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 19, 2018 CONSULTANTS, INC., ET AL.

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REPORTER'S OFFICIAL TRANSCRIPT OF THE JURY TRIAL - DAY FOUR HELD BEFORE THE HONORABLE RICHARD M. GERGEL UNITED STATES DISTRICT JUDGE January 19, 2018

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

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(Call to order of the Court.)

THE COURT: Good morning. Please be seated. Are there any matters for the parties to address to the Court?

MR. LEVENTIS: Yes, Your Honor, just one Mr. Shaheen has for you.

THE COURT: Yes.

MR. SHAHEEN: Just one housekeeping issue, Your Honor. Yesterday, I spoke at great length about -- or the witness, I guess, testified at great length about Plaintiffs' Exhibit Number 1217, and I failed to move it into evidence. I spoke with defense counsel. They seem okay with it, and I'd like to move Plaintiffs' Exhibit Number 1217 into evidence now.

THE COURT: Okay. Exhibit 1217, there's a motion by the plaintiff to move it into evidence.

Is there objection?

MR. GRIFFITH: No objection.

MR. ASHMORE: No, sir.

MR. GRIFFITH: Our standard objection.

THE COURT: Yes, sir. Thank you, Mr. Griffith. And I will take it to protect your record, Mr. Griffith, that is a continuing objection?

MR. GRIFFITH: Thank you, Your Honor.

THE COURT: Yes. Plaintiffs' Exhibit 1217 is admitted over BlueWave's objection.

MR. SHAHEEN: Thank you, Your Honor.

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THE COURT: Anything else?

MR. LEVENTIS: No. Thank you.

THE COURT: Defendants, any matters you need to bring to my attention?

MR. COOKE: Nothing, Your Honor.

MR. ASHMORE: No, sir.

THE COURT: Has the -- have my friends from the Department of Justice conferred with their superiors concerning whether you need an order?

MS. STRAWN: I sought further guidance and have received none, Your Honor.

THE COURT: Very good. At lunchtime, I'm going to enter an order if you haven't gotten it --

MR. LEVENTIS: For the U.S. attorney office folks, I'm going to confirm that, last I heard, we will need an order. So I'll check on that.

THE COURT: I'm delighted to enter it, but I want y'all to understand -- you know, I, from time to time, have lawyers tell me that clients have not paid them and that they don't want me to proceed. And my view is that is between you and your client. But you're an officer of the Court, and I'm going to direct you to be here.

MR. LEVENTIS: Absolutely.

THE COURT: And you understand that?

MR. LEVENTIS: Yes. Thank you, Your Honor.

9:08AM	1	THE COURT: Very good. Okay. Is our jury here?
9:08AM	2	THE DEPUTY: Yes, sir.
9:08AM	3	THE COURT: Very good. Let's bring them in.
9:09AM	4	(Whereupon the jury entered the courtroom.)
9:10AM	5	THE COURT: Please be seated.
9:10AM	6	Examination by BlueWave?
9:10AM	7	MR. GRIFFITH: Thank you, Your Honor.
9:10AM	8	LATONYA MALLORY,
9:10AM	9	a witness called on behalf of the plaintiff, being first duly
9:10AM	10	sworn, was examined and testified as follows:
9:10AM	11	CROSS-EXAMINATION
9:10AM	12	BY MR. GRIFFITH:
9:10AM	13	Q. Good morning, Ms. Mallory.
9:10AM	14	A. Good morning.
9:10AM	15	Q. So we'll be much more limited this morning than yesterday.
9:10AM	16	I want to start out with Mallory Exhibit 115 I
9:10AM	17	mean, excuse me, 114.
9:11AM	18	Do you recognize this email?
9:11AM	19	A. I do.
9:11AM	20	Q. And you got a copy of this email; correct?
9:11AM	21	A. Yes.
9:11AM	22	Q. Can you and so can you read who's it from and who's it
9:11AM	23	to and who's it cc'ing?
9:11AM	24	A. So it's from Mr. Leventis, and it's to Laura Hoey at
9:11AM	25	Ropes & Gray, Brien O'Connor at Ropes & Gray. And it was cc'd
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to Jennifer Short at the DOJ, Elizabeth Strawn at the DOJ, Su Kim at OIG, and David Rhinesmith at Ropes & Gray.

- And at this time, was it your understanding that -- what Q. was your understanding as to what the -- your lawyers were communicating back and forth with the Department of Justice?
- So in -- well, this email had a couple, I guess, reasons for being. One was the completion of handing over the documents that they requested during the subpoena but also trying to get understanding from the DOJ, what was the issues that they were concerned with, what was the point of the subpoena, what were the issues.

P&H had come up internally, of course. that yesterday. And it was very important for the attorneys to try to get a position from the DOJ on the legality. their position on the P&H?

Okay. All right. So let's scroll down to the -- I guess 0. it's the third paragraph where it says "Regarding the draft waiver."

Can you read those first two sentences?

It says, "Regarding the draft waiver, you are right that our client has elected to hold on executing a waiver until we better understand the government's position on the industry practice of the straight payment of P&H fees. We understood from our conversation on December 12th that, as of now, the government is not taking a position on the straight payment of

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P&H fees. So we felt our time and resources better spent" -resources better spent, not are better spent -- "addressing the
issues that you and Elizabeth outlined as the government's
current area of concern."

- **Q.** So when you saw the sentence that "the government is not taking a position on the straight payment of P&H fees," what impact did that have on you?
- A. Our attorneys explained that the government didn't have an issue with P&H. They accepted that it was an industry standard and that there was essentially no position that they were taking at that time that there was any problem with it.
- Q. So did that -- did the position -- when you read that particular statement in this email, did that make your understanding of P&H fees more clear or less clear in terms of --
- A. It made it more clear. I mean, it made -- they told me the government had no issue, that they accepted that it was industry standard, and that we had to address other issues that they had. So at that point in time, we believed that there was no issue whatsoever with P&H.
- **Q.** And did you continue -- did you continue your negotiations or interactions with the Department of Justice?
- A. Absolutely. Between 2013-2014, I wasn't present at all the meetings, but I absolutely got a report back on all of the meetings. There was, I think, three or four meetings, dozens

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and dozens of email communications and phone calls. Our attorneys proactively sought out the government in order to understand the reasons for the subpoena, what the issues were.

After this memo -- I mean after this email exchange, there was two more meetings and -- with the DOJ and many, many communications.

- Q. Okay. And do you recall what the last -- when was the last meeting with DOJ? Do you recall?
- A. I think it was May 20th, May 25th, something like that.
- **Q.** Okay. And did -- did you have -- did you or your lawyers have any communication, to your knowledge, with DOJ between that last meeting and the issuance of the special fraud alert on June 25th?
- A. Yes. So the purpose of the meeting was to explain our -our position legally. Now, I didn't understand all the legal
 terms, but they prepared a discussion for "Here's our position.
 You finally took a position in April, so now here's our
 position from a legal point of view. Let's discuss if you
 really have an issue."

My understanding was that, after that meeting, there was internal communication at the DOJ and that they realized that there was some vagueness in what was available to us as the market. And that's why they issued the special fraud alert.

MR. GRIFFITH: Okay. Well, that leads me right to my

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next exhibit. So, Your Honor, can we call up Exhibit 123 -- BlueWave Exhibit 123, Your Honor.

And, Your Honor, this is without objection, so I'm going to go ahead and move it into evidence.

THE COURT: Okay. BlueWave Exhibit 123. Is there an objection from the government?

MR. SHAHEEN: No, Your Honor.

THE COURT: From --

MR. ASHMORE: No, sir.

THE COURT: From Mallory.

BlueWave Exhibit 123 is admitted without objection.

BY MR. GRIFFITH:

- Q. Now, can you just identify the dates and who the -- the who to and the who from on this particular email.
- A. This was from Cal Dent to me on June 30th, about five days after the special fraud alert was published. Copied was Brad Johnson, Doug Sbertoli, Joe McConnell, and Russ Warnick.
- **Q.** Okay. And so you've talked about Joe McConnell and Russ warnick.

Who is Doug Sbertoli?

- A. Doug Sbertoli was our in-house counsel.
- **Q.** He was a lawyer?
- A. He was a lawyer.
- Q. Okay. And what was the subject matter?

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- A. Subject matter, "Important Attorney-Client Privilege Revised Termination Letter Sentence Removed."
- Q. So just in general terms, what was that about? What termination letter?
- A. Oh, we were terminating P&H fees, and we were sending them -- the notice to the field. And we sent BlueWave a copy of what all the physicians -- I think we sent every contractor a copy of what we were sending to the physicians.
- **Q.** Okay. All right. And so it looks -- if you scroll down, it looks like the -- at the top, that Cal was thanking you for the -- for your prior email; correct?
- A. Correct.
- **Q.** Okay. So let's go to your original email to Cal and Brad. So can you read the first paragraph for us.
- A. "Laura and Brien from Ropes & Gray had a chance to speak with Elizabeth Strawn. Elizabeth confirmed that the advisory was written by the OIG person working on our case and has been present in the room when our attorneys met with them. The OIG person is a female, but I forgot her name."
- **Q.** Okay. So did you know who the OIG person was? Do you recall now who the OIG person was that was in your meetings?
- A. I do not recall her name. I think it was Allison, but I'm terrible with names.
- Q. Okay.

THE COURT: Okay. Let's remind the jury what OIG

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stands for.

MR. GRIFFITH: Oh, yes, sir. Can I do it, Your Honor?

THE COURT: Sure. Just answer it.

MR. GRIFFITH: The office of inspector general --

THE COURT: Great. Thank you.

MR. GRIFFITH: -- Department of Health and Human Services.

BY MR. GRIFFITH:

- **Q.** So let's go to the second paragraph. Can you read the first sentence.
- A. "Laura and Brien said they spoke to Elizabeth for about 20 minutes. Elizabeth told Ropes & Gray that they had 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 the advisory was to state that there was no possible scenario in which P&H payments were okay and to stop the practice in the market."
- Q. Okay. Let's just stop right there.

So what impact -- when you read that -- or when you learned that information and you were conveying this, what impact did it have on you to learn that this was a situation that they'd never had before?

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A. Well, originally -- just to be clear, the OIG writes the rules for the DOJ to follow or prosecute against. So the DOJ had been communicating with HDL, and OIG was involved in that.

So it was helpful to meet. In my mind set, I thought this was great that finally we're going to get an answer to the question we've been asking and that there was finally some understanding that the -- it was vague in the market, and so they clarified it.

And so the impact to me was, thank goodness, finally it's clear. And from a business point of view, we had already stopped paying P&H. And, you know, I was just happy to finally have an answer.

Q. And you say you stopped paying P&H.

Was that -- why did you stop?

A. So when Ropes & Gray -- Elizabeth Strawn sent the OIG advisory -- special fraud alert, not advisory opinion -- special fraud alert to -- to Laura Hoey. Laura Hoey was in our office at a board meeting the day she received it. She was across the table from me.

She received the email, and she showed us the email. And her interpretation at first glance was that the special fraud alert meant that P&H was okay. And we sent that special fraud alert on to Bluewave, and we also -- I started reading it.

By the time the meeting was over, I asked Laura Hoey

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to contact Elizabeth Strawn and the DOJ and get to -- that special fraud alert had the name of the person who wrote it on it at the time, and I asked Laura Hoey to contact Elizabeth Strawn to speak to the person who wrote it to see what they meant from it. Because, as I mentioned before, it was vague.

Laura Hoey thought it meant everything was okay. But as I read it, understanding the steps that they were talking about, from a lab point of view, it didn't look like it was okay to me.

So she didn't immediately contact Elizabeth Strawn. I called her three times to get her to call Elizabeth Strawn. And she said, "Whatever Elizabeth Strawn says is the answer, you're going to have to live with it."

And I said, "Absolutely. That's all we've ever wanted. So call her."

And so she made a phone call. She clarified. And at that point, we sent a -- created a notice, sent the notice to the market. Even though the notice was delayed, there was no P&H payments paid to any physicians as of the day before the fraud alert.

- Q. Okay. So am I understanding you to say that, even after the special fraud alert, that Ropes & Gray understood that it still may be an opportunity to pay P&H?
- A. Yes. At first, their interpretation was that it was okay. I read it. I sent it to BlueWave. Cal read it. Cal is a

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stickler for detail. He also called and said, "This is not how I'm reading it. I agreed with him."

And so I called Laura Hoey and said, "This is not -not how I'm reading this document. You need to go back and clarify again."

So let's go to Mallory 98. I don't want to spend a whole lot of time on this, but if you could go to the last page. Okay. The next-to-last page. Excuse me. Okay.

Can you -- so can you identify the timekeepers that are listed on this one invoice from Ropes & Gray?

- There's David Rhinesmith, who is an attorney. Tromble, who's an attorney. Laura Hoey, who's an attorney. All of these other people are attorneys with Ropes & Gray.
- So Laura Hoey, Shannon Kirk. Caleb Dulis, Lisa Guo, Michael Marzano, David Rhinesmith, Stacy Tromble, Mollie Cavanaugh, and Jessica Jones?
- Α. Correct.
- And so that's -- one, two, three, four, five, six, seven, Q. eight, nine -- nine that particular month; correct?
- On that particular invoice. This is 50 pages. will go through the other pages, there should be a timekeeper summary. And there's nine on this invoice. We worked on a -with Ropes & Gray and -- and, I would say, 25 different attorneys at any given time.
- Do you know what all of these different attorneys were Q.

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working on?

- Have no idea. Α.
- Okay. Okay. So let's go to Government Exhibit 1244, Q. please.

All right. So do you remember discussing this memo from Derek Kung to the Health Diagnostic Lab board of directors yesterday?

- Yes. Α.
- And so was Derek Kung the general counsel for HDL?
- At that time, yes.
- And so when y'all went over the -- this yesterday, 0. you did not go over the first page; did you?
- No. Α.
- okay. So let's go to the second paragraph -- excuse me --Q. third paragraph. All right. So why don't you read the first three sentences.
- "Attached this memo is a chart outlining certain relationships among HDL and third parties. Below is a brief overview of each such relationship and the potential AKS" -which meant for Anti-Kickback Statute -- "and Stark Law implications. While we understand there's not any bad intent with respect to any of the arrangements discussed herein, it is important for the board to understand that fighting with the OIG over intent will be a long, drawn-out investigation that could take years and cost HDL millions in legal and other fees.

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Any arrangement that does not fit within the Anti-Kickback Statute safe harbor or Stark Law exception will draw unwanted scrutiny from the OIG."

Q. Okay. And so you took that information from Mr. Kung; right?

Α. Correct.

Okay. And on the second sentence when it says "while we Q. understand that there is not any bad intent with respect to the arrangements discussed herein," did you at any time have any kind of bad or wrongful intent about -- with respect to any of the arrangements that you entered into?

Absolutely not.

Did you enter into any of the arrangements with any kind Q. of wrongful purpose?

Α. No.

Did you enter into any of the arrangements -- the P&H fee 0. arrangements, the sales commission agreements -- with the intent to violate the Anti-Kickback Statute?

Α. Absolutely not.

when you showed this memo to -- or when the board of directors got this memo, did everybody agree that there was no bad intent?

That was the purpose. I mean, we instructed Absolutely. Derek to find issues and resolve them. So we expected that he understood that he was looking for any possible problem that

could be a problem. 1 9:32AM 2 And so this was -- can you go to the date. Q. 9:33AM 3 So this was on August 12th -- August 30th of 2012 9:33AM 4 when Mr. Kung wrote this; correct? 9:33AM 5 Α. Correct. 9:33AM MR. GRIFFITH: Okay. So let's go to BlueWave 106. 6 9:33AM 7 And, Your Honor, this is -- this is also offered 9:33AM and -- into admission of evidence without any objection. 8 9:33AM 9 THE COURT: Bluewave 106, any objection from 9:33AM 10 government? 9:33AM 11 MR. SHAHEEN: No, Your Honor. 9:33AM 12 From Mallory? THE COURT: 9:33AM 13 MR. ASHMORE: No, sir. 9:33AM BlueWave 106 is admitted without 14 THE COURT: 9:33AM 15 objection. 9:34AM Please continue, Mr. Griffith. 16 9:34AM 17 BY MR. GRIFFITH: 9:34AM 18 So let's pull up the who to, who from. Q. 9:34AM 19 The email started at the bottom from Derek Kung to me, Joe 9:34AM 20 Anastasia, who was in charge of our -- he was the supervisor 9:34AM 21 for all sales support. He was operations person; Kathy 9:34AM Johnson, who was our chief compliance officer; and Tabitha 22 9:34AM 23 Henley, who worked with all the sales support personnel. 9:34AM 24 And he sent this email that had a new P&H agreement 9:34AM 25 on it, and he asked that we communicate -- well, he asked me to 9:34AM

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sign off on the document, and then sales support could start using it.

- Q. Okay. All right. So let's go up to the first part.
- A. The top was me taking that same P&H. The attachments, you see, are underlined in blue. I showed them the new document and the red-line version, the ones that had the marks through the changes, and forwarded them the new P&H agreement that was strengthened for compliance from Derek's point of view.
- Q. Okay. And so this was after you got the Kung memo; correct?
- A. Yes.
- Q. The so-called Kung memo of August 30th, 2012?
- A. Correct.
- Q. Okay. And so let's read -- let's read the first paragraph you got there.
- A. "Cal and Brad: We have modified the P&H agreement to strengthen compliance documentation. Some of the changes are simply rewording that we have already written, and others are truly adding to the compliance efforts. Since we need to add to the documents for our compliance efforts, I have let the insignificant changes go.

"Can you please review the attached document from the physician perspective and let me know if there's anything that you can see that would be problems from their perspective. I cannot see anything that I think will be alarming, but I would

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appreciate a second set of eyes.

"Once you approve, this will be the new agreement going forward (we will pick a future date) but we will not go back and change all those that exist."

- **Q.** Okay. And so did you, in fact, implement this new P&H fee agreement?
- A. Yes.
- Q. So let's go down -- scroll down the email. Right there. So who actually did the redrafting of the P&H fee agreement?
- A. Ropes & Gray.
- **Q.** Okay.
- A. His name was Peter Holman.
- Q. Okay. I didn't see Peter Holman on the other invoice. So this is a tenth Ropes & Gray attorney; right?
- A. He's one of the 25 or so, yeah.
- Q. Okay. Can you read what he said.
- A. "I've attached a revised P&H agreement along with an incremental red line against the previous draft we sent you and a cumulative red line against the original agreement.

"As you will see in the incremental red line, our main additions were to Section 5 in order to provide some more clarity that physicians may accept P&H fees only if, A, the practice's personnel perform the services; or, B, the practice outsources the services to a third party at fair market value

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at a cost that is no less than what the practice receives from HDL to the -- for P&H.

"As you will see, we've drafted B with some other specific requirements, which provides some additional protection under the Stark indirect compensation arrangement exception. Our goal with both A and B are to avoid situations where a practice might otherwise benefit from P&H fees for services for which it either did not incur any cost or for which it incurred costs at a lower value than what HDL pays. Please let us know if you have any questions."

Q. Okay. And so -- and I don't want to go -- we're not going to go line by line, but let's just scroll through the agreements that were sent that were attached.

Let's go -- keep on going down, scroll down. Next page. Next page. Is that it? One more. One more. Okay.

And I'm not going to ask you about all the details on this, but is this representative of the changes that Mr. Holman was making on the document?

A. Yes.

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Q. All right. Keep on going down. Okay. And so -- we call this in the legal business a red line, the before and the after all the changes.

And so did you rely on these changes that he was making?

A. These are the changes we forwarded to the market.

1 9:40AM 2 9:40AM 3 9:40AM 4 9:40AM 5 9:40AM 6 9:40AM 7 9:41AM 8 9:41AM 9 9:41AM 10 9:41AM 11 9:41AM 12 9:41AM 13 9:41AM 14 9:41AM 15 9:41AM 16 9:41AM 17 9:41AM 18 9:41AM 19 9:41AM 20 9:42AM 21 9:42AM 22 9:42AM 23 9:42AM 24 9:42AM

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Q. Okay. Now let's go to Government Exhibit 1253.

So you recall you were talking about this particular document yesterday; correct?

- A. Correct.
- **Q.** And just to refresh everybody's recollection, who -- who was the law firm who issued this particular opinion?
- A. This was LeClairRyan.
- Q. And how did you know LeClairRyan?
- A. So LeClairRyan was the law firm that helped me incorporate HDL and get started. And I worked directly with Dennis Ryan, who's the Ryan of LeClairRyan.
- **Q.** So who actually drafted this particular opinion from LeClairRyan?
- A. This was Mike Ruggio.
- Q. Okay. And how did you know Mike Ruggio?
- A. I was introduced to him by Dennis Ryan, and he had been hired by LeClairRyan because of his health care expertise.
- Q. Okay. So let's go to the second page. And if you can pull out the -- that paragraph, first paragraph.

Now, I just want to -- I just want you to read this to the jury, because -- if you don't mind.

A. From -- from the attorney Mike Ruggio, he wrote, "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

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\$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 Anti-kickback Statutes and civil False Claims Act to alleviate any issues in that regard.

"The safe harbor requires that the aggregate compensation paid for the services are set in advance and 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.** Okay. And so did you rely on this particular legal opinion?
- A. Yes.
- **Q.** Did you believe, based on this opinion, that the P&H fee agreements were arm's length?
- A. Yes.
- **Q.** Did you believe, based on this legal opinion, that the P&H fee agreements were fixed in advance?
- A. Not just this opinion, but that was comments from Dennis Ryan when we -- he created the original P&H agreement.
- **Q.** Okay. And did you -- did you believe at the time that fair market value fee was being paid?

9:44AM	1	A. Yes.
9:44AM	2	Q. Okay.
9:44AM	3	A. Well below fair market value.
9:44AM	4	Q. Now, just to be clear, Brad Johnson and Cal Dent were not
9:44AM	5	on the board of directors at HDL; is that correct?
9:44AM	6	A. That's correct.
9:44AM	7	Q. Okay. And and they had no decision-making authority at
9:44AM	8	HDL; correct?
9:44AM	9	A. Correct.
9:44AM	10	Q. And Brad and Cal had no input as to which claims HDL filed
9:44AM	11	for reimbursement; is that correct?
9:44AM	12	A. That's correct.
9:44AM	13	Q. Okay. And they Brad and Cal had no part in the
9:45AM	14	physical submission of any claims to Medicare or TRICARE; is
9:45AM	15	that correct?
9:45AM	16	A. That's correct.
9:45AM	17	Q. And Brad and Johnson and Cal Dent did not make any
9:45AM	18	certifications to TRICARE or Medicare on HDL's behalf when a
9:45AM	19	claim was submitted; is that correct?
9:45AM	20	A. They couldn't have.
9:45AM	21	Q. Okay.
9:45AM	22	MR. GRIFFITH: One minute, Your Honor.
9:45AM	23	THE COURT: Yes, sir.
9:45AM	24	(Pause.)
9:45AM	25	MR. GRIFFITH: Thank you. That's all, Your Honor.

Thank you, sir. 1 THE COURT: 9:45AM 2 Government redirect? 9:45AM MR. SHAHEEN: Let me pull up Mallory -- I'm sorry. 3 9:45AM 4 Can we pull up Mallory Exhibit 83, please. 9:46AM It's on the ELMO. 5 MR. PHANEUF: 9:46AM MS. SHORT: Can you switch back to the video, please. 6 9:46AM 7 MR. SHAHEEN: Am I able to do that? 9:46AM THE DEPUTY CLERK: I'm on the prosecution. Do you 8 9:46AM 9 want me to pull it up? 9:46AM 10 MR. SHAHEEN: I think we were going to pull it up. 9:46AM 11 THE DEPUTY CLERK: It's on prosecution. 9:46AM 12 MR. LEVENTIS: It's saying "resolution note fire." 9:46AM 13 MR. SHAHEEN: I can use the ELMO. 9:46AM THE DEPUTY CLERK: I can switch back and forth. 14 9:46AM 15 That's all I do. 9:46AM I'll use the ELMO. 16 MR. SHAHEEN: 9:46AM 17 THE DEPUTY CLERK: Hit the button. Turn it on. 9:46AM 18 MR. SHAHEEN: It's red. Everything else is on. 9:46AM Should I do anything more or --19 9:47AM THE DEPUTY CLERK: I don't know. I don't know if 20 9:47AM 21 they unplugged it yesterday. I don't know exactly what's going 9:47AM 22 on, but it's on the doc cam now. It takes a minute to warm up, 9:47AM 23 so it's probably coming up now. 9:47AM 24 MR. SHAHEEN: Okay. 9:47AM 25 THE COURT: Let's see if we can't -- does somebody 9:47AM

else have Mallory 83 you can put up for us, please? 1 9:47AM 2 Thank you very much. 9:47AM 3 REDIRECT EXAMINATION 9:47AM 4 BY MR. SHAHEEN: 9:47AM 5 BY MR. SHAHEEN: 9:47AM What -- this is an invoice from Ropes & Gray from March of 6 9:47AM 7 2013; correct, Ms. Mallory? 9:47AM 8 Α. Yes. 9:47AM 9 And the invoice is for \$145,000; correct? 9:48AM 10 Yes. Α. 9:48AM 11 Or just north of that. 0. 9:48AM 12 That's a lot of money, isn't it? 9:48AM 13 Α. Yes. 9:48AM 14 Q. And so you paid all that money for their advice, and yet 9:48AM 15 you didn't heed their advice to stop paying P&H? 9:48AM 16 They never told us to stop paying P&H. Α. 9:48AM 17 we did see the exhibit yesterday from Mr. Kung, who said Q. 9:48AM 18 Ropes & Gray has advised that we stop paying P&H; correct? 9:48AM 19 Α. This is -- at the top, is this LeClairRyan? 9:48AM 20 No, this is -- I apologize. Let me back up. Ο. 9:48AM Do you recall that Mr. Ashmore and now Mr. Griffith 21 9:48AM 22 showed you several exhibits related to communications Ropes & 9:48AM 23 Gray had with the Department of Justice? 9:48AM 24 Α. Yes. 9:48AM 25 And included in some of those documents were references to Q. 9:48AM

attorney-client communications? 1 9:48AM 2 Α. Yes. 9:48AM And there was a discussion about whether or not HDL would 3 0. 9:48AM 4 waive its privilege as to some of those communications; 9:48AM 5 correct? 9:48AM 6 Α. Yes. 9:48AM 7 was there a team of people helping you collect and provide Q. 9:49AM documents? 8 9:49AM 9 Α. Yes. 9:49AM 10 And was Doug Sbertoli, HDL's general counsel at the time, Q. 9:49AM 11 involved in that process? 9:49AM 12 Yes. Α. 9:49AM 13 And Mr. Sbertoli was HDL's top lawyer at that time; 0. 9:49AM 14 correct? 9:49AM 15 That's correct. Α. 9:49AM During the investigation, you and HDL made the choice to 16 0. 9:49AM 17 provide certain attorney-client communications to the 9:49AM 18 Department of Justice; correct? 9:49AM HDL and the attorneys made that decision. 19 9:49AM 20 And you didn't have to turn over those documents; correct? 9:49AM 21 I don't know. I mean, that was handled by the attorneys. 9:49AM 22 They were at one time protected by the attorney-client Q. 9:49AM 23 privilege. Is that your understanding? 9:49AM 24 I can't answer that without being an attorney. I relied 9:49AM 25 on whatever the attorneys decided. 9:49AM

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- **Q.** Did you make the -- you made the choice to produce those documents because you thought it would help you out; correct?
- A. I didn't make the choice to produce those. That was handled by our legal department and Ropes & Gray, so I was -- had nothing, almost, to do with that choice.
- **Q.** And the attorneys provided the Department of Justice with some of the attorney-client communications; correct?
- A. I believe so, yes.
- **Q.** They provided a selection of the attorney-client communications; is that correct?
- A. I'm not sure everything that they gave you guys.
- **Q.** They provided only the flattering attorney-client communications; correct?
- A. I don't think so, no.
- Q. Prior to April 28th, 2014, you and HDL withheld

 Mr. Freedman's email telling the government -- telling HDL and
 you that the government views P&H as a blatant kickback;
 correct?
- A. I have no idea what was given to the government as far as attorney-client communication.
- Q. Prior to April 28th, 2014, you and HDL also withheld Mr. Kung's memo to the board putting them on notice that the government viewed P&H arrangements to be illegal; correct?

MR. ASHMORE: Objection, Your Honor.

THE COURT: What's the objection?

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MR. ASHMORE: It's a misstatement of the facts.
THE COURT: Overruled.
 Keep going.

BY MR. SHAHEEN:

- Q. You also -- I'm sorry.
- A. Will you ask the question again, please.
- Q. Prior to April 28th, 2014, you and HDL withheld Mr. Kung's memo to the board putting them on notice that the government viewed P&H arrangements to be illegal?
- A. You guys had communications with HDL. I was never present in any of those communications. You settled with HDL. I'm here on my own. I was not part of that communication. I have no idea what was discussed at those meetings or what was produced.
- **Q.** Well, that's contrary to your previous testimony, where you did say that, after each of those meetings, you had multiple calls with all the attorneys; correct?
- A. That's correct. I asked for the communication. Give me what the -- what happened. What's their thought process? I was very hungry for answers.

But getting into the details about what was produced, I remember there being -- I don't know -- six, seven document productions. And you wanted everything from every person in the company. There was 800 people, so there was volumes. So I had very little to do personally with anything that was

produced to the government. 1 9:52AM 2 You and HDL withheld documents referred to Nick Pace and 0. 9:52AM Project Twilight; correct? 3 9:52AM Again, HDL did. You have to separate me. There's nowhere 4 Α. 9:52AM 5 I sent you anything. I was not part of that document 9:52AM production. 6 9:52AM 7 Are you the CEO -- were you the CEO of HDL at the time? Q. 9:52AM And I relied on the in-house counsel as well as Ropes & 8 Α. 9:52AM 9 Gray to handle all communication with you guys. 9:52AM 10 That's the in-house counsel Doug Sbertoli? 0. 9:52AM 11 Doug Sbertoli. There was -- Kathy Johnson was another 9:52AM 12 attorney that was a CCO at that time. And Dennis Ryan and 9:52AM 13 Derek Kung and many others. 9:52AM So you and HDL's attorneys and HDL's outside counsel also 14 9:52AM 15 withheld Ropes & Gray's advice to HDL to terminate the P&H 9:52AM fees: correct? 16 9:53AM 17 No. You cannot say I did. I'm telling you I had no -- no 9:53AM 18 discussion about what to withhold, what not to withhold. That 9:53AM 19 was all done by HDL attorneys and Ropes & Gray attorneys. Ι 9:53AM 20 was not part of any of those decisions or any of those 9:53AM 21 discussions. 9:53AM 22 You were the CEO of HDL at the time; correct? 0. 9:53AM 23 I had nothing to do with that. I was informed --9:53AM 24 THE COURT: Ma'am, answer the question. 9:53AM

Were you the CEO of the --

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9:53AM

1 THE WITNESS: I was the CEO. 9:53AM 2 BY MR. SHAHEEN: 9:53AM And you had numerous and frequent conversations with your 3 Q. 9:53AM 4 in-house counsel and your outside counsel; correct? 9:53AM 5 Not about document production. 9:53AM It was not until the end of April 2014 that HDL first 6 9:53AM 7 disclosed any of its communications with any attorney other 9:53AM than the flattering communications it had with the LeClairRyan 8 9:53AM 9 attorneys; correct? 9:53AM 10 Again, I don't know the timing of document production and 9:53AM 11 what was given to you. 9:53AM 12 But even at that time there was not a full disclosure of 9:54AM 13 all the unfavorable attorney communications HDL had with its 9:54AM 14 own attorneys; correct? 9:54AM 15 Again, I have no idea of the scheduled timing of document Α. 9:54AM 16 productions to the government. 9:54AM 17 May I approach? MR. SHAHEEN: 9:54AM **THE COURT:** Is this going to work? 18 9:54AM 19 MR. SHAHEEN: It's not working? It worked with the 9:54AM 20 other document. Oh, no, it didn't. 9:54AM It didn't work. I already sent an 21 THE DEPUTY CLERK: 9:54AM 22 email to Anthony. 9:54AM 23 May I approach, Your Honor? 9:55AM MR. SHAHEEN: 24 THE COURT: You may. 9:55AM 25 Ladies and gentlemen of the jury, this is again 9:55AM

the example, if it can break during a trial, it will break, all 1 9:55AM 2 technology. 9:55AM BY MR. SHAHEEN: 3 9:55AM 4 Q. Ms. Mallory, can you read the title of this document to 9:55AM 5 the jury. 9:55AM "Agreement of limited privilege waiver in connection with 6 Α. 9:55AM 7 the government's investigation of Health Diagnostic 9:55AM Laboratory." 8 9:55AM 9 And the date? 0. 9:55AM 10 April 28th, 2014. Α. 9:55AM 11 And can you read the first line -- I mean, bullet point 0. 9:55AM 12 number 1 there. 9:55AM 13 "The waiver will cover the time period of HDL's 9:55AM incorporation, November 5th, 2008, to the date Ropes & Gray was 14 9:55AM 15 retained by HDL, October 29th, 2012." 9:55AM 16 Thank you. Q. 9:55AM 17 MR. SHAHEEN: Your Honor, I would like to introduce 9:55AM 18 this as Plaintiffs' Exhibit Number 1616, please. 9:55AM 19 THE COURT: Is there an objection? 9:55AM 20 MR. GRIFFITH: Your Honor, I don't see the relevance 9:56AM 21 to it. Object on relevance grounds. 9:56AM 22 THE COURT: Let me see it. 9:56AM MR. SHAHEEN: I'd be happy to address that, Your 23 9:56AM 24 Honor. 9:56AM 25 THE COURT: Let me read the document. 9:56AM

1 MR. SHAHEEN: Fair enough. 9:56AM 2 (Pause.) 9:56AM Mr. Ashmore, do you have a view? 3 THE COURT: 9:56AM 4 MR. ASHMORE: Well, I join in Mr. Griffith's 9:56AM 5 objection, relevance, Your Honor. 9:56AM THE COURT: Overruled on relevance grounds. 6 9:56AM 7 Overruled. 9:56AM Government Exhibit -- Plaintiffs' Exhibit 1616 8 9:56AM is admitted over defendants' objections. 9 9:56AM 10 BY MR. SHAHEEN: 9:56AM 11 So as you read to the jury, this is the agreement of 0. 9:56AM limited privilege waiver; correct, Ms. Mallory? 12 9:56AM 13 Α. Correct. 9:56AM 14 Q. And it's dated April 28th, 2014? 9:56AM 15 Α. Correct. 9:57AM And the waiver applies to attorney-client privileged 16 0. 9:57AM 17 documents or what were privileged documents between 9:57AM 18 November 25th, 2008, up through October 29, 2012. That's what 9:57AM 19 you read; correct? 9:57AM 20 That's what I read. 9:57AM 21 So up to this time the United States didn't have those 9:57AM 22 documents; correct? 9:57AM 23 I don't think so --Α. 9:57AM 24 MR. GRIFFITH: Objection, Your Honor. She can't 9:57AM 25 testify --9:57AM

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THE COURT: To her knowledge. To her knowledge is the proper question.

Sustained as stated.

BY MR. SHAHEEN:

- **Q.** Did you know -- or do you have any knowledge as to whether or not HDL had produced any attorney-client privileged -- privileged documents other than the LeClairRyan documents prior to April 28, 2014?
- A. I don't know. I remember there was several meetings where the Ropes & Gray folks -- there was the PowerPoint presentations we saw yesterday. There were several meetings prior to that date where there was information provided to the government that was from our attorneys that they declared attorney-client privileged. But I don't know the details of everything that was provided.
- **Q.** And this waiver goes through October 29th, 2012; correct? That's what you read?
- A. Yes.

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9:58AM

- Q. So that wouldn't cover any communications that Mr. Kung had with you where he repeatedly advised you that P&H was a red flag practice that needed to be terminated, correct, after that date?
- A. He didn't -- actually, you're characterizing that memo wrong.

THE COURT: Why don't you restate it. Just ask if

she got communications from Mr. Kung and did not disclose those 1 9:58AM 2 regarding P&H fees -- communications regarding P&H fees. 9:58AM BY MR. SHAHEEN: 3 9:58AM 4 Q. we talked yesterday about communications you had with 9:58AM 5 Mr. Kung about P&H; correct? 9:58AM 6 Α. Correct. 9:58AM 7 And I showed you communications dated after October 29th, Q. 9:58AM 8 2012, where he warned about the practice of paying P&H; 9:58AM 9 correct? 9:59AM 10 Α. Correct. 9:59AM 11 And according to this, it would appear the government did Ο. 9:59AM not have those in its possession because that was dated after 12 9:59AM 13 October 29th, 2012; correct? 9:59AM 14 I can't answer what you had. That was dealt with with the 9:59AM 15 attorneys and Ropes & Gray. I was keeping the business 9:59AM 16 running. 9:59AM 17 Do you know whether or not the Department of Justice would Ο. 9:59AM have had any knowledge about Mr. Kung's communications advising 18 9:59AM that HDL could not rely on the LeClairRyan opinion? 19 9:59AM 20 There was a -- an email, I think you said yesterday, or --9:59AM 21 that there was some concern about that. 9:59AM 22 And that was dated after October 29th, 2012; correct? 0. 9:59AM 23 I don't remember the date of it. 9:59AM 24 0. To the extent Mr. Kung had communications with you and HDL 9:59AM 25 about the flaws with the Exponent study that occurred after 9:59AM

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October 29th, 2012, the United States would not have known about that; correct?

- A. We had no -- I think again you're mischaracterizing the Exponent study. There was some concern about it, but, to this day, I don't know what the concern was. And so what was communicated to the government, again, that's -- you guys settled with HDL, not me. I don't know what you guys talked about.
- **Q.** Again, Ms. Mallory, you were the CEO of HDL at the time that this waiver agreement was signed; correct?
- A. I had no knowledge of the communications in that --

MR. GRIFFITH: Your Honor, I'm going to object. He's repeating the same --

THE COURT: Overruled.

THE WITNESS: I have no knowledge of any of the detailed communications between the attorneys and the DOJ.

BY MR. SHAHEEN:

Q. To the extent that Ropes & Gray advised HDL and you that paying P&H should be terminated -- that HDL's practice of paying P&H should be terminated, and those communications occurred after October 29th, 2012, the United States would not have had those communications either; correct?

THE COURT: To her knowledge.

BY MR. SHAHEEN:

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Q. To your knowledge.

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8	М	Α	1	0	:	0	L
9	М	Α	1	0	:	0	L
10	М	Α	2	0	:	0	L
11	М	Α	2	0	:	0	L
12	М	Α	2	0	:	0	L
13	М	Α	2	0	:	0	L
14	М	Α	2	0	:	0	L
15	М	Α	2	0	:	0	L
16	М	Α	2	0	:	0	L
17	М	Α	2	0	:	0	L
18	М	Α	2	0	:	0	L
19	М	Α	2	0	:	0	L
20	М	Α	2	0	:	0	1
21	М	Α	2	0	:	0	1

- A. To my knowledge, I've never known of any communications that they said "terminate it."
- Q. And so Mr. Ashmore and Mr. Griffith talked about when Ropes & Gray came and gave presentations to the Department of Justice. But, at that time, no one had told the Department of Justice that those same Ropes & Gray attorneys had advised HDL and you that you couldn't pay P&H; correct?
- A. They never advised us that we couldn't. They said you guys would have a problem with it. So then I said, "Let's go find out if they have a problem with it." And until January, March, April of 2014, you clearly didn't have a problem with it.
- Q. HDL held back unflattering attorney-client communications; correct?
- A. Again, I cannot speak to what was communicated between Ropes & Gray and the DOJ. That was handled by our legal department, and I had almost no communication in any of the details.

MR. SHAHEEN: Your Honor, may I approach?

THE COURT: You may.

BY MR. SHAHEEN:

- Q. Ms. Mallory, is this an email from Doug Sbertoli?
- A. Yes.

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Q. And you testified that Doug Sbertoli was HDL's general counsel?

10:02AM	2	Q. And if you turn to right there, what does Mr. Sbertoli
10:02AM	3	say?
10:02AM	4	A. This is an email from Doug Sbertoli to somebody at Hunton
10:03AM	5	and the attorneys. I'm not copied on it.
10:03AM	6	Q. And what does it say there?
10:03AM	7	A. He said, "We held back and retained the privilege on some
10:03AM	8	that were unflattering."
L 0 : 0 3 A M	9	Q. Thank you.
0:03AM	10	MR. SHAHEEN: Your Honor, I have no further
L 0 : 0 3 A M	11	questions.
0:03AM	12	THE COURT: Very good.
0:03AM	13	Ms. Mallory, you may step down.
0:03AM	14	(Witness excused).
0:03AM	15	THE COURT: Government, call your next witness.
0:03AM	16	MR. LEVENTIS: Thank you, Your Honor. The governmen
0:03AM	17	calls Nicholas Pace.
0:03AM	18	THE DEPUTY CLERK: Please place your left hand on the
L 0 : 0 3 A M	19	Bible, raise your right. State your full name for the record,
L 0 : 0 3 A M	20	please.
L 0 : 0 3 A M	21	THE WITNESS: Nicholas Joseph Pace.
0:04AM	22	THE DEPUTY CLERK: Thank you.
0:04AM	23	(Witness sworn.)
0:04AM	24	THE DEPUTY CLERK: You may be seated.
0:04AM	25	MR. LEVENTIS: Your Honor, I am going to give him a

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Yes. turn to right there, what does Mr. Sbertoli email from Doug Sbertoli to somebody at Hunton neys. I'm not copied on it. es it say there? e held back and retained the privilege on some tering." Your Honor, I have no further IAHEEN: **DURT:** Very good. Is. Mallory, you may step down. ess excused). Government, call your next witness. URT: EVENTIS: Thank you, Your Honor. The government ace. EPUTY CLERK: Please place your left hand on the r right. State your full name for the record, TNESS: Nicholas Joseph Pace. PUTY CLERK: Thank you. (Witness sworn.)

10:04AM	1	copy of some of these. So
10:04AM	2	THE COURT: Absolutely. Go right ahead.
10:04AM	3	Mr. Shaheen, before you walk out, did you intend
10:04AM	4	the Sbertoli memo to be in evidence, and is it in evidence?
10:04AM	5	MR. SHAHEEN: If it is not already in evidence, I'd
10:04AM	6	be happy to move it in, Your Honor. It's Plaintiffs' Exhibit
10:04AM	7	Number 1277.
10:04AM	8	THE COURT: Okay. And is there an objection to that?
10:04AM	9	MR. GRIFFITH: Do you have a copy?
10:04AM	10	MR. SHAHEEN: Yeah.
10:05AM	11	MR. GRIFFITH: Just our standing objection, Your
10:05AM	12	Honor.
10:05AM	13	THE COURT: Yes, sir.
10:05AM	14	MR. ASHMORE: No objection, Your Honor.
10:05AM	15	THE COURT: Very good.
10:05AM	16	Government's 1277 1277 admitted over the
10:05AM	17	objection of BlueWave.
10:05AM	18	MR. SHAHEEN: Thank you, Your Honor.
10:05AM	19	THE COURT: Very good.
10:05AM	20	Mr. Leventis, please proceed.
10:05AM	21	MR. LEVENTIS: Thank you, Your Honor.
10:05AM	22	NICHOLAS PACE,
10:05AM	23	a witness called on behalf of the plaintiff, being first duly
10:05AM	24	sworn, was examined and testified as follows:
10:05AM	25	DIRECT EXAMINATION
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BY MR. LEVENTIS:

- Q. Mr. Pace, if you would -- I'm sorry -- state your full name for the court reporter, please.
- A. Sure. Nicholas Joseph Pace.
- **Q.** And, Mr. Pace, first let's talk a little bit about your background.

Do you have any advanced degrees?

- A. I do. I have a law degree and a master's in business administration, an MBA.
- **Q.** Okay. You have -- I'm sorry. You're an attorney and what was the other one?
- A. An MBA, master's in business administration.
- Q. Let's talk a little bit about your work experience ultimately, but were you working at HDL at one point?
- A. I was. I worked there from March 2013 until September 2013.
- **Q.** Okay. If you could tell the jury a little bit about your work experience prior to joining HDL.
- A. Sure. Maybe I'll just start with law school and up through my time at HDL.

So after graduating law school, I went to work for Ernst & Young, which is a Big 4 accounting firm, as a tax consultant, where I advised large companies on structuring transactions in accordance with tax law.

Following that, I joined a Richmond-based law firm

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called LeClairRyan, where I practiced corporate law, mergers and acquisitions, and tax law.

Following LeClairRyan, which I was there for about two years, I went to a firm called Morrison and Foerster, which is a global law firm of about a thousand attorneys. I joined their Palo Alto Silicon Valley office in California, where I practiced corporate law, mergers and acquisitions, securities law --

- Q. Mr. Pace, can you pull the microphone a little closer?
- **A.** -- and advised boards of directors on corporate governance matters.

Following Morrison and Foerster, I returned to Richmond, Virginia, where I worked for a publicly traded company called CarMax, which is a used car auto retailer. And there, I was an assistant general counsel. I practiced in the areas of mergers and acquisitions, corporate governance, advising the board of directors and audit committee on -- on corporate matters. I also advised certain departments on setting up compliance programs. So the marketing department, financial department, tax department, I helped them form compliance programs.

And then in -- so that brings me up to about 2006, to the job I had previously right before HDL. That was with a company called Amerigroup corporation. They were a publicly traded health care company that essentially was a health

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insurer for people on Medicaid and Medicare. I was there approximately seven years until they sold the company to Anthem, which is the country's largest insurer.

My last position with the company was executive vice president, general counsel, and secretary. In that role, I oversaw five corporate departments, which were legal, regulatory, internal audit, risk management, and corporate investigations.

And so that brings me up to then I joined HDL in March of 2013.

- Okay. And let's go ahead and talk about that. 0. you hired by HDL? How were you first approached?
- Sure. So I had left the Amerigroup corporation after our sale and was in the process of determining what I wanted to do next. And so I was on a series of interviews with different companies in Richmond. My preference was to stay in Richmond, have a senior executive-type role at a health care company.
- Can I stop you there? Q.

You wanted to stay in Richmond. Are you from Richmond?

- I'm not originally, but I went to law school there in '93. And other than a two-and-a-half- to three-year stint in California, I spent my time in Richmond.
- Q. Okay.
- And so, as part of that process, I had a mutual contact

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with Tonya Mallory, a gentleman named Craig Forbes, who said, you know, "HDL is a growing company. They may need somebody with your background. Why don't I do an introductory meeting with Tonya?" So it wasn't a job interview per se; it was just a meet-and-greet.

That meeting was scheduled. And prior to that meeting, I happened to bump into Dennis Ryan in Richmond. Ι had worked with Dennis many years before at LeClairRyan. He was at HDL in an executive role. I mentioned to him I was looking for something to do next. He talked to me a little bit about HDL. And then, when I went to the meeting that was set up to meet with Tonya, Dennis was there. And, from there, employment discussions ensued.

- okay. And you said you had worked at LeClairRyan before you went to HDL; is that right?
- It wasn't the immediate position before HDL, but I I did. had worked at LeClairRyan in, I believe, 1998 to about 2000.
- Did you work in the -- does LeClairRyan have a health care Q. practice?
- when I was there, not really. They had -- it was more of a corporate law firm, corporate transactions. They had some medical malpractice defense but not a health care regulatory I'm not sure if they do today. They're not a firm that you think of as a health care regulatory firm. them more as a business firm and some commercial litigation.

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You said you knew Dennis Ryan. Q.

Did you know him from your time at LeClairRyan?

- So Dennis was a named partner at LeClairRyan. He's Ryan on that title. I was an associate in the corporate He was a partner in the corporate group. I worked with group. him on a transaction or two during that time.
- And so, to your knowledge, did Mr. Ryan have any health care law background?
- Not to my knowledge, no. He was more of a business attorney representing small businesses.
- Maybe just for nonlawyers, what is a -- when you 0. Okay. say he was just a business attorney, what does that mean?
- So he represented small privately owned companies and their founders on corporate transactions like commercial If they were to sell their business, Dennis would contracts. have represented them in that sales process.

He was not an attorney who would have done regulatory advice or reviews. He would have been more around the sale of a company or financing a company. So if a company wanted to raise money, Dennis would do the debt or stock offerings for that.

- So would he have been someone you would have gone to for health care advice?
- Α. He would not have been, no.
- And I believe you said you interviewed with Mr. Ryan Q.

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before you started HDL?

A. I did. So what occurred was, when I went to the meeting, I referenced -- before both Dennis and Tonya were there, we talked about my background, what HDL was doing. And when I went through my background with respect to building compliance programs at health care companies, Ms. Mallory made a statement that we need compliance everywhere. And then eventually, in the course of that meeting, said, "Would you want to come be our chief compliance officer?"

I declined. I did not want to be a chief compliance officer. That wasn't my career aspirations at the time. There was other things I wanted to do.

So I left the meeting, got a call, I believe, that evening from Dennis Ryan asking if I would meet with him again the next morning for breakfast.

He and I did meet. We discussed a more broad role that would have some operational authority, operational purview where I'd be over some of the departments, help them build a compliance program and do some other things.

Following that meeting, I had interviews at the HDL offices again with Tonya, with two of the other founders, Joe McConnell and Russ Warnick, and a couple of the other executives. And after that, I accepted an offer.

Q. Mr. Pace, I know you're probably nervous up there testifying. You can maybe slow down just a little bit. The

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court reporter is trying to take down what you're saying.

- A. Sorry. I apologize.
- Q. That's all right.

THE COURT: She's good, but she may not --

MR. LEVENTIS: And if you could, I think also -- I don't know if that microphone is on. Would that help?

THE WITNESS: Can you hear that better?

THE COURT: That's fine.

BY MR. LEVENTIS:

Q. All right. So you were talking about your conversations when you first started at HDL, and you mentioned about Ms. Mallory saying they need compliance everywhere.

What did you take that to mean?

- A. I took that to mean that they were a relatively new company that had grown rapidly and probably didn't have the controls and compliance programs in place that a company of that size should. I don't think they had a chief compliance officer at that time, and so I took it to mean that they were looking for somebody to come in and help with those programs.
- Q. And what time period -- what time period are we talking about?
- A. So this would have been either very late 2012 or probably more likely January or February of 2013.
- Q. And so at that point, how long had HDL been in existence?
- A. My recollection is four or five years at that point but

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had grown more rapidly in the one or two years preceding that interview time.

- **Q.** All right. And so did you accept ultimately a position at HDL?
- A. I did.
- **Q.** And I guess one of the things you had talked about is compliance.

A. Sure. So most companies, and especially companies in the health care space, have programs and functions within the company that are designed to ensure they comply with applicable laws to them. That, in a nutshell, is a compliance program.

Can you tell us what you mean by "compliance"?

I had assisted previously at CarMax certain departments, building compliance programs; and then at Amerigroup Corporation, which was in health care, received a hundred percent of their revenue from either the federal government through Medicare or state government through Medicaid. Helped them build and administer a robust compliance program during my six or seven years there.

- **Q.** Okay. So do you have experience in the Anti-Kickback Statute?
- A. I do. I am not a technical health care regulatory attorney that would analyze provision by provision within that statute, but I have been involved with companies and have helped companies build compliance programs, compliance

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policies, training materials, et cetera, help to ensure the company is in compliance with anti-kickback and other federal regulations.

- **Q.** When you started at HDL, what were some of your duties and responsibilities?
- A. Sure. So my title was executive vice president, operations, regulatory and compliance. It's a mouthful, but -- so I was asked to do certain operational projects. I was asked to help build a compliance program. I was asked, as part of that program, to help implement the recommendations that were given to the company by The Saranac Group. That was an outside consulting firm that had been engaged by the company to review the compliance program at HDL and make recommendations for changes.

My duties morphed over time, but I also eventually had Derek Kung, the general counsel, reporting to me, a gentleman named Mark Herzog reporting to me. He ran government affairs. So if we were trying to build relationships with elected officials, that reported up to me.

And I also had some responsibilities trying to help the company contract with health insurers and managed care companies to get in network.

- Q. So would any of the attorneys at HDL have reported to you?
- A. Derek Kung did, yes.
- Q. Were there any other attorneys at HDL?

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A. There was another attorney named Doug Sbertoli. After Dennis Ryan's resignation, I believe that Doug started reporting to me at that time.

Q. Okay. And do you have any personal knowledge of why Dennis Ryan -- you said he resigned?

A. Yes. Dennis had expressed to me frustration with the position. What he had told me was --

MR. GRIFFITH: Objection, Your Honor. That's hearsay.

THE COURT: Tell me, what's the exception?

MR. LEVENTIS: I just asked him what his personal knowledge was, Your Honor.

THE COURT: Sustained.

MR. LEVENTIS: Okay.

BY MR. LEVENTIS:

Q. Yeah. So when I ask you questions, if you can keep it to what your personal knowledge is, Mr. Pace.

A. Sure.

Q. All right. Thank you. So I had asked you whether there were other attorneys that reported to you. Then you were telling me about any attorneys that were at HDL. I believe you said that Mr. Kung reported to you.

He's an attorney?

A. Yes.

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Q. And what was Mr. Kung's title?

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- A. He was a general counsel of the company.
- Q. And then Mr. Ryan is an attorney. He ultimately resigned.
 But he did not report to you?
- A. That's correct. Dennis was an executive vice president at the company. But he was not, to my knowledge, in a legal role although he was an attorney. He did not report to me.
- Q. Any other attorneys at HDL?
- A. Doug Sbertoli was an attorney who had been at LeClairRyan who joined HDL on or about the same day I joined.
- **Q.** Did you have any personal knowledge of Mr. Sbertoli as far as whether he has any health care law background?
- A. I do. I had worked with Mr. Sbertoli during my time at LeClairRyan and then again at HDL. At LeClairRyan, he was essentially a public finance or bond attorney, so he would do municipal bond offerings. He was not a health care attorney and, to my knowledge, does not have a health care training or background.
- Q. And so, as part of your duties at HDL, did you ever come across a memo that Derek Kung wrote to the board of directors?
- A. Yes, I did see that memo.
- Q. Okay. Do you remember that memo?
- A. I do.
- Q. Were there any things that Mr. Kung brought up in that memo that concerned you? Do you remember?
- A. Yes, there was. So basically the memo detailed certain

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practices of the company, including payment of processing and handling fees to physicians, waiver of copays and deductibles, and other practices that -- the memo discussed the risks that those posed, that they may be violations of federal law.

- Q. And did Mr. Kung write that memo at your request?
- A. No. That memo was written four or five months before I joined the company.
- Q. So you saw it after it had been written?
- A. Correct.
- Q. And did you talk to anyone about your concerns after you read Mr. Kung's memo.
- A. So I often spoke with Dennis, Derek, Ms. Mallory, the other founders about concerns I had with the practices set forth in the memo. I'm not sure I specifically discussed the memo but often discussed those practices and my concerns with those.
- Q. And can you tell me what those practices were again?
- A. Sure. So payment of processing and handling fees to physicians, waiver of copays and deductibles for patient responsibility, other programs that paid money to physicians that were referring HDL tests.

So there was a medical advisory board. There were provision of continuing medical education seminars. There were three health coaches that were provided to physician practices and patients, things of that nature that are detailed in the

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- **Q.** And were you aware of any of those practices before you started at HDL?
- A. In my interview process, Dennis had -- Dennis Ryan had told me that the company was waiving copays and deductibles and evaluating that as well as paying processing and handling fees. So I was aware they were doing it.
- Q. If you could -- let's see. I'll put up -- if the ELMO is working now, I'll put up Exhibit 1244 that's already in evidence.

And, Mr. Pace, I gave you a copy up there just in case the screen doesn't work. It's Exhibit 1244. Okay. Looks like it's up. I have a little out-of-range screen in front of mine. I hope --

THE DEPUTY CLERK: That will go off in a minute.

MR. LEVENTIS: Yeah, it's already in evidence, Your Honor.

THE COURT: Yes.

BY MR. LEVENTIS:

- **Q.** Mr. Pace, I guess if you want to look at the copy you've got there, do you recognize this document?
- A. Yes, I do. This is the Derek Kung memo you just referenced.
- **Q.** And if you would turn to page 2. Let's -- if you could zero in on the processing and handling agreement section.

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So what do you recall from Mr. Kung's memo and your concerns about the processing and handling agreements?

- A. That essentially the processing and handling agreements did not fall within a safe harbor or permitted exception within the Anti-Kickback Statute and, therefore, posed a substantial risk that it was potentially a violation of that law.
- **Q.** And if you look at the last paragraph there, it says, "The process and handling fee practice is a red flag for the OIG and poses a high level of risk under the AKS."

Is the AKS the Anti-Kickback Statute?

- A. Yes, it is.
- Q. And did you talk to Mr. Kung about this part of his memo?
- A. So I spoke to Derek often about the use of process and handling and our concerns with it. I know I spoke with him after reading the memo. But through the course of my employment, this topic came up nearly on a daily basis.
- Q. And in your experience, when he was saying the processing and handling fee is a red flag, what did that mean to you?
- A. That essentially the government, the OIG, had this on their list of items that were problematic practices that they didn't want to occur and that they would be investigating or looking into those.
- Q. Did you have any conversations that you had with Ms. Mallory about the processing and handling agreement?
- A. I had a lot of discussions with Ms. Mallory regarding

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processing and handling and its use. I'm not sure if we specifically discussed the agreement itself. But I often told her that I thought the company should cease that practice, that it caused excessive risk under the statute. And we, again, talked about this -- this issue ad nauseam during my employment there.

- **Q.** And when you talked to Ms. Mallory ad nauseam, in your words, were they always to stop paying processing and handling fees?
- A. Not always. I mean, we often talked about the analysis that was being done by the outside law firm Ropes & Gray and how BlueWave may be using that as part of their sales process to drive further sales. And sometimes it was about we need to stop this practice.

In fact, the advice from Ropes & Gray was the company needs to move away from the use of that practice, and we put a project team together to -- that I led to help try to do that.

- **Q.** Okay. And I want to get to that project, but you mentioned something about how BlueWave was using the processing and handling fees?
- A. Yeah. So it was our person that BlueWave was using the \$20-per-draw fee as a selling tactic; meaning to induce the physician to draw the blood, they were offering a \$20 processing and handling fee. There were pro formas done by BlueWave that basically would show a physician, if you have 100

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patients, you can refer HDL testing times \$20 per referral, here's how much additional revenue you will make.

And they also had kind of a target -- documents I saw had a target physician that they were looking for, one that would be interested in driving up their revenue.

- Okay. You said you saw a document?
- It was -- I don't know what the document was I did. titled, but essentially it listed out the kind of ideal criteria for the physicians that HDL and BlueWave wanted to sell to.

MR. LEVENTIS: Okay. If you could put up Exhibit 1296, please.

BY MR. LEVENTIS:

There's also a copy in the binder, Mr. Pace. Q. Do you recognize this document?

- I do. Α.
- Have you seen this before? Q.
- Yes, I have. Α.
- okay. Can you tell us what -- did you have any concerns when you saw this document?
- Yes, I did. Α.
- And what were those concerns? 0.
- well, the one that jumps off the page is Number 6, that the physician is money hungry, therefore, may be, you know, swayed by a \$20 draw fee to refer the test and not necessarily

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referring HDL testing based on the medical necessity of them but rather looking for additional revenue.

- **Q.** And were there any other examples that you became aware of of this money-hungry criteria idea?
- A. Like I said, I think I recall hearing and seeing documents that certain BlueWave representatives were using a pro forma that would show the amount of additional revenue that a physician could attain by referring HDL testing.
- Q. Are there any other examples that you're aware of of what HDL had learned of what BlueWave was doing in the field?
- A. Sure. So, I mean, these were known practices, payment of processing and handling and waiver of co-pays and deductibles.

Also, within my role at the company, because I had compliance in the title, compliance issues that may be raised either by an internal employee or by an outside person would come to me. Some of those centered around alleged activities by BlueWave representatives in the field.

- Q. Okay. Can you give us an example of one of those.
- A. Sure. So I was contacted by a compliance person at a hospital system in Florida regarding an email they had received from a person named Larry Cushing.

MR. COOKE: Your Honor, could we approach for just a second?

THE COURT: Absolutely.

(Whereupon the following proceedings were held at the

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bench out of the hearing of the jury:)

MR. COOKE: We made a procedural error. This is my witness, and Joe objected earlier. So I just wanted to see if everybody could agree that I could --

THE COURT: Absolutely.

MR. COOKE: -- that I can take over the witness.

THE COURT: Anything else?

MR. COOKE: That's all.

THE COURT: Okay. Good.

MR. COOKE: I just didn't want to start objecting.

THE COURT: No problem.

(Whereupon the following proceedings were held in

open court in the presence and hearing of the jury:)

THE COURT: Please continue.

BY MR. LEVENTIS:

- Q. Mr. Pace, I believe you were discussing an instance with a Larry Cushing.
- A. Yes, I was.

Now everybody can hear me. So --

- Q. Now you can sit back.
- A. Now I can sit back a little bit.

So as I was saying, I received a call from the compliance department at a Florida hospital system regarding an email they had received from a gentleman named Larry Cushing purporting to sell HDL testing and their concern with what he

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had put in his email regarding payment of processing and handling fees; waiver of co-pays and deductibles; comping tests, meaning giving free tests to up to 10 percent of the patient population; providing CMEs at the Ritz-Carlton and other things in that email they were concerned that that was being offered.

- **Q.** And what did you do after you got this communication?
- A. After I got this communication, I contacted that hospital, told them we would look into the matter and report back to them. We then reached out to people inside of HDL to see if they knew who Larry Cushing was and whether or not he was a BlueWave representative, ultimately determined he was not one of the representatives that appeared on the BlueWave roster that we would see.

We contacted Mr. Cushing to ask him about the offers he had made -- and he did, in fact, make those offers -- and come to learn that he was, I believe, the husband of the receptionist for BlueWave -- BlueWave sales rep Kyle Martel and had been asked by Mr. Martel to sell those tests and was being paid something for those tests -- or for -- excuse me -- for selling those tests.

- **Q.** And what did you do after you learned about that?
- A. So I raised that with Ms. Mallory who -- I believe she contacted Bluewave about it. Bluewave -- and this is based on what she told me in the email she had sent me. She was told by

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Bluewave that they didn't know who that was, he wasn't authorized to sell. And so we moved to send him a cease and desist letter that he would stop representing HDL. And I think that was the end of it at that point.

- Q. Okay. Do you have any knowledge of what happened to this Mr. Cushing or Mr. Martel?
- A. I don't, other than we sent Mr. Cushing a cease and desist letter. I believe he tried to contact Derek Kung a couple of times. I'm not sure Derek ever engaged with him. I don't think anything happened with Kyle Martel. He continued to be a BlueWave sales rep and sell HDL tests.
- **Q.** Do you recall any other examples of what BlueWave was doing in the field?
- A. Sure. So a couple that come to mind, our claims payment department was getting a lot of requisition forms in that had free tests or comped tests on those. And we'd come to learn that BlueWave was often giving free testing to -- to physicians and physician families and to a certain percentage of patients, which raised concern. There are federal laws and advice from the OIG on doing that and how that can be done properly.

There was an instance, I believe, in the Wisconsin market -- well, the chief medical officer at the company, Tara Dall, came to me and said I was discussing the panel size, meaning the tests that could be ordered on the requisition form, with a Bluewave sales representative. I believe her name

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was Erica, and she was in Wisconsin.

From -- what Dr. Dall told me was that Erica had said Brad and Cal tell us to tell the physicians they have to order every test on that panel, they just can't select, which, in fact, would not be the case and would be problematic if it was because what that would do is order unnecessary tests and drive up the costs.

I called the sales rep about that, also reported it to Tonya and the other members of the board, which were Joe and Russ. Called the sales rep, and she denied ever saying that to Dr. Dall. So I think we closed the investigation on that, but it -- you know, it gave me concern.

Another instance, we were getting some -- from a -there's a sales rep in the field named Chad Sloat who we got some strange requisition forms in with respect to what the insurance coverage was from Aetna. I believe it was for a physician's family. And it was essentially trying to get around submitting that claim to insurance because they thought it would be denied.

And so I confronted him about it, had a fairly -- he was fairly rude to me on the phone, but we were confronting him on it. That also raised concern. So those are specifics.

we would often hear general noise from people at the company that they believed BlueWave was using processing and handling and other compensation to physicians to sell. And

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those things raised concern.

- Did those sorts of concerns come up in meetings that you Q. were in with Ms. Mallory?
- Α. They did. I expressed my concern numerous times to her about what the sales tactics were in the field, that I was hearing that the company had very limited visibility into what those tactics were or who was selling and how, and that we needed to change that.
- And did you have any other conversations with Ms. Mallory about Chad -- the Bluewave sales rep Chad Sloat that you mentioned?
- Yes, I did. So as part of the compliance program, we were rolling out a check against excluded persons list. And I can explain what that is.
- Yeah, if you would explain what that is. Q.
- So when you participate in federal health care programs like Medicare and Medicaid, you're required to -- and the government would have expected from HDL to screen payments to physicians and others against an excluded person's list.

Excluded person's list is essentially a list of people who have been suspended or debarred from the federal health care program because they violated, you know, federal health care law or otherwise reached a settlement with the government that they can no longer receive funds from Medicare and Medicaid.

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So we were in the process of putting in that process whereby HDL would screen payments to BlueWave reps to make sure they weren't on that list and screen payments to physicians for processing and handling to make sure they weren't on that list.

- **Q.** And so was such a thing not in place before you got there?
- A. I don't believe it was in place, no. So --
- Q. Okay. Sorry. Go ahead.
- A. And so, in any event, I was making inquiries of, I think it was, Derek and Tonya about it in my office. Derek left the meeting, and Tonya looked at me and said, "Well, what could they find on that list?"

She had kind of an inquisitive look on her face, and it struck me as an odd question.

I said, "Generally, if you've been debarred or suspended from the programs, you're going to appear on the list." And I said, "Well, why are you asking that?" Because it occurred to me and appeared to me that there was a specific question behind it.

And she brought up Chad Sloat, the gentleman you just asked about, and told me that Chad Sloat had been indicted on a federal Ponzi scheme, security scheme, and was awaiting trial. And, you know, I was a little shocked by that that he knew -- or that she knew there was a BlueWave sales representative who had been indicted and she continued to allow them to sell and rep the company's products.

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- **Q.** Any other examples that you can think of of BlueWave sales representatives?
- A. Nothing specific comes to mind other than the general practices I just referred to.
- **Q.** Okay. If you could take a look at this -- I'll be laying a foundation for it, so let's not show it to the jury just yet.

But if you could look at Exhibit 1524 that's in front of you, Mr. Pace.

- A. Okay.
- **Q.** Is this an email exchange that you had with Ms. Mallory in 2013?
- A. Yes, it is. And it relates to Larry Cushing, the gentleman I just referred to.

MR. LEVENTIS: Your Honor, we'd like to admit Plaintiffs' Exhibit 1524.

THE COURT: Any objection?

MR. COOKE: Just our usual objection.

MR. ASHMORE: No, sir.

THE COURT: Plaintiffs' 1524 admitted over BlueWave objection.

Mr. Leventis, before you get into it, it's about time for our morning break. If this is going to take a little while, this might be a good time to break before we break into the document.

MR. LEVENTIS: Absolutely.

1 **THE COURT:** Let's take our morning break, if we 10:36AM could, please. 2 10:36AM (Whereupon the jury was excused from the courtroom.) 3 10:36AM 4 THE COURT: Very good. Any matters to address before 10:37AM we break? 5 10:37AM 6 From the government? 10:37AM MR. LEVENTIS: No, Your Honor. 7 10:37AM From the defense? 8 THE COURT: 10:37AM 9 No, Your Honor. 10:37AM MR. COOKE: Very good. Take about a 10-minute break. 10 THE COURT: 10:37AM 11 10:37AM (Recess.) 12 Please be seated. Any matters to raise THE COURT: 10:54AM 13 with the Court before we bring in the jury? 10:54AM 14 MR. LEVENTIS: No, Your Honor. 10:54AM 15 MR. COOKE: Nothing, thanks. 10:54AM 16 Very good. Bring in the jury. THE COURT: 10:54AM 17 (whereupon the jury entered the courtroom.) 10:55AM Please be seated. 18 THE COURT: 10:56AM 19 Mr. Leventis, continue your direct examination. 10:56AM 20 MR. LEVENTIS: Thank you, Your Honor. 10:56AM 21 BY MR. LEVENTIS: 10:56AM 22 Mr. Pace, when we went on break, we were just about to 10:56AM 23 talk about Exhibit 1524, which deals with the scenario you 10:56AM 24 described about Larry Cushing. I guess, let me start, you had 10:56AM 25 mentioned that you were, I believe it was, executive vice 10:56AM

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president that included compliance. And is that what capacity you were in when you were receiving these complaints?

- A. Yes.
- Q. If we could look at 1524, this appears to be an email from you to Tonya Mallory and Derek Kung on April 19th of 2013. If you could read -- I'll read it out for you. It says on this first section, "Tonya, I think we need to treat this matter as being put on notice of potential compliance issues, thus requiring appropriate response."

And then, if you scroll down, you conclude with, "This is pretty serious and needs to be handled accordingly."

As you flip through this email -- it's several pages of an exchange -- and then, at the very end, if you turn -- Peter, if you wouldn't mind, I guess, going to the end, where Mr. --

You actually got a copy of Larry Cushing's email. Do you recall that?

- A. I do recall that, yes.
- Q. And as you look through there, is there anything else you wanted to add to your recollection, having seen the email now?
- A. No, nothing else. I mean, I did receive a copy of the email. I had asked the compliance person who had contacted me to send it to me so that we could properly evaluate it.

And then I believe the emails lay out what our recommendation was. When I say "our," I would have conferred

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with Derek Kung on this, what our recommendations were, how to handle this.

Q. Okay. Next I'd like to direct your attention to an exhibit that --

MR. LEVENTIS: Your Honor, I'll lay the foundation for it first.

BY MR. LEVENTIS:

- **Q.** This is Plaintiffs' Exhibit 1515. You had testified that you also had a compliance role for a while there at HDL; correct?
- A. That's correct.
- **Q.** And as part of your duties, were you looking into compliance concerns with BlueWave?
- A. Yes, I was. Basically, my position was that they were acting as our contracted sales force. They were the ones representing HDL out in the field with the physicians. And, therefore, they had to have a robust compliance program; they needed to be under the HDL compliance program. And any compliance-related issues that we heard about, we were compelled to investigate those.
- **Q.** And I believe you said you had experience in putting compliance programs together; is that right?
- A. Yes, I did. The most relevant experience -- and I think the one that got Dennis Ryan interested in hiring me, and Tonya as well -- was my days at Amerigroup that I referenced before.

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So I joined Amerigroup in 2006. They had had activities in 2000 and 2001 that eventually gave rise to a settlement with the federal government, Department of Justice, related to health care law violation. Part of that was they entered into a corporate integrity agreement, where they had to set up a robust compliance program, do routine reporting to the federal government on it, and interact with the federal government.

I was -- so all of the activity occurred before I joined the company, but when it went into place -- when it went into place, I was at Amerigroup, and I helped put that compliance program in place. I helped make sure we hired appropriate professionals to be compliance officers across the country and within our corporate organization. I also interacted routinely with the OIG, the federal government, on our compliance with that program as the CIO.

- Q. Now, were -- the BlueWave sales reps, were they employees of HDL?
- A. They were not. BlueWave was a contracted third party per a sales agreement with them.
- **Q.** And so why were you concerned about BlueWave having compliance?
- A. Well -- so BlueWave was selling the HDL testing. BlueWave was a contracted vendor of HDL, and it would be the expectation in the health care industry that you would have control and a

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view as to what those salespeople were doing because they were representing your product. You're compelled by law to do that. The federal government would have expected HDL to do that.

And we wanted to ensure that they had a compliant program, they weren't doing practices that were going to put our company at risk for potential violations of law.

- And did Ms. Mallory know about this BlueWave compliance idea you had?
- I had expressed that to her both verbally and in emails.
- All right. So tell us about what you tried to implement Ο. as far as compliance for BlueWave.
- So it was really twofold. It was, one, at HDL, we were trying to put a robust compliance program in place. Saranac Group led by Tom O'Neil, as I mentioned before, did an evaluation of the HDL compliance program and a very detailed recommendation as to changes that needed to be made. That was presented to the board and --
- So this is a -- first, you're starting with HDL's internal compliance?
- Yeah, I am. I think it lays the groundwork for the BlueWave piece of that.

So there was a necessity to put a more robust program in place for the company --

Why was -- sorry to interrupt you, but why was it

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important here -- where are we? -- in 2013, you're saying HDL needs a compliance program?

- A. Yes. Again, in the health care industry, there is an expectation for companies to have an effective compliance program, a program that ensures that you're complying with the law, a program that, if there are violations, you ferret those out, investigate those, and take proper action.
- **Q.** And before you got there, was it your opinion that there was not a compliance program in place?
- A. Yeah, that's my opinion. I think Derek's memo in August -- I believe it was August 2012 -- highlighted some of those practices and issues, that there was not an effective compliance program around those. The company had engaged The Saranac Group to come in and do an evaluation and recommend changes. So, in my view, there was not an effective compliance program in place when I joined.
- Q. Okay.

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A. So, I guess, to continue on, when you build out that program internally, you need to make sure your employees and your contractors are acting in accordance with their compliance program.

The -- the BlueWave sales force and the BlueWave owners were the contracted sales force of the organization in every state except the state of Virginia. Sales activities, sales practices often pose a lot of risks under health care

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federal law. In my experience working with health care companies, contracts with a third party who is selling for you would have had compliance requirements in them, would have allowed you to look into the compliance program by that entity and ensure that it met the standard that you expected.

And so, as we developed the HDL program, the thought was we will roll that program out to cover our contracted sales force, and we will want to see what type of compliance program they have in effect at Bluewave.

- **Q.** Okay. And did you see what sort of compliance program Bluewave had?
- A. So we made a request of Bluewave to provide us with some materials on their compliance program that would allow us to make a proper evaluation. We never got a fulsome response to that request. The only thing I saw that was somewhat compliance-related was a very short, rudimentary compliance test that their salespeople were asked to take.

But I didn't see any compliance policies that you would typically see at a health care company, especially one generating that type of revenue. I didn't see a chief compliance officer in place. Just the things you typically see in a health care company, they didn't have.

- Q. Okay. So what did you do next?
- A. Well, I raised to -- again, we made the request of BlueWave. We didn't get a response. I raised that to Tonya

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that we needed a response.

- And what happened after you raised this to Tonya? Q.
- Essentially -- and I think it's detailed in this email, she said, well, you made too voluminous of a request. requested too many materials. They're a small organization. They can't comply with that.

My recollection is my response was, one, we didn't make a big request. This is stuff that a health care company should have kind of sitting on the shelf. They should be able to produce that very quickly.

Two, they were making millions of dollars. the resources to be able to comply with this request and give us what they had. And I suspected that they had no compliance program and that's why they weren't turning over the materials. And so I raised that with Tonya. And I think there was a back-and-forth in emails about that.

- Okay. And after you raised it with Tonya, what happened? She and I discussed it.
- I don't recall ever seeing any of those materials being delivered to us.
- Okay. What did she tell you? Q.
- You know, I can't recall what we discussed specifically. Α. I think there were some things in the email with her thoughts on it, but I can't recall what we discussed specifically on it.

MR. LEVENTIS: Your Honor, we'd like to admit

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Plaintiffs' Exhibit 1515 into evidence.

THE COURT: Any objection?

MR. COOKE: Just the usual.

THE COURT: Yes.

MR. ASHMORE: No, sir.

THE COURT: Plaintiffs' 1515 admitted over BlueWave objection.

BY MR. LEVENTIS:

- Q. Mr. Pace, sounds like you've had a chance to flip through this. Can you tell us -- it appears, at least on the front page here, it's a response from Tonya Mallory to you. And it's in June of 2013. But there appear to be a number of exchanges back and forth in this document; is that correct?
- A. Yes, that's correct.
- Q. I'm going to turn -- at the bottom, it's going to say "Plaintiffs' Exhibit 1515.3."
- A. Okay.
- Q. This appears to be part of your email. On June 12th, 2013, at 12:23 p.m., it says -- this sounds like what you were discussing earlier.

"I disagree that this list was huge. If they have a compliant program, most of that would have been sitting on the shelf."

Is this what you were describing earlier?

A. Yes.

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- They're pulling in 100 -- is that -- what did you mean by Q. "They are pulling in 100 million a year and have 40-plus subs in almost every state. They have the resources to respond. what they have agreed to in writing isn't, in my opinion, sufficient, reasonable, or customary"?
- So what I was referring to, I believe, if you go to the email that preceded my response, the email from Ms. Mallory, she basically said that it was a large amount of materials. They have a small office. It took them time to -it would take them time to produce that, and that the Cobalt and Bluewave in their contracts, which -- the sales contract And then HDL had another relationship with the BlueWave representatives called IDL, and a sales contract was being negotiated at that point. It's Ms. Mallory's assertion that those contracts contained necessary compliance language.
- And what did you think? 0.
- I thought both of those positions by her were incorrect. I thought, again, what -- you asked me what I was referring to. They were a large organization. I'm not sure if they were pulling in a hundred million a year -- that may have been an exaggeration -- but they were pulling in tens of millions of dollars a year. They had 40 representatives plus across the They had the financial resources, in my opinion, to have an effective compliance program and to be able to generate a response to our request, one that's customary in the health

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care space. So that's with respect to the materials requested.

with respect to the sales agreements, in my view, they're devoid of typical contract language you would have with a contracted sales force that -- the contracted sales force in that contract would generally make representations about their compliance program, allow you to audit their compliance program, and produce these materials upon request. And in the -- and my recollection is that their sales agreements did not have those standard provisions in them.

Q. And then, in the next paragraph, you say, "It is clear that we have a fundamental difference of opinion and you're the boss."

What did you mean by that?

A. Yeah, so I think you're seeing some of my frustration with the progress or lack thereof that we were having in building a compliance program. If you'll recall back to what I said earlier about my interview process, I was told we need compliance everywhere. It was my assumption that I was coming into an environment where the CEO and senior management would embrace an effective compliance program, allow us to put the things in place we needed to. And I was getting met with resistance routinely.

In my view, one of the real important factors was ensuring that the sales force that was run by BlueWave was compliant. And I was trying to do that on behalf of the

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And it seemed as if my boss and CEO was preventing me company. from doing that and negotiating against me. And it was very frustrating.

- Q. Why do you say she was preventing you?
- well, if you look at -- if you look at the email, it's basically saying the agreements are fine. They don't need these provisions. Give BlueWave a break. They're small. They can't respond to this.

Again, I just -- it was -- we were at a time when the company had received a subpoena regarding these practices. were getting advice from outside counsel, Ropes & Gray, that we needed to change certain practices. We needed to put a compliance program in place. And we were trying to do that, but I wasn't getting the support I thought I needed to do that in the speed and manner in which I thought we had to do it. And then we'll go up a bit to your response just before 0. that one. This actually follows as the email chain goes. this first paragraph -- excuse me -- you say, "I'm sure you can sense my frustration."

And then, later on, you say, "I can't remain silent on significant compliance concerns or on a course of conduct that I think is going to be the downfall of the company. You and I have fundamentally different ideas on compliance and BlueWave that I am afraid will never be reconciled. expect that to be the case based on my interview and the fact

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that you have a subpoena squarely focused on compliance and sales tactics."

What did you mean by that?

Α. Basically what I referred to earlier. It was my expectation that I was coming into an environment and a perspective from the CEO that would be to put in a compliance program that addressed all of these issues for a company of its size.

Again, it had grown to hundreds of millions of dollars of revenue per year and didn't have a compliance program, a compliance officer, policies and procedure that a company of that size in the health care space that you would expect them to have. And I thought that's what I was being hired to do, was to help drive the change there. And it just wasn't -- it wasn't happening.

Okay. Let's go back to Mr. Kung's memo. Exhibit 1244. On page 2, we were talking about the processing and handling agreements as one of your concerns. Let's go down to the bottom of the page there, waiver of copays, coinsurance, and deductibles.

what was your concern about this area?

- So my concern was that the blanket waiver of copays and deductibles violated either state or federal law. That's what my concern was.
- Okay. And why did you feel that way?

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For a few reasons. Α.

Before I joined the company, it was my understanding that HDL had a law firm look at this practice who had made the recommendation that copays and deductibles should be collected because it was a violation of law.

Can I just stop you there? Do you remember what law firm that was?

I don't. That was before my time. That was something that Derek would have told me, and it would have been discussed routinely at the company.

when I joined the company -- which, again, was in March -- Ropes & Gray, the health care counsel hired by the company, was looking into this practice, did an analysis, and advised the three board members on multiple occasions that the company needed to collect copays and deductibles; that in certain states there was an actual law that required it -those are listed here in this memo -- that the federal government, through guidance issued by the OIG, said that blanket waivers of copays could be a violation of federal law. And there were issues of common laws in states that it could be a violation. And then contracts and arrangements with third-party insurance companies, they required the collection of that.

So my concern was we've gotten advice from two law firms, two reputable law firms, Ropes & Gray is expert in this

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area, but yet HDL continued to waive copays and deductibles.

- **Q.** And you mentioned two law firms. There's Ropes & Gray. What was the other one?
- A. I don't recall the other law firm. That's the one I don't recall. My understanding was it was a national health care firm.
- Q. So you bring up Ropes & Gray. We talked about the compliance issues with BlueWave that you saw. Where was Ropes & Gray while you were finding these BlueWave compliance issues? Were they involved in discussions?
- A. Yeah. So Ropes & Gray was engaged by the company in two respects. They were brought in at some point late in 2012 to evaluate the compliance program and help build that program.

And then, once the company received the subpoena, Ropes & Gray was helping the company respond to that and defend against that. Ropes & Gray was brought into the loop on any compliance issue we found by BlueWave. I would -- it would either be by me or Derek, we would let them know, because they were doing two things. Again, building the program -- or help us build the program. So we wanted policies around those practices.

And then, two, Ropes & Gray was helping the company respond to the federal government's subpoena. These issues would have been squarely covered by the subpoena. And so Ropes & Gray had to know about those.

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- Q. So what was Ropes & Gray's -- to your knowledge, what was Ropes & Gray's view on the issues you saw at BlueWave?
- A. Their view was similar to mine, that we needed to get to the bottom of what they were doing out in the field, how they were selling, how they were using processing and handling, how they were using other mechanisms to get physicians to refer and make sure that those complied with law.
- Q. Did Ropes & Gray have a view on the processing and handling fees?
- A. Ropes & Gray informed the company that the company should, quote/unquote, move away from that practice, so cease that practice.

I remember Brien O'Connor, their lead partner, often saying the company needs to move away from that practice.

- **Q.** And what did you understand to move away from the practice to mean?
- A. I took that as we needed to stop paying processing and handling. In my view, it created excessive risk that it would be a violation of the Anti-Kickback Statute, which imposes significant criminal and civil penalties.
- Q. And how soon was that supposed to happen, the moving away?
- A. The initial advice was, you know, you need to stop this practice. There were discussions by the company, Ms. Mallory specifically, that if you stopped paying processing and handling, referrals from physicians would drop off

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dramatically. She cited statistics, to my recollection, in the 50 to 70 percent range was the fear.

So we engaged in discussions with Ropes & Gray of putting together a business plan to transition away from the use of processing and handling over a period of time. business plan had in it the method in which we would do it, the time frame by which we needed to stop completely. And that was in a relatively short order.

My recollection was, once we finally developed that plan, we were going to move away from it within six months. And what Ropes & Gray wanted was to have a documented plan that we were going to cease doing it, that, in case the government inquired about that, they could show good-faith efforts to move away from it and, hopefully, the government would take that as a sign that the company was trying to comply with the law.

- Are you familiar with a letter from LeClairRyan by a Michael Ruggio?
- I've seen it. I am familiar with that.
- Okay. So did Ruggio say that the P&H fees were okay?
- So I never had a discussion with Mr. Ruggio. the letter, and that's what it purports to say.
- So what was the difference in what Ropes & Gray was 0. telling you and what LeClairRyan was telling you?
- So the letter from LeClairRyan basically said that the amount paid complied with the Anti-Kickback Statute safe

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harbor, meaning it was permitted. Ropes & Gray had a difference of opinion on that. They told us they didn't think the opinion was accurate.

- Q. Okay. And why did they not think it was accurate?
- A. There were a few reasons. It made conclusions that the payment -- the aggregate compensation payment was fixed. That's a requirement to be an exception to the Anti-Kickback Statute. And, in fact, it wasn't. The amount to be paid varied by the number of the -- varied by the number of tests that the physicians would refer; right? So for every test, they would get an additional \$20. It was that reason.

It relied heavily on a time and motion study of how long it took to collect and process the blood, I believe, that Ropes & Gray felt had significant flaws in it that wouldn't allow you to rely on that.

And it otherwise didn't -- you know, the practice, the documents and everything around it, didn't meet the safe harbors and the exceptions to that Anti-Kickback Statute.

- **Q.** So what was your Ropes & Gray's conclusion on whether you could rely on the LeClairRyan-Ruggio letter?
- A. In discussions with them, they didn't think we should rely on it.
- **Q.** Was Ropes & Gray's advice that you shouldn't rely on the Ruggio letter?
- A. Yes. It was a flawed letter and we should rely on it.

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I'm not sure if Ropes & Gray ever reduced that to writing, but we had discussions on that.

Did you agree with Ropes & Gray's opinion? Q.

I did. I thought, again, the LeClairRyan letter wasn't Α. what you typically see from a law firm with respect to a legal opinion around the Anti-Kickback Statute. It left out a lot of facts that were relevant. It solely focused on the time and motion study in detail there. It did not focus on how that practice was being used in the field to sell. So I disagreed with the opinion.

I also -- again, Ropes & Gray is experts in this field, the attorneys they brought in to look at this. trusted their judgment on it. And so, yeah, I agreed with their opinion.

- And did you -- were there discussions about the Q. Ropes & Gray opinion with Tonya Mallory?
- well, again, I don't think there was a written -- the LeClairRyan opinion or the Ropes & Gray opinion?
- Ropes & Gray. 0.
- So, again, I don't think I ever saw a written Ropes & Gray opinion on this topic. We had verbal advice. There were numerous discussions that stated we needed to move away from the use of processing and handling fees. We needed to cease the practice because they posed excessive risk under these statutes that they would be violations of the statutes.

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yes, there was a lot of discussion on that.

Q. Now, let's go back to Mr. Kung's memo. This time we'll go to page 3 of the memo.

At the top, the BlueWave sales agreement. What were your concerns about the BlueWave sales agreement?

A. Again -- and I stated this earlier -- the agreement, there are a few issues with it.

One, it stated what the processing and handling fee had to be, that essentially there had to be a payment in X dollars for every referral. It had a requirement that you don't balance-bill, meaning a requirement that the company not collect copays and deductibles.

Both of those practices, I thought, were problematic, as we just talked about, and could be violations of law. In fact, the copay deductible one, we were told directly there were laws on the books against it.

- Q. Now, if I could stop you. You said "told directly" that there were what? Laws on the books? What does that mean?
- A. Yeah. So basically, as I mentioned before, Ropes & Gray had told us in certain states there were actual statutes, written laws, that you had to collect copay and deductibles.
- Q. So it would be illegal not to collect them?
- A. Correct. Correct.
- Q. Okay. Go ahead.
- A. And then, finally, the BlueWave sales arrangement was

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largely commission-based, meaning -- and did not fall within an Anti-Kickback Statute safe harbor or permitted exception. was set up in a manner, the more tests they referred, the more -- the more tests they sold, the more money they could And it didn't have a lot of the controls in it that you would typically see in an agreement. And, for those reasons, it was problematic and did not fall within a safe harbor of the Anti-Kickback Statute.

- Let's move to something that I think you're familiar with. Are you familiar with the term "Project Twilight"?
- Yes, I am.
- What is Project Twilight? Q.
- So Project Twilight was a code name given to a project that was designed to do away with processing and handling fees through arranging other ways to collect blood specimens from patients and get it to the HDL laboratories -- laboratory. Excuse me.
- And what was your role in Project Twilight?
- So I was asked to lead Project Twilight. The way this came about was the advice from Ropes & Gray was you have to stop using processing and handling fees; you need to move away from it.
- Q. So let me stop you there.

So was processing and handling the only way you could

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get blood from a doctor?

A. I don't believe so, no.

Q. Why not?

A. Well, there's other labs out there that have phlebotomists in office that draw blood. The physician may have a phlebotomist in the office that draws it. So that occurs routinely. You just -- you get as -- many of those labs don't pay a process and handling fee. The blood is drawn, processed, and shipped to the lab.

- **Q.** So what was your purpose in Project Twilight?
- A. Again, Ropes & Gray said move away from the practice of paying processing and handling fees. The company's position was that's going to have a negative impact on your sales; we need to do this over time.

And so what the project was was to create a network of other draw options available so you didn't have to pay physicians processing and handling.

- **Q.** I'm sorry. Why couldn't you just stop it then? Why do you say it has to be over time?
- A. In theory, we could have. It was Tonya and the board's decision that we didn't want to stop then; it would have a negative impact on sales. So we wanted to do a project to replace the way in which blood was drawn.
- **Q.** So what's your understanding of why process and handling wasn't stopped immediately?

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- A. The company didn't agree to do that, did not agree to stop. Tonya didn't want to stop.
- Q. Okay. Go ahead.
- A. So, in any event, the project, again, was designed to create other ways to draw blood so you wouldn't have to pay physicians. So it was a business project to solve a compliance problem. So what we did, we assembled a team --
- Q. Sorry to interrupt you. Just there are some of the terms you're using, I want to make sure we get.
- A. I'm sorry.
- Q. So when you're saying that -- something about compliance, you're saying processing and handling, the compliance issue.
- A. Yeah, sure. So, again, in Derek's memo and the advice from Ropes & Gray to stop using processing and handling, the fact that the government had submitted a subpoena and was inquiring about this conduct gave rise to the fact that it was a compliance issue and a compliance problem and something we needed to change.

The project was meant to address that and provide a business solution that would allow us to draw blood, collect it, do the testing, and not have to pay physicians.

- Q. Okay. And so what did you do to try to accomplish that?
- A. Sure. So assembled a team of internal people to help come up with what the solution would be. We gathered data on where the draws were occurring, so where -- which physicians. We put

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that across a map to see if there was concentration in particular areas.

And then we tried to come up with a plan to use three different ways to collect the blood. And those ways were put a draw facility in a concentrated market. So, for example, if there was a state where 80 percent of the draws were coming from a particular city, we would put up an HDL-leased site there where they'd have phlebotomists on-site, patients could go there and get their blood drawn. We would want to put that very close to the physician offices that were drawing, therefore to be more convenient for the patient. That was one option.

The other was to put phlebotomists in a doctor's office in a legally compliant manner. There are ways you can do that that are permissible. And, therefore, it would have been an HDL employee drawing the blood there rather than having to pay the physician.

And then the third way was to look at other labs that could potentially draw for us. There are some companies -- I cite one that's called Any Lab Test Now that we talked to. They're a lab in a lot of strip malls that you can come in and do certain types of testing for cash payment. We were in discussions with them on whether or not we could use their sites to draw blood for HDL's patients.

So that was the project, and those were the things we

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were considering.

- **Q.** So that -- the first option you talked about, the draw site, can you explain, was there a difference of opinion about the draw site?
- A. There was. So, again, I thought my charge, what I was being asked to do, was quickly move us away from processing and handling, try to preserve as much as the sales volume as possible, and do it in a cost-efficient manner. So my idea was we set up very simple small draw sites in the right locations so they wouldn't cost a lot of money. We needed a bunch of them to cover where the draws were coming from.
- **Q.** Why do you talk about this cost-efficient manner? Why is that part of your equation?
- A. Well, because the company is there to make money, it wants to be profitable, was spending a certain amount on processing and handling. I believe it was between a million and a million and a half a month.

And the goal was to try to replicate the same amount of draws within that cost structure or close to it. The company had fairly high margins, but you don't want to just go to a practice that's going to tank the business. So there was a business analysis and a cost analysis being done on each of these three options.

Q. So your analysis, were you saying that you could use draw sites for the same amount of money it was costing you guys to

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pay the doctors?

- A. I'm not sure we ever got to that detailed analysis because it -- the project never really progressed on a nationwide basis.
- Q. Okay. Why did it never progress?
- A. Well, Tonya did not want to bring up this project with BlueWave.
- **Q.** Why not bring it up with BlueWave?
- A. She thought they would resist it. Her statements to me were to not tell them about it, that eventually they'll think it's their idea, and at that point we'll be able to do it.
- Q. And what did you take that to mean?
- A. That she knew they didn't want to do this. She -- you know, it was my assumption that she believed processing and handling --

MR. ASHMORE: Objection, Your Honor. Speculation.

THE COURT: Establish a foundation for that.

MR. LEVENTIS: Okay. Sorry.

THE COURT: Sustained.

MR. LEVENTIS: I wasn't following.

BY MR. LEVENTIS:

- Q. So why did you think that -- in your mind, why did you think that -- the scenario where she didn't want to talk to Bluewave about it, why do you think that was?
- A. Any changes to the selling process were generally met with

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resistance by BlueWave. I believe that the processing and handling was being used as a sales tactic to get physicians to refer HDL testing.

And if you took away from the processing and handling fees and the revenue that the physicians would have received, there was a fear that the referrals would go away. And the effect of that would be HDL would lose the revenue. BlueWave was paid a percentage of the revenue of every test. I believe it was between 14 and 18 percent. So they would lose revenue, and therefore she didn't want to address it with them.

- Did you talk to BlueWave about the draw site idea? 0.
- I did not. I did not. I left that to Tonya to do that.
- And why? Q.
- Tonya had the relationship with BlueWave. She didn't want to tell them about the project. I reported to her. the CEO. I was following my boss's instructions.
- were there any attempts to -- for HDL just to stop paying Q. processing and handling without BlueWave's input?
- Not during my tenure at the company.
- And so I believe you had testified that Ropes & Gray told you to stop paying process and handling fees; right?
- They did. They routinely used the phrase, and I've said Α. it a couple of times, "You need to move away from paying processing and handling."
- So at some point, was there an idea to discuss that with

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- A. There was. I'm not sure we discussed Project Twilight specifically, but there -- between April and, say, June of 2013, there was a dialogue occurring between Ropes & Gray and BlueWave's attorneys at the time regarding the need to change this practice. And then there was a meeting in Richmond in June of 2013 where this was also discussed. And BlueWave and their counsel, Ropes & Gray, and members of HDL were present at that.
- **Q.** Okay. So in June of 2013, were you present at a meeting with BlueWave?
- A. Yes, I was.
- **Q.** And who else was there? You mentioned some attorneys. Who were the attorneys you're talking about?
- A. Yes. So to the best of my recollection, members of Ropes & Gray were there. It would have been --
- Q. Do you remember who from Ropes & Gray?
- A. Yes. It would have been Brien O'Connor, who was their senior partner who was hired by the company to defend and respond to the subpoena. That's Brien's expertise. He represents large health care companies in these matters.

Laura Hoey, which is one of Brien's partners. She, too, represents companies responding to subpoenas in the health care space. I believe her background was with the Department of Justice, actually.

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And then I believe Michael Lampkin [verbatim] was And to the best of my recollection, he was there. was often working on HDL matters. He was the health care regulatory specialist. So he was the person analyzing the laws, helping us create the compliance program and policies surrounding it.

That's the Ropes & Gray team.

- Okay. And were they the ones that were representing HDL Ο. at this meeting?
- Yes, they were. Α.
- And who else was representing HDL at the meeting? 0.
- So there was no other outside law firm there. members of HDL who were there was Tonya, Joe McConnell, Russ Warnick, myself, Derek Kung. And I believe Dennis Ryan was there, although I'm not a hundred percent sure on that.
- Okay. And before this meeting, what had Ropes & Gray been 0. telling you?
- Α. I'm sorry?
- What had Ropes & Gray been telling you about processing and handling fees before this meeting?
- Again, that we needed to move away from using processing and handling. This meeting was designed to get full agreement -- or at least HDL's desire for this meeting was to get full agreement from BlueWave that we would stop paying processing and handling, how that would play out, how it would

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be communicated to the physicians. And that was the purpose of the meeting.

- Q. Okay. And who was there on behalf of BlueWave?
- A. So it was the two gentlemen here today, Mr. Dent and Mr. Johnson. They had lawyers with them. I believe a gentleman named Gene Sellers, who I think is a tax attorney, advised them.

And then I believe a gentleman named Mark White, and Mr. White may have had some of his colleagues with him. I just -- I can't recall.

- **Q.** And did you say -- well, who spoke on behalf of HDL at this meeting?
- A. Generally, Brien O'Connor, the lead partner from Ropes & Gray, did most of the speaking on behalf of the company.
- Q. And what's Mr. O'Connor's background? Do you know him?
- A. I do know him. I got to know him through my appointment at HDL. Again, he's one of the lead partners at Ropes & Gray. He helps defend health care and other companies against subpoenas in violations of law and violations of Anti-Kickback Statute, et cetera. So he was hired for that purpose by the company to help respond to the Department of Justice subpoena that we had received earlier this year.
- **Q.** And you said the meeting was in Richmond. Where in Richmond was it held?
- A. I believe it was held in Tonya's office.

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- In her office? Q.
- Α. Yes, correct.
- Tell us what happened at that meeting. Q.
- So, generally, all those parties were assembled. Α. led off with the purpose of the meeting was to move away from processing and handling fees and discuss how that would occur and to get alignment by everybody at the meeting.

He also covered the fact that the company was under subpoena, the company had a lot of practices that were risky, we were trying to change all of that, and that, again, the purpose was for BlueWave to kind of get on board that we were changing away from processing and handling.

And so that's what Brien generally talked about at the beginning of the meeting.

- Now, at HDL, were there concerns that the Anti-Kickback Q. Statute was hard to understand or ambiguous?
- I don't recall those concerns ever being raised.
- So at the meeting that was discussed, HDL did the presenting; is that right?
- Basically, Brian, again, stated the purpose of the meeting, why he thought and Ropes & Gray thought we needed to move away from processing and handling. And the meeting was to gain alignment from BlueWave that they would be supportive of that.
- And why did you need BlueWave's alignment? Q.

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A. You know, I think, again, they were the face of HDL in the sales process. They had the relationship with the physicians. If they didn't communicate that to the physicians, it would have been problematic. That's one.

Two, their sales agreement actually has in it that you have to pay a processing and handling fee. That would have needed to be changed, and we needed their agreement to do that potentially.

And basically, again, they were the contracted sales force. So it was, you know, our partner, our HDL partner in the selling process, and we wanted them aligned with the course we wanted to take.

Q. Okay. So give us an idea. You've got all the attorneys and HDL and the Bluewave folks all in the room together.

Did you say Brien is the one that did the talking?

A. Yeah. So, basically, the meeting went as follows. Brien led off with his statements. There was some discussions, others chiming in. I think I said one or two things. I think Gene Sellers said one or two things. Brien continued on, and then Mr. Dent reacted to Brien's statements.

He basically disputed those, said they weren't accurate, screamed at Brien, got very red-faced and angry and upset about it. And then the meeting ended shortly after that and never accomplished the purpose that we wanted the meeting to accomplish, which was an alignment to move away from

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- processing and handling.
- **Q.** What did Mr. Dent get mad about and scream about?
- A. You know, I'm not sure real sure. I think he disagreed with the legal analysis by Brien. He disagreed that processing and handling was a problem and thought basically saying moving away from it would impact the sales, impact the ability of people to get the testing and shouldn't be done.
- **Q.** Okay. Was it your impression Mr. Dent was against stopping processing and handling fees?
- A. For sure, yes.
- **Q.** Did Mr. Johnson speak at this meeting?
- A. He spoke. I don't recall exactly what he said. He spoke a couple of times, but it wasn't the same manner or tone as Mr. Dent.
- **Q.** And did Ms. Mallory support the idea of stopping processing and handling fees?
- A. To my recollection, she didn't voice any opinion at that meeting.
- **Q.** Did she disagree with Mr. Dent?
- A. I don't know. She didn't voice any opinion at that meeting.
- Q. Were you surprised that Mr. Dent would yell at
- Mr. O'Connor?
- A. I was. Again, it was a business meeting. There was a dozen or so people there. I didn't think it was professional.

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I didn't think it was appropriate.

I also was surprised, you know, Brien, Ropes & Gray, a prominent health care law firm, very well respected, giving us advice -- they had extensive experience in this area, and he was challenging that advice, and to my knowledge he's not a lawyer and doesn't have compliance training.

So it just -- it took me aback. Again, we were trying to do the things that we thought were right for the company and would preserve the company for the long term, and he was resisting that.

- So after this meeting, did HDL continue to pay 0. processing and handling fees?
- To my knowledge, yes.
- Why didn't HDL just stop? Q.
- Α. I don't know, frankly. I think it's -- excuse me. didn't want to lose the business, and that was the excuse.
- when you say they didn't want to lose the business, who do Q. you mean?
- Again, Ms. Mallory had stated on a few occasions that, if you stop paying processing and handling fees, they would see a large -- they believed they would see a large decline in referral volume from physicians.
- Who do you think was the ultimate decision maker at HDL? Q.
- Α. Ms. Mallory.
- Why do you say that? Q.

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- A. She's the CEO and the chair of the board. CEO is the highest officer at the company. And, in practice, Tonya made all the decisions -- material decisions of the company. Everything went through her.
- **Q.** And do you have any other experiences of Ms. Mallory ignoring legal advice at HDL?
- A. Well, I'd go back to the copay issue. Again, the company was told early in 2013 that you needed to collect copays everywhere in all states. The proposed plan was to implement it first in the states where it had written laws that compels you to do it and then roll out to the other states.

It's not just a simple change. There's IT change -information system changes, billing changes that need to be
made. So you just can't do it overnight. The board voted to
do that. And then Ms. Mallory resisted that, delayed it.

And we finally implemented collection of copays in two states, Colorado and Florida, I believe, midyear 2013. And that was more in response to commercial insurers like Aetna, Cigna threatening to stop paying HDL's claims until they started collecting copays and deductibles.

So the board that -- she received legal advice from counsel. The board had voted to do it, but she didn't authorize the billing department to begin to do that on a nationwide basis.

Q. In your opinion, why did she not do it?

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A. I don't know. I mean -- I don't know.

MR. LEVENTIS: Let's turn to Exhibit 1171, Your Honor. I'll set the foundation for this first.

BY MR. LEVENTIS:

Q. Mr. Pace, if you could take a look at Plaintiffs' Exhibit 1171.

Do you recognize this document?

A. Yes, I do. It's an email exchange between me and senior members at HDL and then between me and Tonya.

MR. LEVENTIS: Your Honor, the government moves to admit Plaintiffs' Exhibit 1171.

THE COURT: Any objection?

MR. COOKE: The usual, Your Honor.

THE COURT: Yes, sir.

MR. ASHMORE: No, Your Honor.

THE COURT: Plaintiffs' 1171 admitted over Bluewave objection. Please proceed.

BY MR. LEVENTIS:

Q. So, Mr. Pace, it appears that this is in June of 2013.

Is this -- as you're looking at this, does your recollection about the meeting -- is this around the time of the meeting with BlueWave?

It's a string of emails. I'll give you a minute to look through it.

A. Oh, yes, it is. I think this is an email exchange maybe a

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week or so after the meeting you're referencing.

- Q. Okay. Let's -- let's turn to page 1171.2. It's the second page of your exhibit. If you scroll down -- there we go. That's from Nicholas Pace, dated Friday, June 28th, 2013 --
- A. Yes, I see that.
- **Q.** -- to Tonya Mallory and Derek Kung regarding Monday's BOD meeting.

Is that board of directors meeting?

- A. Correct.
- Q. It says, "I would think the board needs to discuss (unless it already has) a debrief from Monday's meeting with BlueWave and counsel."

Do you see that?

- A. I do.
- **Q.** Okay. So does that appear to be referencing the meeting we were just talking about with BlueWave and all the attorneys?
- A. Yes, it does.
- Q. Under the first part there at "Sales Force," "Monday's meeting made clear to me that Bluewave will never get on the same page as HDL with respect to a change in business model related to blood draws."

What did you mean by that?

A. That we were proposing changing the business model to do away from payment of processing and handling, being replaced

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with the combination of the three options I referenced before. And it was my view that, based on that meeting and BlueWave's actions, that they would not agree to do that.

- **Q.** And then if we turn a couple of pages towards the end of that email on page 171.4, at the top, it says "Project Twilight."
- A. Yes.
- Q. In that first section, you say, "As stated above, it appears that BlueWave is not interested in helping the solution for blood draws. I had hoped that they would be engaged in helping us determine which practices will take an IOP" --

What is an IOP?

- A. In-office phlebotomist.
- Q. -- "and where we might put a service center."
 What's a service center?
- A. I'm sorry?
- Q. Is a service center the -- what is that?
- A. So it's a draw site. I mean, at the company, there was difference of opinion between myself and Tonya Mallory on what a service center should be or a draw site should be.

Again, my view was something very simple, rudimentary, cost efficient where we could draw blood. She had a vision of a much larger building, 2,000 to 4,000 square feet, that offered yoga classes, free cooking health classes, and health education, which was a great idea in concept. The

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problem was, to do that on a large scale to draw blood, it would have been inefficient cost-wise. It's something the company couldn't have done. There was no business case around it either as to how those other services would raise any money for the company.

So when we talk about service center, what I'm talking about is the smaller sites that were designed to solve the processing and handling problem on a nationwide scale, targeted at high draw areas. What she was generally referring to as what I just discussed. So I just want to make that clear as I go forward.

Q. In then you say, "Do you want me to cease and desist on Project Twilight on a national scale?"

What did you mean by that?

A. So, again, BlueWave owned a relationship with the physicians. BlueWave had the better information on how physicians would react to the change, what the physicians would want, whether it be an in-office phlebotomist, a draw site. They had information on where their sales were likely to come from in the future.

My hope had been that they would have engaged with us -- us being HDL -- on where to put draw sites, where to put in-office phlebotomists. They would have communicated that to the physicians and would have been able to do this on a national scale to stop the processing and handling.

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Initially, Tonya would not discuss the idea with them. We discussed the idea at the June meeting. It was met with significant resistance. So what I was saying here was, yeah, do you want me to still do this because we don't have a plan to roll it out anymore and engage our sales force in helping us do that. So what do you want me to do with this project?

- **Q.** So did you think Tonya Mallory was supporting the Project Twilight?
- A. Not in a manner that would take it successful. She supported some actions in the state of Virginia where we did ultimately open some draw sites. But, again, that was a state in which BlueWave did not sell in. The company's internal sales force sold within that state.
- Q. Do you think that made a difference?
- A. I do. I don't think she wanted to challenge BlueWave on it, and I don't think they were receptive to it. So it was easier to do it in the state of Virginia because they were HDL employees.
- Q. Now, if you turn to the first page of Exhibit 1171, it starts off, "Thanks for the" -- and this is responding -- so you had mentioned about the -- or do you recall what time this response to you was?
- A. Response to me -- to this email?
- Q. The things we had just read about the sales force and

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Project Twilight, she responded to you.

- Yes, she did. And it's here in the email, her response. Α.
- Okay. And what was that response? Q.
- Α. If I could have a second to read it.
- 0. Sure.

(Pause.)

- Yeah, so basically she was responding to what I had laid out in the email. She was, you know, giving her view on how you deal with BlueWave in these situations and how she had done in the past. And then her -- her view on what she wanted to do with Project Twilight.
- But what did she want to do with Project Twilight? okay.
- If you look at it, it's basically roll out a test -- or roll it out in the state of Virginia, and do it there, and see if you lose business or not. And then roll it out somewhere, other places potentially, later.
- And you testified Virginia is where HDL has employees versus the rest of the country?
- That's correct. I think they had three sales employees that were HDL employees and were not affiliated with BlueWave in the state of Virginia.
- And then your email, you respond to her, saying, "Thanks Q. for the response. Yes, I've been pretty pissed since Monday as I think the meeting with BlueWave was terrible and the position and attitude they're taking is going to be a problem for HDL."

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And then you conclude, "I think these guys are trouble and only trying to preserve the status quo so they can make as much money as possible before they get shut down."

What did you mean by that?

well, again, the company was under a subpoena from the federal government looking into sales practices and other The company had received advice from expert health care counsel as to things they needed to change, advice from their general counsel who has a background in health care regulatory experience consistent with the outside counsel.

And it was my view that, if we didn't change those practices, there was going to be an enforcement action against the company by the federal government, whether it be criminal or civil. We were also getting inquiries from big insurers as to our practices and whether or not they were permissible.

So it was my view they needed to change. My hope would be that BlueWave would get on board with those changes, we would do it proactively and together, and, hopefully, when and if the federal government started to ask questions and get in depth on this, they could see a pattern of change, that we recognized issues, and spare the company from a large action against it.

I was extremely frustrated that the June meeting did not turn out that way. And in the way in which it ended, it became very clear to me that these changes weren't going to

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happen so long as the company was engaged with Bluewave. That was my opinion at the time.

- **Q.** Why did you think they weren't going to happen as long as you were engaged with BlueWave?
- A. Well, they stated in the meeting they weren't going to change. I didn't think Tonya would challenge them on it and get them to change.
- Q. Why didn't you think Tonya would challenge them on it?
- A. She tended to defer to them, at least that's what I viewed. They were making a lot of money for the company, and I don't think she wanted to upset them.
- Q. Can you think of any example where she deferred to them?
- A. You know, going back to the copay example, there was legal analysis delivered on a call from Ropes & Gray. She heard that, came back later, and challenged it based on some of her discussions with Brad and Cal that they didn't believe it needed to be collected; they were reading the statutory language. So, in that instance, she deferred to them.
- Q. Okay. Mr. Pace, let's move -- I believe at some point you ended up resigning from HDL; is that right?
- A. That's correct.
- Q. Okay. And when was that?
- A. I believe it was in September of 2013.
- Q. So how long did you work at HDL?
- A. Approximately six months.

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- **Q.** Is that a short amount of time?
- A. Yes, it is, for me.

You know, I had taken this job with high hopes; right? It was -- as I stressed before, I wanted to work in Richmond in health care in a senior role and thought I could do some great things for the company. I'd had a career path of upwardly moving positions and a lot of successes and got here and was unable to do my job in the manner in which I thought it was supposed to be done and in the manner in which I had been hired for. And --

- **Q.** Why did you think you were unable to do your job, what you had been hired for?
- A. I was met with resistance from Tonya on various compliance initiatives. I saw that Bluewave wasn't going to agree to what we needed them to agree to. I mean, every day, it felt like an internal battle to try to make some of the compliance changes we wanted to in the manner in which we wanted to, whether that be directly with Tonya or a practice that would affect BlueWave.

And I became extremely frustrated with it. I was fearful that the company was ultimately going to get shut down by the government either for criminal charges or civil charges. I didn't want that on my resumé. And so I made the decision to leave after six months.

It was a difficult decision. I didn't have another

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job lined up. You know, I've got a family I have to support. And when I left, I wasn't able to tell people why I left. I had confidentiality obligations to the company, and so I couldn't say, "Hey, I'm leaving because I don't agree with their compliance practices." It was just -- I had to leave. So it was a very difficult decision.

- Q. Why did you have confidentiality?
- A. So I entered into a separation agreement when I left the company that had confidentiality obligations in it.
- Q. Can you tell us what a separation agreement is?
- A. Sure.

So when I left the company and resigned, what I stated to them was I'm leaving after six months. This is going to be a blip on my resumé. It's going to look bad. People are going to ask me why. I'm going to have difficulty finding a like job, especially in Richmond. And so would you consider paying me severance? I asked for, I think, a year of salary. They ended up paying me six months of salary. They weren't compelled to do so. They didn't have an agreement that would require them, but that's the rationale I gave them. I needed it.

So, in exchange for that payment, I entered into a separation and release agreement, where I released any claim I may have against the company. I agreed to cooperate with them on any investigation, and I had confidentiality obligations

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where I wouldn't talk about confidential matters of the company to third parties unless compelled in a subpoena or in front of a trial. It also had a non-disparagement provision, where I was not allowed to say anything that may be disparaging or negative about the company or its executives.

- **Q.** Okay. So before you decided to resign, what are some of the things that you attempted to do at HDL that you felt like Ms. Mallory did not assist?
- A. Sure. So, again, going back to Project Twilight, the manner in which I wanted to do it to solve the compliance problem in the manner in which I and the members on that team thought was the best way to do it weren't supported by her. I'll say, back to the patient service center, draw site, she wanted these elaborate facilities that to me weren't financially viable. So it would have never accomplished what it needed to. That was one.

With respect to the compliance program, you know, we accomplished some things. We hired a chief compliance officer. We put some policies in place. Many of the policies, she wanted changes in them that would water them down. And, in certain cases, the policies were more on paper rather than in practice.

So, for example, when we decided to collect copays in those two states, Colorado and Florida, Tonya announced that to a team of about 30 people. We had a regular business meeting,

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I think on a monthly basis. But she made the statement that, hey, we're going to send that out. We don't want to do it; we just have to. And it was undermining compliance issues like that and not giving it a tone at the top of it that were supportive of it --

- Q. I'm sorry. They don't have to do what?
- A. Basically that she didn't want to have to collect copays, just had to. And kind of undermined the compliance procedures we were trying to put in place in compliance with law that we were trying to put in place. So, you know, those things.

And then, frankly, the position that I was told I would have in the company, have some operational responsibility, a larger team reporting to me, some of that never came to fruition. Again, all the senior executives reported to Tonya. She made all the material decisions.

And so, for those reasons, I left.

- **Q.** Did you ultimately put your reasons into a letter that you sent to Tonya Mallory?
- A. I did. So I went into Tonya's office in -- I believe it was in August or very early September. I said, "Hey, I need to tell you something." She looked at me and said, "You're going to resign, aren't you, or you're going to quit?" Something along those lines. I guess she saw it on my face.

I said yes. She asked my why. We had probably a 45-minute discussion where I outlined many of the things I've

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talked about today. She asked me if I'd consider staying. She said, "I can give you more equity in the company if you want to stay."

I said, "I don't think so. Let me think about it."

And then I thought about it for a day or two, I think. I

can't -- it was five years ago. My time frame is a little

fuzzy. But I ultimately put it in a resignation letter

detailing the reasons I was leaving, the things I had done at

the company, and my request for severance.

Q. Okay. If you could turn --

MR. LEVENTIS: Your Honor, this one is not into -- is not a published exhibit yet, but I'll set it up here.

BY MR. LEVENTIS:

- Q. It's 1278, Mr. Pace.
- A. Yes, I see that.
- **Q.** Okay. Do you recognize this letter?
- A. I do. This is the resignation letter we were just discussing.
- Q. Okay.

MR. LEVENTIS: Your Honor, we move to have Plaintiffs' Exhibit 1278 admitted into evidence.

MR. COOKE: Same.

MR. ASHMORE: No objection.

THE COURT: Very good. Plaintiffs' 1278 admitted over Bluewave objection.

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BY MR. LEVENTIS:

Q. So, Mr. Pace, we'll scroll down here to -- let's start with this paragraph saying, "In my approximate six months with HDL."

Would you mind just blowing up that paragraph, Peter.

Might be a little easier to see.

Mr. Pace, here you say, "In my approximate six months with HDL, I have recommended to the board" -- when you say "the board," who did you include in there?

- A. So it was the board of directors, which would have been Tonya Mallory, Joe McConnell, and Russ Warnick.
- Q. Okay. You say -- "to the board an assortment of compliance-related changes, including, to mention a few" -- and then let's go through these.

The first is "commencement of billing and collection procedures for patient copays and for coinsurance deductibles."

What happened with this recommendation?

- A. So, again, outside counsel Ropes & Gray had advised that, to comply with law, this needed to be done and should be done on a nationwide basis. And, in my tenure there, the company only ended up collecting those -- or sending out letters to collect those in Colorado and in Florida.
- **Q.** And who at HDL would have made the decision to only collect in certain places?
- A. That would have been Tonya.

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- **Q.** And what was Ropes & Gray's advice? Were they supposed to collect in all states?
- A. Yes, they were to collect in all states. And we had discussed a process by which you roll it out in the first five or six states that had a statute and a law on the books that required you to do so and then move to the other states.
- Q. Okay. Number 2, "The establishment of a nationwide comprehensive network of third-party contractual relationships, IOPs, and draw sites to eliminate process and handling fees."

What happened there?

- A. Right. Again, so that was the Project Twilight we just talked about. My view was that Tonya wasn't supportive of a realistic plan to move that forward, that she was focused on these larger service centers and only focused in the state of Virginia, and, again, that BlueWave would not be receptive to that idea, so it wasn't gaining any traction.
- Q. And who would have decided whether it would gain traction? You said it didn't gain any traction. Why not?
- A. Well, again, I think Tonya and I had a difference of opinion on the mechanisms to do it with respect to the patient service centers, one.

And then, two, it didn't gain traction with BlueWave. She would have been the one that would have had to push that with BlueWave.

Q. In your opinion, did she push it with BlueWave?

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- A. Not to my knowledge.
- **Q.** And then why eliminate process and handling fees? Is that based on Ropes & Gray's legal advice?
- A. Yes, it was.
- **Q.** Number 3, "Revision to policies and procedures to regulate and/or eliminate monetary and in-kind services of physicians and providers," what happened to that?
- A. Yes. So as part of the compliance program rollout, Derek Kung, the general counsel, and Michael Lampkin [verbatim] from Ropes & Gray were developing a set of policies and procedures that would govern the way in which HDL and its contracted sales force interacted with physicians, and any payments to those physicians would make sure they fell within that policy and be permissible by law.

Those policies were being developed. And, in many cases -- and in connection with the development of that, it would go through a review process by both the legal and compliance people as well as the business people. And that included Tonya. And, in those reviews, she often made changes that watered down the policies so they weren't as clear or weren't as effective. And so this is a reference to that.

I don't recall the specific policy sitting here today, but I know that Derek had expressed significant frustration to me about that, and -- to the point where, generally, on the policies it would show that he, as the

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general counsel, had signed off on that policy. He had concerns about signing off on the policies due to the changes that Ms. Mallory had made.

- **Q.** Do you recall any issues with a Dr. Fillingane?
- A. I know who he is, yes.
- **Q.** And who is that?
- A. He was a physician who referred a lot of tests to HDL, so a lot of his patients got the testing. What struck me about him, there was a lot of financial interchanges with him and the company. He was --
- Q. I'm sorry. When you say "financial interchanges" --
- A. Yeah, I was going to get to that. Maybe that's not the best word.

But -- so I remember we looked at his referring patterns. He was essentially -- what it appeared was recommending HDL testing to a vast majority of his patients on -- four times a year, so the processing and handling fees that would have been owed to him would have been substantial. He was on the medical advisory board of the company, so he was receiving payments from the company there.

- Q. What's the -- I don't know if we talked about that yet.
 What's the medical advisory board?
- A. So medical advisory board was a board of physicians put together to advise the company on medical matters, testing, new types of testing, things like that. You can do that in a

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legally permissible way, but there's certain criteria you have to put around that that Derek or Ropes & Gray would have advised the company on.

- **Q.** Do you know how doctors would have been selected for the medical advisory board?
- A. I don't know how they were selected, frankly.
- **Q.** Do you know if doctors were paid to be on the medical advisory board?
- A. I believe they were, and I believe that was referenced in Derek Kung's memo that we discussed earlier.

So, in any event, he was on the medical advisory board receiving payments. I think at one point the company had actually loaned him money, I think around \$100,000 to this physician.

- **Q.** HDL loaned Dr. Fillingane money?
- A. That's my understanding, yes.

And, at the same time, Dr. Fillingane was also serving on a medical advisory board of a company called Singulex, which was also in the lab space and in some respects was a competitor of HDL. And the other two founders, Joe McConnell and Russ Warnick, often raised concerns to me that Singulex was going to become more of a competitor to HDL. BlueWave sold Singulex testing as well, and that struck --

Q. I'm sorry to interrupt you there.

So in your compliance role, had you heard anything

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about this idea that BlueWave was selling HDL and Singulex together?

A. Yeah, so what I had heard kind of bubble up through the company was that they were selling both testing for Singulex, which was a lab based in California, and HDL. And when they would go in to physicians, the physicians would draw blood for each. So the physicians would get draw fees from both -- processing and handling and draw fees from both companies and therefore could have more revenue going to the physician. So that struck me as odd, that the sales force -- contracted sales force would be selling a potential competitor's product.

Also learned from Tonya directly. I think she said that Cal Dent was also selling for a lab called Tethys, which, again, was another lab in that space. Again, it struck me as odd.

But back to Dr. Fillingane, you know, he's on our medical advisory. He's on HDL's medical advisory board. He's a referring physician, but he's also doing the same things for a competitor. So it was just a strange arrangement, in my view.

- **Q.** Okay. And whatever happened with that arrangement with Dr. Fillingane?
- A. I don't know. When I left the company, I think it was still in place. I just don't recall.
- Q. We'll go back to your resignation letter. It's Section 4,

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"adoption and implementation of policies and procedures addressing federal and state laws regulating health care fraud, waste, and abuse."

what happened with that recommendation?

- So, really, that's -- Number 4 is probably cumulative of Items 1, 2, and 3. So the policies that would have been designed to comply with the Anti-Kickback Statute and False Claims Statute and other regulations, again, those were being watered down or not implemented. We weren't changing the copay collection. We weren't changing processing and handling. weren't changing a lot of things that gave rise to potential violations under fraud and abuse laws.
- And they weren't being changed despite legal advice; correct?
- Α. Yes.
- Section 5, "Reform of HDL's business relationship with Bluewave and strict regulation of the activities of Bluewave and its principals, sales representatives, and subcontractors."

Tell us about that recommendation.

So that recommendation was really twofold. on a business front, and then on a legal compliance front.

I'll start with the business front. When BlueWave first was engaged by HDL, HDL was a much smaller company. was having difficulty selling tests. BlueWave came on board, and the sales skyrocketed. Bluewave had left a competitor,

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Berkeley Health, had changed a bunch of the -- or converted over a bunch of the physicians who referred Berkeley to HDL accounts, so the volume spiked.

Bluewave owned the business relationship with the physician. HDL had very limited interaction with the And so, from a business standpoint, I was concerned physician. of the long-term longevity of the company relying on a third party that owned the customer relationship, paying them tens of millions of dollars under that arrangement. And they had, in the past, moved away from a lab, taken most of its business and flipped it to HDL. I was concerned that, if HDL didn't build its own sales force, that that could happen to them.

I was also --

- Paying them the millions, is that the commission part you Q. were talking about earlier?
- That's the commission part, yes. I think they were making somewhere between 14 and 18 percent -- it varied over time -on the sales. And the sales were significant, in the hundreds of millions of dollars.
- And did you see an issue with paying the commissions to the third party, BlueWave?
- Again, if you go back to the Anti-Kickback Statute, there's prohibition against that. There's safe harbors for that, and this was not structured to comply with those.

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- **Q.** And did you talk about that concern in board meetings?
- A. We did. It's also set forth in Derek's memo, those concerns. So, on the business front, you know, those were the concerns.

I was also concerned that being under a subpoena by the federal government, eventually, one party or both parties would have to change practices, would potentially break apart from one another. And if that were to occur, I wanted to ensure that the company had a viable option to have a sales force. And so I was -- and I believe -- you know, I had sent emails. I had discussions with the board on the business concern I had with the HDL-Bluewave arrangement. That's that piece of it.

On the compliance side, we've documented and discussed a bunch of that today. Their agreement had problematic provisions in it with respect to no copay collection, payment of processing and handling. They weren't complying to our requests for a compliance program to see what they were doing. They were resisting changing processing and handling.

All of these things together were big problems, in my view. I think all of those things were designed to, you know, maximize their sales at whatever cost, and they weren't going to change it. And so I had frustrations. It was one of the reasons I left.

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Q. In the last sentence, you say, "These proposals have generally been ignored, rejected outright, or diluted in substance and enforcement so substantially as to have no material effect."

What did you mean by that?

A. Excuse me.

Basically, what it says. If you go down each one of these things: Copays, only started collecting in two states, not nationwide, as advised by counsel. Nationwide comprehensive draw sites or other ways to draw blood, we didn't do that. The company was still paying processing and handling when I left. The policies that I referenced were often diluted or changed. And so that's what I'm making reference there to.

Q. And you said that you had a meeting with Ms. Mallory and

- you discussed these issues with her right before you left?

 A. I did. When I went in to resign, I cited these issues.

 I'm not sure I used these exact words, but I went through my reasons for leaving. And, again, it was a 45-minute or so discussion.
- MR. LEVENTIS: If we could go back out to the whole page, Peter.

BY MR. LEVENTIS:

- Q. At the top there, let's look at the date and to whom. So it looks like it's dated September 3rd, 2013.
- A. Yes.

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12:10PM	1	Q. And it's delivered by hand to Tonya Mallory; correct?
12:10PM	2	A. That's correct.
12:10PM	3	Q. So
12:10PM	4	A. Actually, let me rephrase that. I had the meeting with
12:10PM	5	her, told her I would think about it. Thought about it, wasn't
12:10PM	6	going to change my mind, left the letter, I believe, on her
12:11PM	7	desk or her chair. She was not in the office that week. I
12:11PM	8	think she was traveling for business. I didn't hand it to her;
12:11PM	9	I put it in her office.
12:11PM	10	Q. Okay. But was it around September 2013 that you talked
12:11PM	11	about all these issues with her?
12:11PM	12	A. Yes.
12:11PM	13	MR. LEVENTIS: One second, Your Honor.
12:11PM	14	(Pause.)
12:11PM	15	MR. LEVENTIS: Thank you, Mr. Pace. That's all I
12:11PM	16	have for you at this minute. If you'd please answer any
12:11PM	17	questions defense counsel has for you.
12:11PM	18	THE COURT: I think it might be a good time to take
12:11PM	19	our lunch break.
12:11PM	20	Ladies and gentlemen, do not discuss things
12:11PM	21	during the break. We'll be back in an hour.
12:11PM	22	(Whereupon the jury was excused from the courtroom.)
12:12PM	23	THE COURT: Any matters to address for the Court?
12:12PM	24	You may be seated.
12:12PM	25	MR. LEVENTIS: No, Your Honor.
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For the defense? 1 THE COURT: 12:12PM MR. COOKE: None. Thank you. 2 12:12PM I want to remind everyone the witness 3 MR. ASHMORE: 12:12PM 4 is on the stand, so there should not be any conferring over the 12:12PM lunch break. Come back in an hour. 5 12:12PM (Recess.) 6 12:12PM 7 Please be seated. THE COURT: 1:17PM Any matters we need to address? 8 1:17PM 9 MR. LEVENTIS: No, thank you, Your Honor. 1:17PM From the government? From the defense? 10 THE COURT: 1:17PM 11 Nothing, Your Honor. MR. COOKE: 1:17PM 12 MR. ASHMORE: No, sir. 1:17PM 13 THE COURT: Very good. 1:17PM 14 Miss Eunice, are all the jurors back? 1:17PM 15 THE DEPUTY CLERK: They all back? 1:17PM 16 THE DEPUTY: Yes. 1:17PM 17 THE DEPUTY CLERK: Yes, sir. 1:17PM THE COURT: Let's bring them in. 18 1:17PM 19 (whereupon the jury entered the courtroom.) 1:18PM Please be seated. 20 THE COURT: 1:19PM Cross-examination? 21 1:19PM 22 MR. COOKE: Thank you, Your Honor. 1:19PM 23 **CROSS-EXAMINATION** 24 BY MR. COOKE: 9:10AM 25 Good afternoon, Mr. Pace. I don't think we've met besides Q.

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waiting outside. I am Dawes Cooke, and I represent Cal Dent, Brad Johnson, and BlueWave.

- A. Good afternoon.
- **Q.** Start with a couple of things that you talked about. You said -- you talked about this incident with Mr. Sloat, that you heard that he had been indicted for something.

Where did you hear that?

- A. I heard that from Ms. Mallory.
- **Q.** And where did she get that?
- A. I'm not sure where she got that information.
- Q. You think she might have heard it directly from Brad or Cal?
- A. Possibly.
- **Q.** Okay. And what action did they take as a result of that report?
- A. It's my understanding that, after I expressed concern to Ms. Mallory, she expressed that concern to BlueWave. They terminated his relationship with him but moved his accounts to his live-in girlfriend is my understanding. And so she became their sales rep, Mr. Sloat's live-in girlfriend. That's my understanding.
- **Q.** That's what you heard?
- A. That's what I heard, yes, sir.
- Q. And what about Mr. Larry Cushing? That was the one who was the -- related to a part-time secretary and was not an

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- actual BlueWave representative; correct?
- A. That's what I was told, yes.
- **Q.** And so how was that one resolved?
- A. Again -- I think we covered this earlier -- the company sent a cease and desist letter to him, and I believe that BlueWave informed Ms. Mallory that they had terminated any relationship they had with him.
- Q. So you've been in compliance at other companies as well; right?
- A. Yes, sir.
- **Q.** And the trick of getting your employees to follow the rules is not unique to HDL or BlueWave, is it?
- A. No, it's not.
- **Q.** And you could have problems getting people to comply with your rules whether they're employees or whether they're independent contractors; right?
- A. Yes.
- **Q.** And if you have an independent contractor, you can put things in the contracts that require them to follow the rules; right?
- A. Yes, you can.
- **Q.** And you can give yourself remedies like canceling the contract or doing other things if they don't follow the rules?
- A. Yes.
- Q. Can you put a provision in there allowing you to do a

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compliance audit? Α. Yes, you can. Is that a good idea? Q. Α. Are you asking with respect to the BlueWave relationship or in general? Anybody. In general. Q. Α. If the contract covers matters that are subject to a compliance program, then it probably makes sense to put those in the contract. And HDL itself wasn't immune from having employees who didn't follow the rules; right? Α. Sure, yeah. You weren't here the other day, but did you hear the story Q. about Shane Marquess? I did not hear that story. Α. Do you know who he was? 0. I do not. Α. You don't know if he was an in-house sales rep for HDL? Q. Α. Not that I can recall. You mentioned that you were aware that BlueWave also sold for a company called Singulex. That's correct. Α. And just to recap, they were sort of a competitor -- not 0. really a competitor, but there was some concern on the board that they might become worse competitors in the future; right?

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- Yes, that's my understanding. That was raised to me by Russ Warnick. He also raised that he thought that potentially BlueWave was taking sales materials that they were using for HDL, giving those to Singulex so they could be modified for Singulex's purpose and used to compete. That's what he told me.
- Let me just ask you to make a comment on that point. Q. You would agree that it was important to HDL that their confidential information be kept confidential and not shared with competitors; right?
- Α. Yes.
- Have you ever heard of a company called Navigant? 0.
- I have.
- Q. Do you know who they are?
- I think it's a health care consulting firm or a financial Α. I don't know. That's my recollection. consulting firm. I'm not sure if that's the company you are referring to.
- How about a company called Collaborate? Q.
- Α. I don't know that company.
- would it surprise you to know that those are both companies that do compliance audits?
- If that's what they are, that's what they are. Α.
- All right. Are you aware that both of those companies did 0. compliance audits on behalf of Singulex because their contract with HDL required that they be allowed to do compliance audits?

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- Singulex contract with HDL? Α.
- Yes -- no. No, with BlueWave. Q.
- Yeah, that's what I thought. Α.

I've seen that contract. I don't recall what it specifically said.

- Have you ever seen the results of the Navigant and/or Collaborate compliance audits of BlueWave?
- I have not. Α.
- Were you present during any of the conversations or meetings that Brad or Cal or anybody associated with BlueWave had with Kathy Johnson?
- I don't believe so, no.
- Who is Kathy Johnson? 0.
- Kathy Johnson was an individual that HDL hired to be its first chief compliance officer.
- So it's possible that she had significant interaction with 0. them about their compliance program?
- It's possible. Ms. Johnson was hired by the company very Α. shortly before I left, so I didn't have much, if any, overlap with her. So I don't know what she did in the course of her employment.
- To change subjects and talk a little bit about terms that 0. have been kind of mixed around, but waiver of copays, waiver of deductibles, balance billing, and no-balance billing, do you know what those terms mean?

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- A. Generally.
- **Q.** And so can we agree, for purposes of this discussion, that waiving copay means that the provider will not try to collect any copays that a patient has? Is that fair to say?
- A. Yes.
- **Q.** And a copay would be -- if you go to your doctor, you might have to pay \$7 or \$20 or something like that before your insurance pays anything, and that's called your copay; right?
- A. Yes, your portion of the payment.
- **Q.** And a deductible might be that the insurance company doesn't start paying until you have already paid a certain amount.

That's your deductible?

- A. That's correct.
- Q. Same thing we have on our car. If I crash my car, I might have a \$200 deductible, so I got to pay the first 200?
- A. Sure.
- Q. So when you say the company waives that deductible, that means they agree they're not going to try to collect that from the patient?
- A. That's correct.
- Q. And sometimes that's referred to as no-balance billing, right, because it means that I'm not going to bill the balance of what's not paid by the insurance company to the patient?
- A. Yes.

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Q. And sometimes we slip up, and we kind of call it balance billing.

But balance billing is really the opposite; right? It means you're going to bill them?

A. Okay.

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- Q. But is it fair to say that when you were talking about waiving of copays and no-balance billing, what you were talking about was the basic business philosophy of HDL, which is that it was going to let patients have the test for whatever their insurance company would pay; right?
- A. That's correct, that they would not seek to collect payment from the patient, only the insurance company.
- Q. All right. And the Kung memo and these other discussions, they were talking about, among other things, state laws, right, or relationships with insurance companies because some insurance companies may not like the idea that you're not letting the patient have any skin in the game?
- A. That's correct.
- **Q.** But are you familiar with the copay and deductible policies for Medicare?
- A. Yes, generally.
- **Q.** And you're aware, are you not, that it would be against the law to bill -- to try to bill a Medicare patient for any portions that are not paid by Medicare?
- A. Well, I believe in this instance there aren't copays on

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the lab fees, if that's what you're referring to.

- Q. Right.
- A. Commercial insurance is different.
- Q. Right. So when we're talking about Medicare, which is a big part of why we're here -- you may not know that -- it would actually have been illegal, wouldn't it? It would have been a violation of the Medicare law for HDL to try to bill patients for what Medicare wouldn't pay?
- A. Potentially. I haven't researched that issue in this context. I don't recall it ever coming up.
- **Q.** You talked about, shortly after your arrival at HDL, that they retained a company called Saranac?
- A. I believe they were retained before I joined, but they were under an active engagement when I was there.
- **Q.** Were they retained in response to receiving the subpoena from the Justice Department?
- A. I'm not sure because both of those actions occurred before I joined, but I believe they were engaged before that subpoena.
- **Q.** Do you know who engaged them?
- A. I believe Dennis Ryan had reached out to Tom O'Neil, who was the founder of The Saranac Group.
- Q. And just generally, what is The Saranac Group?
- A. So The Saranac Group was, again, led by a gentleman, Tom O'Neil. My understanding is they would come in and give advice to senior management and boards of directors of medium to large

companies -- or small to large companies that weren't publicly 1 1:29PM 2 traded companies around board governance, how a board oversees 1:29PM operations and things and health care compliance program 3 1:29PM 4 structure. That's my understanding. 1:29PM MR. COOKE: And, Your Honor, without objection, the 5 1:29PM parties have agreed that Exhibit BW159 will come into evidence. 6 1:29PM 7 THE COURT: From the government, any objection? 1:30 P M 8 No, Your Honor. MR. LEVENTIS: 1:30 P M 9 MR. ASHMORE: No objection. 1:30 P M 10 MR. COOKE: Can we pull that up? 1:30 P M 11 Very good. Let me just state for the THE COURT: 1:30 P M record, Bluewave Exhibit 159 is admitted without objection. 12 1:30 P M 13 MR. COOKE: Thank you. Are you able to pull that up? 1:30 P M 14 BY MR. COOKE: 1:30 P M 15 Does that look like the cover page? Q. 1:30 P M 16 I'm sorry? Α. 1:30 P M 17 Can you see the screen in front of you? Q. 1:30 P M 18 Yes, I can see it. Α. 1:30 P M That looks like the cover page for the Saranac 19 0. All right. 1:30 P M 20 report? 1:30 P M 21 Α. It does. 1:30 P M 22 Let's go to the first page beyond that, the table of 0. 1:30 P M 23 contents. 1:30 P M 24 Have you studied this report? 1:30 P M 25 I don't know if I'd say I studied it. When I was employed Α. 1:30 P M

at the company, I received this and I read it. I saw it then
again in my deposition but otherwise haven't seen it since I've
left the company.

- **Q.** Okay. Well, this would be a pretty important document for somebody coming in and being concerned with compliance; right?
- A. Sure, yes.
- Q. Take a quick look at it. Don't read the whole thing while you're sitting here, but I want to make sure that you agree that this is the report.
- A. Yes, it appears to be the report.
- Q. Does the table of contents -- those two pages there, does that seem to fairly summarize the topics that they covered?
- A. I only see the one page. If you could flip to the second. Thank you.
- **Q.** Well --
- A. Yeah, it does.
- Q. Okay. So go back to the page before.

You see down there at the very bottom, "Observations and Recommendations"?

- A. Yes, I do.
- Q. "Relationship with BlueWave"?
- A. Yes.
- **Q.** Do you see that?
- A. I do.
- **Q.** Did you read that when it came in?

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- A. I did.
- **Q.** Well, why was it so important for this company to come in during its compliance review to study the relationship with BlueWave?
- A. Well, I think I touched on a lot of this earlier, but I'll repeat it. They were the front-end sales force of the company, the primary interaction with the physician, and engaged in sales practices that needed to be covered by a compliance program.
- Q. So would you go to page 17. You see it looks like the way it's set up is it has a description of what it's studied, and then there's a thing on the next page -- tell you what I'm going to do. I'm going to make your life easier. I'm going to give you --

Your Honor, may I approach?

THE COURT: You may.

MR. COOKE: I'll watch the step this time.

THE COURT: We thought about putting a yellow tape

down.

MR. COOKE: I'm not wearing my glasses today. Thank you.

BY MR. COOKE:

Q. All right. So you see how that's set up. And on page 18, it has the highlighted part up there, bolded?

Does that appear to be the recommendation that comes

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from their observations?
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                    Can I take a second to read it?
               Α.
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                    Yes.
               Q.
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                                             (Pause.)
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                          MR. COOKE:
                                     While he's doing that, can we go ahead
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               and bring the highlighted part -- the bolded part, can we bring
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               that up.
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                          THE WITNESS: Okay. I've read it.
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               BY MR. COOKE:
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                    And so does that bolded part -- bolded and italics, does
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               that appear to be the recommendations that The Saranac Group
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               had with regard to the relationship with BlueWave?
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                    I don't know if I'd call it recommendations.
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               be a general summary of how a company should view a contracted
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               sales force. I don't know if -- it doesn't mention, I believe,
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               BlueWave in there, but --
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                    well, it's in the section on the relationship with
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                    -- so I'm drawing an inference there.
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                    Yes, although I -- again, I don't see recommended actions
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               in here, but --
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                    Well --
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               Q.
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                    -- draw the inference.
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- **Q.** I've got a little advantage on you in that I read it last night.
- A. Okay.
- **Q.** There's some appendixes at the end that have recommendations.
- A. Okay.
- Q. And if you go there -- and I'll let you do it if you want to, but I'm going to tell you that the recommendation is basically what's here in bold.
- A. Okay. Could you refer me to that page.
- **Q.** You know, I don't think they numbered those pages quite right, but look at the table of contents and you can find your way there.

Mr. Pace, while you're looking at it, what I just want you to do is I want you to satisfy yourself that there's nothing in there that says get rid of BlueWave, get rid of process and handling fees, stop paying copays and deductibles -- stop waiving copays and deductibles.

- A. I'll take your word for that. It's not in the section I read.
- Q. All right. So you agree with me that, at least in what we've shown here where they talk about the relationship with BlueWave, they're not saying BlueWave is bad guys and let's get rid of them?
- A. That's correct. I don't know if The Saranac Group had

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much interaction with BlueWave. I think this relates to the contract they reviewed.

- Q. All right.
- A. Okay.
- **Q.** And they would have been aware certainly of the requirement -- if they read the contract, they would know that process and handling fees were part of the agreement; right?
- A. It's set forth in the agreement, yes.
- Q. So could we -- is it fair for us to conclude that at least as of -- what was the date of that? -- April 30, 2013, that the outside consultants for HDL were not recommending that they give up process and handling fees. They weren't saying the process and handling fees were illegal, and they weren't saying that the contract -- the relationship with Bluewave was illegal?
- A. Not to quibble with words, you said the outside consultants. The Saranac Group did not say that in this report. I don't know about broadly other consultants.
- Q. Right. And we'll talk about Ropes & Gray and other folks in a few minutes.
- A. Sure.
- **Q.** And you testified earlier about Ropes & Gray and that, as of the time you came aboard, the subpoena had already been served; is that right?
- A. Yes, sir.

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Q. So let's make no mistake. We all agree that, once you've been served with a subpoena from the Justice Department, if you're smart, your antennas go up, right, that something is going on?

- A. I would agree with it.
- **Q.** They don't do it just so that they can come in and congratulate you on your excellent practices; they're investigating something; right?
- A. That's my experience.
- **Q.** Okay. And so everybody would be on edge at this point, right, wanting to make sure that everything is being done right?
- A. I would hope so.
- **Q.** Okay. And so they hired Ropes & Gray.

And Ropes & Gray, you would agree, was a very large law firm that has a very large and good health care law section?

- A. Yes, I agree with that.
- **Q.** People that you would trust; right?

In fact, I think you said that a little while ago; you said you would take their word over other law firms?

- A. Yeah, I trust their word, yes.
- Q. Well, tell me something about them.

How many lawyers do they have?

A. I don't know. In the several hundreds.

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- **Q.** Where do they have offices?
- A. This particular office, the people were in Boston and in Chicago. I know they have offices elsewhere. I don't have committed to memory where Ropes & Gray has offices.
- **Q.** And they have lawyers who have worked for the Justice Department and maybe other departments of government, have been in the health care field.

And for some of those lawyers, that's all they do; right?

- A. I believe so, yes.
- Q. Work on health care.

You began interacting with them, I guess, right from the time you came to work?

A. Pretty much so.

MR. COOKE: I'm going to look at -- there's another exhibit, Your Honor, that we've agreed to put in. It's BW464-10.

THE COURT: 464-10?

MR. COOKE: Yes, Your Honor.

THE COURT: Any objection?

MR. LEVENTIS: No, Your Honor.

MR. ASHMORE: No, sir.

THE COURT: Very good. And that's a BlueWave

exhibit, or is that a --

MR. COOKE: That's a BlueWave, yes.

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BlueWave 464-10 is admitted without THE COURT: objection.

MR. COOKE: Yes. Go ahead and put that up.

BY MR. COOKE:

Can you take a moment to look at that. This is dated May 16, 2013. And when you're finished reading it, I'm going to call your attention to the last paragraph.

John, can you go ahead and pull out that last paragraph?

- Okay. I've read it. Α.
- would you do me a favor and read that last paragraph out 0. loud? Because I'm not sure how clear it is on the monitor.
- The entire paragraph?
- Yes, please. And don't go too fast. We all tend to read Q. a little faster than we talk.
- I know. I've been warned by her already. Α.
- She's watching you. 0.
- I'll try to go slow. Α.

"You know I am a firm believer that we have to push forward with these changes and arm Ropes with a legitimate project plan and a date certain as to when P&H will be completely phased out so that they can deal with the DOJ."

That's Department of Justice.

"I also think that P&H will soon be gone for the industry, so we can create a real advantage in both dealing

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with the DOJ and being prepared to serve the market if we start moving away now. The first stage of the project plan would cover" -- excuse me. Let me start that over. "The first stage of the project plan could be Colorado with phlebotomists and Florida, Texas, and North Carolina service centers. know what you think." was this considered part of your Project Twilight? Q. I believe it -- oh, yeah, actually, subject matter,

- "Twilight test market."
- where did the term "twilight" come from? Q.
- That's a term I made up. So on transactions I've worked at -- or worked on in the past, if you don't want them to become public or people know what it relates to, if you wanted to keep it confidential, you give it a name. I chose Twilight.

It seems like a bad joke now but the "Twilight" movies were out with vampires, sucking blood. So Twilight. That's where the name came from.

- So it didn't mean "sunset"; it just meant Q. okay. "twilight"?
- It mean "Twilight" the movies.
- All right. But the idea was to phase out P&H. Is that essentially right?
- Yes, sir. As I stated earlier today, there was a plan to Α. phase that out. And Project Twilight was the plan to do that.
- And that was anticipating -- I also think that P&H will Q.

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soon be gone for the industry.

And does that mean that you think that it will be gone from the industry because the DOJ, Department of Justice, is going to tell them -- tell everybody to stop using P&H fees?

Generally. I thought that would either occur that way or there would be enforcement actions against companies by the DOJ that would get companies to stop doing it.

You're a lawyer? 0.

Yes, sir.

Generally speaking, when there are laws, there are places Q. you can go to look up what the law is; right?

Generally. Α.

In the old days, we used to go pull a book out of 0. Okay. the bookshelf.

Now you can do it pretty much from your cell phone and certainly from your desktop; right?

Yes. Α.

But it looks like what you guys were doing here was -- was prognosticating what the executive branch of the government was going to do about enforcing the laws, is that right, and how they were going to interpret laws?

I don't know if I'd characterize it that way. So I don't Α. know if I can agree with that statement.

well, let me give you kind of a wacky --Q.

I'm not trying to be difficult. I just -- I don't recall Α.

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prognosticating was what the government was doing.

- Q. That's all right. You can be difficult if you want to.
- A. It's not in my nature.
- Q. Let me give you a weird example just to try to illustrate the point.
- A. Okay.
- Q. Suppose when you came to HDL, instead of learning that they were, you know, using a contractor and that they waived copays and deductibles and they were paying process and handling fees, you learned, instead of that, they were selling stolen cars out of the back of the building. All right?

Now, you would know right where to go to look up whether it's legal to sell stolen cars; right?

- A. I would call a criminal defense attorney to look that up, but yes.
- **Q.** All right. And so you wouldn't be talking about phasing out the practice of selling stolen cars out of the back of the building, would you?
- **A.** Probably not.
- **Q.** Or moving away from selling stolen cars?
- A. Correct.
- **Q.** All right. You'd be talking about stopping this yesterday and who do we need to report to the police?
- A. Most likely, yes.
- Q. But that's not what you or Ropes & Gray were saying about

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process and handling fees. You were talking about phasing it out, moving away from it, coming up with alternatives, arming Ropes & Gray with a legitimate project plan and date certain as to when P&H will be completely phased out; right?

- A. That's what the email says, yes.
- **Q.** All right. Now, if you plugged in selling stolen cars for P&H, that would be a pretty silly statement for a lawyer to make, wouldn't it?
- A. It would.
- **Q.** Okay. And Ropes & Gray is certainly a good enough law firm that they wouldn't be talking about moving away from selling stolen cars?
- A. Yeah, I don't think so.
- Q. All right. I think I've beaten that analogy to death.
- A. Yeah, I think so too.
- Q. We have another exhibit, 464-15.

MR. COOKE: I think there's no objection to that.

THE COURT: Any objection?

MR. LEVENTIS: No. Your Honor.

MR. ASHMORE: No, sir.

THE COURT: Very good. BlueWave 464-15 is admitted without objection.

BY MR. COOKE:

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Q. Take a moment and read that, if you would. That's your memo dated May 21, 2013.

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And who are you writing to?

- A. It looks like it's to Steve Carroll, who was the chief financial officer of the company, and Anna McKean, who was another executive at HDL.
- **Q.** And who are they -- I'm sorry. And what was their function and why were you writing to them about this?
- A. So Steve Carroll's function was chief financial officer, so control of the financial department. So he would have had, as it relates to this email, information on sales and where those were occurring, presumably.

Anna McKean, I'm not real sure what her exact title was, but she essentially led the group that tried to sell HDL services to companies for use with their employees. So she and her team often had a lot of data at the company regarding sales and whether those were occurring.

Q. So your memo starts out, "Steve or Anna, do either of you have someone on your team that could assist with some financial strategic analysis related to this project? I'm looking for someone who could assess a particular geographic market and determine the possible business opportunities to HDL if we provide a blood draw solution versus P&H. In other words, what is the percentage of physicians in the market that will not refer to HDL because of the blood draw burden, and what amount of those physicians could we capture, including estimated sales volume/revenue, if we had local PSCs, contracted sites, i.e,

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minute clinic, or in-office phlebotomists? We would like to do this analysis for a handful of large markets. By copy to Tonya, would BlueWave have a sense of this?"

So is it fair to say that what you were doing here was trying to figure out a way to replace P&H with another way of getting the blood specimens delivered to HDL?

- A. Yes. As I stated earlier today, we were advised to stop the practice of process and handling. I was asked to lead a project, which became known as Project Twilight, to replace process and handling. And these were the ways in which we thought we could try to do that.
- **Q.** And did you agree that it would have been a bad practice to just stop it cold turkey without offering an alternative way of getting the specimens?
- A. Could you repeat that, please?
- **Q.** Did you agree that it would be a bad idea to just drop it -- I said "cold turkey," but I meant immediately -- without providing some alternative way of getting the blood specimens to HDL?
- A. Without either providing these ways to do it or instructing the physician that they were to draw and send it, there had to be some way to get the blood to the lab.
- Q. So you're anticipating here that there could be some percentage of physicians in the market who will not refer to HDL because of the blood draw burden.

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Does that mean your recognition that there are going to be a certain number of physicians who aren't going to be willing to burden their staff without being reimbursed for it, that they're going to want some way for you to fulfill your responsibility of getting your blood to your laboratory? So I guess two things in that statement that you just made.

Not getting reimbursed for it, these physicians were being reimbursed for the office visit of that patient. were being paid either by the commercial insurer or the federal or state government, as long as it was Medicare or Medicaid, an office visit fee that would have covered the services or was intended to cover the services of drawing blood. getting reimbursed for that visit from the insurer was one.

Two, you made reference that was I anticipating a percentage would drop? If you recall from my earlier testimony, Ms. Mallory had made statements to that effect on a couple of occasions, estimating 50 to 70 percent. seeking to see if that was true. I didn't have anything to base that on.

- On your first point --
- Α. Yes.
- -- you saw the process and handling fee agreements that were in place; right?
- I didn't see every one of them, though I'm sure I saw a Α.

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form of them.

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- Q. On the ones that you saw, Mr. Pace, did they or did they not, each and every one of them, have a provision that said a physician could not both collect P&H fees and be reimbursed by any other source?
- A. I'd have to see the agreement. I don't recall that. Honestly, I don't. If you want to get me the agreement.
- Q. All right. Let me try to ask it in a more fair way --
- A. Okay.
- Q. -- because you said you didn't see them all.

Do you remember that provision being in one or more of the P&H agreements that you --

- A. Sitting here today, I can't recall. I'll take your word for it.
- Q. All right. Well, you don't need to take my word for it, but wouldn't that be a pretty important safeguard for HDL to have, to put in there and say, Doctor, you can't double dip; right?
- A. Yes, it would be an important safeguard. I don't know how much HDL ever followed up to check if a doctor was double dipping, because I think their practice was generally to pay P&H on almost every blood draw, so -- but I agree, it would be an important provision.
- Q. Well, that takes me to a great point.
- A. Yeah.

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- **Q.** And I didn't mean to drag you to this. You're not holding yourself out as a coding expert, are you?
- A. Not at all.
- **Q.** All right. But you know this much, don't you? You know that nobody from HDL or from BlueWave is in the doctor's office when his staff is filling out his reimbursement request for insurance or --
- A. Yeah, I don't know that.
- Q. There's no way you could know that, is there? I mean, there's no -- is there any way --
- A. There's no way you can monitor every physician, every action, if that's what you're getting at.
- Q. Can you monitor any physician with any action? You're sitting in Richmond, Virginia. Is there any possible way that you can have -- I mean, is there some software or some way that you can go in and check on any of those physician practices to know whether they're asking for reimbursement from another source?
- A. I don't think HDL would have had that capability, no.
- Q. Right. And so the smart thing to do would be to put a provision in your contract saying, Mr. Doctor, if you're going to ask us for P&H fees, you can't get reimbursed anywhere else, and that's up to you to figure out how to not get reimbursed from somewhere else.

That would be fair?

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- A. That's fair.
- Q. But, anyway, back to your thing here.
- A. Okay.
- Q. You were trying to make some provision here so that something could pick up the slack. If you could no longer pay P&H fees to get the doctors to burden their staff to package your specimens and process your specimens and send them to you and that they're going to have to do something else, you wanted to figure out a way that you could take advantage of that from a market standpoint?
- A. Again, I don't know about take advantage of. I'm sorry to be quibbling with your words, but we were trying to replace processing and handling with other means. And that's what -- this was gathering data as part of Project Twilight.
- **Q.** Were you sharing Project Twilight with Cal Dent or Brad Johnson?
- A. No, I did not share that with them.
- Q. What interaction did you have with them at all up until that meeting in June?
- A. Very limited interaction. I believe I met them once in maybe April in the HDL offices. He believe I had one or two emails with them. But other than that, very limited interaction with your clients.
- **Q.** And very limited or no interaction with them after that meeting; correct?

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- That's fair to say, yeah. That's fair to say, yes. Α.
- Okay. You were shown -- or shown a physician criterion Q. document on direct examination. Do you remember seeing that?
- Α. I do.
- And I tried to listen to when you said you first saw that, but it's probable that you never saw that until this litigation was going; right?
- I don't know if that's probable or not. I seem to recall Α. seeing that. I don't know the exact date. I'm sorry.
- Are you willing to state under oath that you saw it while Q. you were still employed at HDL?
- I believe I did, and I'm under oath.
- All right. Well, that's as close as you can come? believe you did?
- Yes. Look, sir, it was over five years ago. Α. thousands of documents there. Okay? I'm testifying to the best of my ability and memory.
- Okay. The June meeting, what day was that? Q.
- Again, five years ago, I'm not sure of the exact date.
- Late June of 2013?
- Yeah. Α. Sure.
- Ropes & Gray was engaged. They were starting to comply Q. with the subpoena. They were interacting with the Justice Department and so forth. I believe we've covered all of that; right?

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- A. Yeah, that's accurate.
- **Q.** And so you had this meeting. Some people refer to this as "the summit conference." Have you ever heard it referred to as that?
- A. I don't recall that.
- Q. Okay. And was this the first time that you had ever heard the topic of moving away from process and handling fees mentioned in the presence of Cal Dent and Brad Johnson or their lawyers?
- A. Yes. I had only -- again, I had only interacted with them one time before. Ropes & Gray wasn't present at that meeting.

 And I had no interaction with their counsel other than at that meeting.
- Q. So Brad and Cal showed up at this meeting, and their lawyers were there, your lawyers are there, a lot of people were there. And so is it your understanding that they are hearing on that day for the first time that you're going to phase out processing and handling fees?
- A. I don't know if that was the first time they heard it. It had been my understanding that Ropes & Gray was in dialogue with their attorneys at the time and would have mentioned it to their attorneys. Whether or not their attorneys mentioned it to them, I don't know.
- **Q.** Okay. Well, did they seem surprised to hear that statement being made?

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- I don't recall if they were surprised or not. They were upset about it, so maybe that was their reaction.
- Did you share with them that day the details of Q. Okay. Project Twilight and how you were going to set up this string of draw centers across the country or provide a fleet of phlebotomists to go to physicians' offices to --
- I don't recall sharing that with them, no. Α.
- You didn't, did you? 0.
- No.
- You said that Bluewave was the face of HDL with regard to physicians; right?
- That's how I interpreted it, yes.
- Okay. And that's actually pretty accurate, isn't it, that they were the ones who would walk into a doctor's office? And they would sit down with them and they would try to persuade him that these tests would help his patients -- help him save his patients' lives. They were the ones that were doing that for HDL, weren't they?
- They were the ones interacting with the physicians, yes.
- And then they were the ones, up to that point at least, who would -- at some point in the conversation, if the physician was interested in doing these tests, they were going to pull out a laboratory service agreement; right?
- I believe so. Α.
- And they were going to give it to the doctor. And the Q.

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doctor was supposed to read it. And if he agreed with it, he would sign it and send it to HDL?

A. I think that -- that's the way it worked.

MR. LEVENTIS: May I just object?

THE WITNESS: I don't have any knowledge --

MR. LEVENTIS: There's no foundation for him to have knowledge of what their sales reps were --

THE COURT: Well, I believe he just answered.

THE WITNESS: Yeah, I don't have knowledge of what they were doing with respect to the doctor. I wasn't present.

BY MR. COOKE:

- **Q.** In any event, what would come out of that was that the physician and HDL would enter into a laboratory services agreement signed by both parties; right?
- A. I believe so.
- Q. I mean, you wouldn't process their tests for them without having that agreement in hand?
- A. I think that was the general program. I don't know if it was followed a hundred percent of the time or not.
- Q. So that agreement was a set of promises that the two parties would make to each other? That's what a contract is, isn't it?
- A. Generally, yes.
- Q. So would it be fair to say that, up to that point, Brad and Cal and the contractors that work for them had gone into

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doctors offices all over the country, thousands of them, and had promised to them on behalf of HDL that you would pay for the service that that doctor rendered for you by taking care of your blood specimens and processing and handling those and sending them to you, that they would reimburse them for part of their cost of doing that? That was a promise that HDL had made to each and every one of those doctors; right?

- A. If that's what you say, if that's what was in those contracts, yes.
- Q. And so do you think it would have been fair for Brad and Cal, having been the face of HDL and having made those promises to those doctors, that they might be a little upset at the idea that they were going to be told to go out and say "We're reneging on that agreement and we have no other plan in place for you"? That could be pretty upsetting, couldn't it?

 A. Potentially.

Can I add to that answer?

That's why I told Ms. Mallory early in the process to get these guys involved and come up and help with a plan.

So --

- Q. Well, is it just possible that they were only hearing part of that plan; that is, the part about let's get rid of P&H fees? That they were only hearing part of that plan at that meeting?
- A. Yeah, I don't know.

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- **Q.** And, after that meeting, you expressed your frustration with Tonya?
- A. I did.

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Q. And she reassured you, "This is Brad and Cal. Let me tell you a little bit about the care and feeding of Brad and Cal, that they're going to push back, but eventually they're going to come around."

Isn't that what she told you?

- A. I think that's what her email said.
- MR. COOKE: Could we have 1171? Let's go down a little bit. I'm looking for Tonya's 401.

Okay. Let's go down to the one below that, just so we can lead up to that.

BY MR. COOKE:

- **Q.** I believe this is what you were looking at on your direct examination. Do you remember seeing these emails?
- A. I do.
- Q. And you are sort of --
- A. Thank you.
- Q. Do you remember that? That's June 28th, which, if you read the whole context, it refers to Monday's meeting. And so it's Friday. So you're sending this, it looks like, if you're reading it in context, the Friday after the Monday meeting?
- A. Yes.
- Q. And you read this earlier about unloading some of your

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"I would think the board needs to discuss, unless it
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              thoughts.
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              has already, a debrief from Monday's meeting."
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              "Nick, thanks. Let's discuss on Monday. I now understand some
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              of your body language this week."
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                         I guess you were expressing your frustrations
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              somehow?
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                         That's BlueWave; right?
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                   I think so.
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                   "And it is something we have to continually think about.
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              Concerning Project Twilight and, frankly, all initiatives that
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              we come up with, are never well received by BW at first."
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                         "At first." You read that part; right?
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              Α.
                   Okay. "It takes a lot of thick skin to deal with them
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              sometimes.
                          I guess I have gotten used to their posturing.
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absolutely make it clear that they are not running this company. I listen to them, but that either makes me know what I am thinking is right or that there is something else I need to know or think about. They can express an opinion, but they do not get to make HDL's decisions. And the day we let them, then they will have us over a barrel. The CMEs are one example."

What was CME?

- A. I believe she was referring to continuing medical education.
- **Q.** Okay.

"The CMEs are one example. We move forward with our initiatives, understanding they always do not have to be completely in line with BW, and they tend to see things our way. They absolutely thought the CMEs were a waste of time and money and didn't want to be involved in it, especially Cal.

And now they think these are hugely valuable and are always at the table asking to discuss the next locations. They did the same with the trade shows. I am confident these centers are the right way to go and that we will have to do away with P&H. When that happens, they will be glad we didn't listen to them but will be sure to never say so. I don't think they have us over a barrel at all, quite the opposite. They cannot make what they make anywhere else. There is no other lab that can run like we run.

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"My opinion is that we should continue the project as we have discussed. I thought we left it off that we were planning to test in Virginia."

That's Virginia; right?

- A. I believe so.
- Q. "You were selecting the locations from the crazy number that Paul and Casey suggested, and we would watch it for eight weeks or so to see if we lose business. One thing that we should measure closely is the number of patients referred to the lab for a draw and the number that actually show up to get the draw. That was Cal's point."

Let me stop there for a second.

The point that Cal made, do you remember him saying that at the meeting, that -- or at some point, that there's a problem --

MR. LEVENTIS: Your Honor, I guess, let's see -- I
don't know what his testimony was exactly --

THE COURT: I think he's -- go ahead and finish your question, Mr. Cooke, and then I'll --

BY MR. COOKE:

Q. Well, the question was, do you recall Cal saying something to the effect that there was going to be some leakage or some loss, that if a patient has to leave a physician's office to go somewhere else to have the blood draw, that a certain number of them are not ever going to make it? Do you remember that?

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- I don't recall him saying that. He may have. Α.
- well, how did you interpret that statement then? Q.
- I interpreted this email exactly like you just said. Α.
- Q. Okay. "We will need to be very proactive about getting to the patients if they don't come to us. Once we can look at some of your intel from this, then we should roll them out to multiple states with the needed adjustments at the same time, as we have already discussed. This is what I will say to everyone at the BOD" -- I guess that's board of directors --"meeting."
- Α. Yes.
- So did you take that information and say, okay, maybe Tonya knows these guys better than I do, and maybe she knows that, given time, they'll come around to this idea just like they have the other ideas that they didn't like?
- She clearly knows them better than I do. She's had a relationship with them and can read them. I did not put a lot of stock in what she was saying with respect to the time frame to do this.

Again, the company was under a federal subpoena. had been told by Ropes & Gray to move away from it. We needed a date certain. I was trying to move with all due speed to get this done. And it's middle of June now, and we haven't done much, if anything, on it.

So I get your point, yes, she knows those guys much

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better than I do.

Q. And did you pick up the phone and call Brad or Cal and say, "Brad, Cal, we got off on the wrong foot, but, you know, we got some really important stuff going on here. Let me explain Project Twilight to you"?

A. I did not. Tonya had the relationship with them; I did not.

Q. Well, did you -- after this date, did you ask Tonya to explain that to them?

A. I can't recall if I did or not.

Q. Did you shoot off an email thinking, oh, you know, maybe these guys didn't know about Project Twilight. Maybe I can explain it to them, and they'll see that we're not going to be breaking our promises to the doctors. We're not going to be leaving the patients in the lurch. It's going to be okay. We're going to find another way to get these blood samples. Did you have a memo like that?

A. I did not. And I wouldn't have said "leave patients in the lurch or break promises to doctors." That's -- but I never typed an email like that. I didn't think it was appropriate or necessary for me to engage with them; the CEO was.

Q. And I didn't mean you to quote me exactly, but that whole idea of Project Twilight was to come up with an alternative to process and handling fees?

A. It was.

2:08PM	1	Q. So did you ever explain that to Brad and Cal?							
2:08PM	2	A. No.							
2:08PM	3	MR. COOKE: Just a moment.							
2:08PM	4	(Pause.)							
2:08PM	5	MR. COOKE: Thank you. That's all I have.							
2:08PM	6	THE COURT: Cross-examination, Mr. Ashmore?							
2:08PM	7	MR. ASHMORE: Thank you, Your Honor.							
2:08PM	8	CROSS-EXAMINATION							
2:08PM	9	BY MR. ASHMORE:							
2:08PM	10	Q. Mr. Pace, I'm Beattie Ashmore. I represent Tonya Mallory.							
2:08PM	11	How are you?							
2:08PM	12	A. I'm well. How are you?							
2:08PM	13	Q. I'm good. Who owned HDL?							
2:08PM	14	A. It was owned by a group of individuals.							
2:08PM	15	Q. And who were those individuals?							
2:08PM	16	A. Ms. Mallory, Mr. McConnell it might have been							
2:08PM	17	Dr. McConnell I can't remember but Joe McConnell, Russ							
2:08PM	18	Warnick, and then a gentleman named Tipton Golias.							
2:08PM	19	Q. And Mr. Golias was the investor; is that correct?							
2:09PM	20	A. He was.							
2:09PM	21	Q. And who was on the board of directors?							
2:09PM	22	A. I believe, at least during my tenure there at the company,							
2:09PM	23	it was Tonya, Joe, and Russ.							
2:09PM	24	Q. And who controls a corporation?							
2:09PM	25	A. What do you mean by "who controls it"?							

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- **Q.** The board of directors controls a corporation, doesn't it?
- **A.** A board of directors, yeah, has oversight over the entire corporation.
- Q. They make all the decisions?
- A. I don't think they make all the decisions. Typically, boards aren't engaged in active management of the company; the executives are.
- Q. And the ultimate decisions that are made at HDL always, at the end of the day, had to be the board of directors -- Russ and Joe and Tonya.
- A. I don't agree with that statement.
- Q. Okay. How did HDL function? Who ran HDL?
- A. Well, generally Tonya, as the CEO, made most of the material decisions with respect to the company. There were some things put either before the board or to the shareholders to vote on. But day to day, things it was doing, it was generally driven by Tonya.
- **Q.** In one of the emails Mr. Cooke went over with you, you pointed out some major issues that had to be addressed by the board, didn't you?
- A. Yes, sir.
- Q. Okay. Not by Tonya, but by the board; correct?
- A. I agree.
- Q. Yeah. And so how did the board -- you interacted with the board during your six months on an occasional basis or --

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describe that for us.

- A. Yes, so I guess I interacted with them more than on an occasional basis because the board members were also three executives at the company. It wasn't an outside board of directors. And so on a weekly, if not more frequent basis, I would have some interaction with them in the ordinary course of business. And then I would have attended a couple of board meetings during that time.
- **Q.** And how did the board operate in terms of a decision-making process?
- A. Do you mean at the meetings or in general? It's a hard question to answer.
- Q. Let me try this. The board, Mr. Pace, didn't do anything unless they all agreed on a particular issue; correct?
- A. Matters presented to the board that were voted on, my recollection is, were generally voted on unanimously. So if there was something to put before the board for a vote, the three tended to vote together.
- Q. So they had individual votes?
- A. Yeah. On a board of directors, each director can approve or not approve a particular item that's put before them.
- Q. So could two people outvote one person?
- A. They could.
- Q. So Russ and Joe could outvote Tonya?
- A. They could.

And so Russ and Joe could have voted at any particular 1 Q. 2:11PM 2 moment to end the payment of P&H fees? 2:11PM 3 Α. Sure. 2:12PM 4 Q. Did they ever do that? 2:12PM 5 Not while I was at the company. Α. 2:12PM Do you know if they ever, ever did that? 6 Q. 2:12PM 7 I don't know. I didn't follow the company after I left. Α. 2:12PM 8 Q. And you were there six months? 2:12PM 9 Approximately, yes. 2:12PM There were 800 employees? 10 Q. 2:12PM 11 That seems like a lot. I want to say it was more 650 and Α. 2:12PM growing, but that's close. 12 2:12PM 13 30 -- I'm sorry. You finished? Q. 2:12PM 14 Α. Yes. 2:12PM 15 Q. 30 managers? 2:12PM I don't recall. 16 Α. 2:12PM 17 But your -- your line of communication went straight to Q. 2:12PM 18 Tonya; right? 2:12PM 19 Α. I reported to Tonya, yes. 2:12PM Sure. And so I mean what did Joe McConnell do at HDL? 20 2:12PM 21 He essentially, my understanding is, helped, you know, run 2:12PM 22 the labs. I believe the lab directors reported to him. 2:12PM 23 had some say in the testing that was being developed. 2:12PM 24 And so normally and naturally, you wouldn't have many Q. 2:12PM

reasons to communicate on a daily basis with Joe McConnell?

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- A. That's fair to say.
- Q. Okay. Likewise, Russ Warnick, what did he do?
- A. So I believe his title was chief scientific officer.
- Again, I think Russ typically was looking at new tests,
- potential new arrangements with other companies. And I had
- more interaction with Russ than I did Joe probably.
- **Q.** When you agreed to work for HDL, you were aware of the subpoena from Department of Justice; is that correct?
- A. I was.
- **Q.** And you were aware that HDL paid P&H fees at the time you accepted your employment?
- A. Yes, sir.
- Q. And waived copays and deductibles?
- A. Yeah, I think that was on their website.
- **Q.** And so you entered your relationship with HDL knowing all of that was going on; correct?
- A. Yes.
- **Q.** And you had high hopes; right?
- A. In what regard?
- Q. Well, you had high hopes -- well, you tell me. I believe you testified earlier, when you took the employment with HDL, that you had high hopes.
- A. Okay. If that's what I said. I'm sure I was referring to the fact that, again, prominent company, executive position in the state of Richmond where I lived in, in health care, the

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industry I had been working in for the prior seven years. was excited about the opportunity. And I believe we've established Ropes & Gray is a premier We've beat that one to death. Beat it to death. But I have to mention Laura Hoey and Brien O'Connor,

some of the best of the best?

- And you trust their judgment?
- Now, there's a word that we kept hearing today, and that is "move away"; right?
- And that was Ropes & Gray's advice to HDL concerning P&H fees: Move away from P&H fees; correct?
- Now, there's a significant difference between saying "move away," which implies over a period of time, and "stop right
- Potentially, yeah.
- Sure. And they didn't ever say "stop right now" because Q. P&H fees are illegal," did they?
- I never heard them use the word "illegal." I think what I Α. said previously, they said the practice needed to stop.

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was a business discussion there was a fear we'd lose volume. They recognized that, I guess, and said, "Then get us a credibility plan, one that will stop at a certain date, and start to do it, but you need to do it."

Q. And, again, I'm going last -- and I am not trying to beat a dead horse here.

But HDL was moving away through your Project Twilight; correct?

- A. Not -- not at the speed I thought was necessary, frankly, but yes.
- Q. I concede that.

But that was the plan?

- A. I was asked to put together a project plan to move away from it. That's what I'd done, yes.
- Q. And part of your disagreement with Tonya Mallory was that she wanted a Cadillac with these draw sites with yoga and cooking and you wanted something much more spartan, I take it?

Yes. You know, my view was the company was incurring a

- ton of risk continuing the practice here under subpoena and advice to stop the practice, so we needed to move very fast. What she was proposing would have slowed that down substantially, and I just -- I didn't understand why there wasn't a sense of urgency.
- Q. And although we may disagree on her level of enthusiasm or whether it was moving fast enough, she was part of that

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business plan of moving away from P&H fees?

- A. Yes, I think she was invited to the meetings. And her being my boss, I would have sent her the plan and kept her in the loop on that for sure.
- **Q.** You mentioned earlier in one of your previous positions at another company a corporate integrity agreement?
- A. Yes, sir.
- Q. Can you tell the members of the jury what that is.
- A. It's essentially an agreement that a company enters into with the office of inspector general, Department of Health and Human Services in this case, typically as a result of a judgment or a settlement for violation of health care laws that requires a company to put in place a compliance program. It generally spells out the program, what it needs to include, and then provides reporting from that company to the government. And it's usually focused on the activities that gave rise to the settlement or judgment.
- **Q.** And so that's when a company works with OIG, office of inspector general, together; is that correct?
- A. That's correct.
- Q. To address issues that needs to be addressed that OIG objects to; correct?
- **A.** Generally.
- Q. And so was that part of -- to the best of your knowledge, part of Ropes & Gray's initiative?

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To -- I'm sorry.
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              of Justice, what were they trying to accomplish?
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                   So I think, at least at the time period I was with the
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              company, their discussions with the Department of Justice were
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              in response to the subpoena. I don't recall that they were
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              ever discussing a corporate integrity agreement when I was
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                       I don't know what happened after I left.
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              there.
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                         MR. ASHMORE: That's all I have, Your Honor.
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                         THE COURT: Thank you.
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                              Government?
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                                        No redirect, Your Honor.
                                                                    Thank you.
                         MR. LEVENTIS:
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                         THE COURT: You may step down.
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                         THE WITNESS:
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                                      (Witness excused.)
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                                     Call your next witness.
                         THE COURT:
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                                        The government calls Dr. Jeffrey
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                                           (Pause.)
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                                         I saw him outside, Your Honor.
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              he's there.
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                         THE DEPUTY CLERK: Please place your left hand on the
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              Bible and raise your right. State your full name for the
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(Witness sworn.)

THE DEPUTY CLERK: Thank you. You may be seated.

THE WITNESS: Thank you.

THE DEPUTY CLERK: Uh-huh. Watch, there's a step up.

THE WITNESS: Oh, okay. Thank you.

MR. KASS: Your Honor, just to speed things along,

may I hand Dr. Trost some exhibits for him to use?

THE COURT: Absolutely.

MR. KASS: Thank you very much. Thank you.

THE WITNESS: Thank you.

JEFFREY C. TROST,

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

DIRECT EXAMINATION

BY MR. KASS:

Q. Good afternoon, Dr. Trost. We've met before, but my name is Michael Kass. I represent the United States, and I'd like to ask you some questions. We'll try to move this along as quickly as we can.

would you please state your name for the record.

- A. My name is Jeff Trost.
- **Q.** And where are you employed?
- A. I'm employed with Johns Hopkins Medicine and the affiliated hospitals with Johns Hopkins Medicine.
- **Q.** What positions do you hold there?

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- A. I am currently an assistant professor of medicine there and also the director of the cardiac catheterization lab at Johns Hopkins Bayview Medical Center.
- **Q.** Would you please summarize your educational background.
- A. Briefly, I did my undergraduate degree at Princeton, graduated in 1992. Went to medical school at the University of Pennsylvania, graduated in 1996.

For the next three years, I was a resident in internal medicine at the University of Texas Southwestern in Dallas, Texas, and then spent a year as chief resident for the same medical school supervising the residency program.

After that, I spent a year on faculty as an assistant professor of medicine at the University of Texas Southwestern in internal medicine seeing patients and teaching. And then for the next three years, I stayed in Dallas at the University of Texas Southwestern doing a general cardiology fellowship.

My final year of training was up in Rhode Island at -- in a hospital -- a hospital affiliated with Brown University as an interventional cardiology fellow.

- Q. What is interventional cardiology?
- A. Interventional cardiology refers to a specialty within cardiology in which doctors are trained how to take pictures of arteries and how to open up arteries with what's called angioplasty or stenting.
- Q. And what is stenting?

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- A. Stenting refers to basically an instrument. Basically, it's like a Pringles can that's cut on both ends with slots that serves as a scaffold for heart arteries to keep the blockages from coming back.
- **Q.** Would you please briefly summarize your professional background after completing your fellowship in interventional cardiology.
- A. Sure. So I joined Johns Hopkins in 2005. I was appointed instructor of medicine, which is the lowest rank in academics. Just like the military, there are ranks and you're promoted based on your accomplishments. Spent two years as instructor and then was promoted to assistant professor of medicine, which is the rank that I currently hold.
- Q. And what are your responsibilities at Johns Hopkins?
- A. So everybody at Johns Hopkins has three responsibilities. There's something called the tripartite mission at Johns Hopkins, which involves taking care of patients first, clinical care, teaching, and research.
- **Q.** Do you -- would you tell us a little bit about your teaching responsibilities at Johns Hopkins School of Medicine?
- A. Sure. Very briefly, I teach all levels of trainees at the medical school all the way from second-year medical students all the way up to fellows, which is the last kind of level of training in medicine in cardiology.
- Q. And generally speaking, at a high level, what subjects do

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you teach?

- A. Generally speaking, at a high level, I teach all aspects of cardiovascular medicine. I work in the cardiac catheterization lab teaching fellows how to perform the procedure and how to perform the stenting. I also teach medical students with relation to heart attacks and basically all aspects of treatment and management of heart attacks.
- Q. You referred earlier, I believe, to research.
 Do you perform medical research?
- A. I do.
- Q. In what areas?
- A. I -- my primary area of interest is in the appropriateness of heart testing, of cardiovascular lab testing. I also have done research in cardiovascular imaging, taking pictures of the heart, as well as measuring pressures within the heart to try to determine if a heart's working correctly.
- Q. Have you published any articles in peer-review journals?
- A. I have.
- **Q.** Roughly how many?
- A. About 20 overall over the past 12-plus years.
- **Q.** And you referred earlier to the cardiac catheterization laboratory at Johns Hopkins Bayview.

What is your role there?

A. So I'm the director of the cardiac catheterization library at Bayview.

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- Q. And what are your responsibilities as director?
- A. So I oversee everything related to quality and safety in the catheterization lab. As I alluded to, the catheterization itself is a procedure that's invasive. We basically try to find the artery in a patient's either leg or wrist and insert a tube in -- up and then thread it up into the heart to take pictures of the arteries.

So you can imagine there are risks involved, and there's certainly quality measures that have to be in place.

So I'm the go-to person for any issues relating to quality and safety and staffing issues.

- **Q.** Do you treat patients outside of your work in the catheterization lab?
- A. I do.
- **Q.** Would you tell us about your work treating patients outside of the cath lab?
- A. Sure. So primarily the other area that I work in is the outpatient area. So that's basically, in layman's terms, a doctor's office that I have once a week where I see patients from all around the world who have either symptoms or have established heart disease.
- Q. And this case involves blood testing.

Do you use blood tests in your medical practice?

A. I do.

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Q. Which blood tests do you use most frequently in your

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medical practice?

- The most frequent blood test that I use is something called the fasting lipid profile, also known as the traditional lipid profile. Basically it's cholesterol, total cholesterol. The good cholesterol is known as LDL; the bad cholesterol known as HDL; and the triglycerides, which is the fourth component of the lipid profile.
- I'm sorry. Which cholesterol is the bad? 0.
- Oh, the bad is LDL. LDL, yes.
- Do you use any other blood tests frequently in your Q. practice?
- I do from time to time. I can give you a few examples.
- Sure. Please. 0.
- Certainly when you're looking at folks with heart disease, you want to look at some things that might be related to heart disease like kidney functions. The kidneys are related to the heart, so I use something called the basic metabolic panel, which measures electrolytes and kidney function, and something called a complete blood count, which looks at patients to see if they have anemia, because sometimes folks who we think might have heart problems actually may have problems with anemia instead.

Other tests, liver function tests of folks who are on medications that sometimes can affect liver function. order that.

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And coagulation tests, tests of blood thinning because a lot of my patients, because they have heart disease, are on blood thinners. So I may order that from time to time.

- **Q.** Do you work at any hospitals?
- A. I do.
- **Q.** Which ones?
- A. I work primarily at Johns Hopkins Bayview Medical Center. That's where I spend most of my time. I also work at Johns Hopkins Hospital, which is the main hospital at Hopkins University. The third hospital I work in is Howard County General Hospital, and that's an affiliated hospital within the suburbs of Baltimore.
- Q. Have you received any awards for your work?
- A. I have.
- Q. Would you please briefly tell us about those.
- A. Sure. In 2011, I was awarded a grant by the American Board of Internal Medicine Foundation for my work in terms of researching cardiovascular testing.

2016, I won two awards. I won a cardiology divisional teaching award from the fellows and a Hopkins Medicine award for clinical excellence.

- Q. And, Dr. Trost, do you have any board certifications?
- A. I do.

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- Q. Which board certifications do you have?
- A. I'm board-certified in cardiovascular medicine or

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cardiology as well as interventional cardiology.

- Are you affiliated with any professional organizations? Q.
- Tam. Α.
- Q. Which ones?
- I'm what's called a fellow, which is a member of the American College of Cardiology.
- Have you been retained to serve as an expert before? Q.
- I have. Α.
- Have you ever testified at trial as an expert?
- I have not.
- Why not? 0.
- Every time that I've been retained as an expert, the cases never actually went to trial. They were all settled.
- MR. KASS: Your Honor, at this time, based on Dr. Trost's education and experience in the medical field, the United States would ask that the Court qualify Dr. Trost as an expert in cardiology and the medical necessity of the tests offered by Health Diagnostic Laboratory and Singulex.

THE COURT: You mentioned cardiology and then?

The medical necessity of the tests offered MR. KASS: by Health Diagnostic Laboratory and Singulex.

I would normally recognize somebody as an THE COURT: expert in cardiology and cardiology testing more neutrally. I'll let him offer his opinions.

Is there any objection to designating the doctor

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as an expert in cardiology and cardiology testing? MR. COOKE: Not as the Court has limited it, no objection to that. MR. ASHMORE: Agree, Your Honor, no objection. THE COURT: Very good. The doctor is recognized as an expert in cardiology and cardiology testing. BY MR. KASS: Dr. Trost, have you been compensated for the work that you 0. performed in this case? Α. I have. And how have you been compensated for the work that you 0. performed in this case? So I have a fee of \$350 an hour for reviewing the records that were provided me by the United States. I have a fee of \$500 an hour for testimony preparation and trial testimony. Is your compensation contingent in any way on the outcome 0. of this case? Α. No. Is your compensation contingent in any way on the opinions 0. that you offer in this case? Α. No. What did the United States ask you to do in this case? Q.

The United States asked me to review the complaint as well

as review documents related to the case with respect to giving

my opinion with respect to the medical necessity of the tests

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that were involved in the case.

- **Q.** And which tests are those?
- A. Those tests were the tests that were basically from two companies, HDL, or Health Diagnostic Laboratory, Incorporated, and Singulex.
- Q. And I've been reminded that I need to slow down for the benefit of the court reporter. It's a struggle with me, as you can probably tell. We'll both try to do that.

What did you conclude, generally speaking, at a high level?

- A. Generally speaking, what I concluded is that the tests that were used and ordered and marketed by HDL and Singulex -- HDL, Incorporated -- excuse me -- and Singulex were in general not consistent with medical necessity, were not medically necessary for a routine population of patients. And it seemed to me that the testing in this particular case was for a routine population of patients.
- **Q.** What do you mean by "routine population of patients"?
- A. So what I mean is, if I'm a doctor in an office, I would consider basically any patient who walked in the door as basically consideration for a routine test. For example, a patient that walked into door, I might consider ordering cholesterol.

Everybody -- according to the guidelines, everybody over the age of 20 should have at least one cholesterol level

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check. That's actually free medical advice.

And so if a patient comes to me and they haven't had their cholesterol checked, I'm certainly going to offer them a cholesterol. Obviously, you can't force patients to have blood testing.

But that would be a routine medical test, in my view.

Q. And you referred to medical necessity.

What did you mean by that term?

- A. So very simply, medical necessity is a test or a procedure that is thought to be needed for preventing disease, for diagnosing disease, and for treating disease.
- **Q.** What information did you consider that led you to these conclusions?
- A. So there are several sources of information. I was able to review HDL marketing material to physicians -- HDL and Singulex marketing materials to physicians. I also reviewed actual requisitions from physicians. These are order forms that physicians filled out related to HDL and Singulex, what are called panels in individual tests. And finally email communications between physicians and representatives of HDL, Singulex -- excuse me -- and BlueWave.
- **Q.** Which steps generally did you take to reach your conclusions in this case?
- A. So I considered really three things.

Number one, what's my experience with these tests?

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Looking at these tests, basically, are these things that I've ordered? Are they things I've seen being ordered on other patients? Are these things that colleagues of mine have ordered? So my own clinical experience, number one.

Number two, I looked at the existing published evidence with respect to supporting basically the use or not use of each of these tests, so the medical literature essentially associated with each of these tests.

And then the third thing that I looked at were the existing guidelines that existed. And what I found were there are three major guidelines, interestingly enough, from three different groups. One group were the cardiologists. the group that I belong to. Another group was from the American Society of Pathology, which are the folks -- they're the folks who actually process the labs. And then the third was from the National Lipid Association, which are the folks who do research with regard to cholesterol and lipids and that sort of nature.

I believe you referred earlier to the fasting lipid profile, and you told us what that referred to.

what does the fasting lipid profile tell you about a patient's risk of cardiovascular disease?

It tells me quite a lot, along with other risk factors. We know from a lot of literature that folks who have high cholesterol, particularly folks who have the bad cholesterol,

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LDL, are at a much higher risk of developing heart attacks or dying from heart attacks.

We also know that lowering the bad cholesterol results in benefit, that these folks can have a lower risk of a heart attack or stroke or a cardiovascular event.

So a fasting lipid profile is one of the cornerstones of evaluating folks where you suspect or are worried about heart disease.

- **Q.** Are there other risk factors that you typically consider in evaluating a patient's risk of cardiovascular disease?
- A. Yes, there are.
- Q. Would you please tell us about this.
- A. Sure. I'd be happy to. So when I'm looking at patients and trying to determine are they at risk of having a heart attack, there's actually a calculator that one can access online -- and you don't have to be a doctor to do it -- that summarizes a lot of the risk factors. But I'll talk about each risk factor individually, if I might very briefly.

First, there are a couple of things that we can't change, like age. The older we get, essentially the higher risk we are of having a heart attack. That, we can't change.

Gender, men happen to have heart attacks more frequently than women do, at least premenopausal women. Once you develop menopause, women tend to catch up.

There's some modifiable risk factors, like smoking.

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Folks who smoke are at higher risk of having a heart attack than those who don't. Even prior smokers have an elevated risk compared to folks who never smoked.

Diabetes; a family history of early heart disease, meaning if you have a first-degree relative who was fairly young, ideally -- or I should say, unfortunately, below the age of 60, younger than 60, who's had a heart attack, then you're actually at risk of having a heart attack as well.

High blood pressure would be the last one. If you have high blood pressure, that's a risk associated with heart disease.

- **Q.** And how do you calculate a patient's risk of cardiovascular disease?
- A. So as I said, there are several ways to do it. The one that I use is called the American Heart Association pooled risk calculator. Again, you can pull it up online. That's the most contemporary tool that you can use.

And you input some of the things that I mentioned.

And what it does is it will calculate for you a 10-year risk,
basically, your risk within 10 years of having a heart attack
as a percentage. So a low-risk person would be someone who has
a 5 percent or less risk of having a heart attack. Your risk
of having a heart attack in 10 years is about 1 in 20. A
high-risk person would be someone who has a 20 percent or
greater risk of having a heart attack. So that means you have

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a 1 in 5 chance of having a heart attack. And then there are folks who are in between, and they are called the intermediaries.

- Q. I'd like to refer to an exhibit that's already in evidence. This is Exhibit 1139, please, and I believe you have a copy in front of you, Dr. Trost?
- A. I do.
- Q. Great. Have you seen this document before?
- A. I have.
- **Q.** What is it?
- A. It is a requisition from Health Diagnostic Laboratory, Inc. Basically, it's an order form that doctors use to order tests.
- Q. I'd like to direct your attention to the part of the form titled "custom panels." Underneath that, there's a section -- if you wouldn't mind scrolling up just a little bit -- that says "comprehensive baseline assessment."

Maybe we can zoom in on that.

And, Dr. Trost, if you look on the left side of that, you see something called a comprehensive baseline assessment with a bunch of tests listed under it?

A. I do.

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- **Q.** Are these the Health Diagnostic Laboratory tests that you considered in forming your conclusions?
- A. They are. Although, Mr. Kass, I would say -- I'm not sure

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why, on my screen, the first column is -- is cut off. I know -- and now it's back. Perfect. Thank you. The magic works, folks. Thank you.

Q. Thank you.

And for which of these tests did you form a conclusion that they were medically not necessary?

- A. All of the tests, with the exception of the lipid panel, in my opinion, were not medically necessary in this particular case because they are not meant for routine use or use in a routine clinical population.
- **Q.** And by "lipid panel," you're referring to the first test under "comprehensive baseline assessment"?
- A. I am.
- **Q.** And is it your understanding that that is the fasting lipid profile you referred to earlier?
- A. That is correct.
- **Q.** I'd like to ask you in particular about a few of these tests, but before I do, which of these tests are commonly ordered by physicians in clinical practice?
- A. I would say, going through the list, the ones that are commonly ordered in clinical practice would include things like glucose in the second column. Glucose means sugar. Basically, diabetics gets glucose measured all the time. People who you think might be diabetic get that measured all the time.

Uric acid, which is commonly used to measure folks

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who are suspected of having gout. For those of you who know what gout is, it's an inflammation of the joints. It's a horrible disease. It's a very painful disease. And it's one that uric acid is an essential component of.

Vitamin D is measured fairly commonly, and somewhat controversially, by primary care physicians. Vitamin D has to do with, basically, sun exposure and dietary intake.

Hemoglobin A1c -- HbA1c -- is used fairly commonly.

That's also a marker for diabetic control, for sugar control.

Uric acid is, by the way, mentioned twice in this baseline assessment. I'm not sure exactly why.

That would summarize the tests that I see that I would characterize as commonly ordered.

- Q. If you look down in the left-hand column under "comprehensive baseline assessment," do you see a reference to CYPC19?
- A. I do see that.
- Q. Do you know what that test it?
- A. I do know what that test is.
- **Q.** What is that test?
- A. It's a test I'm very familiar with because it is the primary kind of impetus for looking at that test was basically in patients with stents. As folks may or may not know, when we put in stents, stents are foreign bodies. They can potentially develop blood clots if we don't do something, if we don't give

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medication to prevent them. So everybody who has a stent in their heart is on aspirin unless they can't tolerate it. And everybody who has a stent is on a second anticlotting medication. And, most commonly, it's a medicine called Plavix, or clopidogrel.

This test looks at basically a enzyme in the liver that actually processes Plavix. And when it is abnormal, it suggests that people who have this abnormality don't process Plavix as well. And if they don't process it as well, that means that it may predispose that patient actually to developing a blood clot in their stent. And so we have to think about changing them to a different medication.

The good news is there are other related medications to Plavix that we can change them to. But the overwhelming majority of evidence supports this test use primarily in folks who have stents.

- **Q.** And are there any other indications or uses that you're aware of for this test?
- A. So there are some who have -- some physicians who are of the opinion that one can extrapolate the data on folks with stents to a broader population of anybody who's on Plavix for any reason. So patients who are not on stents but are on Plavix, they include patients with strokes. Patients with strokes do need blood thinners from time to time. Sometimes there are some patients you may know that don't tolerate

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aspirin and need to be on another medicine, so they might be on Plavix.

Those are folks that some physicians believe this test may be helpful, because, again, if this test shows that they can't metabolize, they can't process Plavix well, that they might be in danger of having a stroke or having a heart attack. So, in those folks, this might be appropriate.

- **Q.** Are there -- are there any other situations other than -- well, let me ask it to you this way: When is it necessary to order the Plavix -- excuse me -- the CYPC19 test?
- A. So, strictly speaking, the data doesn't support an absolutely necessary indication. What it does suggest is that it -- for folks with stents who are on Plavix, if there is a concern or a high risk of them developing a blood clot, CYP2 -- CYP2C19 is a reasonable test to order.
- **Q.** Any other circumstances in which it is necessary to order the CYPC19 test?
- A. In my opinion, no.
- **Q.** And in your opinion, is it appropriate to include this test on a comprehensive baseline assessment?
- A. Not for a routine group of patients, no.
- Q. Now, are your conclusions regarding this test consistent with your review of the medical literature?
- A. They are.
- Q. I'd like to ask you about the test right underneath that

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on the panel, which is called Factor V Leiden. That's Roman numeral V.

Do you see that?

- A. I do.
- **Q.** Are you familiar with this test?
- A. I am.
- **Q.** What is that?
- A. Factor V Leiden is another genetic test, looking for a completely different, basically, abnormality. Folks with this genetic abnormality are predisposed to developing blood clots in their veins, blood clots that can travel to the lungs and potentially be life-threatening.

So it's a test that is commonly ordered for a very specific purpose. It's for folks who either have blood clots or have -- blood clots in their legs, have blood clots anywhere in their venous system, or have blood clots that go to their lungs and we have no other reason for why that is.

Now, there is other reasons that can cause blood clots in the veins that are actually much more common than Factor V Leiden. So we have to exclude those conditions before we can even think about ordering this test. But it is a test that can be ordered for that specific purpose.

- **Q.** And I believe you refer to the venous system. What do you mean by that?
- A. Sure. So there are arteries and there are veins.

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Arteries are things that deliver blood to organs. Veins are things that carry blood back to the heart. This test is exclusively designed for veins, for basically blood clots within the veins. It's not something that has to do anything with the heart arteries or the heart itself.

- **Q.** In your opinion, is it appropriate to include this test in a base -- comprehensive baseline assessment?
- A. In my opinion, it is not appropriate to include this in a baseline assessment in an evaluation of a routine patient population.
- **Q.** And is your opinion consistent with your review of the medical literature?
- A. It is.
- Q. I'd like to talk about the test right underneath Factor V Leiden, which is titled prothrombin mutation. Do you see that?
- A. I do.
- **Q.** Are you familiar with this test?
- A. I am.
- **Q.** What is this test?
- A. So this test is just like Factor V Leiden. It's another genetic variant. Those two tests are commonly ordered together for the exact same reason, for patients who develop blood clots in their veins or blood clots basically that travel to their lungs. These tests almost always are ordered together for specifically that purpose.

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- **Q.** And for -- for which categories of patients is it necessary to order the prothrombin mutation test?
- A. As I said, for patients who develop blood clots in their veins or blood clots to their lungs where another cause has not been excluded. In other words, we -- we have thought about some other basically things that could potentially produce those blood clots. I'll give you an example.

Folks who have surgery in their hips or in their legs, they are predisposed to blood clots. It's very common to see those blood clots in the veins of their legs. We would not order this test for them because they have an obvious explanation for why they would have a blood clot in their vein. This is for folks who, again, we have no explanation for why they develop the blood clot in their vein or to their lungs and we want to see if they're genetically predisposed to developing them.

- **Q.** Is it appropriate to include this test in a comprehensive baseline assessment panel?
- A. In my opinion, no, it is not.
- **Q.** And -- forgive me.
- A. Sure.
- **Q.** And are your opinions consistent with your review of the medical literature?
- A. They are.
- Q. I'd like to ask you about another test on this panel. If

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you look at the second test above CYPC19, you'll see a test titled "NT-probnp." Do you see that?

- A. I do.
- **Q.** Are you familiar with this test?
- A. I am.
- Q. What is this test?
- A. So this is a test also that's specifically designed for one purpose; that is, for folks who come in -- usually in the emergency room or occasionally in the office -- with shortness of breath. And we're not sure what the cause is. They may have risk factors for either lung disease or heart disease. This is actually a hormone that's released by the heart when it's stressed and when it's failing.

And so what this test does is enables us to give us some information as to whether or not the patient is in what's called heart failure, meaning their heart isn't working right. And it helps distinguish between that and lung-related problems like pneumonia.

- Q. When is it necessary to order this test?
- A. So, in my opinion, it's necessary to order this test in folks who come to the emergency room or come to a doctor's office, have shortness of breath, and it's unclear exactly why they're having shortness of breath based on basically taking what's called a clinical history and physical exam.
- Q. Any other circumstances that you believe it's appropriate

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to order this test?

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- In my opinion, it's not appropriate for routine Α. patient management or routine patient care.
- Is it appropriate to include this test on a comprehensive Q. baseline assessment panel?
- In my opinion, no, it is not.
- And are your opinions consistent with your review of the Q. medical literature?
- Yes, they are.
- One more test on this panel that I'd like to ask you Q. Right above NT-proBNP, you may see a test called galectin-3. Do you see that?
- I do.
- Are you familiar with this test? Q.
- Α. I am.
- What is this test? 0.
- This is a test -- it's basically a test that is used as what's called a biomarker, meaning it's basically a particle that's released in the blood that's associated with increased risk of dying in folks who have acute heart failure or basically acute weakening of the heart or something called chronic heart failure, meaning their heart is weak for a long, long time.
- And when is it -- well, is there ever any reason to order this test?

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- A. There is evidence that suggests that in folks with either -- let's call it acute heart failure, acute heart weakening, or chronic heart weakening, it may give some prognostic information for doctors. So, again, this is a very specific population of patients that this test is designed for. It is not designed for a broad population of patients that walk into a doctor's office.
- **Q.** And is it appropriate to include this test on a comprehensive baseline assessment panel?
- A. In my opinion, no, it is not.
- **Q.** Are your opinions consistent with your review of the medical literature?
- A. They are.

MR. KASS: Your Honor, I'd like to ask about an exhibit before we admit it into evidence.

Can you bring up -- well, let me start by doing this.

BY MR. KASS:

- **Q.** Dr. Trost, do you have in your stack Plaintiff Exhibit 3003? Do you see that?
- A. I do not see that. I see a Plaintiff Exhibit 3064.
- Q. Allow me to --
- A. I'm sorry. I do see it.
- Q. Terrific.
- **A.** 3003.

2:50PM	1	Q. Have you seen this document before?
2:50PM	2	A. It's my first time. I'm sorry.
2:50PM	3	Q. Mine too, if it's not obvious.
2:50PM	4	Have you seen this document before?
2:50PM	5	A. I have.
2:50PM	6	Q. And what is this document?
2:51PM	7	A. So this is a Singulex ordering form.
2:51PM	8	Q. Did you consider this document in forming your
2:51PM	9	conclusions?
2:51PM	10	A. I did.
2:51PM	11	MR. KASS: Your Honor, at this time I'd like to move
2:51PM	12	Plaintiffs' Exhibit 3003 into evidence.
2:51PM	13	THE COURT: Any objection?
2:51PM	14	MR. COOKE: No objection.
2:51PM	15	MR. ASHMORE: No, sir.
2:51PM	16	THE COURT: Plaintiffs' 3003 admitted without
2:51PM	17	objection.
2:51PM	18	MR. KASS: Peter, if we could, would you mind zooming
2:51PM	19	in on the part of this document titled "panels."
2:51PM	20	Terrific. And can you move it over a little bit
2:51PM	21	like before? Amazing.
2:51PM	22	BY MR. KASS:
2:51PM	23	Q. Dr. Trost, are these the Singulex tests that you
2:51PM	24	considered in forming your conclusions?
2:51PM	25	A. They are.

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- **Q.** Which of these tests, if any, do you regard as medically necessary?
- A. So there are three tests that are listed: Cardiac troponin-I, interleukin-6, and interleukin-17A. I'll start out with cardiac troponin-I.

Cardiac troponin-I is a -- one of the -- actually, the most commonly ordered tests in the country, but it's ordered for a very specific reason. Basically, anyone who comes into the emergency room where we're concerned about having a heart attack, cardiac troponin would be ordered. It is not meant to be used as an outpatient screening test because most patients don't come to their doctor's office saying "I have a heart attack." They're going to the emergency room.

Interleukin-6 and interleukin-17A, in my opinion, have no clinical utility whatsoever. There is evidence to support their use in research because they are basically molecules that are involved in inflammation. The inflammation is really not specific. It could be to any organ. And so, in my opinion, these two tests do not really convey any useful information to someone who's taking care of patients because there's really nothing that we can do differently than we ordinarily would just with our usual risk factors in terms of treating that patient.

Q. And if we could zoom out on this document for a second, just to see the whole thing.

2:53PM	1	This is the Singulex requisition form; correct?
2:53PM	2	A. It is.
2:53PM	3	Q. Did you, in the course of forming your opinions, have the
2:53PM	4	opportunity to review actual filled-in requisition forms?
2:53PM	5	A. I did.
2:53PM	6	Q. You should have in your stack a document labeled Plaintiff
2:53PM	7	Exhibit 3064.
2:53PM	8	A. I do.
2:53PM	9	Q. Have you seen this document before?
2:53PM	10	A. I have.
2:53PM	11	Q. What is it?
2:53PM	12	A. This is a document that it looks at a specific lab test
2:54PM	13	known as the omega-3 index.
2:54PM	14	Q. Forgive me. Just to move things along, if you wouldn't
2:54PM	15	mind turning to the sixth page of this document
2:54PM	16	A. Okay.
2:54PM	17	Q which is Bates-labeled in the lower right-hand corner,
2:54PM	18	USADOC1481586.
2:54PM	19	A. I have it. Thank you.
2:54PM	20	Q. Okay. Perfect. Do you recognize this document?
2:54PM	21	A. I do recognize this document.
2:54PM	22	Q. What is this document?
2:54PM	23	A. This is another this is a completed lab requisition or
2:54PM	24	lab order form by HDL, Inc or I should say the HDL, Inc.,
2:54PM	25	lab order form that's completed presumably by a doctor or a

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doctor's representative.

Q. And if you wouldn't mind just briefly flipping through the pages of the entirety of the document, I'd like to know if this is among the documents that you reviewed in forming your conclusions.

A. It is.

MR. KASS: Your Honor, I'd like to move Plaintiffs' Exhibit 3064 into evidence, please.

THE COURT: Any objection?

MR. COOKE: No objection.

MR. ASHMORE: No, sir.

THE COURT: Plaintiffs' 3064 admitted without objection.

BY MR. KASS:

- Q. Dr. Trost, roughly ballpark, how many -- oh, and -- great. Roughly, how many requisition forms that were filled in did you review in the course of forming your conclusions?
- A. I could give you a number or I could give you kind of a paper thickness.
- Q. I think a paper thickness will be fine.
- A. Paper thickness would be about that thick, and I would say probably several hundred.
- Q. Thank you.
- A. Okay.
- Q. And if you look at this particular requisition form that's

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in front of us on the screen --

Peter, if you wouldn't mind going down to the bottom of the page.

I know it's a little fuzzy, but you'll see a section there that says "diagnosis ICD-9 code." Do you see that?

- A. I see that, yes.
- **Q.** Dr. Trost, have you ever ordered any lab tests from Health Diagnostic Laboratory?
- A. I can honestly say I never have ordered from HDL or Singulex.
- Q. Have you ordered other lab tests from other lab entities using requisition forms?
- A. I have.
- **Q.** And are you generally familiar with the diagnosis portion of a requisition form?
- A. I am.
- **Q.** In your experience, what is the diagnosis portion of a requisition form?
- A. So for every test that we order as doctors, we have to justify why we order the test. Makes sense, because, obviously, we're giving insight not only to patients but also to folks who are looking at our documents in terms of why we're ordering the test.

So we would indicate not only the tests that we want to order, but also the diagnosis that's associated with that

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test.

- **Q.** I believe you mentioned earlier you reviewed a stack about this thick of completed requisition forms. Did you form any conclusions based on your review of these requisition forms?
- A. Yes, I did.
- Q. What conclusions did you form?
- A. I formed several basic conclusions.

Number one, that basically it seemed as if all of the requisitions -- almost all, if not all, of the requisitions showed that the physicians or physician agents were ordering these tests in groups in the panels, basically groups of tests as opposed to individual tests. Although they had the option of ordering individual tests, it seemed like there was a pattern that they were being ordered in groups.

The second thing that I noticed is that, when you look at the diagnosis on the bottom, it seemed like the most common diagnoses were high cholesterol, high blood pressure, diabetes. These are risk factors that we basically use every day in our traditional risk assessment. So it wasn't clear to me why it would be important to add these additional tests that seem -- didn't seem to be medically necessary in addition to an evaluation of those things.

- **Q.** Dr. Trost, did you review any patient file in connection with your work on this matter?
- A. I did.

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1 MR. KASS: Your Honor, may I approach the witness? 2:58PM 2 THE COURT: You may. 2:58PM 3 BY MR. KASS: 2:58PM 4 This is a patient file that we received from the BlueWave 2:58PM 5 defendants on Wednesday. 2:58PM Dr. Trost, have you reviewed this patient file? 6 2:58PM 7 I have briefly. It was given to me yesterday, as you Α. 2:58PM 8 noted. 2:58PM 9 And it's pretty thick; right? 2:58PM 10 It's even thicker, about that thick. 2:58PM 11 MR. KASS: Your Honor, I'd like to enter this patient 2:58PM 12 file into evidence. 2:58PM 13 Okay. Any objection? THE COURT: 2:58PM 14 MR. COOKE: No objection. I assume provisions are 2:58PM 15 made to delete patient information. 2:58PM 16 MR. KASS: We do have a version that we'll put up on 2:58PM 17 the screen, and that is the redacted version that we received 2:58PM 18 from you. 2:58PM 19 MR. COOKE: Okay. Thank you. 2:58PM 20 MR. ASHMORE: No objection, Your Honor. 2:58PM 21 Very good. What number is that? THE COURT: 2:58PM 22 MR. KASS: Can we call it 7001? Let's call it 2:59PM Plaintiff Exhibit 7001. 23 2:59PM 24 And there's no objection? THE COURT: 2:59PM 25 No objection. MR. COOKE: 2:59PM

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THE COURT: Plaintiffs' 7001 is admitted without objection.

BY MR. KASS:

- **Q.** Dr. Trost, based on your review of this patient file, what observations did you make?
- A. So I made two major observations with regard to this patient. The first is that this is a patient who was 56 who had a history of bypass surgery. If you read among the scribbling, you might be able to figure out some of the details of his medical history.

So he had bypass surgery in his 40s, which is unusual. He also had a history of what sounds like a stroke and had blockages in both arteries, basically major arteries leading to his brain. And he was a smoker and a current smoker at that -- at the time that the first note that I reviewed was.

So what that means to me is that this patient is about as high a risk as possible of having a future heart attack. He's had bypass already at a young age. He's had strokes. He has known ulcerative disease in his neck.

There is basically no patient that we see that is any higher risk than this one in terms of having a heart attack. And for that reason the treatment in terms of dealing with this patient is quite clear. You don't need a lot of lab tests to figure out that he's a high risk.

The second thing that really struck me was that I

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take care of patients like him frequently. The amount of testing that was done in this particular patient far exceeded anything that I'd ever seen. Literally, it's the most testing that I'd ever seen in terms of blood work, in terms of other heart testing, in terms of the frequency of testing that was done.

At one point, although he had a known basically bilateral, that is both-side, blockage of his heart arteries -- excuse me -- arteries to his neck, as I mentioned, at one point he had four different ultrasounds over a span of a year to look at basically what was already known to be blockages -- to be several blockages. And, unfortunately, when blockages exist, they don't get any better.

So I was really struck with the intensity of testing with respect to this case.

Q. And you mentioned at least one of the tests that this patient had.

Did this patient receive Health Diagnostic Laboratory tests?

A. He did.

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- **Q.** And, generally speaking, which Health Diagnostic Laboratory tests did he receive?
- A. So I note that he received both Health Diagnostic Lab testing and Singulex testing. Both were ordered in pairs. Both were essentially the baseline panel as well as the

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follow-up panels.

- Q. That's the baseline panel that we looked at earlier?
- A. Yes, that's correct. And the frequency of those panels was roughly about every four to six months over the course of a six-year period.

I will tell you, by comparison, when we're looking at just fasting lipid cholesterol, maybe if you have someone who's -- basically has an abnormal cholesterol and we treat it, we might check that about once every six months or so at most frequent. But we don't do it for years and years and years.

In fact, if you have a normal cholesterol, if you go out and you haven't had one and you check your cholesterol and it's normal, you don't need to have it checked for another five years.

So, again, in terms of the frequency of blood testing in this case, this is off the charts for me in terms of what I've seen in clinical practice.

- **Q.** And setting aside even the fasting lipid panel, talking about the other HDL and Singulex tests, can you tell from the patient file whether the patient's treatment was affected by all that testing?
- A. No, I cannot. That was the most difficult part. I was trying to figure out what the motivation was for Dr. Fillingane in terms of ordering these tests. I would see him indicate that he wanted a test ordered, but I didn't see any basically

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changes in therapy once he got the results back. And there was no real reason for him -- that he gave as to why he was ordering the test in the first place, much less ordering it as frequently as he did.

- **Q.** Dr. Trost, what is your opinion about whether ordering medically unnecessary tests can cause harm?
- A. I do believe that medically unnecessary tests can cause harm.
- **Q.** What do you mean by that?
- A. Well, to give you an example, I had a patient probably within the past year, a young woman who was a marathon runner in her 40s, extremely healthy, no risk factors whatsoever, none of the risk factors I mentioned, not a smoker. She went to her primary care physician. She mentioned to him that she had had a family history of heart trouble, that I think her -- one of her parents had died in his 70s of heart disease.

Now, to me, as a heart doctor, that is actually not a risk factor for basically -- for people who -- in terms of having an increased risk for a heart attack. It's pretty normal to have parents in their 70s or 80s have heart disease. As I mentioned before, the older you get, epidemiologically that's not a risk factor.

But yet this primary care physician decided to order a test called the high sensitivity CRP test, and it came back as elevated. And so the primary care physician told this

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person, "You need to see a cardiologist right away. This test is elevated, and I'm worried that you might be at risk of having a heart attack."

So she came to see me, and she was scared out of her mind. And I had to do all that I could to basically tell her, Listen, you're young. You're female. You don't have any risk factors. You run marathons. You're a perfect weight. Your risk of having a future heart attack is probably better than mine. So I had to basically talk her down from the ledge.

So one obvious, in my opinion, risk of unnecessary testing is it causes tremendous patient anxiety about the future.

There are other things that can happen. It's possible that this same patient may have gone to a cardiologist and may have tried to basically talk that cardiologist into doing a stress test, stress test being that test that basically tries to put the heart through stress, if you will, physiologic stress, making you exercise to see if basically there's a blood flow limitation or some abnormality in an EKG.

I've heard stories and certainly have read incidences where such a patient might have an abnormal stress test. And stress tests can be abnormal and be what we call falsely positive -- that is they're abnormal, but there's nothing wrong with the patient about -- 30 percent of the time.

So that patient would ordinarily get a stress test.

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It would be abnormal. There would be a high risk that that would be a false positive.

But the physician is left with basically a choice of saying, "Oh, don't worry about it" -- and usually the patient worries about it -- or should I order another test to see if the stress test is a false positive or not?

So in this circumstance, what usually happens -- and I see this in the cath lab very frequently -- is they come to me with a stress test that is, again, abnormal even though they're at low risk of having heart disease. And they get a heart catheterization. And heart catheterizations are They're not without risk. I'm very honest with my patients about these things.

There's a risk of dying, about a 1-in-100 risk of dying -- 1-to-200 risk of dying from a heart catheterization. There's a risk of stroke. There's a risk of an allergic reaction that could kill you. There is a risk of kidney There's basically exposure to x-rays. disease.

All of these things could have been avoided if that doctor didn't order that test that was not indicated for that low-risk patient.

Dr. Trost, I have just one more question for you at this 0. time.

Going back to that voluminous patient file, in the course of your review of that file, did you happen to note the

name of the physician who treated the patient? 1 3:07PM 2 Yes, I did. Α. 3:07PM 3 3:07PM 4 Α. 3:07PM 5 Thank you, Dr. Trost. 0. 3:07PM 6 3:07PM 7 at this time. 3:07PM 8 THE COURT: 3:07PM for about 10 minutes. 9 3:07PM 10 MR. KASS: 3:07PM 11 3:07PM 12 THE COURT: 3:08PM 13 3:08PM 14 THE COURT: 3:19PM 15 3:19PM 16 me? 3:19PM 17 3:19PM 18 3:19PM 19 3:20PM talked about. 20 3:20PM 21 THE COURT: 3:20PM 22 So Mr. Duffy is here MR. LEVENTIS: Yeah. 3:20PM 23 representing Mr. Martel. I didn't know if there were any --3:20PM 24 just to give you a heads-up, if he --3:20PM 25 THE COURT: I can just tell you Mr. Martel has an 3:20PM

what was the name of that physician? I only see the last name, which is Dr. Fillingane. I believe the defense may have some questions for you We're going to take our afternoon break Thank you, Your Honor. (Whereupon the jury was excused from the courtroom.) Take a 10-minute break. (Recess.) Please be seated. Mr. Leventis, you need to raise something with MR. LEVENTIS: I'm sorry, Your Honor. I know we're trying to push, but I wanted to just bring up quickly on deck we have now former BlueWave salesman Kyle Martel, who we've I was wondering about him.

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excellent lawyer. That's all I can say.

MR. LEVENTIS: Okay. Thank you.

THE COURT: And what do we have after that?

MR. LEVENTIS: I guess we'll see how long that goes. We have another witness that will come up that will be a short one.

THE COURT: Okay. You know, we've got these depositions to still play at some point; correct?

MR. LEVENTIS: Correct.

THE COURT: You know, we've tried to do it -- how much more do you have after Martel, who's a short witness, and the deposition excerpts?

MS. SHORT: Well, Your Honor, I think our plan is to play the deposition excerpts on Monday just because we have witnesses who have been waiting to testify.

THE COURT: I have no problem with that. What I'm wondering is how many additional -- whatever we do today and plus the deposition excerpts, are there additional witnesses?

MS. SHORT: Yes, there are. Three or four.

MR. LEVENTIS: Three or four, Your Honor.

THE COURT: So it sounds like you're going to take most of Monday.

MR. LEVENTIS: It's looking that way.

THE COURT: And I'm just -- you know, and I will say to you just like you told Mr. Ashmore, who was feeling a little

pressured, take your time. This is important to everybody. 1 3:21PM 2 We've worked hard. It would have been better to have finished 3:21PM today, but that's not -- it's very hard to predict these 3 3:21PM 4 things. I've tried lots of cases. I know your problem. 3:21PM 5 So -- but I was trying to bring it out to help 3:21PM the defense counsel know in terms of their own situation that 6 3:21PM 7 you're not likely to start until at least sometime Monday. 3:21PM 8 MR. COOKE: We were expecting to be going into 3:21PM 9 Monday. 3:21PM 10 THE COURT: Okay. Good. Then --3:21PM 11 MR. COOKE: We didn't start until Tuesday, so --3:21PM 12 **THE COURT:** I'm just trying to give fair warning to 3:21PM 13 y'all so you wouldn't have people teed up Monday morning. 3:21PM 14 All right. Let's bring in the jury. 3:21PM 15 (Whereupon the jury entered the courtroom.) 3:21PM Please be seated. 16 THE COURT: 3:23PM Cross-examination? 17 3:23PM 18 MR. COOKE: Thank you, Your Honor. 3:23PM 19 **CROSS-EXAMINATION** 3:23PM 20 BY MR. COOKE: 9:10AM 21 Good afternoon, Dr. Trost. I'm Dawes Cooke. I represent 3:23PM 22 BlueWave, Brad Dent, and Cal -- I mean Cal Dent and Brad 3:23PM 23 Johnson. 3:24 P M 24 You don't know these gentlemen, do you? 3:24 P M 25 I do not. Α. 3:24 P M

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- Q. You are what's referred to as an interventional cardiologist?
- A. That's correct.
- Q. And that means basically you do stents.
 Is that primarily what you do?
- A. That's not primarily what I do. That's part of what I do, yes.
- **Q.** And catheterization?
- A. That's part of what I do, yes.
- **Q.** So by the time the patient comes to you, they've already been diagnosed with cardiovascular disease; correct?
- A. That's not true. I -- as an interventional cardiologist, I also am trained as a general cardiologist. And perhaps I wasn't clear in my earlier testimony, but I have an office in which I see cardiology patients of all sorts of backgrounds, basically a general cardiology practice in the office.
- Q. And maybe my question wasn't clear. I said -- I thought I'd said, as an interventional cardiologist, by the time someone comes to you, they've generally already had a diagnosis made of cardiovascular disease?
- A. And I would repeat my answer that, even though I'm an interventional cardiologist, I do general cardiology. So I do see patients who don't have a diagnosis made.
- Q. Doctor, the generally accepted standards of medical care embraces quite a variety of differences of opinions of things;

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correct?

- A. I think that certainly there are differences of opinion with regard to standards of care. But in general, the -- what's called generally accepted standard of care, quite simply, in my view, is viewing what your colleagues do, what practice exists in your particular locale. And that can be certainly represented by the patients that you see and the records that you review of patients that you see and what physicians do as well.
- **Q.** Right. But not all physicians agree on everything, do they?
- A. No, they do not.
- **Q.** And, in fact, over time, physicians often change their opinions about things, don't they?
- A. They certainly could.
- **Q.** Can you think of any examples of things that are considered state-of-the-art standard of practice today that would have been outside the standard of care five years ago?
- A. Not off the top of my head, I cannot.
- **Q.** How about 10 years ago?
- A. Again, not off the top of my head. But I suppose there are probably examples of things that were not state of the art 10 years ago that are now.
- Q. Thank goodness medicine changes; right?
- A. Yes. We -- everything that we do is for the benefit of

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the patient.

- Q. We haven't always done stents on patients, have we?
- A. We have not always done stents on patients, that's correct.
- **Q.** We haven't always been able to do catheterization? The circumstances under which you would do them have changed over time; correct?
- A. True. We've looked at the evidence. We follow the evidence. We follow the evidence where it leads us in every case where we're evaluating new technology or new testing.
- **Q.** But not everybody even today agrees that stenting is useful, do they?
- A. In terms of stenting as a whole, there are differences of opinion related to how it should be applied. But in general, I think there's general agreement among cardiologists in terms of instances or circumstances where stenting is beneficial.
- Q. Have you ever heard of something called the COURAGE trial or the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation?
- A. Yes, I have.
- Q. And they were published in the New England Journal of Medicine; correct?
- A. That's right.
- **Q.** And was their article recently in Lancet? Do you remember seeing that?

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- There are many articles in Lancet. I'm not sure which one you're referring to.
- well, one that challenges the utility of stenting as Q. opposed to medical -- medical treatment.
- Yes, sir. What you're referring to is the ORBITA trial or ORBITA trial. Yes, I'm aware of that trial.
- And you're aware of the COURAGE trial as well? Q.
- Α. I am.
- So you're a aware, then, that not everyone agrees Q. with you as to the utility of stenting?
- Again, with regard to stenting, there is certainly room Α. for disagreement.
- Okay. But that doesn't stop you from ordering stents or 0. doing stents when you think it's going to help your patient?
- I think that's accurate. I, again, look at the Α. evidence -- the totality of evidence, and I make a decision related to the validity of that evidence in order to help patients.
- And as we, I think, perhaps now agree, that maybe the physicians who participated in or believe in the COURAGE trial or the ORBITA trial might not stent a patient that you would stent?
- Perhaps. Α.
- They might look at your charts and say, I wouldn't have Q. stented this patient. I think the risks of hurting this

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patient were greater than the risk of -- the chances of helping him.

A. Well, it's interesting you mention that, sir. We do have what's called in Maryland an external peer-review system where actually folks -- doctors from other hospitals look at our decisions to stent or not. And that's been in existence for several years.

And consistently since it's been in existence, the rate of agreement in terms of our hospital, both mine and my colleagues' rate in terms of stenting is well above 98 percent agreement in terms of whether stents are necessary.

So while I would agree with you that there is room for disagreement, in my personal practice and certainly when I've been personally examined by what are called external peer reviewers, basically other doctors from other hospitals, the agreement is actually quite good.

- Q. Are you certified in lipidology?
- A. I'm not.
- **Q.** Is there a board certification, a nationally recognized board certification for lipidology?
- A. Not one that I am aware of, but I'm honestly -- I'm not aware of one.
- **Q.** Are you aware of any studies that are being conducted currently of Johns Hopkins, for example, one entitled Very Large Database of Lipids?

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There are a lot of studies that are conducted at Johns
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               Hopkins, and that's not one that I'm aware of. But certainly I
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               have over 300 colleagues of mine in the division of cardiology,
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               so it would be impossible for me to kind of keep up with all
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               the studies that are done.
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                    I know him personally.
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                    Dr. Chiadi Ndumele?
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- Dr. Chiadi Ndumele is also a former fellow now on faculty. Α.
- Dr. Wendy Post? Q.
- I know Dr. Post. She is married to Dr. Blumenthal. Α.
- Q. Dr. --

Are there any more questions? THE COURT: I can tell you their hobbies. THE WITNESS:

BY MR. COOKE:

- I'd like to be at the dinner table when they're talking. 0. Dr. Elizabeth Ratchford?
- Dr. Ratchford, I know well. Α.
- And the point is these are cardiovascular disease 0. specialists who, probably as we speak, are studying advanced lipids at your university?
- I'm not aware of that. Α.
- Okay. Do you believe that anybody at your university is, Q. in fact, studying advanced lipids?
- I'm aware that there have been papers that have been Α. written by Dr. Blumenthal and others related to their opinion on advanced lipids, but I'm not aware of any studies related to advanced lipids.
- what about the -- do you know what the C-I-C-C-A-R-O-N-E Center is?
- It's pronounced the Ciccarone Center. I do. Α.
- Q. I was going to try that. The Ciccarone Center?
- Ciccarone Center, that's right. Α.

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- **Q.** And what is that?
- A. It's basically a center for preventative cardiology. It basically treats patients who are referred for evaluation of prevention of cardiovascular disease.
- **Q.** Would it be fair to say that we should all hope that people at institutions like that or studying tests will have doctors doing things next year that they weren't doing 10 years ago?
- A. Sure. It's absolutely important to do research in prevention. Yes, I agree.
- Q. How much does it cost to do a stent?
- A. It's a good question. And the answer is it depends on what state basically you're in and what insurance company, what they will pay, what the government will pay. To be honest with you, I've seen widely varying estimates of the cost of stenting. I really could not give you a solid number.
- **Q.** But it's a lot more expensive than not having to do one; right?
- A. Not necessarily.
- Q. Okay. You don't have to pay for stents?
- A. You have to pay for stents, but you have to pay for blood work and all of the consequences of blood work like other testing downstream as well.
- Q. That notwithstanding, would you agree with me that if there's a way to take better care of patients earlier so that

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they don't get to the point where they have to have a stent, that would be generally a good thing?

- A. It would be a good thing.
- **Q.** Are you a member of an organization called Providers for Responsible Ordering?
- A. I am a member of that organization, yes.
- Q. That's Providers for Responsible Ordering, and I gather it's an organization at Johns Hopkins Bayview. What is that?
- A. Johns Hopkins Bayview is one of the affiliate -- when you said, "What is that?" I assume you're not asking what is Johns Hopkins Bayview; you're asking about the organization of Providers for Responsible Ordering?
- Q. Yes, yes, yes.
- A. So Providers for Responsible Ordering is an organization that was created by a combination of trainees at Bayview, basically people learning how to -- learning about how to be internal medicine doctors, and faculty members to talk about basically areas where we can improve our care for patients, specifically areas in which we could reduce the inappropriate use of tests.

There's a clear consensus, in the medical community and also in the health policy community, that, of the \$3.2 trillion that is spent in this country, we're not getting a bang for our buck and there's a lot of waste in medicine. There's a lot of duplication, both administrative as well as in

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medicine.

And so this group was founded in 2009 to reflect upon ways where we could do better for patients, ways where we could eliminate care that is really of no benefit to patients but costs money. And there are examples of that.

- **Q.** So this one is basically an organization that's dedicated to studying the cost-benefit aspects of medical care?
- A. I think that is a fair characterization, but it's really -- yes, cost-benefit or what -- we prefer to say benefit over cost, which is, right now, referred to as value.
- Q. Does that have anything to do with your being asked to be an expert in this case?
- A. It does not.
- **Q.** The fact that you have concerns about the cost of providing medical care?
- A. You'd certainly have to ask the attorneys for the United States about that, but to my knowledge, no.
- **Q.** Fair enough. Have you ever heard the term "pharmacogenetics"?
- A. I have.
- Q. Is that a real medical term?
- A. Yes, it is.
- Q. Okay. What does it mean?
- A. Pharmacogenetics refers to, in layman's terms, looking at genetic, basically, links that may confer -- I'm going to try

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to keep it in layman's terms -- genetic issues that may make drugs either more or less likely to work.

- **Q.** And is that a legitimate field of study?
- A. It is.
- Q. You talked about risks of false negatives, for example, on a nuclear stress test. They will have a certain number of false negatives and that you might cause undue anxiety to a patient.
- A. Actually, let me correct you, sir. It wasn't false negatives; they're referred to as false positives.
- **Q.** That's what I meant. I'm sorry. I jumped to the next question. False positives?
- A. Yes. And I did talk about that, yes.
- Q. But there's also a risk in false negatives, isn't there?
- A. There is a risk of false negatives, yes, absolutely.
- **Q.** And what might happen to you if you have a test like that and you have a false negative?
- A. It's hard to say. You'd have to give me a scenario.
- **Q.** Well, how about if you drop dead of a heart attack two weeks after you've had a stress test under your cardiologist's supervision? That can happen; right?
- A. That can happen, and it does happen. And, quite frankly, no matter what test you order, whether it be a stress test or a blood test, there is always the possibility for that happening.
- Q. Now, if your colleagues over at the Ciccarone Center or

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any of these other folks that are studying lipids, if they were able to come up with some studies that would allow patients to be diagnosed with cardiovascular disease and specific types of cardiovascular disease earlier so that interventions could be taken and avoid even the possibility that they could have a false negative from a stress test, that would be a good thing, wouldn't it?

- A. I'm sure it would, yes.
- Q. These records that you studied, you said there was -- I couldn't see from where I was, and I think you were showing how thick the stack was. Can you show me how thick the stack was?
- **A.** It depends which records you're referring to. The requisitions?
- Q. Yes. Yes.
- A. Okay. So -- sure. I think I can.

I'm not sure these are all the requisitions, but it's probably a little thicker than this.

- Q. And you said there are several hundred in there?
- A. I would say so.
- Q. Who selected those for you to review?
- A. The United States did.
- Q. Did you tell them which ones you wanted to look at?
- A. No.

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Q. Well, how do you know how they selected the ones that they gave you?

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- I don't know how they selected. Α.
- So what did they ask you? They just sent them to you and Q. said what?
- They said, "We'd like you to review them for any --Α. basically, your opinions related to what you see on them and whether there are any consistencies or patterns that might suggest whether or not these tests are being ordered in a medically necessary way."
- Now, you're a student of the scientific method, aren't 0. you?
- Α. I am.
- So if you were going to really do a credible All right. 0. study to try to determine across the country if people were ordering medically necessary tests, what would you do? Would you ask perhaps for maybe a random selection of forms for you to review?
- That's one possible method. There are many other possible methods. But, yes, I think one possible method might be to review basically either patient medical records or, certainly, utilization forms.
- would you be at all concerned from a scientist's point of view if the people who hired you to testify that these were medically unnecessary tests were the ones to select the 2 or 300 forms out of the millions of them that have been ordered over the years?

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- A. I wouldn't be terribly concerned, no. I would trust that they would give me a representative sample of the tests that were ordered.
- **Q.** Okay. So what did you ask them? What safeguards did you ask them to put in place to make sure that you got a representative cross section of the forms?
- A. I pretty much assumed that they were going to provide me with a representative section of forms.
- **Q.** Okay. And you got of course the patient charts associated with those so that you could study those patient charts to determine why the doctors in those cases decided to order those tests?
- A. No, I did not. We talked about whether patient charts were available, and it's been a long time since we had that conversation, so I don't exactly recollect how that conversation went. But what I know is that those patient charts weren't made available to me.
- Q. So the sum total of what you had to review, then, was those forms?
- A. No. The sum total was not only those forms but also, as I said, emails between physicians and the HDL and Singulex and BlueWave representatives as well as marketing materials by the companies to physicians.
- Q. I think you're maybe getting me into a different question.
 With regard to that stack that you were asked to

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review and you testified from them, you said, oh, this panel shouldn't have been ordered as a panel, it shouldn't be ordered as screening test, and so forth, you did not have any patient charts to go with those?

- A. I had one patient chart that was provided to me yesterday.
- **Q.** That was Dr. Fillingane's, but I'm talking about that stack that you showed us.
- A. So there were no patient charts associated with that stack. I felt that, just by reviewing the requisitions alone, I could make some reasonable conclusions regarding medical necessity.
- Q. Did you? Okay.

Well, who makes the decision about medical necessity?

- A. As far as I know, it's the physician.
- **Q.** Okay. And he does it by examining the patient?
- A. He or she does it --
- Q. He or she?
- A. -- in terms of examining the patient.
- **Q.** Right. And creates a chart and does all kinds of things, probably takes the blood pressure, the temperature, I mean, asks them family history, all those kind of things; right?
- A. Sure.
- **Q.** And how many of those things are reflected in those pages that you had?
- A. So those things aren't reflected. What is reflected is

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the diagnosis that was associated with the lab ordering the test.

- **Q.** Okay. So what you did was you just looked at the diagnosis and said "I don't think this diagnosis matches with what this doctor ordered"?
- A. That's only part of the equation. The other -- the other thing that I noticed was that the tests themselves were all ordered as one group consistently. And when you look at the tests themselves ordered as one group, what strikes you is that each of the tests really corresponds to a much different medical condition. So just by virtue of the fact that these tests are ordered as a group -- and some of them basically aren't applicable to the diagnoses that I see, and some of them may be -- in my mind, that's an example of not being medically necessary.
- **Q.** Well, did the government tell you that HDL actually received over 5,000 different combinations of tests that their doctors ordered?
- A. No. They did -- I would say, sir, that they did provide me with a list of all of the various medical practices that they serve as well as the numbers of tests that those medical practices ordered.
- **Q.** Did you believe, as you were looking at this, that doctors were required to order an entire panel?
- A. No.

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- **Q.** Okay. So you understood that a doctor could scratch through what he didn't want to order and he could check the boxes for the things that he did want to order; right?
- A. Sure. He or she could do that.
- O. He or she could do that.

If I say "he" inadvertently, I mean he or she.

- A. I hear you.
- Q. Are we okay with that?
- A. Absolutely.
- **Q.** So is there a safeguard in the medical reimbursement system to protect against providers paying for tests and other procedures that are medically unnecessary?

MR. KASS: Your Honor, if I may, I could be mistaken, but I don't think the medical reimbursement system was one of the areas you suggested Dr. Trost be qualified on.

THE COURT: What's your -- what's the relevance to his testimony?

MR. COOKE: Well, I would like to establish that -- that there is a check -- a safeguard that he would be aware of against providers paying for unnecessary tests.

THE COURT: That's really outside the scope of his expert opinion. Move on. I sustain the objection.

MR. COOKE: That's fine.

BY MR. COOKE:

Q. Do you know who Humana is?

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- A. I'm sorry. Can you repeat that.
- Q. Humana? Do you know who Humana is?
- A. Humana? I'm aware that it's a health care organization.

MR. COOKE: Can I get Mallory's Exhibit 88?

MR. KASS: Your Honor, I'm happy to wait to see the exhibit, but considering this case does not involve Humana, I'm not sure I understand the relevance.

THE COURT: Well, let's see. Give Mr. Cooke a chance.

MR. KASS: Fair enough.

MR. COOKE: This is in evidence.

BY MR. COOKE:

- Q. Can you see it in front of you?
- A. I do.
- **Q.** All right. And I'm going to ask you to scroll down until they get to the clinical part. This is -- excuse me. Go back to the beginning.

This is a letter dated May 7, 2014. And I'm going to get you to scroll down.

First of all, I'm going to bet that you've never seen this before; right?

- A. I would agree with that, yes.
- **Q.** Okay. Let me get you to scroll down to the bottom. Keep going. All right. Back up a little bit.

Can I assume that you were never shown this Exhibit A

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as well?

A. I've never seen this before.

MR. KASS: Your Honor, I'm so sorry to interrupt, but I believe I saw something about Humana's commercial coverage policies, which, as far as I understand, has no relevance to this case.

THE COURT: What's the relevance of this document.

It's written by a lawyer?

MR. COOKE: Right, but it includes references to clinical support for these tests. And I want to just establish that he didn't take that into consideration.

THE COURT: Well, I think you could ask him -- I think using this document, which he's never seen, to ask him -- you can ask him without using the document if he's familiar with -- you're trying -- using it in the way you're using it would not be appropriate. I sustain the objection.

MR. COOKE: I thought because it was already in evidence, I could, but I'll pass --

THE COURT: Only for the purpose in which it was offered.

BY MR. COOKE:

- **Q.** Have you, in fact, reviewed any of the clinical trials that HDL has collected reports on in support of the tests that it offers?
- A. What I've done is reviewed the references in the HDL

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marketing literature to physicians, which I assume is what you're referring to; in other words, studies that have been referenced in support of the tests, I have.

- Q. How much material did you receive on clinical studies?
- A. I didn't receive anything from the United States. I was asked to perform an independent review, and I performed my own analysis, my own search and review.
- **Q.** So were you not given the reports on clinical studies that HDL makes available to -- or did make available to the physicians who were considering using their tests?
- A. I'm not sure if we are or are not talking about the same thing. I was given a binder from HDL, Inc., that was basically targeted to physicians that explained its rationale for the ordering of tests, which, to me, sounds a lot like what you're referring to. We may not be calling it the same thing.
- Q. Did it actually have clinical studies in it?
- A. It referred to clinical studies, yes.
- **Q.** Did it have the clinical studies in it?
- A. It didn't have the specific clinical studies; it had references to clinical studies.
- Q. You're not board-certified in internal medicine either, are you?
- A. I used to be board-certified in internal medicine, but I can only afford so many board certifications. And the good news is that, because I'm a cardiologist, I am not required to

be board-certified in internal medicine. 1 3:48PM 2 board-certified in internal medicine for 10 years. 3:48PM On the subject of determining medical All right. 3 Q. 3:48PM 4 necessity, you would agree with me, would you not, that it's 3:48PM the -- the physician has both the ability and the 5 3:49PM responsibility to determine whether any particular treatment or 6 3:49PM 7 diagnostic procedure, including any clinical tests, rests with 3:49PM 8 the physician --3:49PM 9 I do agree with you, yes. 3:49PM 10 -- responsibility --Q. 3:49PM 11 I'm sorry to interrupt you. Α. 3:49PM 12 I do agree with you. 3:49PM 13 Okay. And only the physician can make that determination? Q. 3:49PM 14 Α. I'd agree with that statement, yes. 3:49PM 15 And so if the physician believed that an entire panel of Q. 3:49PM 16 tests was medically necessary for his patient, he would have 3:49PM 17 the prerogative to order that? 3:49PM 18 And certainly he would. Α. 3:49PM All right. And if, in his professional judgment, he 19 0. 3:49PM 20 determined that some of the tests were not indicated, he would 3:49PM 21 have the ability to cross those tests out or to not order 3:49PM 22 those? 3:49PM 23 That's correct. 3:49PM Α. 24 Q. Have you ever ordered panels yourself? 3:49PM 25 I have certainly ordered panels of tests, not -- I have Α. 3:49PM

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not ordered any HDL or Singulex panels.

- **Q.** Right. I think you said that before, but it's not uncommon for physicians to have panels of tests that they regularly order?
- A. Right. As I mentioned earlier, there's something called a basic metabolic panel, which is a very commonly ordered test, and it looks at electrolytes and kidney function. There are other things called panels. "Panels" is a very general term.
- **Q.** And if you -- and then different doctors have different types of panels that they put together for themselves, don't they?
- A. I would say that's certainly possible, but, in practice, most doctors that I work with tend to order the same sorts of things. There isn't a great deal of variation in terms of what we do. And I'm fairly familiar with what my colleagues order. And when I mean colleagues, I mean not only cardiologists but any doctor who might refer to me a patient.
- Q. But it's possible that a physician might be offered some tests and say, "Well, I only understand this one. I don't have a good experience with this one, I don't have good results, whereas I really like that one." And that physician, if he's responsible, would choose the ones that he's comfortable with and leave out the ones he's not comfortable with?
- A. That's certainly possible.
- Q. And that's the way it's supposed to work; right?

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- A. Well, physicians also have to have some thought put into basically why they're ordering the test. A basic rule of basically ordering tests is that you really don't want to order a test unless you know that it's going to change your management of a patient. So physicians are expected to, if they're going to order a test, they should know something about the test and what the evidence is that goes into it.
- Q. Do you happen to know what percentage of patients who have a normal lipid panel -- excuse me.

Do you happen to know what percentage of people who have heart attacks had normal lipid panels before?

- A. I don't know the exact number, but I certainly know there is a percentage of folks who have basically normal -- basically manage risk factors and lipids that ultimately go on to have heart attacks. And I think that number is about between 30 and 40 percent.
- Q. Have you ever heard of the JUPITER trial?
- A. I have.
- **Q.** What is the JUPITER trial?
- A. The JUPITER trial was a trial of men and women -- men aged 50 and over and women, I believe, aged 60 and over. And I may get those ages wrong. Excuse my recollection. It was done sometime around, I would say, 2007 or 2008. And it looked at a population of mostly healthy people who had cholesterol levels less than 130 and basically measured their -- something called

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their high-sensitivity CRP levels.

And for those patients who had high -high-sensitivity or abnormal high-sensitivity CRP levels, they
were randomized to a cholesterol medicine, what's called a
statin, versus placebo.

- Q. And was that one of the studies that supported the idea that as many as 40 -- have you ever heard 50 percent? 50 percent of heart attack victims actually had normal lipid panels?
- A. Yes, I've heard that number. And high-sensitivity CRP, the lab test that was highlighted, for lack of a better word, in the JUPITER trial, was developed essentially in response to that, to try to identify another lab test that might prove useful in terms of predicting folks to have heart attacks. That's correct.
- Q. Just give me a moment, if you will.

(Pause.)

BY MR. COOKE:

Q. I just want to make sure I understand. When you gave your testimony earlier, your testimony was that the tests that were all listed in those panels were medically unnecessary as a screening measure. You weren't trying to say that none of those tests could have medical necessity for a physician who made an independent medical judgment that they were appropriate?

I'm sorry, Your Honor, that misstates his 1 MR. KASS: 3:54PM 2 testimony. 3:54PM Overruled. Let him answer the question. 3 THE COURT: 3:54PM 4 THE WITNESS: Can you answer that -- I'm sorry -- ask 3:54PM 5 that question again. 3:54PM BY MR. COOKE: 6 3:54PM 7 I thought I understood that your testimony was Yes. 3:54PM 8 that -- when you were going through the various panels, that 3:54PM 9 your testimony was that the -- not that each and every test on 3:54PM 10 that panel could never be medically necessary but that they 3:54PM 11 were inappropriate, in your opinion, as a screening panel? 3:54PM I think there's -- I think that's actually correct, that 12 3:54PM 13 if ordered as a group for a routine patient population, that 3:54PM 14 test, with the exception of the lipid panel, would be 3:54PM 15 considered medically unnecessary. 3:55PM 16 Right. Thanks very much. 0. 3:55PM 17 THE COURT: Thank you. 3:55PM Mr. Ashmore? 18 3:55PM 19 MR. ASHMORE: Thank you, Your Honor. 3:55PM 20 **CROSS-EXAMINATION** 3:55PM 21 BY MR. ASHMORE: 3:55PM 22 Dr. Trost, I'm Beattie Ashmore. I represent Tonya Q. 3:55PM Mallory. 23 How are you? 3:55PM 24 Α. I'm well. Thank you. How are you? 3:55PM 25 Good. Q. Good. 3:55PM

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It's a friendly bunch you've got up there at Johns Hopkins.

- A. Thank you.
- Q. I'll be brief.

who does your blood testing for your patients?

- A. So, as far as I know, most of it is done in-house by Johns Hopkins. There are occasional send-outs to various national labs like Quest or LabCorp. I'm honestly not very familiar with all of the names of the national companies. I am there to order the tests electronically now, and, obviously, follow up on the result to the patient. I don't really bother myself with the details of who does the tests.
- **Q.** But to the best of your knowledge, some of the testing at Johns Hopkins is actually sent out to other blood testing facilities -- Quest, LabCorp?
- A. That's correct.
- Q. Any other blood testing facilities that you know of that Johns Hopkins may use?
- A. None that I know of, but again, I don't really predispose myself to those details. There may be other companies that Hopkins use.
- **Q.** Sure. Now, the tests that you order for your patients, do they come with a health coach or a dietician?
- A. So there are certainly -- so when I order a lab, they don't come with a health coach or a dietician, but I can, if I

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think it's appropriate, certainly ask for a dietician to help with patients. We don't have health coaches per se, but we do have an extensive support staff for helping educate patients in terms of losing weight, quitting smoking, those sorts of things. So it's not called a health coach per se, but we do have patients -- excuse me -- we do have staff who would function as health coaches, if you will.

- **Q.** And how does -- how does the patient understand what is -- his or her blood test results are?
- A. So it's the responsibility of the person ordering the test, most likely the physician, to follow up with those results in a timely fashion. And so if a blood test is ordered, there's a system that every physician has, which is slightly different depending on the physician, in terms of making sure that that lab test is followed up, because, again, ultimately, if the patient is getting the blood test, they need to know that information.
- **Q.** And the way you handle it is you're the one that explains the blood tests to your patients?
- A. Absolutely, every single time.
- **Q.** Sure. Did you talk to any of the doctors that ordered the HDL tests?
- A. I did not. I was not given that opportunity.
- Q. Are you aware that over 10,000 doctors ordered HDL tests?
- A. I was not aware of that.

3:57PM	1	Q. And you hadn't talked to any patients that had HDL
3:58PM	2	testing?
3:58PM	3	A. Again, I was not given that opportunity, no.
3:58PM	4	Q. Sure. And, lastly, you indicated there's a widely varying
3:58PM	5	cost of stents. Am I correct? That was your direct testimony?
3:58PM	6	A. Yes, that's right.
3:58PM	7	Q. Sure. And as you implied, it's it's not uniform. Is
3:58PM	8	that fair enough?
3:58PM	9	A. I think that's fair.
3:58PM	10	Q. Sure. And so that's sort of the health care industry as a
3:58PM	11	whole, is it not?
3:58PM	12	A. There certainly is variation in health care that's been
3:58PM	13	well documented in terms of costs and expense, yes.
3:58PM	14	Q. Sure. And did you indicate earlier that that the
3:58PM	15	health care industry, as we would call it, is a
3:58PM	16	\$3.2-trillion-a-year industry?
3:58PM	17	A. Yes. That's the number I'm aware of, yes.
3:58PM	18	MR. ASHMORE: That's all I have. Thank you very
3:58PM	19	much.
3:58PM	20	THE COURT: Thank you.
3:58PM	21	Redirect?
3:58PM	22	MR. KASS: Thank you, Your Honor.
3:58PM	23	REDIRECT EXAMINATION
3:58PM	24	BY MR. KASS:
3:58PM	25	Q. Dr. Trost, I will try to keep this very brief.

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- Α. Thank you, sir.
- Let me start by asking you this: Earlier, we talked a 0. little bit about your work in the cardiac catheterization lab at Johns Hopkins Bayview. Do you treat patients outside of your work in the catheterization lab?
- Yes, I do.
- would you briefly tell us about your work treating Q. patients outside of the cardiac catheterization lab?
- As I said, I have office hours -- basically, a clinic -that is once a week. I see about, roughly, 12 to 14 patients per session. And those are all -- what we call all-comer Those are folks who have all sorts of symptoms. Some of them may have heart disease. Some of them are sent to me because people think they have heart disease. The good news is some of them may not have heart disease, and I'm the one to tell them that. But to drive home the point, I see general cardiology patients.
- Earlier, I asked you to explain what the term "medically Q. necessary" means. Do you recall that?
- Yes, I do.
- And just remind me, what does that term mean again? Q.
- what that term means is basically tests or procedures that Α. are required or needed to -- for the prevention, for the diagnosis, and for the treatment of disease, including heart disease.

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Q. And if I understood you correctly, I believe you testified earlier in response to Mr. Cooke's questions that a physician has the prerogative to order medical tests for his or her patients. I'm paraphrasing. Forgive me.

In your view, does that mean just because a physician somewhere in the United States orders a test, that test is, by definition, medically necessary?

- A. No, that's not my view at all.
- **Q.** And why is that?
- A. Because, again, every physician is expected to -- when they order a test, to have some working knowledge of the evidence that supports ordering that test. And so, certainly, if there is a predominance of physicians, if there's a standard of care that you see as well as an awareness of the evidence, then it becomes quite evident, when you're looking at patterns of testing, whether something's consistent with medical necessity or not.
- Q. Thank you.

MR. KASS: No further questions.

THE COURT: Very good.

Doctor, thank you very much. You may step down.

THE WITNESS: Thank you, Your Honor.

(Witness excused.)

THE COURT: Government, call your next witness.

MR. LEVENTIS: Your Honor, the government calls Kyle

1 Martel. 4:01PM 2 THE DEPUTY CLERK: Please come forward to be sworn. 4:01PM THE WITNESS: Over there? 3 4:01PM 4 THE DEPUTY CLERK: Yes. Please place your left hand 4:01PM on the Bible, raise your right. State your full name for the 5 4:01PM record. 6 4:01PM 7 THE WITNESS: Kyle James Martel. 4:01PM 8 Thank you. THE DEPUTY CLERK: 4:02PM 9 (Witness sworn.) 4:02PM 10 THE DEPUTY CLERK: Thank you. You may be seated 4:02PM 11 right over there. Be careful of the step right there. 4:02PM 12 THE WITNESS: Thank you. Yep. 4:02PM 13 MR. SHAHEEN: Your Honor, may I approach just to hand 4:02PM 14 him a binder? 4:02PM 15 THE COURT: You may. 4:02PM 16 MR. SHAHEEN: There are several records here. 4:02PM 17 probably easier if I just take them, Your Honor. 4:02PM 18 THE COURT: Okay. Very good. Go ahead and take 4:02PM 19 them. Make sure anything that's in evidence, that you get back 4:02PM 20 to Ms. Ravenel. 4:02PM 21 Yes, Your Honor. MR. SHAHEEN: 4:02PM 22 THE DEPUTY CLERK: I think they know by now. 4:02PM 23 MR. SHAHEEN: What? 4:02PM 24 KYLE MARTEL, 4:02PM 25 a witness called on behalf of the plaintiff, being first duly 4:02PM

sworn, was examined and testified as follows: 1 4:02PM 2 **DIRECT EXAMINATION** 4:02PM 3 BY MR. SHAHEEN: 4:02PM 4 Q. Good afternoon, Mr. Martel. 4:02PM 5 Good afternoon. Α. 4:02PM Can you state your full name for the record? 6 Q. 4:02PM 7 Kyle James Martel. Α. 4:02PM 8 And where do you live, Mr. Martel? 0. 4:03PM 9 Tampa, Florida. 4:03PM 10 Did there come a time when you went to work with BlueWave Q. 4:03PM 11 Healthcare consultants, Incorporated? 4:03PM Based on the advice of counsel, I assert my rights under 12 4:03PM 13 the Fifth Amendment of the United States Constitution and 4:03PM 14 respectfully decline to answer that question. 4:03PM 15 were you an employee of Bluewave or did you serve as an Q. 4:03PM 16 independent contractor? 4:03PM 17 Based on the advice of counsel, I assert my rights under Α. 4:03PM the Fifth Amendment of the United States Constitution and 18 4:03PM 19 respectfully decline to answer that question. 4:03PM 20 Did you sell HDL and Singulex tests for BlueWave? 4:03PM 21 Based on the advice of counsel, I assert my rights under 4:03PM 22 the Fifth Amendment of the United States Constitution and 4:03PM 23 respectfully decline to answer that question. 4:03PM 24 when you met with potential clients, did your sales pitch 4:03PM 25 include touting the fact that HDL paid physicians \$20 for every 4:03PM

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- sample referred?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Did your sales pitch also include touting the fact that \$20 per sample that HDL paid was significantly more than what competitor labs paid?
- Again based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Did your sales pitch also include touting the fact that 0. Singulex paid physicians for every sample referred?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Did your sales pitch tout the fact that your clients could 0. refer samples to HDL and Singulex and then receive \$30 or more for every sample referred?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Did your sales pitch to potential clients include touting 0. the fact that HDL and Singulex waived copays and deductibles for their patients?
- Based on the advice of counsel, I assert my rights under

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the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

- Q. If you could turn to Tab 1162 in your binder, Mr. Martel.

 Mr. Martel, can you tell me the date of this email?
- A. 6/16/2010.
- **Q.** And can you tell me the name of the author of this document, at least the author of the email at the top of this document?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Can you tell me the address to whom Ms. Kamachie Chinapen, assuming she is a woman, sends this email to?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United states Constitution and respectfully decline to answer that question.
- Q. Mr. Martel, do you see halfway down the page, there's another email chain from kmartel@bluewavehealth.com?
- A. Based on the advice of counsel, I assert by rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. And so the author, kmartel@bluewavehealth.com, writes, "Per our discussion, I have an opportunity that would make more clinical and business sense for your practice than your current in-office lab services provided by Premier Laboratories.

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12	М	Ρ	6	0	:	4
13	М	Ρ	6	0	:	4
14	М	Ρ	6	0	:	4
15	М	Ρ	6	0	:	4
16	М	Ρ	7	0	:	4
17	М	Ρ	7	0	:	4
18	М	Ρ	7	0	:	4
19	М	Ρ	7	0	:	4
20	М	Ρ	7	0	:	4
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Do you see that?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, why did this opportunity make more clinical and business sense for that practice?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- second page of this document, the author, kmartel@bluewavehealth.com writes, "An estimation, the practice has the potential to draw close to 100 panels a week if we were to include all the other insurances we were not able to include previously. Therefore, 100 panels a week would result in a revenue stream for the office of 2,000 panels per week."

would you turn to the back of this document -- or the

Do you see that?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** And then in the next paragraph, the author of this document, kmartel@bluewavehealth.com, writes, "This would far outweigh any rent money an outside laboratory could legitimately compensate the office to assist in collecting blood specimen."

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Do you see that?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. And, again, if we look at the next sentence, the author of this document, kmartel@bluewavehealth.com, writes, "I know that the Lady Lake office does just about the same amount of blood draws, which would be an additional 2,000 per week minimally."

Do you see that, Mr. Martel?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** And do you see the signature that reads "Kyle J. Martel, Executive Disease Management Consultant for BlueWave Healthcare Consultants," Mr. Martel?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Is this an example of one of the ways in which you approached potential clients about HDL and Singulex?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Is this an example of you selling HDL tests by using the per-specimen payments as a sales tool, Mr. Martel?

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- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, did you sell HDL tests by talking about the revenue stream that potential clients could generate?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. As part of your sales pitch, you also mentioned that HDL paid significant --

MR. SHAHEEN: Actually, I apologize, Your Honor. I would like to move Plaintiffs' Exhibit Number 1162 into evidence.

THE COURT: Is there an objection?

MR. GRIFFITH: No objection, Your Honor.

MR. ASHMORE: Your Honor, I'll object. There's no foundation.

MR. SHAHEEN: Your Honor, I have just been told that this, in fact, had been previously admitted. And I would also add that the foundation is established by the fact that kmartel@bluewavehealth.com appears all over this. And it appears as though --

THE COURT: It's already into evidence?

MR. SHAHEEN: Yes, Your Honor.

THE COURT: It's academic then.

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MR. ASHMORE: I stand corrected.

THE COURT: Anything further?

MR. SHAHEEN: Yes, Your Honor.

BY MR. SHAHEEN:

- **Q.** As part of your sales pitch, you also told doctors that HDL paid significantly more per specimen than its competitors; correct, Mr. Martel?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Can you turn to the next tab in your binder, Mr. Martel, Plaintiffs' Exhibit Number 1268.

And do you see that this document or this email is from kmartel@bluewavehealth.net -- or bluewavehealth.com, Mr. Martel?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** And this is drafted or sent on September 13th, 2011, and the author of this document writes, "Our processing and handling fees are also much better than the other companies' as well."

Do you see that, Mr. Martel?

A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and

4:10PM	1	respectfully decline to answer that question.
4:10PM	2	Q. Do you see that the signature block at the bottom of this
4:10PM	3	email comes from Kyle J. Martel, Executive Disease Management
4:10PM	4	Consultant, BlueWave Healthcare Consultants, Mr. Martel?
4:10PM	5	A. Based on the advice of counsel, I assert my rights under
4:10PM	6	the Fifth Amendment of the United States Constitution and
4:10PM	7	respectfully decline to answer that question.
4:10PM	8	MR. SHAHEEN: Your Honor, I would ask that
4:10PM	9	Plaintiffs' Exhibit Number 1268 be entered into evidence.
4:10PM	10	THE COURT: Is there an objection?
4:10PM	11	MR. GRIFFITH: No objection, Your Honor.
4:10PM	12	MR. ASHMORE: Same objection, Your Honor. Lack of
4:10PM	13	foundation.
4:10PM	14	THE COURT: Can I see the document, please?
4:11PM	15	MR. SHAHEEN: It's appearing on your screen, Your
4:11PM	16	Honor. I'd be happy to approach and
4:11PM	17	THE COURT: Is it on the I think I've got to look
4:11PM	18	at it before the jury does.
4:11PM	19	MR. SHAHEEN: Okay.
4:11PM	20	THE COURT: Take it off the screen.
4:11PM	21	Let me speak to counsel, please.
4:12PM	22	(Whereupon the following proceedings were held at the
4:12PM	23	bench out of the hearing of the jury:)
4:12PM	24	THE COURT: You're making an authentication
4:12PM	25	objection? We're confused what the basis it's identified.

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I think there's a foundation based on the document itself.
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              can see what it is.
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                        MR. ASHMORE: Well, but he's given absolutely no
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              answers whatsoever.
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                                   But it may be -- if it's an
                        THE COURT:
4:12PM
              authentication issue --
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                        MR. ASHMORE: It is not. I'm not going to raise
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              that.
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                        THE COURT: Okay. So what's the basis?
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                        MR. ASHMORE:
                                      Your Honor --
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                        THE COURT: The document itself lays a foundation.
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              It says it's from him, and it's a memo.
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                        MR. ASHMORE: It's a self-authenticating document,
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              Your Honor?
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                        THE COURT: Well, I thought you weren't objecting to
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              authentication.
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                        MR. ASHMORE: I'm not. I'm just thinking out loud.
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              I don't know how they get this in. I don't -- it seems like
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              they have to have a witness identify what that document is.
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                        THE COURT: What's the government's response?
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                        MR. SHAHEEN: Your Honor, he's pleading the Fifth,
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         22
              and an inference can be drawn from that that he's pleading the
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              Fifth because he's -- certain -- I'm sorry -- because he's
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              concerned about the contents of this document.
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                        THE COURT: How was this document obtained?
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1 MR. SHAHEEN: 4:13PM 2 4:13PM 3 MR. LEVENTIS: 4:13PM 4 4:13PM 5 4:13PM 6 THE COURT: 4:13PM 7 4:14PM 8 4:14PM 9 4:14PM 10 approach? 4:14PM 11 THE COURT: 4:14PM 12 4:14PM 13 4:14PM 14 MR. GRIFFITH: 4:14PM 15 4:14PM 16 4:14PM 17 4:15PM 18 4:15PM 19 4:15PM 20 4:15PM 21 objection. 4:15PM 22 4:15PM 23 4:15PM 24 THE COURT: 4:15PM 25 4:15PM

This came from BlueWave emails. was produced by BlueWave initially, Your Honor.

He's made himself -- he's made himself unavailable by declaring the Fifth, and under 804(b)(3)(1) exception to this statement against interest --

> Let me take a look at that. (Whereupon the following proceedings were held in open court in the presence and hearing of the jury:) MR. GRIFFITH: Your Honor, before you rule, can I

You may, yes, sir.

(Whereupon the following proceedings were held at the bench out of the hearing of the jury:)

It's not a criminal -- there's no evidence that it's in furtherance of a criminal conspiracy, and there's no evidence that -- and he's an independent contractor.

THE COURT: I believe there's adequate inference here that he is a co-conspirator. This would go to a prior statement by a co-conspirator under 801(d)(2)(E), and as such, it would be admissible on that basis. I overrule the

> (Whereupon the following proceedings were held in open court in the presence and hearing of the jury:) Ms. Ravenel, I hand that back to you. Plaintiffs' 1268 is admitted over the objection

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of the defendants.

BY MR. SHAHEEN:

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4:15PM

- Q. Mr. Martel, looking at Plaintiffs' Exhibit Number 1268, is it -- this is an example of you selling HDL and Singulex testing by noting that their process and handling fees were better than other companies; correct?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Did you send emails like this to other practices, Mr. Martel?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United states Constitution and respectfully decline to answer that question.
- **Q.** Did you tout HDL and Singulex testing as having higher per-specimen payments than your competitors in face-to-face sales pitches, Mr. Martel?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, how did you identify potential clients in your region?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

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Q. Mr. Martel, can you turn to the tab for Plaintiffs' Exhibit Number 3044.

Have you seen this document before, Mr. Martel?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Did BlueWave instruct you to look for practices that have their own labs?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Did BlueWave give that instruction because practices with their own labs were more likely to refer more tests?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Looking at Criteria 2, did BlueWave instruct you to look for practices that had the ability to draw their own blood?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Did BlueWave give that instruction because the practices that had the ability to draw their own blood were more likely to refer more tests?
- A. Based on the advice of counsel, I assert my rights under

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the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

- **Q.** Mr. Martel, were practices that had the ability to draw their own blood more likely to be induced by the money they received from the labs for each specimen referred?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, now turning to Criteria Number 3 on this document, did BlueWave instruct you to look for physicians who believed they were smarter than the average physician?
- **A.** Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Did BlueWave instruct you to look for physicians who were smarter than the average physician because those physicians were more likely to understand how much revenue they could realize from the money they received from the labs?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Turning to Criteria Number 4, did BlueWave instruct you to look for practices consisting of only a small group of physicians?
- A. Based on the advice of counsel, I assert my rights under

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the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

- **Q.** Mr. Martel, were practices consisting of only a small group of physicians less likely to express concerns about the payments from HDL and Singulex?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. If you could turn to Criteria Number 6, Mr. Martel.

 Did BlueWave instruct you to look for money-hungry doctors?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, were money-hungry physicians more likely to order more tests to get more specimen payments from HDL and Singulex?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Did BlueWave instruct you to look for physician practices that already had a nurse practitioner or physician's assistant?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

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- Did you target such practices that already had nurse 0. practitioners and physician's assistants because they already had the infrastructure in place to draw blood? Α. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question. The practice that already had the infrastructure in place would be more likely to realize just straight profit from the specimen payments; correct? Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question. Mr. Martel, did some of your clients order tests from Singulex and HDL on the same patient? Α.
 - Based on the advice of counsel, I assert my rights under the Fifth Amendment. United States Constitution and respectfully decline to answer that question.
- would a physician that ordered tests from both Singulex Q. and HDL receive a larger P&H payment, Mr. Martel?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Did BlueWave pay you commissions for selling HDL and 0. Singulex lab tests?
- Based on the advice of counsel, I assert my rights under Α.

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the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

- **Q.** Mr. Martel, those commission payments were dependent on the number of tests your physicians ordered; correct?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. So the more tests your client referred, the larger the commission you received; correct?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Mr. Martel, did you push your clients to order more tests in order to boost your commissions?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Mr. Martel, can you turn to Tab 1033 in your witness binder.

Mr. Martel, this document is from Kyle Martel and is sent to Renee Hume. Do you know who Renee Hume is?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. And it's a response to an email from Ms. Hume, and

1 4:22PM 2 4:22PM 3 4:22PM 4 4:22PM 5 4:22PM 6 4:22PM 7 4:22PM 8 4:22PM 9 4:22PM 10 4:22PM 11 4:22PM 12 4:22PM 13 4:22PM 14 4:23PM 15 4:23PM 16 4:23PM 17 4:23PM 18 4:23PM 19 4:23PM 20 4:23PM 21 4:23PM 22 4:23PM 23 4:23PM 24 4:23PM 25 4:23PM

Ms. Hume has an email address that ends with @hdlabinc.com.

Did you see that, Mr. Martel?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** And in this document, Ms. Hume communicates to you that one of your clients is wanting to drop several tests from his panel.

Do you see that, Mr. Martel?

- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** And, Mr. Martel, your response to this news or information is "That's not going to work. Let me call them."

Do you see that, Mr. Martel?

A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

MR. SHAHEEN: Your Honor, I would ask that Plaintiffs' Exhibit Number 1033 be entered into evidence.

THE COURT: Any objection?

MR. GRIFFITH: Same objection, Your Honor.

MR. ASHMORE: Same objection, Your Honor.

THE COURT: Plaintiffs' Exhibit 1033 is admitted over objections of defense.

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BY MR. SHAHEEN:

- Q. Mr. Martel, this email exchange is dated March 5, 2013.
- Do you know whether HDL and BlueWave knew that they were under investigation by the Department of Justice at that time?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Was your client's desire to drop the tests not going to work for you because that meant less money in your pocket, Mr. Martel?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- **Q.** Mr. Martel, did some of your physician clients tell you that the per-specimen payments were illegal kickbacks?
- A. Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Q. Mr. Martel, can you turn to Plaintiffs' Exhibit Number 1276 in your exhibit binder.

THE COURT: Mr. Shaheen, how much longer are you going to do on this? I'm concerned. I think I previously told y'all that we were going to go a certain limit here on Fifth Amendment assertions.

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MR. SHAHEEN: I can make it very quick, Your Honor.

THE COURT: Okay. Good.

MR. SHAHEEN: I think I have just three documents.

BY MR. SHAHEEN:

- Mr. Martel, is this email from Vikram Saini to Scott Trombino and kmartel@bluewavehealth.com?
- I'm sorry. What was the question? Α.
- Is this email from Vikram Saini and sent to Scott Trombino 0. and kmartel@bluewavehealth.com?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.
- Do you see where Mr. Saini, who has the initials J.D. next to his name, writes, "Please tell me how this is not a kickback"?
- Based on the advice of counsel, I assert my rights under the Fifth Amendment of the United States Constitution and respectfully decline to answer that question.

MR. SHAHEEN: Your Honor, I would like to move for Plaintiffs' Exhibit Number 1276 to be entered into evidence.

Is that a -- I haven't seen it. THE COURT: a statement by somebody else or is that a statement by Mr. Martel?

MR. SHAHEEN: It is a statement sent to Mr. Martel from Vikram J. Saini.

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4:27PM

THE COURT: Is there an objection?

MR. GRIFFITH: Objection, Your Honor.

THE COURT: I sustain that objection.

MR. SHAHEEN: Your Honor, if I may just have one

moment.

you.

Your Honor, I have no further questions. Thank

THE COURT: Cross-examination?

MR. GRIFFITH: No cross, Your Honor.

MR. ASHMORE: No questions, Your Honor.

THE COURT: You may step down.

THE WITNESS: Thank you, sir.

(Witness excused.)

THE COURT: Ladies and gentlemen, we'll provide you a brief instruction regarding the assertion of a Fifth Amendment right by a witness.

The Fifth Amendment of the United States

Constitution provides that no person can be compelled to be a witness against himself. This is properly -- popularly known as the right against self-incrimination. Where a witness reasonably believes that his response to a question could expose him to probable criminal prosecution, he may refuse to answer that question.

You may consider a witness's refusal to answer a question as evidence in the case. I will discuss with you

1 4:27PM 2 4:27PM 3 4:27PM 4 later. 4:27PM 5 Call your next witness. 4:27PM 6 4:27PM 7 Alison Coleman. 4:27PM 8 4:27PM 9 4:27PM 10 record, please. 4:27PM 11 THE WITNESS: 4:27PM (Witness sworn.) 12 4:27PM 13 THE DEPUTY CLERK: 4:27PM 14 right there, so be careful. 4:27PM 15 THE WITNESS: Okay. Thanks. 4:27PM 16 4:27PM 17 soft-spoken. 4:27PM 18 THE WITNESS: Okay. 4:27PM 19 4:28PM 20 4:28PM 21 THE COURT: Absolutely. 4:28PM 22 MR. KASS: Thank you, sir. 4:28PM 23 ALISON HILDRETH COLEMAN, 4:28PM 24 4:28PM 25 4:28PM

further in my closing charge a witness's assertion of his or her Fifth Amendment right against self-incrimination and the significance it may play in your deliberations. I will do that

MR. LEVENTIS: Thank you, Your Honor. We'll call

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

Alison Hildreth Coleman.

You may be seated. There's a step

THE COURT: Please speak into the microphone. You're

MR. KASS: Your Honor, to speed things along, may I just put up there a document for her to refer to.

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

4:28PM	1	DIRECT EXAMINATION
4:28PM	2	BY MR. KASS:
4:28PM	3	Q. Good afternoon, Ms. Coleman. Will you please state your
4:28PM	4	name for the record?
4:28PM	5	A. Alison Coleman.
4:28PM	6	Q. And we have met before, but for the benefit of the record,
4:28PM	7	my name is Michael Kass. I represent the United States.
4:28PM	8	Ms. Coleman, where are you employed?
4:28PM	9	A. I'm employed with the Defense Health Agency.
4:28PM	10	Q. What is the Defense Health Agency?
4:28PM	11	A. The Defense Health Agency is a United States agency that
4:28PM	12	oversees the TRICARE program and the military health system.
4:28PM	13	THE COURT: Ms. Coleman, could you speak closer to
4:28PM	14	the microphone. I think it'll be easier for the jury to hear
4:28PM	15	you.
4:28PM	16	BY MR. KASS:
4:28PM	17	Q. Thank you. What is the TRICARE program?
4:29PM	18	A. The TRICARE program is the health benefit program that
4:29PM	19	provides health care coverage for active duty service members,
4:29PM	20	retirees, and their families.
4:29PM	21	Q. And what is your title at the Defense Health Agency?
4:29PM	22	A. I'm a chief of contractor compliance oversight and a
4:29PM	23	supervisory health care fraud specialist.
4:29PM	24	Q. Ms. Coleman, do you have any professional certifications?
4:29PM	25	A. Yes, I do.

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- Q. Which professional certifications do you have?
- A. I'm an accredited health care fraud investigator, a certified fraud examiner, I'm a certified coding specialist, a certified professional coder, a certified professional compliance officer, and I have specialty credentials in evaluation and management coding.
- **Q.** Ms. Coleman, you referred to coding. What does coding refer to in layman's term?
- A. Medical code is storytelling. So as a coder, what I do is I'll read the patient encounter and determine what the diagnosis is and what services -- procedures and services have been performed. The shorthand version is translated into codes. Those codes are what a doctor or a lab is going to bill to the insurance company for payment.
- Q. When did you first join the Defense Health Agency?
- A. I joined Defense Health Agency in 2010.
- Q. What was your first position at the Defense Health Agency?
- A. When I joined Defense Health Agency, I was a health care fraud specialist.
- Q. For how long were you in that position?
- A. Seven and a half years, until just recently, November.
- **Q.** And what happened just recently?
- A. I was promoted to branch chief.
- **Q.** What were your responsibilities during your seven and a half years as a health care fraud specialist at the Defense

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Health Agency?

The office I work in is the Office of Program Integrity, and we are the central coordinating office for all fraud and abuse within the TRICARE program. I would handle health care fraud and abuse, civil and criminal matters, provide technical support to Department of Justice, FBI, defense criminal investigative services.

I was a subject matter expert on coding, so I was the go-to person for anything coding or billing-related. also responsible for knowing TRICARE policy, procedures, also overseeing the contractors that administer the TRICARE program for us, in addition to responding to whistle-blower qui tam cases and data analysis.

- And you mentioned now you've been promoted to chief of contractor oversight branch. What are your responsibilities currently?
- In that role, I am responsible for the oversight of eight contracts. How that works with TRICARE, we have -- previous to just recently, January 1st, we had three managed care support contractors. We have the north, the south, and the east. And they handle all of the claims for -- and the program for those regions for all TRICARE beneficiaries.

We have a pharmacy contractor. We have an overseas contractor since many of our beneficiaries are overseas and still seeking health care. We have dental contractors.

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have TRICARE for, like, contract, which handles all of our individuals who have -- typically Medicare is primary and TRICARE pays secondary.

And so my team is made up of subject matter experts that make sure that they are meeting their contractual requirement in the program integrity. So each contractor is required to have a program integrity office within each contract to address fraud and abuse in the program.

- **Q.** Ms. Coleman, what kinds of benefits does the TRICARE program provide?
- A. The TRICARE benefit provides comprehensive health care services for our members. That can be anywhere between your normal office visit, your prescriptions. If you need to have surgery, maternity care, laboratory services, x-rays, pretty much everything.
- **Q.** What determines, generally speaking, whether a particular procedure or service is covered by TRICARE?
- A. Well, under the TRICARE program, it needs to be, one, a covered beneficiary or patient but performed by an authorized provider, be medically necessary, and be a covered benefit under the program.
- **Q.** And from where does the TRICARE program receive its funding?
- A. The TRICARE program receives all of its funding from the U.S. taxpayers.

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- **Q.** Are you familiar with a company called Health Diagnostic Laboratory, Inc.?
- A. Excuse me. Yes, I am.
- **Q.** How did you become familiar with Health Diagnostic Laboratory?
- A. I became familiar with that company when Department of Justice and FBI requested TRICARE case support.
- **Q.** And are you familiar with a company called Singulex, Inc.?
- A. Yes, I am.
- **Q.** How did you become aware of Singulex?
- A. In the same manner.
- **Q.** What relationship did Health Diagnostic Laboratory have to the TRICARE program?
- **A.** HDL, within the TRICARE program, would be considered a nonnetwork participating provider.
- **Q.** And what relationship did Singulex have to the TRICARE program?
- A. Singulex had the same, a nonnetwork participating provider status.
- **Q.** I'd like to break down that term a little bit. What does nonnetwork refer to?
- A. Nonnetwork means that they chose not to sign a network agreement with one of our managed care support contractors.
- Q. And how does a laboratory become a provider for TRICARE?
- A. Under the TRICARE program, they need to be an authorized

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provider. But for labs, they need to be certified and approved by the Medicare program.

- **Q.** You also referred to the term "participating." What does participating provider refer to?
- A. Under our program, a participating provider has agreed, on a claim assignment, to bill the TRICARE beneficiary -- on behalf of the TRICARE beneficiary, to bill the program directly and accept the TRICARE-allowable maximum as the payment in full.
- **Q.** What is the -- I believe you called it the TRICARE-allowable maximum? What is that?
- A. The TRICARE-allowable maximum is the dollar amount or the fee that TRICARE is going to allow and pay for a certain service or supply.
- **Q.** What is a TRICARE claim?
- A. A TRICARE claim is pretty simple. A TRICARE patient goes and sees their doctor. The doctor performs services. The claim is what the doctor puts his codes on and submits to TRICARE to receive payment for services provided to a TRICARE patient.
- Q. And how are claims submitted by providers to TRICARE?
- A. Claims can be submitted in two ways, either on a paper CMS-1500 or electronically.
- MR. KASS: Peter, would you mind bringing up the CMS-1500 demonstrative.

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And for the benefit of the record, this is a demonstrative we've used previously in the trial.

BY MR. KASS:

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Q. Ms. Coleman, it may be a little hard to read on your screen. We can zoom in if it would be helpful.

But do you recognize the document that appears on that first page?

- A. Yes, I do.
- Q. What is that document?
- A. This document is a CMS-1500.
- **Q.** And what relation to the TRICARE program does this document have?
- A. This is the document that providers and labs submit to TRICARE for payment for service.
- Q. Is this the same claims form that Medicare uses?
- A. Yes, it is.
- **Q.** When a provider submits this CMS-1500 form to TRICARE, is the provider making any certifications?
- A. Yes, they do. If you look -- oops. Sorry
- **Q.** We're ahead of you, apparently.
- A. That's a good thing.

If you can read this, you'll see that, at the top line, the information on this form is true, accurate, and complete. The claim is meeting all the rules and regulations and program instructions and is not violating any federal

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Anti-Kickback Statute, and that these services were medically necessary.

- And as someone who's worked at TRICARE for over seven and a half years, in layman's terms, what does this mean?
- when they're certifying, they're just -- every time they attest and submit a claim to our program, they're certifying this with each claim; that it's truthful, accurate, complete, and meeting all the requirements on the back side of the form.
- And earlier you mentioned that a provider can submit claims electronically. If a provider submits claims electronically, does the provider make any certifications to TRICARE?
- They make the same certifications.
- would you briefly describe how the claims process works Q. for a situation involving blood testing at a high level?
- We go see our doctor. Our doctor does an examination on us and decides he's going to have some blood drawn. He's going to prepare that specimen. But he's going to bill TRICARE directly for that office visit; right? We know how that all works.

So that doctor submits the claim directly to TRICARE for his services for that office visit. The doctor then submits the specimen and sends the specimen to the lab. lab does lab testing. Then the lab bills TRICARE directly to receive payment for the services they performed on the TRICARE

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patient.

- **Q.** Let's talk a little bit about the claim that the physician's office submits to TRICARE. Are you familiar with something called the evaluation and management codes?
- A. Yes, I am.
- **Q.** Generally speaking, at a high level, what are the evaluation and management codes?
- A. The evaluation and management codes are going to be the codes that doctors bill for the services performed in the office. We would know them as office visits, the typical you go in and see the doctor, and, depending on level of exam, what treatment options, and your history, the doctor will be submitting a claim with a code that equates to -- or is an equivalent to an office visit.
- **Q.** What types of services are paid for as part of this office visit under the evaluation and management codes?
- A. In the office visit, what's included is of course the physician's work, so the time spent that the doctor is working with you, the decision-making, your physical exam. The other part that goes into that is kind of the overhead, covering for clinical staff and the tasks that they're completing for the front office.

So they're kind of split 50-50, what the doctor gets, and then all the overhead tasks that are included. When your nurse takes your blood pressure or, as we all love it, when you

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get your weight when you walk in, that's also included. So the doctor is getting one payment, and in that payment includes everything and the kitchen sink. So there's perhaps a lab specimen that needs to be prepared. The clinical staff is being paid for that under the clinic payment to the doctor.

- Q. So in the scenario you described earlier, a patient goes into a physician's office, blood is drawn. How, if at all, does TRICARE pay for the process and handling work related to that blood sample?
- A. Well, the processing and handling process, there's a code that kind of talks about it, 99000, which is processing and handling. It has a status of a B, which means blood work. So what that tells me -- and I'll let you guys know how it works -- there's no additional payment made. It's made in with that office visit. So there's no additional payment. It is included already in the primary service. And, in this case, with your primary care physician or your family doctor, it's going to be paid for in that one payment that the doctor receives when he bills TRICARE for that office visit.
- **Q.** How much does TRICARE pay primary care physicians for office visits?
- A. There's five levels. The typical average, middle-of-the-road offices, it would be a Level 3. For an established patient, TRICARE is going to pay approximately \$73, kind of a 15-minute visit. Doctor will submit that claim to

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TRICARE, and TRICARE will pay the doctor about \$73.

- Q. And you mentioned that there are five different levels to the evaluation and management codes. Just to give some context, what's sort of the upper or lower limits for a primary care physician?
- A. With established visits, you'll have a 99211, doctor is going to get paid 20 -- approximately \$20 on that. That's the lowest level. Then at Level 5, for an established office visit, TRICARE is going to pay approximately 215, \$220.
- **Q.** And the processing and handling work that's performed in relation to the blood sample is covered as part of that?
- A. That overhead is included in each of those levels of E&M.
- Q. If the doctor then sends the blood sample to a laboratory, how does TRICARE pay the lab for the lab testing it performs?
- A. The lab would be required to bill TRICARE directly for the lab services they performed. The same claims process would exist. They would submit the claims to the claims processor for payment, and TRICARE would process the claim and cut a check back to the lab for their services and include a TRICARE explanation of benefit or a payment summary telling the lab how much money they were getting paid.
- Q. I'd like to ask you about the document in front of you, but allow me one moment.

Ms. Coleman, are you familiar with this document?

A. Yes, I am.

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- hat is this document?
- his is a TRICARE payment summary.

MR. KASS: Your Honor, I'd like to move Exhibit -iffs' Exhibit 6042 into evidence, please.

> MR. GRIFFITH: No objection.

MR. ASHMORE: No objection.

Plaintiffs' Exhibit 6042 is admitted THE COURT: t objection.

KASS:

- s. Coleman, I'd just like to very briefly walk through ocument. If you don't mind turning to the third page, is labeled in the lower right-hand corner USADOC2230105. see that?
- h-huh. Yes, I do.
- kay. And --

I'm sorry, Your Honor. Could I have just MR. KASS: nt, please?

> THE COURT: Sure.

> > (Pause.)

Sorry, Your Honor. I just wanted to MR. KASS: t patient confidentiality.

> THE COURT: No problem.

KASS:

s. Coleman, forgive me. I'd like to draw your attention if you look a couple of columns in from the left, do you

see the "dates of service" column? 1 4:45PM 2 Α. Yes. 4:45PM What does that column refer to? 3 Q. 4:45PM 4 Α. Those are the dates that the services were performed. 4:45PM 5 And next to that column, do you see a "procedure" 0. 4:45PM column -- or excuse me -- a column labeled "procedure"? 6 4:45PM Yes, those are CPT codes indicating what services were 7 4:45PM 8 performed. 4:45 P M 9 And if you look a couple to the right of that, do you see 4:45PM 10 a "total charges" column? 4:45PM 11 Yes, I do. Α. 4:45PM What does that column refer to? 12 4:45PM 13 The total charges indicate the dollar amount that the lab 4:45PM 14 billed TRICARE for each service. 4:45PM 15 And one column to the right of that, there's a column Q. 4:45PM 16 labeled "allowed covered charges." 4:45PM 17 Do you see that? 4:45PM Yes, I do. 18 4:45PM Α. What does that column refer to? 19 Q. 4:45 P M That's the TRICARE allowable. 20 4:46PM In layperson's terms, what does that mean? 21 Q. 4:46PM 22 It's what TRICARE would pay for that specific lab test. Α. 4:46PM 23 And if you back up to the first page of this 0. 4:46PM 24 document, which is Bates-labeled USADOC2230103, can you tell 4:46PM 25 from that page which provider provided the services that we're 4:46PM

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talking about here?

- A. Health Diagnostic Laboratory.
- Q. Okay. And if you don't mind turning back to the third page again, that's USADOC2230105. And looking back at the allowed covered charges, so in the case of this document, how much did TRICARE pay Health Diagnostic Laboratory for the services that were provided?
- **A.** TRICARE paid \$108.14.
- Q. Oh, I see.

Okay. So what is the difference between the allowed covered charges column and the TRICARE payment box which is a little bit to the right and below?

- A. The allowed covered charges is the maximum that TRICARE would pay. The TRICARE payment is what was paid to the provider. The \$27.04 is the amount the patient is responsible for paying.
- Q. Somehow you knew my next question. What does that mean in layman's terms?
- A. A cost share can include coinsurance, copays, deductibles. It's the term we use in TRICARE. And it just means the amount the patient is responsible for paying for their share of their health care.
- **Q.** What determines the amount of patient's responsibility, generally speaking?
- A. The services they receive and the program they are

4:47PM	2	Q. And how does a provider know how much to collect from a
4:47PM	3	patient?
4:47PM	4	A. The provider goes by reading the payment summary, and it
4:48PM	5	clearly states what's the patient responsibility.
4:48PM	6	Q. And by "payment summary," you're referring to this
4:48PM	7	document?
4:48PM	8	A. Yes.
4:48PM	9	Q. Does a provider get a document in this format for each and
4:48PM	10	every claim that is paid by TRICARE?
4:48PM	11	A. Yes, they do.
4:48PM	12	Q. So they look at this document and they know what the
4:48PM	13	patient responsibility is?
4:48PM	14	A. Yes.
4:48PM	15	Q. Who is responsible for collecting the patient
4:48PM	16	responsibility?
4:48PM	17	A. The provider who received the payment from TRICARE.
4:48PM	18	Q. So in the case of this particular document, who
4:48PM	19	specifically would be responsible for collecting the patient
4:48PM	20	responsibility?
4:48PM	21	A. Health Diagnostic Laboratory.
4:48PM	22	Q. Does TRICARE require Health Diagnostic Laboratory to
4:48PM	23	collect the patient responsibility from a patient?
4:48PM	24	A. Yes. It's a requirement under our program.

Why does the TRICARE program require Health Diagnostic

enrolled in.

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Laboratory and other providers to collect patient responsibility?

- A. It's a requirement under our program. It keeps our patients involved as stakeholders in their health care, and, in addition, it keeps the communication, the relationship, open with the provider to incentivize open care and make sure that the services that are being performed are medically necessary and the patient is aware of them.
- **Q.** So in the case of this particular document, how much was Health Diagnostic Laboratory required to collect from the patient?
- A. According to this document, \$27.04 was to be received by the patient.
- **Q.** At a high level, generally speaking, if a patient cannot afford to pay the patient responsibility, how, if at all, does TRICARE deal with that, at a high level?
- A. At a high level, we do have the ability under the TRICARE program for a provider to write it off as bad debt. But it can't -- it has to be a documented process going through with multiple attempts at collection, communication with the TRICARE patient, and documentation.
- **Q.** Earlier you referred to medical necessity. How does medical necessity affect whether a provider is entitled to payment for a claim under the TRICARE program?
- A. If the TRICARE program finds out a claim was submitted

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that was not medically necessary, then no payment would be allowed.

- **Q.** And let me ask you this: The fact that a provider submits a claim, does that necessarily mean that the claim is medically necessary?
- A. They certify and make the attestation every time they submit that claim to the TRICARE program. We discussed on the back side of that claim, you know, about the medical necessity and following the rules. So every time a claim is submitted, that certification is being made.
- **Q.** Are you familiar with something called the Anti-Kickback Statute?
- A. Yes, I am.
- **Q.** How does the Anti-Kickback Statute affect whether a provider is entitled to payment for a claim under the TRICARE program?
- A. If a claim has been found to be the result of an anti-kickback violation, in the TRICARE program, it would be considered false and no payment would be allowed.
- **Q.** Do violations of the Anti-Kickback Statute matter to the TRICARE program?
- A. Yes, they do.
- **Q.** Why is that?
- A. The TRICARE programs needs to have the faith and confidence that the medical doctors are using their clinical

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judgment when determining the services necessary for our TRICARE patients, and the risk of kickback influencing that decision to make those -- or the decision to -- if they're influencing the decision to order those services, it is a problem to the TRICARE program.

- **Q.** And how does the TRICARE program address potential Anti-Kickback Statute violations?
- A. We partner and collaborate with Department of Justice, FBI, defense criminal investigative services.
- **Q.** Thank you, Ms. Coleman. Defendants may have some questions for you.

MR. KASS: And I'll reserve.

THE COURT: Very good.

Cross-examination?

CROSS-EXAMINATION

BY MR. GRIFFITH:

- Q. Good afternoon, Ms. Coleman. Just a few questions.
- The -- does TRICARE generally follow the rules of Medicare?
- A. In many cases, yes.
- **Q.** Now, do you -- is it your understanding that Medicare does not require a copay or deductible with respect to lab services, or do you know?
- A. It is my understanding that outpatient lab services under the Medicare program do not require.
- Q. Okay. Now, if we go to the exhibit you just went over,

1 4:53PM 2 4:53PM 3 4:53PM 4 4:54PM 5 4:54PM 6 4:54PM 7 4:54PM 8 4:54PM 9 4:54PM 10 4:54PM 11 4:54PM 12 4:54PM 13 4:54PM 14 4:54PM 15 4:54PM 16 4:55PM 17 4:55PM 18 4:55PM 19 4:55PM 20 4:55PM 21 4:55PM 22 4:55PM 23 4:55PM 24 4:55PM 25 4:55PM

Plaintiffs' Exhibit 6042.

Can you bring that up?

And go to the third page, at least in my --

MR. KASS: We got it. No, we don't. Yes, we do.

MR. GRIFFITH: Thank you.

So if you could blow up the part that says the copay section, I've got a little --

THE DEPUTY CLERK: I think it's going to go away.

BY MR. GRIFFITH:

- Q. So do you see on the screen where it says a copay of zero?
- A. Yes.
- **Q.** So does that mean that there's no copay required for this particular patient?
- A. Under the TRICARE program, cost share covers multiple terminology. It comes down to what the patient is responsible for.
- **Q.** I understand what you said, but does this indicate that there was no copay in this particular claim?
- A. Depend -- based on how this TRICARE patient is enrolled, they don't have a copay; they have a cost share.
- **Q.** Okay.

Can you explain the difference between a cost share and a copay?

A. In the TRICARE program, cost share is going to be something -- in this case, we know it's coinsurance. So say

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you have a PPO, you owe 10 percent of your services. It's the 10 percent of the allowable. So that's kind of -- the difference is -- and many times with the copay, it would be in an office visit, where you'd just pay the \$12 and the \$17.

THE COURT: Okay. I'm sorry. Go ahead, Mr. Griffith.

BY MR. GRIFFITH:

- **Q.** I just want to make sure, because the information that we've been provided by TRICARE defines cost share and deductible and copay separately. Do you agree with that?
- A. I'm -- and where are you referencing it from?
- O. TRICARE manuals.
- A. Under "basic definitions" under 199-2, if you look under the definition, and it will talk about cost share and then also refer to the other elements that can be cross-referenced when using the term.
- Q. Okay. Cross-referenced, but do you agree with me that, in the TRICARE manuals, that cost share is defined different than deductible and copay?
- A. I would need to see actual examples to be able to confirm or deny.
- Q. Okay. So you don't know without looking at it?
- A. I would need to have an example.
- Q. Okay. But under this scenario that we have right here, there is no copay to waive; correct?

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- A. No, there's a cost share to waive.
- **Q.** Are you familiar with any -- any allegation in this particular case that any defendant waived a cost share?

MR. KASS: I'm just going to put an objection on the record because I feel like there's one, but I don't know what it is.

THE COURT: To be honest with you, I'm not smart enough to figure out how to rule. I deny it.

MR. KASS: I appreciate your consideration.

THE WITNESS: Could you ask your question again.

BY MR. GRIFFITH:

- **Q.** Are you aware of any allegation in this particular case that anybody waived a cost share?
- A. Under the definition of the TRICARE program and what a cost share is, yes, I'm aware that allegations of waiving of cost shares and/or copays were made.
- Q. Have you read the complaint in this case?
- A. The qui tam filings?
- Q. Yes.
- A. Yes.

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4:58PM

- Q. Not the qui tam filing which was in 2011, but the government's complaint in this case.
- A. No, I have not.
- Q. Okay. But you are making -- when you made your statement that you believe that there was cost shares involved, was that

4:58PM	2	A. The the complaint with the government or the original
4:58PM	3	complaints?
4:58PM	4	Q. The complaint and intervention. Yeah, the government's
4:58PM	5	complaint.
4:58PM	6	A. Was I aware that there were allegations of waiving of
4:58PM	7	copay
4:58PM	8	Q. Cost share.
4:58PM	9	A. Cost share?
4:58PM	10	Q. Yeah.
4:59PM	11	A. I was not made of any of the made aware of the actual
4:59PM	12	complaint terminology, cost share versus copay.
4:59PM	13	Q. Okay. So there are plans within TRICARE that have no
4:59PM	14	copay; correct?
4:59PM	15	A. That is true.
4:59PM	16	Q. Okay. How many plans are in TRICARE that have no copay?
4:59PM	17	A. Active duty service members don't have copays, cost
4:59PM	18	shares, coinsurance, or catastrophic caps.
4:59PM	19	Q. Okay. But that was not my question. My question is how
4:59PM	20	many plans are there in TRICARE that don't have copays?
4:59PM	21	A. I can't answer that. It depends on location. If you're
4:59PM	22	out of your network. It's too there's too many elements
5:00PM	23	that fall into that. The one thing is, though, if you bill
5:00PM	24	TRICARE for a service, the provider doesn't have to figure out
5:00PM	25	the cost share, copay, coinsurance. It comes along with the

based in any way on the allegations in the complaint?

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5	:	0	2	Ρ	M	23	
5	:	0	2	Ρ	M	24	
5	:	0	2	Ρ	M	25	

payment to the provider, how much money you need to be collecting from the patient.

- Q. Okay. And the only time -- I just want to make sure I understand what you're saying. The time when you -- when a provider will know about the cost share is after the claim has been submitted; right? And an EOB has been produced?
- A. The provider's put on notification when they receive the payment summary.
- **Q.** And does TRICARE have what they call medical necessity reviews?
- A. Can you provide an example of what type you're inquiring about?
- Q. I just read your deposition, and you said that TRICARE has medical necessity reviews. I'm just asking the question.
- A. Medical necessity reviews can occur.
- **Q.** Okay. And what -- generally, what is a medical necessity review?
- A. A medical necessity review, from my understanding, is when a medical record or records are reviewed -- received -- sorry -- requested first, then reviewed to determine if the medical necessity exists with the claim that was submitted.
- **Q.** Okay. And are you familiar -- isn't it true that there have been no medical necessity reviews of any HDL claim?
- A. I am not aware of any medical necessity reviews for an HDL claim.

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- **Q.** And isn't it true that there's no medical necessity reviews of any Singulex claim?
- A. Not that I'm aware of.
- Q. Okay. And TRICARE has allowed lipid panel testing from 2011 to 2015; correct?
- A. I can't, with certainty, say yes or no.
- **Q.** Okay. And, in fact, when a provider obtains a copay or deductible from a patient and the provider's a lab, the lab does not have to report that payment to TRICARE; correct?
- A. Providers are not required to report back to the program that copays have been received from the patient.
- Q. And so in your -- in the claims data that you provided -- did you, in fact, provide the claims -- the TRICARE claims data to the DOJ in this particular case?
- A. Yes, I did.
- Q. Okay. And so that -- can you confirm, then, that the TRICARE -- TRICARE claims data does not contain any information about a copay collection or deductible collection?
- A. No. The only data that's included is the amount that was calculated on behalf of that claim.
- **Q.** So what happens when an individual is covered both by Medicare and TRICARE?
- A. Can you provide an example?
- **Q.** Well, can an individual be covered by both Medicare and TRICARE?

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- A. Yes, they can.
- Q. Okay. And how do they figure out which copay to pay?
- A. Well, if we're talking lab services, Medicare wouldn't submit a claim to TRICARE because there's no coinsurance or copay required.
- **Q.** So is Medicare always the primary?
- A. In the majority of the cases.
- Q. And so when you were talking about Code 99000 -- I just want to make sure -- and you were talking about the different evaluation and management codes that -- regardless, if somebody does an evaluation, submits an evaluation and management code claim, it's going to get -- and it's a doctor, he's going to get paid the same whether he did a venipuncture and blood processing or whether he didn't; correct?
- A. No, that's not true.
- Q. I stand corrected. You got me on that one.

He's going to get -- he's going to get the same amount under the evaluation and management whether he processed and handles the blood or whether he didn't; correct?

A. That is true.

MR. GRIFFITH: Okay. Thank you.

THE COURT: Cross-examination, Mr. Ashmore?

MR. ASHMORE: No questions, Your Honor.

THE COURT: You may step down --

MR. KASS: Your Honor, and maybe --

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THE COURT: I'm sorry. Redirect.

MR. KASS: I'll be very brief.

THE COURT: You're absolutely correct.

REDIRECT-EXAMINATION

BY MR. KASS:

Q. I just want to briefly clarify something, and I'm sorry to keep you, Ms. Coleman.

Mr. Griffith asked you about something that you referred to as the medical necessity review. And if I understood your testimony correctly, you indicated that you were not aware of any medical necessity review for HDL or Singulex; right?

- A. That is correct.
- **Q.** And let me ask you this. You've been at TRICARE for a while now. Are you aware of any medical necessity review involving a laboratory, using that term in the way that Mr. Griffith used it?
- A. I'm not aware of any with a lab of the magnitude and the amount of claims submitted that had been submitted by HDL and Singulex, no.
- **Q.** And why is that?
- A. It requires a person to physically review them, to request all the records from the lab, and also request the records from the referring provider. And then it has a manual review. And the defendants had billed over 200 -- or 2 million lab tests,

so it would not have been feasible. 1 5:07PM 2 In addition, every time they submitted a claim, they 5:08PM certified and made the attestation that the services were, 3 5:08PM 4 indeed, truthful, accurate, complete, and medically necessary, 5:08PM 5 meeting the program requirements and not a violation of the 5:08PM anti-kickback. 6 5:08PM 7 Are there ways that the TRICARE program can address 5:08PM concerns about medical necessity other than through what 8 5:08PM Mr. Griffith calls the medical necessity review? 9 5:08PM 10 Like I had mentioned about the anti-kickback, we can also 5:08PM 11 take it to Department of Justice, FBI, Defense Criminal 5:08PM Investigative Services for potential investigation, yes. 12 5:08PM 13 And is that what has happened here? 0. 5:08PM 14 Α. No. 5:08PM 15 Q. That has not happened here? 5:08PM 16 Department of Justice came to us. No. 5:08PM 17 Fair enough. I stand corrected. Q. 5:08PM Thank you, Ms. Coleman. 18 MR. KASS: Have a nice 5:08PM 19 weekend. 5:08PM 20 Thank you. You may step down now. THE COURT: 5:08PM 21 (Witness excused.) 5:08PM 22 I take it that's the government witnesses THE COURT: 5:09PM 23 for today. Am I correct? You don't have anybody hanging 5:09PM 24 around? 5:09PM 25 Probably makes -- I'll leave it to MR. LEVENTIS: 5:09PM

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you, Your Honor. We -- probably the next thing we're going to do is do the 30(b)(6) that we've all agreed --

THE COURT: No, we're not doing that now.

MR. LEVENTIS: Yes, that's why I'm saying --

THE COURT: I got to look after my jury.

MR. LEVENTIS: Absolutely. Thank you, Your Honor.

THE COURT: Ladies and gentlemen, we're going to call it a day; and, of course, we got a weekend coming up. And, again, do not do any of your own research. Do not talk to anyone about the case. You may read in the paper that there's some discussion about a federal government shutdown. We'll all hope the politicians will work that out. But regardless of that, our trial will continue, and we will be back here bright and early Monday morning at 9 a.m.

So have a good weekend, and I'll see you then. (Whereupon the jury was excused from the courtroom.)

THE COURT: Very good. You may be seated.

Any matters we need to address?

MR. LEVENTIS: There's one issue. Ms. Strawn.

THE COURT: Yes, Ms. Strawn.

MS. STRAWN: Your Honor, this is about a document that the defendants used to cross-examine Mr. Cornwell on Wednesday.

THE COURT: Okay.

MS. STRAWN: They elicited some testimony about a

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document. And from the sound of it, it sounds like something that should have been produced to the government during discovery. We've asked for a copy of it. We're getting the runaround. I still haven't seen a document --

THE COURT: These guys give you a runaround? That's almost unbelievable. That's a phenomenal suggestion.

What's the exhibit?

MR. COOKE: It was not an exhibit, Your Honor. You remember at the end of -- I think this is what she's referring to -- at the end of Mr. Boomer's testimony, I asked him if he'd written a letter and asked him about it, and he agreed that he did. We did not offer it as an exhibit.

THE COURT: Did you show it to the jury?

MR. COOKE: No.

MS. STRAWN: Your Honor --

THE COURT: Why wasn't it produced in discovery?

MR. COOKE: We're investigating -- I've asked

Ms. Strawn to identify for us which request for production it would have been responsive to, because this was a personal letter that was written --

THE COURT: Tell me what the letter is.

MR. COOKE: Beg your pardon?

THE COURT: Tell me what the letter is, to whom -- who it was written to and so forth.

MR. COOKE: It was a letter from -- from Boomer to --

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I believe it was to both Mr. Dent and Mr. Johnson in January --
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                         THE COURT:
                                      Is it related to the allegations in this
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              case?
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                         MR. COOKE:
                                      No.
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                         THE COURT:
                                      Then why did you ask him about it in the
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              trial?
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                                      Because, remember, he cried at the end of
                         MR. COOKE:
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              his testimony and --
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                         THE COURT:
                                     He found out how wonderful they were?
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                         MR. COOKE:
                                      He talked about how much he regretted
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              ever being associated with them.
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                                      I remember the letter now.
                         THE COURT:
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                         MR. COOKE:
                                      So at lunchtime, I --
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                         THE COURT:
                                      Why would you not show it to the
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              government? What's the problem?
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                                      I didn't have it.
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                         MR. COOKE:
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                                      Do you have it now?
                         THE COURT:
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                                      I do have it now.
                         MR. COOKE:
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                         THE COURT:
                                      Give it to the government.
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                         MR. COOKE:
                                      It was texted to me at lunch.
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                              Do we have a copy of it?
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                                      Thank you, Mr. Cooke. Just had to ask
                         THE COURT:
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              the right question.
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                              Anything else?
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                         MR. COOKE: I don't think that's what she asked.
                                                                              Ι
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think she was --
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                        MS. STRAWN: That is what I asked.
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                                     Oh, I'm sorry. That was easy.
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                        MR. COOKE:
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                        THE COURT:
                                    That was easy enough.
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                        MR. COOKE:
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                                     That was not the question. The question
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              she had asked was had we produced it in discovery? And that's
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              what we were trying to --
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                        THE COURT: Well, whatever. If it's relevant enough
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              to ask about in the trial --
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                        MR. COOKE: I completely misunderstood what she was
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              asking.
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                                    Anything else?
                        THE COURT:
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                                      No.
                                             Thank you, Your Honor.
                        MR. LEVENTIS:
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                        THE COURT:
                                   Okay, folks. I'll see everybody Monday
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              morning.
                        I've entered an order, gift to the Department of
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              Justice.
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                                     Judge, I'm sorry. I do have a question.
                        MR. COOKE:
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                        THE COURT:
                                     Yes.
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                                    If they -- if they finish Monday, are we
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                        MR. COOKE:
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              supposed to start witnesses Monday?
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                        THE COURT:
                                           Yes.
                                     Yes.
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                                    Then can we find out --
                        MR. COOKE:
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                                     Let's talk about that a second.
                        THE COURT:
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              give the defendants a little warning here.
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                              We've got the 30(b)(6)s. You know how long that
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is. That's one thing we can predict.

MR. GRIFFITH: Well, Your Honor, we actually have -to my knowledge, we haven't been provided a copy of the video
yet.

THE COURT: We're going to solve that problem real quick.

Do y'all have a copy of the video, the 30(b) video with all the edits?

MS. SHORT: It's the deposition transcript. They have the transcript, and they have all of the exhibits. These are just excerpts from -- I'm not sure what they need.

MR. GRIFFITH: Well, we just want to look, make sure that the video is the same thing as the transcript.

MS. SHORT: It was taken from -- we ordered a copy of the video, transcript of the video --

THE COURT: Y'all have got one copy. You're telling me that you only have one copy of the video?

MS. SHORT: Well, I just don't know if the file, the video file, is transferable and viewable without the software. Can we do it? Can we provide them a copy of the video excerpts?

With the document callouts and everything, that's all the software. The video itself is pretty straightforward. All the moving and the documents and all that.

MR. GRIFFITH: Your Honor, we just don't want to get

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caught in the middle of the trial and have to jump up and say that's not within the --

THE COURT: Y'all are going to be here this weekend, I presume. Y'all can arrange to show him -- if it's not available otherwise on your laptop, we can arrange for someone to sit there and watch it, if they wish to do that.

MS. SHORT: Your Honor, I think we have a solution. I didn't know that the question was out there, that they needed to see the video, the way that it's been -- we'll take care of it.

THE COURT: Okay. Very good. Another solved problem. Just merely asking the right question.

Okay. Anything else?

MR. COOKE: We did want to sort of figure out when they plan to finish.

THE COURT: Yeah. Let's go ahead and do that. I was distracted here. What do we have here? How long are the 30(b)(6)s going to run?

MS. SHORT: Your Honor, I can speak to the -- I'm video/AV girl on this one. So each of the video deposition excerpts run for about an hour, and we have three of them. Some are a little longer and some are a little shorter.

THE COURT: Okay. Wear out the jury. Okay. What else?

MS. SHORT: It was that or call the defendants in our

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case in chief.

THE COURT: I hear you. What else?

MR. LEVENTIS: So we're going to talk after this, Your Honor. There may be some shuffling to do, but we -- it's possible we could be done by the end of the day Monday.

THE COURT: How many more witnesses you have?

MR. LEVENTIS: That's what we're going to have to discuss this afternoon. We'll certainly let the defendants know.

THE COURT: The question they want to know, which is a very reasonable one, do they need to have witnesses here Monday? Because I don't want to stop at 2:00 in the afternoon.

MR. LEVENTIS: If you give us a minute, we just needed to huddle after everything that happened today to figure out -- our goal is to be done by the end of Monday, so --

THE COURT: I understand. But if you finish at 2:00 Monday, I do not want to send my jury home. And I don't really care myself, but I care that the defendants know so they'll have their witnesses here. And I don't want them if they don't have to.

Some of this is not predictable. We have a very fixed prediction here. We have three hours of video. And you can figure that that's going to take the morning. Okay? That's going to be before lunch. It's three hours of testimony.

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So the next question is how much after lunch?

And what I don't want to do is send my jury home early in the afternoon.

MR. LEVENTIS: Can you just give us a minute?

THE COURT: Sure.

(Pause.)

MR. LEVENTIS: So, Your Honor, we've had a short discussion here, and it -- we are going to try our hardest. It's possible that we can be done midafternoon on Monday. So I think probably the safest thing is to have them have at least a couple of witnesses ready. We'll try our hardest. A lot of variables. We're not sure of cross-exam and everything.

THE COURT: Correct. You don't have control of that. But we know -- we actually have more prediction than we normally would because we know exactly the length of the video depositions. So I think you need to have prepared some witnesses here in the event they finish; and if they don't, we'll start them up Tuesday morning.

MR. COOKE: What are your intentions about -- we're going to actually probably make directed verdict motions. Do you typically defer those, or do you want to hear it in full?

THE COURT: I typically hear them -- when you say in full, I usually have a very brief argument. I do not have protracted argument about that. Obviously, I have issued extensive orders in this case. I have not heard all the

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evidence offered, so I can't tell you now how I view, but there is -- at least I think we could forecast -- there is considerable evidence in support of the government's position.

The jury's decision, whether that is -- meets the standards of the False Claims Act and the Anti-Kickback Statute. That's not mine. But unless something dramatically changes, I would think this matter is, you know, going to go -- it's not going to be disposed of by a directed verdict.

So, I mean, I'm glad to hear argument. I don't need extensive argument. I feel like I have exhaustively dealt with almost every conceivable legal issue in this case already, unless there's something you want to forecast to me that I didn't look at, that I haven't already addressed.

MR. COOKE: I was going to forecast, for example, that they didn't put any evidence of damages on the TRICARE waiver and deductible.

THE COURT: Right. And I think we already addressed the issue that it goes to state of mind. If they're knowingly violating provisions, that could be relevant to that issue. So I agree with you that they have not offered damages of the TRICARE, and it may be a very specific question about whether there should be such a -- I can't remember now if they asked me -- did they ask me to separate TRICARE from -- on the verdict form from Medicare?

MR. TERRANOVA: No, Your Honor.

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THE COURT: There was not. Then -- and I haven't looked at -- if there had been such a request, I think there would not be a damage claim, but I think it could be relevant to the issue of state of mind. So I would -- that would be permissible on that.

MR. COOKE: And I wasn't trying to argue. I just was -- to the extent that they had a claim based on waivers of copays and deductibles, that would be one motion for a directed verdict that we would make.

THE COURT: Regarding TRICARE?

MR. COOKE: TRICARE, right. Right.

THE COURT: I think y'all ought to talk -- since you didn't put up damage witnesses on TRICARE -- I mean, as I recall, the expert said he was having trouble correlating the documentation.

Mr. Shaheen, was there any damage information put in?

MR. SHAHEEN: Your Honor, as we addressed this earlier on in the week, we are not bringing a district claim regarding the waiver of copays and deductibles to TRICARE patients.

THE COURT: So your claims are really just Medicare claims?

MR. SHAHEEN: No, no.

MS. SHORT: No, no, no.

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MR. SHAHEEN: So we have -- originally, when we filed the claim intervention, we did have a separate set of distinct claims related to TRICARE and the waiver of copays and deductibles as to TRICARE.

THE COURT: Okay.

MR. SHAHEEN: We are not bringing that claim right now.

THE COURT: Okay.

MR. SHAHEEN: We are bringing claims regarding defendants' practice of paying P&H and defendants' practice of paying the commission payments.

THE COURT: But you have damage information about it?

MR. SHAHEEN: We had damage information from both

Medicare and TRICARE as to that, and Mr. Hines split that up in his testimony.

THE COURT: I'll have to go back and look at it, but I thought he had, like, only 16 claims under TRICARE or something. Wasn't it some very small number and a very large number for Medicare? Am I misremembering that?

MR. SHAHEEN: You are correct, but those were distinct claims that we are bringing.

THE COURT: 16?

MR. SHAHEEN: It's wrapped up in one, Your Honor. I
mean --

THE COURT: Well, I mean, I think you're right to the

extent there's one, there's a claim. 1 5:22PM 2 MR. SHAHEEN: Yes, Your Honor. 5:22PM That answers my question. 3 MR. COOKE: 5:22PM 4 THE COURT: Do we have a financial amount associated 5:22PM with that? 5 5:22PM MR. SHAHEEN: Yes, Your Honor. He explained both the 6 5:22PM 7 amount per quarter, as you may recall, which was very fun for 5:23PM everyone, I'm sure. But he did divvy it up by quarter for 8 5:23PM 9 Medicare and for TRICARE. 5:23PM 10 THE COURT: Okay. So he's got sufficient, probably, 5:23PM 11 to survive. I thought he had not given a number, that he had 5:23PM trouble. But, actually, he gave the number for 16 claims. 12 5:23PM 13 think that's -- 16 claims; isn't that right? 5:23PM 14 MR. SHAHEEN: I don't remember the exact number, Your 5:23PM 15 Honor --5:23PM 16 It was a very low number. THE COURT: 5:23PM 17 But there it is, Mr. Cooke. 5:23PM 18 MR. COOKE: I've got one clerical thing. 5:23PM 19 that Exhibit 1162, which I believe was thought to have already 5:23PM 20 been put into evidence, my crack team over here says that they 5:23PM 21 don't have any record of it having been --5:23PM 22 1162. This is from our master list? THE COURT: 5:23PM 23 I don't see that that's it --THE DEPUTY CLERK: 5:23PM 24 What is 1162? THE COURT: Okay. 1162. 5:23PM 25 MR. LEVENTIS: I thought that one came in on the 5:23PM

opening. Do you have that one down? 1 5:23PM THE DEPUTY CLERK: I don't have that. 2 5:24PM 3 THE COURT: Hold on a second. Let me look. Let me 5:24PM 4 check my list. 5:24PM THE DEPUTY CLERK: Ms. Short got up and said it was 5 5:24PM in. 6 5:24PM 7 1162 came in on my list. THE COURT: 5:24PM 8 THE DEPUTY CLERK: Do you have a date? 5:24PM That's the first day, on the opening 9 THE COURT: 5:24PM 10 statement. That was among those listed. 5:24PM 11 THE DEPUTY CLERK: I think that's probably when I 5:24PM 12 didn't even have a list at that time. 5:24PM 13 THE COURT: Y'all need to go back, again, go back 5:24PM over and make sure that everything on her list is on this list, 14 5:24PM but 1162 is admitted. That's why I bother to do it myself here 15 5:24PM as well, as a backup. 16 5:24PM 17 0kay? 5:24PM 18 MR. LEVENTIS: Thank you. 5:24PM 19 THE COURT: Thank you. 5:24PM 20 5:24PM 21 5:24PM 22 23 24 25

5:24PM

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