

You've heard other testimony where the rep said, after P&H stopped, they saw very little drop in their business, which was the same impression that I was under. In fact, the highest number I've every heard was an 11 percent drop in specimen count when P&H went away.

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Well, I could have easily gotten all that business back. It's just a matter of time of placing phlebotomists or finding alternatives for those providers to order the tests. But you have to realize, other things were going on too. Competitive activity; companies running out there saying that HDL is doing things that are improper; agents, federal agents going into doctor practices, including my personal doctor, saying "Cal Dent is going to prison."

There's a lot of reasons people were stopping ordering tests. I would hardly agree that a 10 percent drop linked to a date is appropriate. In fact, if you look at July 2014, if I want to take their argument, it went up. Revenue went up. But you can have a lag in submission and getting the reimbursement.

**Q.** And let me put another line up here at the peak of the -- of the revenue. That second line.

So do you see any other sales period that is higher than where this line is drawn? And that would be back, I believe, in August of 2013; is that right?

A. That's -- I would say July, August 2013. I don't know exactly the data point, but I think it's irrelevant here.

But if you want to argue there's a decline in revenue, I would say that started back in July of 2013.

There's a clear decline in revenue, and you can't -- I can testify to this with my engineering background, mathematical

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background.

To plot a trend line, it's unfair to take two data points. You really need three data points. If you --

- Q. Well -- I'm sorry. Go ahead.
- A. But if you even take the two highest data points and plot those after July of 2013, you've got a negative trend line. It's manipulation of data, which I think is inappropriate to suggest that business was hurt and completely fell off after June 2014 fraud alert, which was June the 25th.

In fact, I went back to look at those very same four accounts that you referenced earlier, to look at their specimen count drop, and there wasn't any.

- Q. For those practices?
- A. That's correct. And I intentionally wanted to look at ones that the government was classifying as top 20 accounts.
- Q. Were processing and handling fees still being paid back here in July or August of 2013?
- A. They were.
- Q. And they were discontinued when?
- A. Well, really, it was effective July 1, 2014, when the fraud alert came out, by the time the letters and everything got to the providers.
- Q. Do you believe that your customers, or any of the customers of BlueWave, stopped ordering tests that they thought were medically necessary for their patients because you were no

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longer paying processing and handling fees?

- A. I don't believe that. But, in all fairness, it wouldn't surprise me if a physician stopped. If he or she is devoting their employee to do work and they were told that there was compensation for that employee to do that work and it all of a sudden stops, they could be working to find another alternative solution for that. That may be another lab. That may be a phlebotomist. It may be one of their employees. There could be a gap in there until they get that back in there. And I wouldn't blame them for that.
- **Q.** Did you go around and try to offer any sort of other compensation to physicians to --
- A. I did not.
- **Q.** -- to keep their business? Would that have been appropriate for you to do that?
- A. No, it would not. And you also have to remember another drop here. Our contract, HDL was moving. Tonya Mallory wasn't there anymore, so that can't be blamed on Tonya. They had agreed to buy BlueWave out, HDL did. Then all of a sudden they reneged on that deal and they terminated the contract with BlueWave.

That contract termination was effective January 2015. They didn't pay us for December, nor did they pay us for November of 2014 or all the sales that were made in those months that would be collected on in a future year. They

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stopped paying us. So I think that's very important to note.

- Did you -- did you tell your sales force -- when you found Q. out the processing and handling fees were going to cease, did you tell your folks to continue to go out there and try to sell the tests?
- well, again, remember, our contract was terminated. So we're not working with them anymore.
- I said when the P&H fees were dropped. 0.
- we had legal counsel host a conference call -- when it came to legal matters -- we had been through enough legal situations with those prior lawsuits, if it was legal, I let the attorneys deal with it.

So we would get a representative from White Arnold & Dowd, usually Mark White, on the phone, and relay the information that was relayed to him by the laboratories to our contractors.

- Did you ever change the philosophy of BlueWave of selling these tests based on their clinical utility?
- we always sold the tests off clinical utility. out there today, I would still be selling them on clinical utility.
- Just a moment, if I may. 0.

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

THE COURT: Cross-examination by the government?

CROSS-EXAMINATION

4:33PM	1	BY MS. SHORT:				
4:33PM	2	Q. Good afternoon, Mr. Dent. How are you doing?				
4:33PM	3	A. Good afternoon. I'm fine.				
4:33PM	4	Q. Good. Let me start, you testified earlier about your				
4:33PM	5	interactions with the Heritage Medical Group. Do you remember				
4:34PM	6	talking about that?				
4:34PM	7	A. I do.				
4:34PM	8	Q. Okay. And you had said that they were on the do-not-call				
4:34PM	9	list. Is that right?				
4:34PM	10	A. That's correct.				
4:34PM	11	<b>Q.</b> Okay.				
4:34PM	12	I wonder if we can pull up Plaintiffs' Exhibit 1311.				
4:34PM	13	And if we look at the Peter, can you zoom in on the very top				
4:34PM	14	part where it's talking about the do-not-call list.				
4:34PM	15	A. Can you represent what document I'm looking at?				
4:34PM	16	Q. Do you recognize this document? Do you remember				
4:34PM	17	testifying about it during your deposition?				
4:34PM	18	A. Can I look at the document and tell me what it is				
4:34PM	19	THE COURT: Bring up the whole document so he can				
4:34PM	20	look at it.				
4:34PM	21	MS. SHORT: Do we have a copy of 1311? I can bring				
4:34PM	22	it up.				
4:34PM	23	THE WITNESS: Thank you. I recognize it.				
4:35PM	24	BY MS. SHORT:				
4:35PM	25	Q. Okay. Are you good is it good to do the screen?				

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- I recognize it. Α.
- Mr. Dent, do you recognize this as essentially a Q. Okay. call script that the BlueWave sales reps were going to use back in 2010?
- This is instructions to ensure that we're complying with a court order about not calling on physicians that are on a do-not-call list, yes.
- So what was that do-not-call list? Can you tell Okay. 0. the jury what that meant?
- I thought I testified to it earlier. Maybe I wasn't clear. When we left Berkeley HeartLab within the first month, Berkeley HeartLab sued myself, Brad Johnson, and three other sales reps from Berkeley HeartLab. Within that first month, a judge -- Judge Payne up in the commonwealth of Virginia -- immediately signed an injunction that we had to stop, cease and desist selling.

We engaged in settlement discussions with our prior employer. They weren't very successful. We went to court with our prior employer. We were ordered into mediation again, and we worked out a settlement agreement.

Part of that settlement agreement was a list of customers that had been Berkeley HeartLab customers before that we could not call on for 12 months.

- Q. Okay. So Heritage was on that list; right?
- Heritage was on that list. Α.

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- Q. Okay. So if you'd go -- if we can focus in on the "if not" on the do-not-call list, what were the instructions to the Bluewave sales reps -- well, let me ask it this way: Do you see where it says "Do not try and sell the tests. This will hurt the sale in the long run?"
- A. "Here are a few pointers that will assist you in setting up the account. Ask a few simple questions. Do not try and sell the tests. This will hurt the sale in the long run. If not on the do-not-call list."
- **Q.** So these were new accounts. They weren't Berkeley Heart accounts. These were new physicians that you were trying to get to be interested in HDL; right?
- A. Correct.
- **Q.** Okay. And the instruction here is "don't try to sell the tests." Isn't that right?
- A. "Do not try and sell the tests. This will hurt the sale in the long run."
- **Q.** That's what the document says; correct?
- A. That's what the document says, yes.
- Q. Okay. And if you go down to the very bottom of this document, there's another reminder.

"Remember, if you try and sell the testing too much, the physician will ask what's in it for you."

That was another instruction that BlueWave gave to its sales reps; correct?

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- A. That's what this says, yes.
- Q. You testified earlier about the sales agreement between BlueWave and Singulex. Do you remember some of that testimony?
- A. I do.
- **Q.** Okay. And I believe you testified that Singulex was represented by counsel; is that right?
- A. That's correct.
- **Q.** Who did Singulex's counsel represent? Did they represent BlueWave or did they represent Singulex?
- A. Singulex counsel would represent Singulex.
- **Q.** And I believe your testimony was that their attorneys didn't raise with you that there was any problem with the sales agreement; is that right?
- A. I think the testimony was no attorneys raised any problem with the sales agreement with me.
- Q. Okay. Do you remember that HDL -- or I'm sorry -- BlueWave sent the initial draft of that sales agreement to Singulex?
- A. Singulex asked if they could see a copy of the sales agreement between HDL and BlueWave.
- Q. Uh-huh.
- A. We agreed that we would provide them one redacting anything that was specific to HDL, yes.
- Q. Okay. And then Singulex had its attorneys review that?
- A. That's correct.

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- Q. You don't know what Singulex's attorneys told their client, do you?
- A. I would disagree with that statement.
- **Q.** You were privy to conversations between Singulex's counsel and their client?
- A. Singulex would relay to me -- we went back and forth, back and forth, back and forth. Their attorneys would review it; our attorneys would review it. And we periodically would be involved in those discussions, yes.
- **Q.** Periodically?
- A. Yes.
- **Q.** You weren't involved in all of those discussions, were you?
- A. I'm positive I wouldn't have been involved in all of those discussions.
- Q. Right. I believe your testimony was also that you believe that Singulex had a written legal opinion that payment of P&H fees was legal; is that right?
- A. At different points in time, they had a legal opinion on the legality of processing and handling fees, that is correct.
- Q. What attorney wrote that legal opinion?
- A. I don't know because I was never given a copy of it.
- Q. You never saw --
- A. Despite --
- Q. -- you never saw the legal opinion?

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- A. Not until this discovery process and this investigation, no. It wasn't due to a lack of asking for it. And I can understand their position. They paid for those legal opinions. We represent other laboratories. A lot of labs were hypersensitive about their materials getting in the hands of other laboratories. They told us about it. They showed us parts of it at our meetings at the regional management committee meetings, but they would never give us a copy of it.
- **Q.** How many compliance reviews did Singulex conduct of BlueWave's operations?
- A. Well, there were two large compliance audit reviews.
- **Q.** Just two; correct?
- A. Two.
- Q. Okay. And I believe you testified earlier about the Navigant compliance review; is that correct?
- A. I did.
- Q. Now, when Navigant was conducting its compliance review, it asked BlueWave to provide it with documents, didn't it?
- A. Yes.
- Q. BlueWave provided Navigant with a redacted copy of the P&H agreement with Singulex, didn't it? The P&H agreement between Singulex and a physician, you provided Navigant a redacted copy of that document, didn't you?
- A. I don't believe that to be true. They were also working with Singulex, and Singulex gave them every single letter of

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agreement between them and physician practices. Processing and handling letter of agreement is not between Bluewave and the practice; it's between the laboratory and the practice.

- **Q.** Okay. Bluewave also provided a redacted copy, but portions of the agreement were blocked out, of a Bluewave sales agreement with its own independent contractors; isn't that right?
- A. Ma'am, again, this is a compliance audit, Singulex and BlueWave. Why would I have a blacked-out, redacted copy of a sales contract agreement between Singulex and BlueWave?
- Q. No, no, no. I'm sorry. Between BlueWave and BlueWave's independent contractors.

You provided -- BlueWave provided Singulex -- provided Navigant with a redacted copy of the independent contractor agreements between BlueWave and its independent contractors; isn't that right?

- A. I would not deny that. You would have to show me. And if there was anything that we would have redacted, it would have been the name of the contractor and the actual percent collection. And --
- Q. Correct. The commission portion?
- A. That's correct.
- Q. So Navigant wasn't able to review the commission structure of BlueWave's business?
- A. That's not true. We entered into a confidentiality

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agreement with them. Our concern was them giving all the names of our contractors and the commission rates to Singulex and Singulex going out and trying to hire our contractors as employees for them.

So there was attorney discussion about exactly what was provided and the things that we wouldn't provide. That was protecting BlueWave's business and contractors. Our contractors also sold for HDL.

- **Q.** Now, the Navigant compliance review was just a snapshot in time; isn't that right?
- A. It was a snapshot of the entire time we had been in business.
- Q. Well, Navigant's study wasn't over the course of the year where they checked in with you every once in a while; isn't that right? In fact, what they did, they interviewed you; correct?
- A. Ma'am, I've never been through an audit -- a compliance audit that went in over a course of a year. They came in, and we opened our doors and welcomed them. There was some discussion about certain items we would not provide them.
- **Q.** Okay.

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**A.** Okay? And we got confidentiality agreements that they would not provide things to Singulex. And we worked out agreements of what we would provide them.

We were very cooperative through that entire process.

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And that is a very respected consulting firm. And not one time did they have problem with any of BlueWave practices.

- **Q.** All right. Well, they were able to interview you; is that correct?
- A. They interviewed me personally in Atlanta, at the Atlanta Marriott airport hotel.
- Q. Okay. They interviewed Cal Dent -- Brad Johnson; correct?
- A. You'd have to ask my business partner if they interviewed him in person or over the phone, but I'm absolutely under the impression they had an interview with Brad Johnson too, yes.
- **Q.** And they interviewed one other BlueWave sales representative; is that correct?
- A. No, I wouldn't say that was correct at all.
- **Q.** The Florida independent sales representative; is that correct?
- A. Ma'am, we provided them a list of all of the contractors that they would coordinate and set up interviews.
- **Q.** With their names redacted?
- A. Ma'am, we gave them a list of all the contractors. We provided them a redacted list of that until we got confidentiality agreements in place that they would not give that information to Singulex.
- **Q.** Okay. So --
- A. So, again, it's a snipping a certain point in time --MR. COOKE: Objection, Your Honor.

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THE COURT: Let him finish.

MS. SHORT: Yes, sir.

THE WITNESS: Trying to insinuate -- this is what a lot of this case is about, is trying to insinuate impropriety by taking little snips of things and taking them out of context. And that is not what happened. That's my testimony, and I stick to it.

We cooperated with them. If we had not cooperated with them, then I don't think they'd give us the glowing report that they did.

## BY MS. SHORT:

- **Q.** Are you aware of any BlueWave sales representatives that Navigant interviewed other than yourself, Mr. Johnson, and a single Florida independent sales representative?
- A. Ma'am, I'd have to go back and read the report. I haven't even worked in this industry for four years because of this.
- **Q.** Navigant also conducted some ride-along visits so that they could see the BlueWave sales pitch; is that right?
- A. I'm under the impression they conducted ride-along visits, just like you said; plural, multiple, not one.
- Q. Well, in New Jersey and North Carolina; correct?
- A. So now it's two or three? Is it one, two, or three? Was it Florida, North Carolina and New Jersey? This is what I'm talking about. I'm a black-and-white kind of guy. Please shoot me straight.

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Q. Okay. Well, let's look at BlueWave Exhibit 142. Can we pull that up? And let's look at page 414 at the top, although it's page 2 of the exhibit, 2 and 3 of the exhibit. It's the third page.

You see it? It's the project scope. Does this refresh your recollection? This is the Navigant report.

- A. Which portion do you want me to read, ma'am?
- Q. Well, I was looking at the bottom of the page.

Peter, if you could pull up "interviews were conducted."

- A. "Interviews were conducted with the following BlueWave representatives: Brad Johnson, Cal Dent, and a Florida independent sales representative."
- Q. Okay.
- A. "Ride-alongs were conducted with BlueWave's independent sales representatives contracted to promote Singulex products in the following regions: New Jersey and North Carolina."

Does that continue on another page?

- Q. You can feel free. Look at the next page.
- A. Okay.

"Overview of BlueWave. BlueWave is an independent contract sales organization founded by Brad and Cal in January 2010."

THE COURT: I don't think this is responsive to your question.

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MS. SHORT: I agree.

## BY MS. SHORT:

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- Q. Can we move on?
- A. I'd love to.
- **Q.** Okay. Would it surprise you to learn that Navigant believes that it was not shown all of the documentation it needed to assess BlueWave's compliance?
- A. It wouldn't surprise me at all, because I was shown a document as part of this investigation where I guess they testified that BlueWave was not compliant or cooperative in giving them the information. And then we explained and reminded them -- reminded them and everyone of what it was.

We absolutely were not going to give them information that Singulex could take and possibly go target our sales reps to come work for them directly.

- **Q.** Even if Navigant itself had a contractual obligation to BlueWave not to disclose that information?
- A. We eventually got the agreement -- confidentiality agreement signed and gave them everything. Obviously, we gave them a name of contractors if they rode along with them. So we complied with that once we had a confidentiality agreement worked out with the consulting company.
- **Q.** Mr. Dent, earlier today you testified about some case studies and the way that you are -- that you would go into a physician's office and sell the physician on the tests; is that

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- A. Yes, I did.
- **Q.** Okay. And I think you referred to the JUPITER trial as the gold standard?
- A. I referred to the JUPITER trial as being one of the gold standard statin long therapy trials, absolutely.
- **Q.** And you're aware that that JUPITER trial caused quite a stir of controversy in the medical field; correct?
- A. I don't know if I'd classify it as controversy. Are you specifically talking about the debate on hsCRP?
- **Q.** Correct, and specifically about the JUPITER trial. In fact, the trial itself, wouldn't you agree, calls out the fact that there were some deficiencies in the trial?
- A. Well, there's deficiencies in every trial. The best trials that are out there are double-blinded, randomized, placebo-controlled, multi-center, large number of patient population. I've been in the industry for 20 years, and I have reviewed hundreds, if not thousands, of clinical trials. And I will stand by that being one of the -- the epitome of one of the most perfectly designed trials out there.
- **Q.** Even though the authors of the study themselves noted the deficiencies in the trial; isn't that right?
- A. I'm unaware of that.
- Q. Now, you testified about the case study that is contained in BlueWave 496.

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Can we pull that up, Peter?

Do you remember giving a fairly dramatic discussion of what had happened to this poor patient?

- A. Ma'am, I give dramatic presentations on anything when you're saving a life. I do.
- Q. Well, did you save this man's life?
- A. No, I did not.
- **Q.** Did you ever meet this patient?
- A. I'll say no. I might get charged with a HIPAA violation if I say yes.
- Q. Well, you could tell us everything about this patient.

  I'm not asking for his identity. Just do you know him?
- A. I can tell you that I know the case study inside out and backwards. And this is just the report from the case study.

Every lab I've worked for gives you case studies about their tests, and you have the entire description of the patient. Y'all have that. That's been turned over.

- Q. Okay. So you got the information, the background that you talked about earlier today, from HDL; is that right?
- A. Ma'am, I've had this case study memorized since the very beginning of promoting for Health Diagnostic Laboratories.
- **Q.** And the information came from HDL. Is that what you're saying?
- A. Yes.

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Q. Okay. Now, you never attended medical school, did you?

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- Never claimed to be a doctor. Α. Absolutely not.
- All right. And you're not a physician, are you? Q.
- No, I'm not a physician. I have done a lipidology certification, but I can't take the test to become certified because I'm not a medical doctor and I'm not a nurse practitioner and I'm not a PA or a Form D.
- And you also understood that in your role as a sales representative, you can't advise your physician clients on medical necessity; correct?
- I'm not advising on medical necessity.
- Okay. You understood that that -- that would cross the 0. line for you; correct?
- Ma'am, is it going to be illegal now for me to promote case studies provided by a laboratory?
- Well, that wasn't my question. My question was, you Q. understand that you cannot advise your physician clients on whether -- on medical necessity; correct?
- I'm not advising on medical necessity. I'm presenting a case study and showing what diagnostics were used to reveal abnormality. And it's coupled with treatment suggestions that are approved by Dr. McConnell on the report that the physician can look at and choose what treatment modality they want to use or not use.
- All right. Later this afternoon, you had testified Q. something to the effect of after you had sold the physician on

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HDL's tests you would sometimes come back and learn that the phlebotomist had not done the draws. Do you remember that testimony?

- A. Yeah, I remember that.
- **Q.** So isn't it true if the physician has ordered these labs, is it the role of the phlebotomist to refuse to carry out a physician's order?
- A. I would think so.
- **Q.** To refuse to carry out a physician's order?
- A. I would think that that would actually be a problem, that it was a problem with that physician and that phlebotomist.
- **Q.** I'm sorry. I don't think I understand your testimony. Isn't it true a phlebotomist could not appropriately refuse to carry out a physician's order, could they?
- A. Ma'am, physicians have all kinds of orders with their labs. Some of them can go down to their lab and say, "Hey, for the next two weeks, I want you to run this test every time I order a lipid panel because I want to compare it against a lipid panel," which is what had happened in this particular practice.

I went back to do a test review, and the reports weren't there. They didn't have the reports. So the doctor walked with me down to the lab. And she started crying and said, "I was too busy to order these for you." You have all kinds of issues that go on in practices that I have zero

4:54PM	1	control over. But, yes, there's times that there would be				
4:54PM	2	tests that were ordered that never got processed.				
4:55PM	3	Q. All right. You also testified earlier today about the				
4:55PM	4	legal training that you received during your years in the				
4:55PM	5	health care field. Do you remember that?				
4:55PM	6	A. Yes.				
4:55PM	7	Q. All right. I think you said that you had training				
4:55PM	8	annually when you worked at Pfizer; is that right?				
4:55PM	9	A. Generally speaking, compliance training was something that				
4:55PM	10	was done annually.				
4:55PM	11	Q. All right. You were there for about four or five years;				
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- 4:55PM 13 A. 2000 and -- 1997 to 2000, 2001. I'd agree with that statement, yes.
  - **Q.** And the same thing happened when you went to Aventis; is that right?
  - A. Generally speaking, they train you annually on compliance training. That's correct.
  - **Q.** And then also when you joined Berkeley HeartLab, you had required compliance training; is that right?
  - A. Yes, we did.

is that right?

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- **Q.** And that compliance training included training on the Anti-Kickback Statute specifically?
- A. That's correct.
- Q. And so you got that every year?

4:56PM	1	A. I got that every year my entire medical career, yes.				
4:56PM	2	<b>Q.</b> Okay.				
4:56PM	3	THE COURT: Not medical career, sales career.				
4:56PM	4	THE WITNESS: Sales career in the medical field.				
4:56PM	5	THE COURT: Yes.				
4:56PM	6	THE WITNESS: Thank you.				
4:56PM	7	BY MS. SHORT:				
4:56PM	8	Q. And there's been well, you also had training on HIPAA,				
4:56PM	9	which is patient privacy; isn't that right?				
4:56PM	10	A. Yes.				
4:56PM	11	Q. All right. And Stark Laws, which is essentially physician				
4:56PM	12	self-referral prohibitions?				
4:56PM	13	A. All of that was usually a part of your compliance				
4:56PM	14	training, yes.				
4:56PM	15	Q. False Claims Act, you knew what it was; is that right?				
4:56PM	16	A. Yes.				
4:56PM	17	Q. And then when you got to Berkeley in 2005, you had				
4:57PM	18	training on processing and handling fees; is that right?				
4:57PM	19	A. Yes.				
4:57PM	20	Q. Was that the first time in your experience that you had				
4:57PM	21	been trained on process and handling fees?				
4:57PM	22	A. Yes.				
4:57PM	23	Q. Was Berkeley HeartLab the first company that you had				
4:57PM	24	worked for that offered process and handling fees?				
4:57PM	25	A. Yes.				

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- Q. You testified several times that P&H fees were common in the industry. And I understand you to say that that industry -- or understand you to mean that that industry is in advanced lipid testing; is that correct?
- A. Yes.
- **Q.** All right. So this isn't the health care industry writ large? It wasn't in pharma; correct? It wasn't in pharmaceuticals; is that right?
- A. Well, again, that's the first laboratory I ever worked for. That is the first time I've ever heard of a processing and handling fee.
- **Q.** Okay.
- A. I testified earlier that it was the first time I'd heard about it, and I questioned the practice. And I got trained on it. And then I learned, while I was out in the field, that the other laboratories did it too, which reassured me that there was nothing inappropriate with processing and handling fees; it was an industry standard.
- **Q.** Okay. And when you started in this industry of advanced lipid blood testings, there were three companies in the industry; is that right?
- A. There were more than three companies. I said there were two primary competitors with Berkeley HeartLab, which were Atherotech and LipoScience.
- Q. Okay. And those were the two competitors that you

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believed were paying processing and handling fees; is that correct?

- A. I know that they were paying processing and handling fees. Both of those were, yes.
- **Q.** Because you had seen process and handling agreements between those labs and physicians?
- A. You would see those out in the field. The letter of agreement was in every practice. They had those in the lab. You wouldn't necessarily see the legal opinion or their time and motion study. As I testified earlier, labs were pretty tight-handed with those. They didn't want those out because -- I've learned a new term in this industry -- attorney-client privilege. But that didn't matter in this case.
- **Q.** I believe your testimony would put the payment of process and handling fees within the advanced lipid blood testing industry going back to about 1982. Is that your understanding?
- A. That's what I've been shown since I've been involved in this investigation.
- **Q.** Well --
- A. That it goes back all the way to 1982.
- Q. All right. So, Mr. Dent, I'm not especially interested in what you've learned during the course of this litigation. I'm trying to go back to when you first started working at Berkeley HeartLab and you made the statement, "This -- I've learned that there were -- this was happening across this industry," that it

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was standard industry practice when you joined Berkeley and had been going on for years.

Was that your understanding in 2005 when you joined Berkeley HeartLab?

A. Yes, that it had been going on for years. The fact that it went all the way back to 1982, I did not know that.

But we started asking questions in this investigation, because I was accused of inventing processing and handling fees in the course of this investigation, that Brad Johnson and I came up with this scheme of processing and handling fees. And I'm like this has been going on ever since I've known. And I was trained it's been going on for a long period of time.

- **Q.** All right. So when you and Mr. Johnson -- well, let me ask this question. When you received training in legal compliance at Pfizer and Aventis and at Berkeley HeartLab, I believe your testimony was that that training was typically given either by the company's attorneys or by a compliance officer; is that right?
- A. I would consider those one and the same. With the companies I've worked for, most compliance officers were attorneys, yes.
- **Q.** Okay. So when you and Mr. Johnson started BlueWave, both of you were aware of the importance of legal compliance training in this industry; correct?

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- A. Yes.
- **Q.** Did you hire an attorney to provide training to your sales reps?
- A. Not as an employee, no.
- Q. I'm sorry. You didn't hire somebody as an employee?
- A. I did not hire an attorney as an employee for BlueWave, no.
- **Q.** Okay. My question is, you didn't hire an attorney to give compliance training to the BlueWave sales reps; correct?
- A. No. We used the compliance officers of the labs that we represented to give compliance training.
- **Q.** Okay. I understood your testimony to be earlier that you and Mr. Johnson prepared the compliance questionnaire, the legal compliance test?
- A. Yes, we did.
- **Q.** And that you administered that compliance training to your sales staff; is that right?
- A. And we gave that test to the compliance officers of the labs that we represented, yes.
- Q. Did the compliance -- okay.
- A. We've done both, ma'am. We've had training done by the compliance officers of the labs, where they would get on the phone and conduct conference calls. They traveled to Atlanta, that same Atlanta airport Marriott. They've given training at our meetings. We've utilized legal counsel to give the

5:02PM	1	training before. And we too have gone over the training line					
5:02PM	2	by line off the PowerPoint presentations.					
5:03PM	3	$oldsymbol{Q}_{oldsymbol{\cdot}}$ What legal counsel provided compliance training to the					
5:03PM	4	BlueWave sales staff?					
5:03PM	5	A. Kathy Johnson. She was compliance officer at HDL.					
5:03PM	6	Q. Okay. I believe I misunderstood your testimony. So					
5:03PM	7	you're saying that Kathy Johnson, who joined HDL in 2014; is					
5:03PM	8	that right?					
5:03PM	9	A. I believe Kathy Johnson joined 2013, 2014. That's					
5:03PM	10	correct.					
5:03PM	11	<b>Q.</b> Okay. So she provided some compliance training to the					
5:03PM	12	BlueWave sales staff; is that right?					
5:03PM	13	A. She has provided training to the BlueWave sales					
5:03PM	14	contractors, yes, that's correct.					
5:03PM	15	<b>Q.</b> Okay. And she happens to be an attorney; is that right?					
5:03PM	16	A. She is an attorney. That's correct.					
5:03PM	17	Q. Okay. So did BlueWave hire its own attorney to provide					
5:03PM	18	compliance training?					
5:03PM	19	A. Ma'am, again, no. BlueWave did not hire an attorney to					
5:03PM	20	give compliance training.					
5:03PM	21	Q. You and Mr. Johnson provided most of the compliance					
5:03PM	22	training to your sales staff; correct?					
5:04PM	23	A. We have provided compliance training off of the PowerPoint					
5:04PM	24	presentations, oftentimes provided by the laboratory, yes.					

They shared their compliance programs with us too. We're

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representing the laboratory.

- Q. Do you remember your testimony at your deposition that that -- those compliance PowerPoint slides from HDL started in 2014?
- A. From HDL. We were given a PowerPoint presentation from HDL, yes, in 2014.
- Q. Were there other PowerPoint presentations that you --
- A. Yes.
- **Q.** -- used --
- A. I testified to the ones we pulled directly off CMS.gov for training on anti-kickback, Stark, False Claims Act, yes. Y'all have approved PowerPoint presentations for those very laws that are available right off the internet.
- **Q.** Do you remember testifying at your deposition that the HDL PowerPoint slides that you received in 2014 were one and the same as the slides that were pulled off the internet?
- A. No, I don't recall testifying they're one and the same.

Again, this is where we're trying to act like there's something inappropriate. I mean, we gave compliance training. We've been giving compliance training since the beginning. And now I guess it's inappropriate for CEOs and COOs to give compliance training; we have to go hire another attorney.

Q. Don't read too much into it. I'm just trying to understand your testimony and understand who at BlueWave provided compliance training to the sales staff.

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- I've testified I've provided it. Brad's provided it. Compliance officers from the various labs we represented have provided compliance training to the BlueWave contractors.
- 0. Okay. And I believe your testimony has been that, with respect to the legal conference call test, that that was prepared by you and Mr. Johnson; correct?
- Brad and I did prepare that conference call test. you'll notice the language is pretty elementary. We wanted to dumb it down so that the questions and review could generate discussion. That's why some of the test questions were intentionally a little tricky and playing with words, because there's a lot of playing with words that go on in this industry, apparently.

**THE COURT:** Ms. Short, it's getting late in the day. I think we'll break it off here. I imagine you have a way to we've had a long day, and I think we'll do good by breaking and coming back tomorrow morning.

Please do not discuss the case with anyone. we'll see you bright and early at 9:00 tomorrow morning. not do any of your own research.

> (Whereupon the jury was excused from the courtroom.) THE COURT: You may be seated.

Mr. Cooke, you want to give me some forecast for tomorrow?

MR. COOKE: Yes, Your Honor. We'll finish with

Mr. Dent, and then we have -- not necessarily in this order, we 1 5:07PM 2 have Mr. Sellers and then Mr. Lively. Is that right? 5:07PM MR. GRIFFITH: Yeah. 3 5:07PM 4 MR. COOKE: And then we have Dr. Fishberg, our expert 5:07PM on medical necessity. And at this moment, I'm not sure who 5 5:07PM else we have waiting in the wings. We're -- we've been trying 6 5:07PM 7 to compress our schedule and bring people a little earlier, and 5:07PM I'm not sure how successful yet we've been. 8 5:07PM 9 THE COURT: okay. I gotcha. Okay. That's all I 5:07PM 10 needed, to just kind of get a forecast. 5:07PM 11 Anything I need to address before we break for 5:07PM 12 the day? 5:07PM 13 MR. LEVENTIS: Thank you, Your Honor. No. 5:07PM Defense? 14 THE COURT: 5:07PM 15 Thank you all. See you at 9:00 tomorrow 5:07PM morning. 16 5:08PM 17 5:08PM 18 5:08PM 19 20 21 22 23 24 25

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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.

Tana J. Hess, CRR, FCRR, RMR Official Court Reporter