#### 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 25, 2018 CONSULTANTS, INC., ET AL.

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REPORTER'S OFFICIAL TRANSCRIPT OF THE JURY TRIAL - DAY EIGHT HELD BEFORE THE HONORABLE RICHARD M. GERGEL UNITED STATES DISTRICT JUDGE January 25, 2018

### Appearances:

For the United States U.S. Department of Justice of America

Civil Division

Elizabeth Strawn, Esq. BY: Michael David Kass, Esq. Jennifer Short, Esq. Michael Shaheen, Esq.

Christopher Terranova, Esq.

601 D Street NW

Washington, DC 20005

202.616.7986

U.S. Attorney's Office BY: James C. Leventis, Jr., Esq. 1441 Main Street, Suite 500

Columbia, SC 29201

803.343.3172

For BlueWave Healthcare Joseph P. Griffith Law Firm Consultants, Inc.

BY: Joseph P. Griffith, Jr.

Seven State Street Charleston, SC 29401

843.225.5563

For BlueWave Healthcare

Consultants, Inc.

Barnwell, Whaley, Patterson

and Helms

Morris Dawes Cooke, Jr., Esq. BY:

Christopher M. Kovách, Ésq.

P.O. Drawer H

Charleston, SC 29402

843.577.7700

# Appearances:

For BlueWave Healthcare

Consultants

Mr. Philip L. Lawrence

Attorney at Law Charleston, SC 843.200.2794

For Latonya Mallory

Beattie B. Ashmore Law Office BY: Beattie B. Ashmore, Esq.

650 E. Washington Street Greenville, SC 29601 864.467.1001

Official Court Reporter:

Tana J. Hess, CRR, FCRR, RMR U.S. District Court Reporter

85 Broad Street

Charleston, SC 29401 843.779.0837

tana\_hess@scd.uscourts.gov

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(Call to order of the Court.)

THE COURT: Good morning. Please be seated. Okay Any matters we need to address before we bring in the jury?

MR. COOKE: There are, Your Honor. We -- not big ones or not a lot, but we had identified a demonstrative exhibit. It's a model that the expert was going to refer to, and we sent a photograph of it the earlier part of the week to the government, and they object. So I guess I'll let them speak for what their objection is.

THE COURT: And when will this witness be called?

MR. COOKE: Right now.

THE COURT: I wish y'all would have let me know that. I would have taken it up at 8:30 this morning.

Okay. Tell me what the issue is. Mr. Kass, you're doing that?

MR. KASS: Yes, sir. Thank you, Your Honor.

Our issue is did -- and we received two models from defendants this week, so I'm not entirely sure which one they're talking about. But these appear to be HDL constructed models. They have HDL branding on them. I presume they were -- thank you -- in the possession, custody, or control of defendants. This one has Abbott branding on it. We never received it in discovery. So that's my concern.

THE COURT: What is it? It's damage of a vessel?

MR. COOKE: It's a picture of the blood vessel. I

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shows the progression of plague. It's not an HDL piece. sent it several days ago. And I thought our agreement was, if you're going to use a demonstrative, just produce in advance, which is what they did.

> THE COURT: Let me see it.

THE COURT:

MR. COOKE: I'm not planning to introduce it into evidence.

Mr. Kass, what's wrong with this?

MR. KASS: Your Honor, my only concern is, if defendants believe it's relevant, why wasn't it produced in

discovery?

That's a fair issue. We have, like, THE COURT: 5,000 documents, and it was something that was really a surprise. But the development of plaque is not a surprise.

MR. KASS: Your Honor --

It's well established. And in a perfect THE COURT: world, of course, you know you have an obligation to produce, and then there's a question of what's the remedy, what's the injury and the remedy under Rule 37.

And I'm confident that -- that this wasn't hidden from y'all. And this is like really basic stuff. 0kay? basic science.

So, yes, Mr. Cooke, I would have preferred you had offered it bit earlier, but I'm not going to -- I overrule the government's objection.

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MR. KASS: Thank you, Your Honor.

MR. COOKE: Thank you, Your Honor.

And in my defense, they always say you're supposed to shut up once the judge has ruled in your favor, but I can't help it this time. None of those graphs and charts that have been shown were ever produced in discovery. They were all given to us a day or so in advance, and I think --

MR. KASS: I think there's a provision in the federal rules of evidence for that, Your Honor. This is different.

This is actual --

THE COURT: I'm a really big person on not being hypertechnical about the rules. The rules are very important. They need to be followed. But some things are important, and others are just sort of technical. And what I just observed there on that vessel is pretty basic science, and -- and I would have preferred they did it a bit earlier, but I can't imagine any harm to the government from not getting it before then. Anybody who's ever litigated in this area -- and God knows I have -- that kind of image is like -- it's like saying, oh, I didn't know there was a Netter's out there; right? I mean, it's like, oh, my God.

Y'all know what Netter's is?

MR. KASS: No, sir, I'm afraid I don't.

THE COURT: Mr. Cooke does. Mr. Cooke does.

MR. COOKE: I know too well.

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THE COURT: It a medical illustration book by a gentleman, although he's been dead for many years, it's like the best medical illustrations ever done. And I can just imagine someone walking into court and wanting to show Netter's, and you can't say "Surprise." It's been there since the '30s. This is like a physical version of Netter's.

MR. COOKE: That's exactly right. It may have come from Netter's.

Don't you think that's a fair description of it?

THE COURT: It may have well. You could probably find the image in Netter's. That's immediately what I thought when I saw it. Overruled.

Okay. Anything else?

MR. COOKE: I think that's all.

THE COURT: Very good. Let's bring in the jury.

(whereupon the jury entered the courtroom.)

THE COURT: Please be seated. Good morning.

JURY: Good morning.

THE COURT: I understand a couple of you got caught on the interstate. That's the bane of existence of my staff frequently. Just never know when it's going to happen.

But I want to, again, thank y'all for your attention. This is not easy information, and I look over and watch y'all because I'm concerned if you're, like, too tired, I want -- I'll take a break or whatever. And y'all are just like

I just want to tell you, I've tried lots of cases, 1 fantastic. 9:25AM 2 and y'all are really just right at the top there of paying 9:25AM attention. And I thank you for your attention, and I know the 3 9:25AM 4 parties do. 9:25AM 5 Okay. Call your next witness. 9:25AM MR. COOKE: Your Honor, the defendants BlueWave, 6 9:25AM 7 Dent, and Johnson would call Dr. Robert Daniel Fishberg. 9:25AM 8 THE COURT: Someone going to get Dr. Fishberg? 9:25AM 9 MR. COOKE: I think we did. We've been taking the 9:25AM 10 sequester thing literally. 9:25AM THE COURT: Well, it's important. 11 9:25AM THE DEPUTY CLERK: Please come forward to be sworn. 12 9:25AM 13 Please place your left hand on the Bible, raise your right. 9:26AM State your full name for the record. 14 9:26AM 15 Robert Daniel Fishberg. THE WITNESS: 9:26AM 16 THE DEPUTY CLERK: Could you spell your last name for 9:26AM the record? 17 9:26AM 18 **THE WITNESS:** F-i-s-h-b-e-r-g. 9:26AM 19 THE DEPUTY CLERK: Thank you. 9:26AM 20 (Witness sworn.) 9:26AM 21 THE DEPUTY CLERK: Thank you. You may be seated. 9:26AM 22 There's a step right there, so be careful. 9:26AM 23 ROBERT DANIEL FISHBERG, MD, 9:26AM 24 a witness called on behalf of the defendants, being first duly 9:26AM 25 sworn, was examined and testified as follows: 9:26AM

9:26AM	1	DIRECT EXAMINATION	
9:26AM	2	BY MR. COOKE:	
9:26AM	3	Q. Good morning, Dr. Fishberg. Would you state your full	
9:26AM	4	name, please.	
9:26AM	5	A. Robert Daniel Fishberg.	
9:26AM	6	Q. What is your occupation?	
9:26AM	7	A. I'm a cardiologist.	
9:26AM	8	Q. Where do you practice?	
9:26AM	9	A. I practice in New Jersey, in Springfield, New Jersey.	
9:26AM	10	Q. I'd like to talk about your educational background. First	
9:27AM	11	of all, have you agreed to serve as an expert witness in this	
9:27AM	12	matter?	
9:27AM	13	A. Yes.	
9:27AM	14	Q. Have you done that before?	
9:27AM	15	A. I have served as an expert, not in a case like this, but	
9:27AM	16	about maybe 10 years ago I was an expert in a in a case.	
9:27AM	17	Q. Would you would you call yourself a professional expert	
9:27AM	18	witness?	
9:27AM	19	A. Absolutely not.	
9:27AM	20	Q. All right. Where did you go to college?	
9:27AM	21	A. I went to Cornell University.	
9:27AM	22	Q. When did you graduate?	
9:27AM	23	A. I was class of '77.	
9:27AM	24	Q. Okay. What did you do after that?	
9:27AM	25	A. I went to medical school at SUNY Upstate Medical Center in	

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Syracuse. I graduated in '81.

- Q. Okay. Then what did you do after that?
- A. Well, I went to Overlook Hospital in Summit. I served as a resident and then chief resident.
- O. And then --
- A. And then I went to University of Connecticut to do a cardiology fellowship. And then I was in practice for a year; then I was the first interventional fellow at the University of Connecticut.
- Q. And can you explain what that means? Did you do an --
- A. So I was -- I spent two years as a cardiology fellow, learning all aspects of cardiology. Then I went into at that time a relatively new field, interventional cardiology. That's the field where you actually -- at that point there would be four stents. We actually went in, did catheterizations, and we put balloons to open up blood vessels to stop heart attacks. So I was actually the first fellow in interventional cardiology at University of Connecticut.
- **Q.** So can you make a distinction between an interventional cardiologist and a regular cardiologist?
- A. Well, interventional cardiologist is one that spends most of their time doing procedures. They're kind of like surgeons in some ways, that they go in and they -- they take care of people with heart attacks. They put balloons in, now they put stents in to stop heart attacks and also to open up blocked

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vessels.

And, you know, this is a relatively new field. It was developed -- it was actually discovered by Dr. Gruentzig in Switzerland. He actually wasn't a cardiologist; he was a radiologist. And at that time we thought -- this is even before I was a physician -- they thought that, you know, you can't -- you know, people have heart attacks. They lay in a bed for a month. You recover.

No cardiologist would have thought you could put a balloon and stent to open up a blood vessel. It took a radiologist to think about that, that he could use a balloon. He also discovered that you could use a stent to open up a blood vessel.

So this was a radical thing, and most of the cardiologists pooh-poohed this. So doctors have a way of pooh-poohing things they don't understand. So they actually pooh-poohed this. But then a few EVT shows — it was discovered a few kind of revolutionary cardiologists from the States came to Switzerland, watched the technique, and brought it back to the States. And we developed a field, interventional cardiology, which to me was one of the great advances in medicine, to actually open up a blood vessel and stop a heart attack.

- Q. And you studied that back in 1988 and '89, I believe?
- A. Yes.

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- Q. And did you become board-certified in any specialties?
- A. Well, I was board-certified in cardiology, and I was board-certified in nuclear medicine and also internal medicine. I actually stopped being at some point in my career, I decided not to be in interventional cardiology anymore, just to be a regular cardiologist, because at some point I thought that, well, you know, I've done interventional cardiology for many, many years, but actually I was more interested in preventive cardiology, preventing a heart attack from occurring than actually doing the intervention.

And I had lots and lots of partners who wanted to do intervention, but not as many was interested in preventive cardiology. So, actually, I concentrated more on preventive cardiology after -- so about 10 years ago I stopped doing intervention and concentrated just on prevention.

- Q. We'll talk about that a little bit more in a few minutes.
  Are you currently in a private practice?
- A. I am.
- **Q.** How many cardiologists are in your group?
- **A.** About 15.
- Q. Do you hold any --
- A. I'm sorry.

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- **Q.** Do you hold any academic appointments?
- A. I am. I'm appointed the -- at Jefferson University, I'm a clinical assistant professor. And that really involves more

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teaching the residents and teaching medical students at my local hospital, which is Overlook Hospital.

- Q. And what professional associations do you belong to?
- A. Well, I belong to the American College of Cardiology, National Lipid Association. Those are the two major organizations I belong to.
- **Q.** Have you been involved in the American Society of Nuclear Cardiology?
- A. Yes, I've also been a member of the American Society of Nuclear Cardiology too.
- Q. How about the Society of Vascular Ultrasound?
- A. In the past I have, not -- some of these things you maintain for a few years. You're not paying the dues anymore. They keep sending you messages to pay dues every year. And, you know, some years I do, some years I don't.
- **Q.** Have you published any papers?
- A. I have been involved with some publications. So I've been involved with -- over the years, I've been involved with clinical research. I'm very interested in research, and I've been involved with a number of research trials.

So a lot of them have listed me as one of the authors. So I've been involved with the -- a couple of the important trials, the TIMI 22 trial, which is the trial that we did looking at -- looking at atorvastatin, which is -- statins are drugs that lower cholesterol. So we actually looked at two

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statins, atorvastatin and pravastatin, to see which one was more effective.

At that point it wasn't clear -- this is a number of years ago -- whether high doses of statin made a difference such as low doses of statin. And we found in this trial that using -- using atorvastatinin, 80 milligrams, would reduce the incidents of heart attacks, reduce morbidity mortality.

And what's interesting about this trial is that not only did it reduce LDL, it reduces CLP inflammation. So this is one of the first trials we showed that a statin could reduce both LDL, which is cholesterol, and also inflammation. And they seemed to be independent. And reducing inflammation seemed to be, you know, as important as reducing LDL in this trial.

So that's one of the trials I was involved in. I was listed on that.

But a lot of these trials I was listed as one of the authors, you understand, I mean, subinvestigators.

- **Q.** And, Dr. Fishberg, I don't think we want to go through all the studies that you've been involved in, but could you just give a ballpark number how many different studies have you been involved in?
- A. Oh, I think -- I'd have to count them up. Probably 30-plus studies.
- Q. Okay. And have you published as well?

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I have published some smaller articles. I recently -last year, I published an abstract on -- I'm very interested in familial hypercholesterolemia, which is a genetic disorder, occurs in 1 in 250 people. And I actually published an article -- published an abstract looking at, if you're testing for familial hypercholesterolemia, whether it's cost-effective. whether -- if disease occurs in 1 in 250 -- at that time the test cost \$500.

And it's interesting where this test is at. have this gene, you have three times the chance of having a heart attack than not having the gene.

So I said, well, maybe you should test this on everyone that has high LDL. And if you have high LDL -- if you're 60 years old and your LDL is high, you have, say, 6 percent risk, if nothing else, risk of heart attack. If you have this gene, it becomes threefold, 18 percent chance. if you test for that, is that cost effective?

So I actually did a model, and it got published. My abstract got published that, by testing for this gene, it cost -- it cost maybe \$500 actually testing for the gene, and you would save so much money.

Then the other things is what's the cost of a heart Someone has a heart attack, what's the cost of it? attack? How do you gauge a heart attack? Is it 20,000? Is it 500,000? If you could prevent heart attack in a 20-year-old -- a

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20-year-old never has a heart attack, what's the cost saving of that? It's probably invaluable.

So I put a figure of \$170,000 on the cost of a heart attack. And by doing that, it appeared that doing -- you save, you know, 10 times the amount of money by doing the test. And, if you look at a thousand people, you could prevent 35 heart attacks.

what's interesting about a genetic test is not only are you saving that person but every person that you find that has a genetic abnormality, you may find a relative that has it. So I found a lot of people who has this gene, who has children, has grandchildren, and it's a 50-50 chance that children may have it.

So I diagnosed a 9-year-old. Because their father had it, the 9-year-old had the disease. And if I could prevent that 9-year-old from ever developing atherosclerosis, I've saved a life. That person is going to live a full life and not have a heart attack.

So for my study, for a thousand people, I could prevent 35 heart attacks and another 35 in a relative; and for a thousand people, I actually may save, you know, \$9 million, you know, for a thousand people.

Again, this is theoretical, but I presented it, and it got a lot of -- people thought this made sense for a lot of people. I'm not an economist, but it made sense that, if you

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could prevent something from happening, that's more cost-effective than letting it happen. And, again, it's hard to put a value on saving someone's life.

Q. All right. Doctor, let me ask you to pause there for just a moment.

MR. COOKE: And I'm going to tender Dr. Fishberg as an expert in cardiology.

> THE COURT: Is there -- response from the government?

MR. KASS: No objection, sir.

MR. ASHMORE: No objection, Your Honor.

**THE COURT:** Very good. I recognize Dr. Fishberg as an expert in cardiology. Please proceed.

### BY MR. COOKE:

- Doctor, we've asked you to serve as an expert witness in Q. this case; is that correct?
- Α. Yes.
- And would you describe briefly what you have reviewed in 0. preparation to share your opinions here?
- well, I reviewed every document that you sent me, which I reviewed the reports from Singulex, HDL lab. reviewed the expert testimony from Dr. Trost and also his deposition. I reviewed -- I went through a number of different papers, articles that were published in the literature about heart disease.
- when you refer to the testimony of Dr. Trost, do you mean

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his report and then his deposition?

- A. Report and the deposition.
- **Q.** And have you -- have you tried to bring to bear your experience and your knowledge of cardiology to bring these opinions here today?
- A. I have.
- Q. Would you -- would you talk to us about the difference, if any, between the standard lipid studies that every doctor does in his office with what you have referred to as advanced lipid studies and talk about the development of that over time.
- A. So this really goes back to my career as a cardiologist and my concept of atherosclerosis and what caused atherosclerosis and how can it be prevented.

So a standard lipid panel, which really hasn't changed for 30 years or 40 years or maybe longer, is a cholesterol HDL, triglycerides -- that's the major lipid panel -- and LDL. And a lot of this has to do with conception of how atherosclerosis forms and -- and looking at these particles. And there is -- you know, there's a strong theory that LDL, high cholesterol levels causes -- causes atherosclerosis, causes coronary disease.

One of the problems with a basic lipid panel itself is actually how it's measured. And the LDL is a calculated measure, meaning that the way it was originally done -- and it has to do with methodologies in the lab -- it wasn't measured

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correctly. They use a calculation of cholesterol minus HDL minus triglycerides divided by 5.

And one of the problems with that is, if triglyceride levels are high, the LDL is inaccurate. That's a gradable equation. It's not the most accurate measure. And even from the start, a lot of cardiologists thought there's better ways of measuring LDL. You can measure it directly. You can look at ApoB, which is actually the protein that carries cholesterol, and that looks to be a better measurement. A lot of doctors thought that looking at particle number was more important.

Because it's not the -- the problem with LDL, it's a milligram-per-deciliter measurement, so it's like the weight of LDL. But it turns out that it's a particle number. The number of particles appear to be more related to atherosclerosis. So if you have lots and lots of -- so you could have the same LDL milligram number; but if you have small dense-cell LDL, you have lots and lots of particles, it's a number of particles, which is more related to risk for coronary disease than just the milligram per deciliter, the measurement of LDL.

So, again, the problem with the basic lipid panel right from the start is the LDL, which is what we used to put someone's risk, is not really an accurate measurement.

None-HDL cholesterol, which is cholesterol minus HDL, is actually a better measurement. Even that is hard for people to

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accept.

- **Q.** Can I stop you for a second? One, you used the term HDL. That's not the same HDL which is Health Diagnostic Laboratories?
- A. Let me tell you. Okay? Let's go -- I'm sorry. I'm going to start off very basic.
- Q. Even before that, did you bring a model?
- A. I brought a model we could talk about too.
- **Q.** Okay.

MR. COOKE: May I approach?

THE COURT: You may.

THE WITNESS: So, well, first, let me discuss about LDL and HDL. LDL and HDL, you have lipoproteins. And just to make it simple, the LDLs are bad cholesterol; HDLs are good cholesterol. The more good cholesterol you have, the more protective; the more bad LDL you have, the higher the risk.

But, again, the problem is, if you look at risk, LDL itself is not -- the measurement of LDL has a lot of inaccuracies in it, and it may not reflect the full risk. But if you look -- let me just show you. I have a little heart model to show you.

So when you're born, your arteries look like this.

This is what it looks like when you're born as a newborn. You have very thin arteries. What's interesting about the arteries is that the surface is smooth, the layers are very thin. The

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thin layer protects your body from clotting because the layer itself has a lot of chemicals in it that prevent blood clots from forming. It has -- it's remarkable. There's no other surface in the body -- no other surface actually prevents blood from clotting. So the newborn artery is thin and has -- has protective surfaces, prevents clots from forming.

The problem is, as you get older, it's no longer thin. And teenagers, in fact, development -- I'm really worried now with teenagers because, if you look at a lot of teenagers now -- when we were young, we were out in the street, playing ball, riding our bikes. Now kids are sitting home playing on their phones or playing video games, and they're having higher-fat diets, and they -- they have a problem with childhood obesity.

So if you look at teenagers now, a lot of them will start forming fatty streaks even as teenagers. We know that from autopsy studies in the Vietnam War when they actually autopsied some arteries, and they found that teenagers started developing plaque in their teens. And I know that from my studies with familial hypercholesterolemia that, if you have a genetic abnormality, you may start forming plaque the minute you're born.

So the battle is to prevent -- is to keep this as long as possible and to prevent this from happening, prevent the heart -- the heart attack from -- stopping.

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So what happened here is you have high levels of cholesterol, that LDL cholesterol. It gets into the endothelium and starts forming clots. And the LDL becomes oxidized, which is a worse form of LDL.

Not only that, you have leukocytes, which is white blood cells, that migrate into the artery and becomes -- the monocytes become macrophages, and then they're full of cholesterol and they become -- they become mass cells. And they actually start to actually explode with cholesterol. They actually rupture, and cholesterol deposits can get filled over here.

The other thing you also have -- you also have lymphocytes that migrate into this area, and the lymphocytes produce cytokines, which are interleukins, is one of them, interleukin-1 and interleukin-6. And that causes more breakdown of the cells.

You also have smooth muscle cells that migrate from the media into the cell, and these forms matrix metalloproteins. And they actually cause the cells to rupture, apoptosis, premature rupture. And you have collagen that breaks down. So what happens here, you have a fibrous cap that becomes very thin and become prone to rupture.

What could cause this to rupture?

Well, causes of rupture could be high-fat diet, increased stress, diabetes, smoking. All of these things that

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can cause it to rupture.

But if you just do angiograms, this angiogram here looks like it's open. You do an angiogram, you just do a view through the artery. This is normal. This doesn't look that bad. It's still full of plaque.

This doesn't look that bad either if you did an angiogram. Well, it looks almost normal, but half the artery is filled with plaque. And this plaque here can be prone to rupture. Here's a plaque rupturing over here at this point.

when a plaque ruptures, you have platelets and thrombins, which is -- which is platelets stick to this and blood clots starts to form. And that could cause a plaque to form a clot, and that could cause actually the artery to close off.

when I get called in as interventional cardiologist, when I was in interventional cardiology, I see the patient over here. I'm actually interested in a patient at this point to prevent this from happening.

So what I try to do is try to diagnose this at this point, find someone that has a plaque, and prevent it from ever becoming this.

By this point here, I'm putting us -- now, when I used to put stents in people, people were all very happy, and they go, "Thank you, Dr. Fishberg, for saving my life." Well, I want to save someone's life over here and have them never

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have heart attacks. Let them nag me for keeping them on the cholesterol medications and other medications, but I'm happiest if I can prevent them from ever having a heart attack over here.

and, you know, at this point, they might have to have a bypass operation. But over half the patients who have heart attacks, many of them die suddenly. And, often, they have no side effects because you could go from this point here to this point in a day.

So if you look at people who have had heart attacks, a good example, I think -- a great example -- is Tim Russert.

Y'all know who Tim Russert was from --

## BY MR. COOKE:

Q. You can't ask any questions.

THE COURT: You can't ask them questions. They're not doctors. Don't talk with that guy and --

THE WITNESS: I'm sorry. I'm not a professional expert. Sorry.

Most people know who Tim Russert is. I know who Tim Russert is. He was from "Meet the Press." About 10 years ago, he died suddenly of a heart attack. He was 58 years old, and he had -- his cholesterol was elevated. He was on a statin and -- but, you know, he was overweight. His waist was -- he had metabolic -- metabolic syndrome is someone who has low HDL,

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high triglycerides, increased waist size. But, apparently, he passed a stress test and his doctor said he was in good health.

But turns out, 10 years earlier, he had had a test called a calcium score. Calcium score is a CAT scan of the chest. So if you do a stress -- the problem with stress tests is you could pass a stress test with this blockage over here, because even though there's a -- half the artery is filled with plaque, there's still a good opening here. You could actually pass a stress test with this. But this vessel here has a thin fibrous cap with a lot of liquid that may rupture at any time.

A calcium score is a CAT scan looking for calcium. This amount of plaque, you'd probably have enough calcium to detect in a CAT scan. So at 58, he died. At 48, he had a calcium score of 200. A calcium score of 200, age 48, is a really high, high risk. At age 48, they have a clue that he was at very high risk of having a heart attack.

You know, that -- and calcium progresses 15 to 30 percent or more every year. So, 10 years later -- they never did his calcium score again -- it was probably closer to 3,000, his calcium score, if they had tested it. So he was at high risk. At a level over 1,000, your chance of having a heart attack -- they thought his risk was 5 percent; his risk was really more like 15 to 20 percent per year, not 5 percent for 10 years. So he was at high risk.

What they were doing may not have been sufficient.

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Certainly, someone -- I don't know everything that he had. I don't know what his genetic makeup -- he may have had abnormal genetics, but he's someone who, if he had seen someone who was a more preventive cardiologist, they may have been able to prevent him from having a heart attack and surviving.

#### BY MR. COOKE:

Q. Okay. Thank you. Go ahead and take your seat.

I'm going to take you back. Could you talk about some of the important clinical trials that led to advancements in lipid studies?

A. Yes. So -- so besides intervention, doing angioplasty, one of the great advances in my career has been the studies looking for prevention. When I was an interventional cardiologist, I thought the artery was just a tube that didn't change. And I didn't realize that the arteries and the surface of the artery itself was very active and that things you could do, subtle changes you could do with medicine and change, could actually have a major effect on survival and also on keeping the vessel open.

So some of the trials that I did, I mentioned the TIMI 22 trial. That's a study looking at -- I was involved with looking at atorvastatin versus pravastatin. A very important trial was the JUPITER trial. That's a trial looking at rosuvastatin, 20 milligrams, versus placebo. These are patients who are just people who are normal people who had --

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LDLs were not elevated, but they had elevation of CRP, which is an inflammation marker.

**Q.** Doctor, I don't want to interrupt you, just set the stage for this.

Now, the JUPITER trial, is that a famous trial that --

A. This is a very famous trial. Again, these are -- what we talk about in cardiology are landmark trials. The TIMI 22 is a landmark trial. The JUPITER trial is a landmark trial because this established that inflammation itself -- so, again, this hypothesis in cardiology that all you have to do is measure LDL -- and, again, I'm concerned the LDL measure itself was inaccurate, but most cardiologists just measured LDL.

The JUPITER trial showed that measuring CRP, which is a marker for inflammation, that by itself was an independent risk factor. And medicine that lowered inflammation also reduced heart attacks and improved survival.

- **Q.** And, Doctor, can you tell us an anecdote about the JUPITER trial and how successful they found that to be?
- A. Well, the JUPITER trial was so successful that they actually had to stop the trial early, because, again, you know, they do -- when we do trials, we actually -- you know, we want to make sure people are safe. If a drug is harmful, they stop the trial early. But, also, if the drug is very effective, they stop the trial early. And this actually -- the study was

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stopped early because 20 milligrams of rosuvastatin reduced morbidity and mortality -- you know, the ends points we were looking at -- more effectively than placebo.

So, you know, I think the JUPITER trial was one of the trials that established CRP as a major risk factor for heart attacks.

- Q. Do you know Dr. Robert Superko?
- A. Yes, I do.
- Q. Who is he?
- A. Robert Superko was a thought leader in cardiology. He was one of the -- he developed one of the early tests looking at cholesterol, looking at LDL. And he actually developed a test called gel electrophoresis. Again, I was looking for -- as an interventional -- as a cardiologist and an interventional cardiologist, I was looking for ways, what can I do better for my patients? Is there a way that I could better predict risk?

And his studies show that doing -- doing gel electrophoresis -- isolating LDL and looking for small, dense LDL -- you could identify patients who are at higher risk. So he was one of the thought leaders in cardiology.

Actually, going to one of his classes in 1993 really -- really changed the way I thought about heart disease. You know, it was in the Grand Tetons, so it was a great destination I went to. But it turns out that completely changed my thought process. I changed from being an

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interventional cardiologist to really switch my focus to prevention. And his studies helped show that, by looking at advanced lipid testing, you could actually find ways to help patients.

> THE COURT: Mr. Cooke, let's move this on.

MR. COOKE: Thank you.

#### BY MR. COOKE:

- Doctor, does research show -- or current research show 0. whether it's possible to actually reverse plague growth?
- Absolutely. So what's interesting about that, the studies we've done, we've actually done studies showing that, by aggressive therapy, you can actually reduce plaque growth.

And the best study came out last year. I'm an investigator. One of the trials that I'm doing right now is called the ODYSSEY trial, which is a new agent that reduces LDL on top of a statin. So the interesting thing about that is these PCSK9 inhibitors. They actually work by inhibiting the receptor -- affecting the receptor on LDL, the LDL receptor.

And when you take a statin, people have problems with statins, they have muscle aches, they stop the statin. of patients can't take statins for different reasons. these agents on top of a statin can reduce LDL 70 percent. So they have actually shown that -- you know, previously we thought LDL should be 100 down to 70. Now they show that reducing LDL down to 20 actually prevents events, but,

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actually, they did -- the Glascow study showed that you could actually have regression.

They looked in the artery, intracoronary ultrasound in the vessel with an ultrasound device. And they saw the plaque, the size of the plaque. And they actually showed, by using this medication, you can reduce the size of the plaque from this maybe down to this.

Interesting thing about reducing plaque is if you reduce plaque a little bit, not only do you reduce the size of the plaque, what's really important is stabilizing the plaque. If you have plaque, I'm more concerned about, do you have unstable plaque? If your plaque can go from this to this, how quickly will that happen?

So one of the things about reducing LDL or reducing inflammation is you could potentially stabilize the plaque. But they also have done it on ultrasound device, so not only does it stabilize the plaque, you can actually reduce the plaque size.

**Q.** Doctor, I'm sorry. I know I'm interrupting, but I do want to kind of move things along.

THE COURT: You need to move to the issues more directly.

# BY MR. COOKE:

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**Q.** Do you agree or disagree with the statement that, unfortunately, when blockages exist, they don't get any better?

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- A. I disagree with that.
- Q. For the reasons that you just said?
- A. Yes.
- Q. I'm going to show you --

If you could put up Exhibit 496, please.

And I've handed you -- I think I handed you this morning a copy of that for you to refer to. While we're calling that up, I'm going to ask you your opinion; and that is, have you reviewed the panels of tests offered by HDL and by Singulex?

- A. I have.
- Q. All right. And then this is just going to be a yes or no.

Do you believe, to a reasonable degree of medical certainty, that those tests have medical utility when properly used?

- A. I do. I believe they do.
- **Q.** And who within the whole medical process makes a determination of whether a particular test is medically necessary for a patient?
- A. I think that rests on the individual physician. Only the physician himself can make that determination. I mean, he has to use his best judgment. He has to look at the individual patient and decide what tests they need to prevent that patient from, you know, from having a problem, having an event.

That's -- my job is someone sees me, he's seeing me

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because they don't want to have a heart attack. And it's my job to do everything I can, every tool I have, to prevent that.

Doctor, I asked you to look -- and it's on the screen in front of you, but it's also in your hand, I think. been previously introduced as Bluewave Exhibit 496. And it's referred to as Case Study Number 2.

Have you had a chance to look that over?

- I have. Α.
- Does that illustrate the medical utility of the tests offered by HDL?
- Absolutely. So looking over --Α.
- And you can hold that up if you need to. It's the same thing that the jury has. And they've got that on their screen.
- So this is the basic dilemma we have with patients, is that, many patients, you look at their basic lipid profile, it And does that take in all the risk the patient seems normal. may have?

And, again, it's important for me -- looking at this case study, it's hard for me to evaluate this without actually knowing the patient. I have to know, is this patient a smoker? Does he have disease? Is there a family history? All those things are important in my assessment.

Let me ask you to pause on that. Do you believe that it 0. would be fair to judge whether a particular panel was medically necessary without seeing the patient's chart and understanding

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what the diagnosis --

- A. It's impossible. You have to know the background and history of the patient. You have to know what the patient's coming to you with. And you can't judge this in any way without knowing -- without knowing the patient.
- **Q.** So looking at that paper in front of you, one of the panels that are up at the top, where it says "lipids," is that the standard test?
- A. So on the very top, the lipids, those are the standard lipid panel. And they're normal. But this is a 64-year-old gentleman. Again, he's 5 foot 5, 139. So it sounds like his weight is good. His BMI is good. But he had a basic panel that's normal.
- Q. And then what do the advanced lipid studies show?
- A. Well, again, my -- looking at -- looking at this, his

  LDL -- let's start with the LDL. The ApoB and LDL particle

  number, these are things which are a better assessment of LDL.

So the LDL of 67 is normal, but the ApoB and LDLP are kind of borderline. Those are not as -- those are not as normal as -- those are intermediates. But then he also has small, dense LDL. So not only is the LDL normal, but the problem is he has more small, dense LDL. Small, dense LDL is more atherogenic. So that's one problem.

The next problem going down is Lp(a). Lp(a) is a major risk factor for heart disease. And I think the problem

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with Lp(a), it's probably the most common genetic disorder that we have. 20 percent of people have elevated Lp(a). Lp(a) is a hidden risk factor. Just as an aside, in the -- if you watch Dr. Oz or looked at the New York Times, there's a discussion about Bob Harper. Bob Harper was fitness trainer for "The Biggest Loser."

Turns out he looked like the most fit person you'd He ate well. His weight was down. All his basic things were normal. He had a major, massive heart attack. He was in a coma for two days. And they discovered he had elevated Lp(a). That was his only risk factor. Again, that was just --Dr. Oz had a whole --

- Is that a genetic factor? Q.
- That's a genetic factor. It turns out, if you have that genetic factor, you have three times the risk of having a heart attack.

So, again, if your risk is 4 percent, 5 percent, if your Lp(a) is elevated, that increases your risk to probably close to 15 percent.

- This is a good point to take it to another -- do some but not all of these tests require follow-up from time to time?
- Some tests require follow-up. For instance, LDL requires follow-up. And, generally, when I treat someone with a cholesterol agent, if I'm -- I make a change in the cholesterol agent, I usually, in six to eight weeks, I recheck the levels.

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I'll check the liver enzymes too every six to eight weeks.

I -- generally, I would check it -- if it's stable, I would check it either -- at least twice a year or sometimes four times a year.

Actually, one of the reasons you actually check it is that a lot of patients -- they've done studies with statins, people stop their medications. So it turns out that one of the reasons to check it, they ran out of medications. They stopped the medications. So that's actually one of the reasons why you need to check it more than once a year.

But, generally, I check statins -- levels -- lipid levels at least -- at least -- in my office, at least twice a year, sometimes four times a year. Some agents which are genetic -- purely genetic factors, you check once in a lifetime.

Lp(a) is a combination of a -- this is a measure here of a level. And that actually could change somewhat with different factors. I would check that probably at least once or twice a year, the Lp(a) level.

- **Q.** Doctor, if I ask you to assume that the average frequency of testing by HDL customers was around 1.6 times per year, would that strike you as excessive or conservative?
- A. I think that's conservative. I think the -- I would have -- if I was using that lab, I would have -- generally, when I use advanced lipid testing, I do it at least twice a

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year.

- Q. Before I take you to the Singulex test --
- A. Can I finish this? There's more on this.
- Q. Yes.
- A. I'm sorry. I'll be faster.

This also has an abnormality besides Lp(a) of Lp-PLA2. That's an inflammation marker, and that appears also to be -- people who have elevation, particularly a marked elevation, of that have a higher risks of atherosclerosis. Fibrinogen is a risk factor.

One interesting test here is AspirinWorks. So one of the problems with Lp(a) is if the Lp(a) is elevated -- again, a test should have some impact on what you do with the patients. So every test you do should have -- you know, we're not doing tests for the sake of doing tests; we're doing tests to have an effect on what we do.

So on this patient here -- again, I don't know what the baseline history of the patient is, but certainly based on this, with an elevated Lp(a) -- an Lp(a) is interesting because it has two things. It looks like plasminogen. So Lp(a) elevates the -- elevates the cholesterol. It's an additional risk factor, but it also looks like a clotting factor.

So one of the things about Lp(a) is that causes increased atherogenesis. Actually, it puts you at higher risk for blood clotting. So, again, if you have elevated Lp(a), you

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may be more likely to have a clot that forms in the heart.

So in those people with elevated Lp(a), I like to have them on aspirin to prevent that. So one of the things here -- if all I had was Lp(a), I would put that person on an That would be one intervention I would do. AspirinWorks here shows that 81 milligrams of aspirin may not be sufficient. Here's an example of a test that would actually make one of these 160 milligrams and make 325 in this person in order to prevent a blood clot, or maybe use an alternative agent like Plavix, which is another platelet agent.

On the next page, he is ApoE 3/4. You know, ApoE is a genetic test. You do it once in a lifetime. But ApoE 3/4 puts someone at higher risk for atherosclerosis and also slightly increased risk for Alzheimer's.

He's also Factor V Leiden positive. Factor V Leiden is very important test looking for blood clots. So if you think on how important this test is, is that Factor V Leiden -it's, again, a very common test. It's in 5 percent of the population, 1 in 20. If you have Factor V Leiden, you are at risk for having a deep vein thrombosis or a pulmonary embolus.

It's really important for women, because, for women, if they take birth control bills, Factor V Leiden puts them at higher risk for having blood clots. Also, if they've had miscarriages or anyone in the family has had miscarriages, this

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puts them at higher risk if they have Factor V Leiden. The thing about Factor V Leiden, if you have it, your child may have it. It's a 50-50 chance your child has it. So it would actually help you but also help your child. If they want to say, "Well, I want to go on birth control pills. I'm going to go on a plane flight to Europe." It's an important test. It's good to know that, and it's even more important for your children.

So looking at all this test together, and this test here, I definitely -- again, not knowing the whole situation, but this would make me change how I approached the patient. This patient goes from a low-risk patient to at least a moderate, maybe a higher-risk patient. I certainly would do a stress test, and I'd absolutely do a calcium score this patient. This patient may turn out to have a very elevated calcium score that would change how I would treat this patient.

- **Q.** And is that information that you would not have had had you just done the standard lipid panels?
- A. Absolutely not. I'd be blindsided, just the same way with the -- Tim Russert's doctor was blindsided when he had a heart attack. Tim Russert had the autopsy done. He had diffuse atherosclerosis, every vessel was blocked off. And the doctors thought he was at low risk. So, again, this test would allow me -- for this patient here, this may be evidence that I would -- the patient could have severe -- at age 64, he may

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have severe atherosclerosis, and you wouldn't necessary have a clue from the basic lipid panel.

- Doctor, as you looked through the tests that were offered by HDL, did you see any that looked like fake tests or tests that you didn't recognize?
- All the tests, to my -- to my view, had some validity. Now, some of the tests, I didn't use. Some of the tests were more specific to a endocrinologist and to a diabetes doctor. And so some of those tests, if I was doing them, I never did an HDL panel myself; but if I used HDL lab, I would have tailored the lab to my patient population. I would have picked and choosed which tests I wanted.

And that's generally what I do. I develop my own panels based on my experience. But sometimes you're surprised. Sometimes a test you thought is not as important turns out to be more important.

I was going to ask you -- take you to the next question.

Does it trouble you that HDL organized its tests according to panels on its requisition form?

That's a -- I mean, I think they -- their scientists put together panels they thought would be most important. of the panels were designed for cardiologists. Some of them were designed for endocrinologists. But all laboratories do that. When you do a complex metabolic panel, it comes with 12 tests and 18 tests. When you do a liver panel, it comes with

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certain tests.

So laboratories, for -- for 50 years, have always had panels on tests. And you put together a panel you think is most important for the patient population and for the physician group you're doing. But, again, every physician could decide which -- which ones they think are most important.

Let me -- I'm sorry. I know I'm interrupting you, but --I'm going to interrupt you every now and then.

Okay. Good.

In your experience, do physicians generally know enough that they can mark off the tests that they don't want or check the tests that they do want?

Yeah, I think physicians have a pretty -- a broad knowledge, and they decide -- the physicians could cross off the tests which they think are most effective. And, generally, physicians do that. At least in my assessment, that's what I I hope that most physicians do that too. do.

And you said something earlier that I -- bears follow-up. Q. You've never been an HDL customer; is that right?

I haven't been an HDL customer. Right.

And you use currently --Q.

I use -- primarily, I use Quest Diagnostics for my Α. advanced lipid testing.

Q. Did you use Berkeley back --

I used Berkeley in the past, and Dr. Superko was Α.

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associated with Berkeley at the time. I was a Berkeley customer for many years.

- Q. Let's talk about Singulex for a few minutes. Did you look at the panels -- the tests Singulex offered?
- A. I have. And I think Singulex is a very unique panel of tests. And it turns out -- you know, I'm familiar with Singulex lab. I've used Singulex lab, not as frequently as Quest, but I have used them in the past.

And the reason I like Singulex lab, they offer some tests which no other lab offers. They offer -- and they offer tests for inflammation for interleukin-6 and interleukins. It turns out there was a recent study that just came out within the past couple of months that -- the CANTOS trial, it was an inhibitor of interleukin-1. It had no effect on lipids. So it wasn't like the JUPITER trial or -- it wasn't a statin. It was just a drug that lowered interleukin. And that drug showed independent reduction in events. So it was the first time they actually had a drug which wasn't a statin.

See, statins reduced inflammation, reduced lipids.

So some people would say, well, it's only because of reducing the cholesterol. But this drug reduced interleukin-1, which is an inflammatory marker. And that by itself reduced cardiovascular events. So it's the first time -- and that's one of the tests -- interleukin-6 and interleukins are one of the tests that Singulex offered.

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The other test that Singulex offers that no one else offered at the time is high-sensitivity troponin. And, actually, one of the studies that I've done at Overlook, I worked with the residents looking at people coming in with heart attacks. And one of the problems with heart attack is how quickly we diagnose it and how accurately.

And troponin is a -- it's a measurement of blood -- of an enzyme -- a protein that's elevated, it indicates you've had a heart attack. And when you usually look at a certain level, if it doubles, they've had a heart attack. It turns out people have elevation of troponins which are -- at basal overflow, that troponin is elevated, it's not significant.

But turns out, in Europe, they've done studies that low-level troponins, very low levels, much lower than measured here, puts someone at risk. If you're a diabetic -- if anyone is a diabetic -- they have elevated troponin, that puts them at higher risk.

And it turns out Singulex is the only lab in the U.S. which actually offered that test. And I was impressed by that but even more so now with the most recent studies. And now -- we're adopting that now. We're adopting troponins here in this country. So back then, all they had were less-sensitive troponins. Now we're adopting high-sensitive troponins. But Singulex was actually ahead of the curve. They offered this a number of years ago.

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And, again, if you find a diabetic who has elevated high-sensitivity troponin, that person is at higher risk.

That's something you should do further investigation. They may be at risk for having a heart attack.

So those are two tests that Singulex offered which no other lab I know of offered.

- **Q.** Did you find that a lot of physicians didn't really know how to interpret Singulex tests and therefore didn't use them?
- A. I find -- yes, I found some doctors didn't -- didn't know how to interpret the tests. They weren't sure what to do with the results.

Again, you have to know -- if you order a test, you have to be comfortable and have to know why you're ordering -- what to do with the results; right? I think it's -- you know, I don't know why more doctors didn't order these tests.

- Q. And that takes me to kind of a summary question; and that is, if these tests do everything that you say they do, why isn't everybody using them? Why don't all doctors use these tests?
- A. Yeah, that's something which I've -- you know, I've certainly tried to -- you know, in my career I tried to -- I found these tests -- I'm sure I've had a number of patients these tests have saved their lives on. Doing these tests have saved a number of lives in my patients. I have one patient recently who his whole family has elevated Lp(a). His --

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his -- both sisters had bypasses. And he was only diagnosed, they ordered one of these tests. They had elevated Lp(a). Only reason they knew it.

He comes to see me. Both sisters bypasses, his Lp(a) was elevated, wasn't as high. He passed his stress test. He had no symptoms. His basic LipoProfile was normal, absolutely normal. He looked thin. He exercised. He ate well.

I said, well, I'm just not sure.

I did a calcium score on him. His calcium score was 5,000, which is extraordinarily high. He had a catheterization. He actually -- he needed a bypass operation. So I'm sure I saved his life.

But why -- why doesn't every doctor order these tests? It's -- sometimes -- it's mind-baffling to me.

One thing is that the American College of Cardiology, American Heart Association came up with guidelines in 2013 and left these tests off their guidelines. I actually asked Dr. Stone, who wrote the guidelines, "Well, why isn't LDL particle number on this? Why isn't ApoB? Why isn't Lp(a)?"

He says, "Well, we're looking at randomized trials. Randomized trials are ones which pharmaceutical companies put together to prove that their drug's effective. They're not really looking at markers. They just want to prove that statins work, other drugs work."

So -- so they actually didn't look at these studies

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well. And he actually told me that at that time there was a government sequester. I think they had ran out of money. He said, "Well, every doctor has to decide what to use."

So I think that the -- there's a bias against this in the general -- a lot of doctors are biased against using these tests because the guidelines don't include them.

If you look at some other guidelines, the European guidelines, for instance -- I'm a member of the International Atherosclerosis Society; I'm a member of the International Lipid Society. Those societies recommend using it. So members of the National Lipid Association do recommend using many of these tests. Again, that's not the majority of the physicians in this country.

- **Q.** Do you believe that the use of these tests will increase over time?
- A. I think they will. I think that -- again, if you look at some of these tests -- for instance, CRP, that has increased over time with the studies and I think with the publication of the CANTOS trial -- I think we're going to see people using -- adopting CRP as standard of care for everyone. And I think now what's in evidence with Lp(a), we may see a higher use of Lp(a) in a wider population.

And, again, a lot has to do with family history. If you really look at family history, you really look at some of these risk factors, a lot of doctors don't delve into family

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history well enough. And -- but if you really look at family history, you're going to find many more people that may benefit from these tests than is used today.

- Q. Doctor, do you have an opinion to a reasonable degree of medical certainty whether each and every one of the tests that was offered by HDL and by Singulex could be medically necessary if an appropriate diagnosis is made of an individual patient?
- A. That's a very difficult question for me. Medical necessity is different than what I'm necessarily looking at.

  I'm looking at things that will prevent someone from having a heart attack than medically necessary. Medically necessary is a different -- is a different term.

I think many of these tests are medically necessary for the individual, but, again, I'm looking for tests that will help prevent heart attacks and keep my patient alive. And that's what I'm most concerned about.

- Q. But when you -- when you apply -- when you order a test and apply -- and the patient applies for the reimbursement, they have to certify that it's medically necessary, right, in order for it to be reimbursed?
- A. I have to have a reason for ordering the test. So in my mind, it's medically -- in my mind, I think it's medically important.
- Q. Because it will help the patient?
- A. Help the patient.

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- And make the patient safer and healthier? Q.
- Make the patient safer and healthier. Again, many of these tests have met the criteria for medical necessity. not sure if every test in the panel has met that, but there's probably some patients that -- it would be medically necessary for some patients.
- And I wasn't suggesting that you order every test for every patient. I think what my question was is there an instance when any one of those tests could be medically necessary for a patient if the doctor, in his professional judgment, determines --
- Yeah, I think so. And I don't think the FDA would allow those tests on the panel. Each of those tests were approved as an approved test for a specific syndrome in an individual. all the tests are there. Every test has been approved to some degree and validated.
- So would you agree that not every one of those tests is for every patient but each of those tests could be for some patient?
- Yes, each of those tests for some patients. And, again, as an example you showed here, sometimes I'm surprised how -sometimes you get a panel like this back and you're amazed how impressive the panel is. It's thank God I actually ordered this test because this test actually may save the life of the patient.

Just a moment, if you would. 1 Q. 10:23AM 2 (Pause.) 10:23AM 3 BY MR. COOKE: 10:24AM 4 I should ask you this question. Do you -- do you know Cal Q. 10:24AM Dent or Brad Johnson? 5 10:24AM 6 No. 10:24AM And when you were a customer of Berkeley HeartLabs, were 7 10:24AM Q. you a customer of theirs? 8 10:24AM I wasn't. 9 10:24AM 10 would it be fair to say that they didn't influence you in Q. 10:24AM 11 any way to become a user of advanced lipid tests and genetics 10:24AM 12 tests? 10:24AM 13 No, absolutely not. Α. 10:24AM 14 MR. COOKE: Thank you. 10:24AM 15 THE COURT: Cross-examination by the government. 10:24AM 16 MR. KASS: Thank you, Your Honor. 10:24AM 17 **CROSS-EXAMINATION** 10:24AM BY MR. KASS: 18 10:24AM 19 Dr. Fishberg, how are you, sir? Q. 10:24AM 20 very good. 10:24AM 21 Thank you for your time today. Q. 10:24AM 22 For the benefit of the record, we met during your 10:24AM 23 deposition back in April, just up the road on Meeting Street? 10:24AM 24 Α. Right. 10:24AM 25 But it's nice to see you again. Q. 10:24AM

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I have a lot of questions, but I'm going to try to cut them. I'm going to try to go quickly here.

- A. Good.
- **Q.** You referred to the National Lipid Association; correct?
- A. Yes.
- **Q.** Yes. Were you aware that Health Diagnostic Laboratory provided funding for the National Lipid Association?
- A. I wouldn't be surprised by that.
- **Q.** Why wouldn't you be surprised?
- A. Because they -- the National Lipid Association took funding from many companies, laboratories and pharmaceutical companies. So that doesn't surprise me.
- Q. I'm sorry, sir. I didn't mean to interrupt you. And in spite of that, I believe you're referring indirectly to a 2011 study that came out from the National Lipid Association regarding some of the tests that are at issue in this case. And even in that study, the National Lipid Association, funded in part by Health Diagnostic Laboratory, did not recommend those tests for what it determined to be low-risk patients; isn't that correct?
- A. They said that low-risk patients would not recommend it for -- not for all the tests, but they outlined it for some tests.
- Q. Well -- and I can bring it up if it would be helpful. I think for all the tests that they look at in that study, they

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said these tests are not appropriate for low-risk patients; isn't that correct?

- A. That's what they came up, yes.
- Q. That's what they came up with.

You referred in your testimony to a study that came out in the last couple of months about interleukin-1, I believe. Is that correct?

- A. Yes.
- **Q.** Now, is interleukin-1 different than interleukin-6?
- A. They're related. Interleukin-1 actually causes elevation of interleukin-6.
- **Q.** I see. And that study that came out in the last couple of months, did that study come out during the relevant time period in this case, which is 2010 to 2014?
- A. It came out within the past year.
- **Q.** Right. So it was not available to the physicians who were ordering Singulex tests between 2010 and 2014?
- A. Well, the test was -- the design of the test was during that period, and the doctors who developed the test had smaller studies that justified -- every study -- if you did a larger study -- you have smaller studies that justify that. So there were studies preceding that that justified the hypothesis.

So the hypothesis for the CANTOS trial was developed, and this was a -- this was a study -- so they've done smaller studies looking at it. This was a larger study to prove the

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concept was correct.

But the concept was developed during this period. It was developed back many years ago that -- that reducing interleukins would reduce -- and there's other studies looking at interleukin-6, showing reduction of interleukin-6 did show a reduction of events.

So hypothesis was developed. This was a large Phase 3 trial that proved -- proved the concept.

Q. Let's talk a little bit about these interleukin tests.

Peter, can we bring up Exhibit 3003, which has already been introduced into evidence. Thank you. And, Peter, would you mind zooming in on the panels here, just that section. Okay.

Everybody get that on their screens?

Could you move it over a little bit to the right?
Other way. Perfect. Terrific.

We talked about some of these tests during your deposition in April of last year, and you said, "I think interleukin testing is something which is an evolving science. I'm not sure about the long-term benefit."

Do you remember that?

- A. Well, yeah. It's -- my opinion has evolved since CANTOS. So I've actually evolved my thinking since then.
- Q. You've evolved your opinion since you and I spoke during your deposition in April of 2017?

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- Α. Exactly.
- Right. And you're the expert in cardiology up on the Q. stand. And prior to April 2017, you weren't sure about the long-term benefit of interleukin testing; correct?
- That's why I -- I didn't actually use this I wasn't sure. I used this test on people I thought were at risk for higher inflammation, people with rheumatoid arthritis. That's the type of person I would use this test with.

So sometimes the tests are -- amazing how effective, you know, again test was developed. They had science behind But, again, as a physician, you know, I want to make sure the test I order, you know, is -- you know, in my mind is effective enough to justify ordering it. Other doctors may have been convinced of that five years ago.

- Q. They may have been, but you weren't?
- I wasn't. And that's why I only used this test sporadically.
- You used this test sporadically; right? Q.
- Yes. Α.
- You don't use the interleukin test offered by Singulex on each and every patient who comes in the door; right?
- I do not. Α.

MR. KASS: Peter, can you bring up Exhibit 1139, please?

And, again, I'll just note for the record this is

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already in evidence.

And, Peter, would you mind zooming in on this comprehensive baseline assessment here under custom panels. Thank you. And would you just scooch that over to the right a little bit? Great.

## BY MR. KASS:

- Earlier, Dr. Fishberg, we were talking about Tim Russert, who I was a big fan of, which is very sad. And you mentioned that at age 48 he had had the calcium score which, I believe you said, showed that he was at really high risk for --
- Yeah. Α. It was over 200 at age 48, yes.
- So at age 48, I guess that was -- what? -- 10, 11 years before he passed away.
- Α. 10 years before he passed away.
- He had the calcium score test, showed that he was at Q. really high risk of a heart attack? Yeah. Thank God for the calcium score test.

Do you, sir, see the calcium score --

- It wasn't -- he died. It wasn't thank God for the calcium They didn't do anything with it. score.
- well, maybe his doctor should be in here, but that's another story for another time.

Would you tell me, sir, do you see the calcium score test anywhere under the comprehensive baseline assessment?

No. Α.

And, by the

If I had someone at

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- No, you don't. Let's move on to --Q. I would have ordered this test. I would have ordered a Α. test like this. If I could add to that. age 48 who had a calcium score in my practice, that to me is an absolute indication to do advanced lipid testing. Let's talk about some advanced lipid testing. way, you've seen this before, right, this comprehensive baseline assessment offered by Health Diagnostic Laboratory? I have. Okay. Let's look down. There's a reference three from Q. the bottom on the left-hand column to CYPC19. Do you see that? Α. Yes. Do you know what that refers to? Q. That has to do with -- it has to do with -- essentially, it's enzyme -- it's a gene. It helps you assess whether Plavix is effective for someone. okay.
  - And just to put perhaps too fine a point on that -- well, So this is a test to see if the Plavix medication is

going to be effective for patients; right?

- Α. Right.
- And when we spoke during your deposition last year, you 0. indicated that, if a patient is not on Plavix and if a physician is not considering Plavix for the patient, the CYP2C19 test is not helpful; correct?

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I did not find it -- you have to have a risk for either -- either you have atherosclerosis, you had a stroke, you have known coronary disease. Positive calcium score actually might be a reason to use it. You might need Plavix in the future.

But, generally, if there is an atherosclerosis at that time, if they're not on Plavix, if they haven't had a stroke, this test -- I probably wouldn't have ordered the test.

- You're certainly not ordering the test on every patient who comes in the door; right?
- Α. I am not.
- And, again, not to put too fine a point on it, Okay. would this test have saved Tim Russert's life?
- I can't actually answer that because I probably would have put him on Plavix at that point, given his disease that he had, and I may have needed the test. So I actually may -- knowing that his calcium score was 200, I probably would have ordered the test on Tim Russert.
- But this test wouldn't have told you that he was going to pass away from a heart attack 10 years after his calcium score, would it? Has nothing do with that?
- The CY19 or the whole panel, the whole comprehensive panel?
- I'm asking about -- for now, I'm just asking you about the CYP2C19 test.

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- That would show us whether Plavix would be effective for Α. it.
- Not whether he's going to pass away from a massive Q. heart attack 10 years in the future.

Let's talk about -- right underneath the Okay. CYP2C19 test, do you see a reference to Factor V Leiden?

- Α. Yes.
- You're familiar with this test, of course; right? 0.
- Yes, I am.
- I think you spoke about it earlier. When we spoke at your deposition last year, you indicated that you found the Factor V Leiden test useful for patients with venous disease; right?
- Primarily with venous disease. It may have some indication for cardio disease if they have other risk factors for thrombosis, like if they have -- like for this patient, when they presented here the Lp(a), if that was elevated and they have Factor V Leiden and they can't take aspirin, then it actually was helpful in this case.
- So we're talking about very specific categories of patients in whom you would order the Factor V Leiden test; correct?
- Well, I actually think that Factor V Leiden -- again, depends on family history and it depends on -- I think that women probably should have this more often -- probably more often than men because it's related to birth control pills,

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pregnancies. This is a higher risk.

So I think in the general population, since it's so common, it's 5 percent of the population, there may be -- I wouldn't order it for everyone, but I would have a lower threshold for this. Again, you have to take an extensive family history. You may find someone -- some reasons for ordering it.

- **Q.** So you wouldn't order this test for every patient that comes in the door; correct?
- A. I would not.
- **Q.** And the same is true of the prothrombin mutation test, which is right underneath the Factor V Leiden test; correct?
- A. Yeah, I would put those two together. Again, I saw a patient where they both were positive. So you just never know.
- **Q.** Breaking stride for a second here, earlier there was a question during your direct testimony about plaque and how plaque can be reduced over time.

what about a 100 percent blockage of an artery in the neck? Does that just get better magically on its own without any treatment?

A. So a blockage, 100 percent blockage in the neck, again, it's hard to know how it's being measured 100 percent. But you actually can shrink the plaque down if a vessel is totally blocked off. There is some evidence, if you look at some evidence with MR, you can actually see shrinkage of plaque with

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the blockage. 100 percent blockage of the neck, sometimes it's 99 percent. It looks 100 percent. So you could have some shrinkage of blockage with aggressive treatment.

- **Q.** With aggressive treatment; not going to get better on its own. Is that your position?
- A. It's -- it doesn't -- yeah. Aggressive treatment may involve high-dose statins, other things to reduce inflammation. I think, theoretically, it could get -- could get -- you could reduce the size of the plaque. Whether or not the vessel opens up again, I'm not sure.
- Q. You're not sure if the vessel is going to open up?
- A. Yes.
- Q. Okay. Let's go back and take a look at Health Diagnostic Laboratory's comprehensive baseline assessment. If you look back at CYPC19 and you count up four from there, do you see the galectin-3 test?
- A. Yes.
- Q. Okay. Now, when we spoke during your deposition last year, you said, and I quote, "I've never ordered the test, and I can't tell you anything about it."

I asked you, "Sitting here today, you don't have any opinions about galectin-3?"

And you answered, "I have no opinion, yes."

You probably don't know if that's an accurate

statement of your testimony, but does that sound right to you?

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A. Yeah, I never ordered galectin-3. Some doctors find it very helpful for heart failure. I just never ordered it. I order other tests for heart failure. Galectin-3, if you look through the data -- I've looked through it -- you know, reviewing the testimony, I've looked through data for galectin-3, and it appears to have similar benefit to NT-proBNP, which is a measure of heart failure that I do measure. So I've never used it, but I use other measures of heart failure similar to that.

Q. And if you look at the right-hand column under "Comprehensive Baseline Assessment," the second test from the top there is FFA (NEFA).

Do you see that?

- A. Yes.
- **Q.** And when I asked about this test during your deposition in April of 2017, you said, "Yeah, I don't order this test. I have no comments on it."

Does that sound about right?

- A. That sounds fair enough.
- Q. And then there's the cystatin C test. And forgive me if I'm mispronouncing these. It's the fourth from the bottom in the right-hand column under "Comprehensive Baseline Assessment."

Do you see that?

A. Yes.

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when I asked you -- I said, "Let's talk about cystatin C 1 Q. 10:38AM here. Are you familiar with this test?" 2 10:38AM You answered, "I'm not." 3 10:38AM 4 I said, "Do you have any opinions on?" 10:38AM You answered, "I have no opinion on that." 5 10:39AM Does that sound like your testimony? 6 10:39AM 7 Yes. Α. 10:39AM Sounds like your opinion on cystatin C? 8 0. 10:39AM Some people may find it effective. I'm not someone 9 Yeah. 10:39AM 10 that -- I've never used HDL labs. That's not a test which I 10:39AM 11 But, again, some doctors may find it helpful. 10:39AM it's all about the individual doctor trying to prevent that 12 10:39AM 13 person from having an event. 10:39AM 14 MR. KASS: May I have just one moment? 10:39AM 15 THE COURT: You may. 10:39AM 16 MR. KASS: Thank you for your time. Appreciate it. 10:39AM 17 No further questions. 10:39AM 18 THE WITNESS: Thank you. 10:39AM 19 THE COURT: Mr. Ashmore? 10:39AM 20 MR. ASHMORE: No questions, Your Honor. 10:39AM 21 Very good. THE COURT: 10:39AM 22 Anything on redirect? 10:39AM 23 MR. COOKE: Briefly, Your Honor. Thank you. 10:39AM 24 REDIRECT EXAMINATION 10:39AM 25 BY MR. COOKE: 10:39AM

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- **Q.** Do you happen to know how -- what percentage of doctors that used HDL would also order from Singulex?
- A. Would order both?
- **Q.** Yeah. Do you happen to have any idea?
- A. No, I have no idea.
- **Q.** In your opinion, would it be left to the individual judgment of the doctor as to whether he felt that the test from both panels were helpful?
- A. Well, I'll tell from you my personal experience.

  Sometimes I'll use tests from different panels. When I've used Singulex, I may do a basic test. I may do a test from, like, one lab. And then, well, you know, I've -- everything looks good on my panel, but does the patient have inflammation? Is the troponin elevated?

So I actually may sometimes use a lab like Singulex to look for things which is not available in the -- in the Quest advanced panel that I use.

So I think it's not unreasonable to have a patient have HDL one time or -- or Quest and then try a different lab like that or Boston or Cleveland to see if there's something else that may -- may be additional.

Again, in my case, if my patient had rheumatoid arthritis, and, you know, if you have rheumatoid arthritis, inflammation, you may actually have heart disease. If you see a dentist, you have a lot of periodontal disease. You have

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inflammation, you actually may have -- it's diffuse. It may be associated with rheumatoid arthritis; it may be associated with heart disease.

So if you have inflammation in one part of the body, it may cause inflammation in the heart. So it's reasonable in some cases to look for a test like Singulex.

I'm going to bring up the exhibit you just looked at, 1139. And this is the Singulex requisition form.

HDL.

I'm sorry. HDL requisition form. And could we go down here to these panels that were reviewed a minute ago.

Take a look at that. You see the comprehensive baseline assessment and then the follow-up profile?

Yes. Α.

Do you see that they're grouped in two different sections? Q.

Α. Yes.

Now, you testified earlier that some tests wouldn't need follow-up; right? Like genetic tests?

Right. Α.

Is that because your genetic makeup, you're kind of stuck with it?

In fact, if I have Leiden, CYPC19, ApoA, Α. prothrombin mutation, you do it once in your lifetime. Ιt never changes.

Now, when you see these custom panels, do you interpret

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that as saying that the doctor has to order all those tests?

A. No, absolutely not. I mean, again, my -- I'm not sure what other doctors do exactly, but in my practice, I would have the answers -- okay. I'd like a lot of these tests you have. I'm going to set up a panel myself for a basic panel, comprehensive baseline panel and a follow-up panel. And then on an individual patient, if I think a patient needs a special test, I would order it separately.

So I think this is a -- I would -- I would -- I would take -- I would pick and choose which ones I want. Nice thing about HDL lab is one of the difficulty with a lot of these labs is a lot of them are made by different companies. So, normally, if I want someone to have LDL 2, MPO, Lp(a), I'm going to have to send samples to six different -- four different labs. And that's a lot of time for my tech to draw the blood, send it out. It's actually -- one of the things I was impressed by HDL lab, I spoke to them a couple of times, was that all the tests I want is sent to one lab, and they would -- they would send out to the different reference labs. It would be comprehensive back to me.

Another thing I liked about -- that's one thing I liked about the HDL lab. It was comprehensive. It was -- and -- it's more than just -- it was more than just a lab.

- Q. A one-stop shop?
- A. Yeah, they also provide a nutritionist. And, you know,

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Quest, the lab I use now, does the same thing too. They actually provide a nutritionist. I think it's really good because it shows a commitment to the company. It's not just a laboratory; they provide nutritionists that would help the patient with diet. I think that was really helpful. I still use it for Quest.

So if I see a patient four times a year, twice -whatever -- two to four times a year, I give my spiel. I tell
them they have to lose weight and exercise. Nothing happens in
six months. They're back the same weight with some excuses.

A nutritionist, though, they could talk to every week. And I found that, when they use a nutritionist from Quest -- I think HDL offered that; I'm not sure if Singulex offered that -- they're actually more likely to comply. They would lose the weight. They would exercise more. It was actually a -- really, it added service. To me, that's one of the hidden benefits of some of these labs.

- **Q.** All right. Let me just call your attention back to this custom panels. On the follow-up profile, do you see any genetic tests listed there?
- A. No, there's no genetic tests in the follow-up panel.
- **Q.** And would that be consistent with what you said earlier; and that is that your genetics stay as they are and don't need follow-up?
- A. Exactly. Exactly. There's no -- genetics, you only have

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to check once.

- **Q.** And, finally, you were asked about a couple of these tests that you don't personally use or are familiar with, like FFA (NEFA), do you know what that is?
- A. Free fatty acids. Yeah, I don't order that test. I think maybe some -- someone who's an endocrinologist would be more likely to use that test than me.
- **Q.** Is it a real test?
- A. It's a real test. And there's some data -- all these tests have some data supporting it. And they all have some risk-benefit if it's abnormal. The question is you have to decide, you know, how many tests you need, how do you put it together? What's the additive risk?

So it's up to the individual physician to decide which tests he wants. But they all have some -- I think there's nothing -- there's no tests here I thought was, you know, out of the ordinary. They all had some value. I just -- for me, you know, I just wanted to pick the tests I think would be most helpful for the patient.

- Q. And you would expect any physician to do that?
- A. I hope every physician does that.
- Q. Thank you very much.

THE COURT: Very good.

Doctor, you may step down.

MR. COOKE: I'm sorry. May I have one more question?

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               BY MR. COOKE:
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                    Doctor, I just want to make sure. You understand that
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               what I just showed you, that's a sample; that that's not an
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               actual requisition?
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                    Right.
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               Α.
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                    All right. Thank you.
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               Q.
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                          THE COURT:
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                          You may step down, Doctor. Thank you.
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                                       (Witness excused.)
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                                     Call your next witness.
                          THE COURT:
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                         MR. GRIFFITH: Doug Sbertoli.
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                                      I'll tell you what. It's -- how lengthy
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                          THE COURT:
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               is this witness going to be?
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                         MR. GRIFFITH: He's not going to be long, Your Honor,
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               but it probably would be a good time to break.
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                                      Let's take our morning break.
                          THE COURT:
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                          (Whereupon the jury was excused from the courtroom.)
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                          THE COURT:
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                                     Please be seated. Any matters I need to
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               address?
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                          MR. LEVENTIS: Your Honor, I would just say we're
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               getting documents as some of the witnesses are getting ready,
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               so there may be some we'll have to discuss before a witness
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               is --
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                          THE COURT: Very good. I'll be back in just a
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               minute.
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Can I give his model back to him? 1 MR. COOKE: 10:48AM THE COURT: You may give his model back to him. 2 Let 10:48AM him take it home with him. 3 10:48AM 4 MR. COOKE: Thank you. 10:48AM (Recess.) 5 10:48AM Please be seated. Okay. 6 THE COURT: Do we have 11:05AM 7 issues concerning any exhibits? 11:05AM MR. GRIFFITH: Your Honor, no issues. 8 11:05AM 9 we are admitting by stipulation Bluewave 255, 11:05AM 10 BlueWave 256, and BlueWave 258. 11:06AM 11 THE COURT: Okay. There's an offer of Bluewave 255, 11:06AM 12 256, and 258. Any objection from the government? 11:06AM 13 MR. SHAHEEN: No, Your Honor. 11:06AM 14 THE COURT: From Ms. Mallory? 11:06AM 15 MR. ASHMORE: No, sir. 11:06AM 16 BlueWave 255, 256, and 258 THE COURT: Okay. 11:06AM 17 admitted without objection. 11:06AM 18 Anything else? 11:06AM 19 MR. GRIFFITH: No, Your Honor. 11:06AM 20 THE COURT: We ready -- bring in the jury. 11:06AM 21 (Whereupon the jury entered the courtroom.) 11:07AM 22 Please be seated. THE COURT: 11:08AM 23 Government, call your -- I mean, BlueWave, call your 11:08AM next witness. 24 11:08AM 25 MR. GRIFFITH: Your Honor, BlueWave calls Douglas 11:08AM

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Sbertoli.

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

THE WITNESS: Douglas L. Sbertoli.

THE DEPUTY CLERK: Can you spell your last name for the record?

THE WITNESS: S as in sun, B as in boy, e-r-t-o-l-i.

THE DEPUTY CLERK: Thank you.

(Witness sworn.)

THE DEPUTY CLERK: You may be seated.

## DOUGLAS L. SBERTOLI,

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

## **DIRECT EXAMINATION**

## BY MR. GRIFFITH:

Q. Good morning, Mr. Sbertoli. My name is Joe Griffith. I represent BlueWave and defendants Cal Dent and Brad Johnson in this matter. I'm just going to ask you some questions.

Have you ever testified in court before?

- A. At a bankruptcy proceeding as an expert witness.
- Q. Okay. Well, let's start off a little bit of background.
  Where are you from?
- A. Richmond, Virginia.
- Q. And have you been there all your life?

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- I spent three years in Cleveland when I Α. Virtually. graduated from law school.
- well, speaking of education, where did you go to okay. Q. undergrad?
- University of Virginia.
- Okay. And what -- what did you get a degree in? Q.
- I double-majored in government and English. Α.
- Okay. And after University of Virginia, where did you go 0. to law school?
- I spent two years before law school at the public finance department of Hunton & Williams as a paralegal. And I went to William & Mary and graduated in 1987 with a law degree.
- And are you currently licensed to practice law? Q.
- I am. Α.
- Have you been since you graduated from law school? Q.
- Yes, I have been. Α.
- So, generally, what type of law practice have you had in Q. your career?
- Capital markets, finance, corporate, business. Α.
- And were you employed with any law firms after you graduated?
- Yes. Α.
- Q. Okay.
- 1987 to 1990, I was with Calfee, Halter & Griswold in Cleveland, Ohio.

From 1990 to 1993, I was at Williams Mullen in 1 11:10AM 2 Richmond, Virginia. 11:10AM From 1993 to 2013, I was with LeClairRyan in 3 11:10AM 4 Richmond, Virginia. 11:10AM 5 And I returned to Williams Mullen in February of 11:10AM 2015. 6 11:10AM 7 Okay. Now, at the time that you were at LeClairRyan, did Q. 11:10AM it have health care lawyers? 8 11:11AM 9 Yes. 11:11AM 10 Now -- and did you know a lawyer at LeClairRyan Q. 11:11AM 11 named Patrick Hurd? 11:11AM 12 Α. Yes. 11:11AM 13 Was he a health care lawyer? Okay. Q. 11:11AM 14 Α. Yes. 11:11AM 15 And what about Charles Sims -- Charles Ryan -- I mean --Q. 11:11AM 16 excuse me -- Charles Sims? Was there a Sims? Are you familiar 11:11AM 17 with them at --11:11AM 18 Yes. Α. 11:11AM 19 was he a health care lawyer? Q. 11:11AM 20 11:11AM No. 21 And did you know Dennis Ryan? Q. 11:11AM 22 Α. Yes. 11:11AM 23 Okay. And was he a health care lawyer? 11:11AM Q. 24 Α. Yes. 11:11AM 25 Okay. So did there come a time when you became employed Q. 11:11AM

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to what HDL was experiencing?

at Health Diagnostic Laboratories? I'm sorry? I didn't --Α. Did you -- did you ever work for HDL? Q. Α. Oh, yes. I'm sorry. I'm sorry. At Health Diagnostic Laboratories? Yeah. 0. Α. Correct. Okay. And when did you start? Q. March of 2013. Α. And approximately how long were you at HDL? Q. Until September 29th, 2015. Α. Now, while you were employed at HDL, what were you Q. specifically hired to do? Two-prong. Dennis Ryan extended me the opportunity to join HDL. It was at the time that the subpoena had been issued in January of 2013. There was also a need on the part of HDL to access the capital markets and raise additional funds. because of my background that he recalled from what I would consider to be an episodic engagement that we had at LeClairRyan in the early to mid 1990s, let's say, he thought I would be able to both oversee and manage a complex investigatory event and assist the company in raising capital, which is my historical background and expertise. And what -- when you make a reference to your 0. Okay. experience with investigation -- with an investigation similar

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- A. Not similar; analogous.
- **Q.** Okay. And in terms of the capital market component of your role, what exactly did that entail?
- A. At HDL?
- Q. Yes. Correct.
- A. We entered the process of selecting an investment banker who managed the process of soliciting interest in the marketplace and efforts generally to do due diligence and raise funds for the business.
- **Q.** Okay. And so during the time period that you were employed at HDL, did you actually seek or go into the capital market looking for funds?
- A. Yes, actively.
- **Q.** Okay. And did the fact that there was a DOJ investigation impair your ability to be successful within the capital markets?
- A. Yeah, it was an issue. I mean, transparency is the rule of thumb. And we disclosed the situation to the extent we needed to and could to all investors.
- Q. Okay. And why is that important?
- A. Transparency is critical for everything.
- **Q.** Because they want to know what's going on with the company?
- A. Correct.
- Q. And they -- they want some certainty as to what -- if they

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were to invest their money, what they're investing their money in. Is that a fair statement?

- A. They would need to assess risk before they would deploy capital in that sort of investment.
- Q. Well, at the time that the investigation was going on, did you become aware that process and handling fees were a potential issue to the Department of Justice?
- A. Yes.
- Q. And how did that information generally get to you?
- A. It would come to me from a variety of sources. Obviously, the Justice Department investigation was something I was more tangentially involved in when Mr. Kung was with HDL. And I became more enmeshed in the process after I had been with HDL for eight or nine months and Mr. Kung departed.
- Q. Okay. Well, as you made your interactions with the capital markets, were you able to disclose to the potential investors or lenders the position that DOJ was taking with respect to P&H fees?
- A. I'm not sure how detailed we were. There were discussions and disclosures. And our counsel was made available to counsel for certain investors to discuss the state of the DOJ investigation. They had to be serious investors and/or parties that had delivered financing commitment letters. But there was that dialogue, yes.
- Q. Well, I'm just trying to parse out, were you able to --

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were you able to definitively state what the DOJ's position was to the potential investors or lenders?

- A. I was not the party leading the dialogue in the description of the DOJ events. That was our counsel, Ropes & Gray, and I think everything was presented in terms of risk.
- **Q.** Okay. Well, did you have interaction with Ropes & Gray while the investigation was going on?
- A. Yes.
- Q. And did you -- did you meet with Ropes & Gray attorneys?
- A. Yes.
- Q. I know it's a while back, but how many -- approximately how many times would you estimate that you met with Ropes & Gray attorneys?
- **A.** In person or telephonically?
- Q. well, let's do both.
  What about in person?
- A. Well, they would come to Richmond from time to time on various occasions to provide guidance to the board. They'd do it telephonically sometimes on board meetings. We'd get together and had visits with the Department of Justice during the summer of 2014, maybe going back into the spring.
- **Q.** Okay. And when you say "we," did you actually participate or join in the meetings with Ropes & Gray and the Department of Justice?

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- Α. Some, but not all, yes.
- Okay. And I just want to try to clarify, get a timeline. Q. when did the meet -- did the meetings that you attended occur?
- Α. Probably the second and third quarter of 2014.
- Now, when you talk about Ropes & Gray, do you recall 0. who -- what -- which attorneys were representing Ropes & Gray?
- Brien O'Connor, Laura Hoey, and David Rhinesmith. associate was quite involved. And there was also Michael Lampert, who was the health care partner that helped collaborate with them.
- Okay. Was Laura Hoey a health care attorney? 0.
- I think, to some extent, perhaps; but trial lawyers, litigators, can move from one topic area to another. she had some expertise in the field, as did Brien O'Connor, but I don't think they did that exclusively.
- well, is there a -- I understood that, but, in your 0. experience, can you have a health care litigator as opposed to a health care transaction lawyer?
- They exist, yeah, sure.
- And so what would be the difference?
- The difference would be if you exclusively focused on health care and litigation versus someone who did a lot of litigation and health care work but not comprehensively.
- So there was a meeting that has come up in the trial which occurred in June of 2014 with Cal Dent, Brad Johnson, and some

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Ropes & Gray attorneys, and Ms. Mallory. Do you recall such a meeting?

- A. I don't recall attending it myself.
- Q. Okay. Excuse me. Excuse me. It was 2013. I misspoke.

  In June of 2013, there was a meeting between -- with

Cal Dent, Brad Johnson, Gene Sellers, Laura Hoey, Ms. Mallory.

Were you in attendance in that meeting?

- A. I was not.
- Q. Okay. Sorry about that. So at some -- so you were -- as I understand it, you were assisting in the -- assisting Ropes & Gray in their response to the DOJ investigation; is that correct?
- A. Correct.
- **Q.** Okay. And -- and you mentioned Derek Kung. Who was Derek Kung?
- A. Derek Kung was at HDL from sometime in 2012 until his departure in December 2013, and he was the general counsel of the organization.
- **Q.** Okay. And just -- just for everybody's edification, what is a general counsel at a corporation?
- A. I think it would be an individual that provides legal advice to the corporation. I myself was a lawyer, and my title was corporate counsel because my expertise was on the finance side, and Mr. Kung was a health care lawyer.
- Q. Okay. So do you recall approximately when you first heard

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that process and handling fees might be an issue for HDL?

A. Probably in -- I heard of it in the midpoint of 2013,

because I did not attend the meeting, but I understand and recall that there was a meeting with the Department of Justice whereby Mr. Kung and other HDL representatives made a presentation just for informational purposes to the Department of Justice sometime in the summer.

Q. okay.

A. And I had awareness of that.

Q. Okay. And did you attend board meetings at HDL?

A. Yes.

**Q.** And was it -- was it routine for you to attend every board meeting?

A. At some point in time, it became routine. My first six, nine months in the organization, I was still learning about the business and undertaking responsibilities that were not associated with corporate governance.

**Q.** Okay. And when -- approximately when did you start attending board meetings at HDL?

A. Certainly at or near the time that Derek Kung departed, which was in December of 2013.

Q. And so when you attended board meetings at HDL starting in December of 2013, did the issue of the Department of Justice investigation come up for discussion?

A. Yes.

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- At the HDL board meetings, besides you, were there any Q. other attorneys usually in attendance?
- Typically there'd be a telephonic update from Ropes & Gray as to the Justice Department investigation. I mean, I don't know what -- I don't have access to the minutes. probably other counsel updating the board on other legal matters handled by outside counsel.
- And how often did the HDL board meet? Okay. 0.
- Once a month, generally. I don't know if there were other meetings that were special, if you would, but there was a regular monthly meeting, and it sometimes shifted based on schedules.
- And when you say "a special meeting," what -- were there any special meetings that you attended?
- Α. No.
- Q. Okay.
- I'm not aware of any. I haven't seen any minutes that would reflect that. And, certainly, you'd want to have minutes if there were such meetings.
- And would a special meeting basically be for a particular topic --
- Correct. Α.
- -- of hot interest or that needed to be resolved? Q.
- Α. Yes.
- And so -- I just want to make it clear, in your Q.

experience, when you were attending these board meetings, 1 11:27AM Ropes & Gray were making, like, a conference call to the board; 2 11:27AM is that right? 3 11:27AM 4 Α. Correct. 11:27AM Did Ropes & Gray ever attend any of the HDL board 5 Okay. 0. 11:27AM meetings in person while you were in attendance? 6 11:28AM I think they did. I'm going to say that they did, yes. 7 Α. 11:28AM And about how many times did that occur? 8 0. 11:28AM 9 well, not frequently, because, you know, one party who was 11:28AM 10 in charge was in Boston; the other was in Chicago. 11:28AM 11 Q. Okay. 11:28AM So it was logistically challenging. 12 Α. 11:28AM And HDL is located in Richmond? 13 Q. 11:28AM 14 Correct. 11:28AM 15 MR. GRIFFITH: Can we pull up BlueWave 256. 11:28AM 16 BY MR. GRIFFITH: 11:29AM 17 Do you -- can you see this? 11:29AM Q. 18 I can. Α. 11:29AM 19 So it appears to be an email from Kathy Johnson dated 11:29AM November 26th, 2013. Do you see that? 20 11:29AM 21 I do. 11:29AM 22 Okay. And there were -- the recipients included Brad Q. 11:29AM 23 Johnson, Cal Dent, Ms. Stafford of BlueWave, Tonya Mallory, and 11:29AM 24 you; correct? 11:29AM 25 Α. Yes. 11:29AM

And the topic is "tomorrow's call re new P&H process." 1 Q. 11:29AM Do you see that? 2 11:29AM 3 I do. Α. 11:29AM 4 Okay. And so who was Kathy Johnson? Q. 11:29AM Chief compliance officer for Health Diagnostic Laboratory. 5 11:29AM And was Kathy Johnson also a lawyer? 6 11:30 A M Q. 7 Α. Yes. 11:30AM So if you look at the first line, the first sentence, it 8 0. 11:30 A M 9 says, "We are going forward tomorrow with a BW sales call at 4 11:30 A M 10 p.m. EST -- 3 p.m. CST -- to roll out HDL's new P&H agreement 11:30 A M 11 which is attached." 11:30AM 12 Do you see that? 11:30AM 13 Yes. Α. 11:30 A M 14 okay. So in November 2013, there was a revised process Q. 11:30 A M 15 and handling agreement at HDL; correct? 11:31AM 16 Based on this email, I would say yes. 11:31AM And so -- but you were copied on this email; 17 Okay. 11:31AM Q. 18 correct? 11:31AM 19 Α. Yes. 11:31AM And I take it you were not actually involved in the 20 11:31AM 21 revision part of the new P&H agreement; correct? 11:31AM 22 Correct. Α. 11:31AM 23 Okay. And do you know -- or can you recall who actually Q. 11:31AM 24 did the revisions to the P&H fee agreement in November of 2013? 11:31AM 25 I don't recall, but given the fact it looks like Kathy 11:31AM

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Johnson is transmitting it, she had a role and she could have gotten input from outside counsel.

- **Q.** Okay. Well, to your knowledge -- well, Derek Kung was still at HDL in November of 2013; is that right?
- A. That's right.
- Q. Okay. To your knowledge, was it typical for Derek Kung to review documents such as a P&H fee agreement?
- A. Yes.
- **Q.** To your knowledge, did he review the revised P&H fee agreement?
- A. I don't know.
- Q. Do you know whether Ropes & Gray had any input on the revision of the P&H fee agreement in November of 2013?
- A. I don't recall that they did or they didn't; I just don't know.
- **Q.** Okay. Fair enough. While I'm thinking about it, at the board meetings at HDL that you attended, did Cal Dent ever attend any of the board meetings?
- A. No.
- Q. Did Brad Johnson ever attend any of the board meetings?
- A. No.
- **Q.** So at this point in November of 2013, it -- you were not involved in actually drafting any of the P&H fee agreements; right?
- A. I don't recall that role.

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- was it typical for HDL to have its P&H fee Q. Okay. agreements reviewed by outside counsel?
- I think once -- the template model would, I think, Α. generally have been reviewed by outside counsel, yes.
- well, were you aware of -- in November of 2013, of any health care lawyer who was representing HDL who had told HDL not to revise or use the P&H fee agreement?
- I don't recall. I have no knowledge of that. Α.
- During the board meetings that you attended, did Ropes & Gray ever tell the board members to stop using P&H fees?
- Α. No.
- And so this exhibit, BlueWave 256, it talks about "we are Q. going forward with a BW sales call."

Did you interpret that to be BlueWave?

- Α. Yes.
- Did the -- did the phone call actually occur, the Okay. Q. conference call?
- I don't remember being on that call. That doesn't mean it didn't occur.
- Understood. If you look down in that same last paragraph, the last three lines.
- Uh-huh. Α.
- It says, "Doug will be on the call to field any legal Q. questions, if any, that arise regarding the P&H agreement

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revisions."

Do you see that?

- A. Yes.
- **Q.** Okay. And so -- and I understand it's, you know, years ago and you say you don't recall being on the phone call -- but at least the expectation, according to this email, was that you were going to be on the phone call to talk about any kind of legal questions?
- **A.** That was Kathy Johnson's expectation based on that communication.
- **Q.** Yes. And the -- and the information -- I mean, because, obviously, you testified that you're not a health care lawyer, but the information that you had obtained regarding P&H fees, would that have been obtained by you from Ropes & Gray?
- A. Yes.
- Q. Okay. So let's go to BlueWave Exhibit 255. And so this is an email from Kathy the next day -- Kathy Johnson -- to Ms. Stafford at BlueWave, Cal Dent, Brad Johnson, Ms. Mallory, Joe Anastasia, Tabitha Henley, and Derek Kung, and yourself.

Do you see that?

- A. I do.
- Q. And it appears to be very similar to the email that we just saw in the prior exhibit; correct?
- A. Correct.

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Q. Okay. Who was Joe Anastasia?

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- A. He was an employee of HDL.
- **Q.** And what was his role?
- A. I'm trying to see if I can recall how to describe it. He managed certain elements of the business associated with sales practices.
- **Q.** Okay. And what about -- and what about Tabitha Henley? Who was she?
- A. She was an employee of HDL.
- Q. Okay. And what was her role?
- A. The same as I just described for Mr. Anastasia.
- Q. Okay. And to your knowledge -- in the first paragraph, it says, "Attached is the revised P&H example agreement and P&H cover letter for distribution to the contractors prior to today's call."

Do you see that?

- A. I do.
- **Q.** To your knowledge, were these revised P&H fee agreements distributed to the Bluewave contractors or sales reps?
- A. Relying on this email that said they would be, I would say yes.

MR. GRIFFITH: Can you bring up BlueWave 258.

# BY MR. GRIFFITH:

- **Q.** This appears to be a revised processing and handling agreement. Are you familiar with this particular document?
- A. Generally, yes.

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- Q. And you can see kind of in the background it has "example" or "sample." Do you see that?
- A. I do.
- Q. Okay. And so, to the best of your recollection, would this have been the new P&H sample agreement that was distributed to the BlueWave sales reps?
- A. It could very well have served that -- that objective, yes.
- **Q.** Okay.

Let's pull up Mallory Exhibit Number 10. And if you could pull up the header.

Okay. So this is a -- an email from you to Laura Hoey, Tonya Mallory, Joe McConnell, and Russ Warnick. Do you see that?

- A. I do.
- Q. Dated January 6th, 2014; correct?
- A. Yes, that's what it says.
- Q. And the topic is "DOJ update."
- A. Yes.
- **Q.** Okay. And we've all seen this email before, so I'm not going to go into it in any depth, but I would like to go down just real quickly to the next page.

Well, the -- yeah, those paragraphs right there.

All right. And so I would just ask you to look at the first line in the first paragraph, where it says "waiver."

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"Ropes & Gray made clear that HDL is putting further waiver discussions on hold in light of DOJ's present refusal to take a position on the straight payment of P&H fees."

Do you see that?

I do. Α.

And then if you look at the next -- the next Okay. paragraph, it says, "In discussions with DOJ, Leventis noted that he expects DOJ will have to take a position on this issue at some point during the course of the investigation."

Do you see that?

I do. Α.

So is it fair to say that at least your Okay. understanding in January of 2014 was that DOJ was not taking a position on the legality of P&H fees?

That's clearly what Ms. Hoey described, and I transmitted Α. to the board in my email.

well, after January of 2014 -- in fact, on January 25th --0. I mean, June 25th, 2014, a special fraud alert was issued by the OIG. Do you recall that?

I do.

And prior to that special fraud alert, prior to Okay. June 25th, 2014, had Ropes & Gray ever told you or the board of directors at HDL to stop paying P&H fees?

Α. No.

Prior to June 25th, 2014, did Ropes & Gray tell you and Q.

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the board of directors at HDL that P&H fees were defensible?

- A. I don't know what -- the time frame in which that was stated, but it was stated to the board.
- Q. It was -- Ropes & Gray stated to the board that P&H fees were defensible?
- A. They said they would be willing to defend it.
- Q. Did they say it was defensible?
- A. I don't know what the precise nomenclature used was.
- **Q.** Well, do you recall -- you said you don't recall the exact nomenclature, but was it your interpretation that Ropes & Gray was saying that they had a -- that HDL had a defensible case with respect to P&H fees?
- A. Yes.
- **Q.** Now, do you recall -- moving on to another topic. Do you recall generally that HDL terminated the sales contract with BlueWave?
- A. I do.
- Q. Okay. And generally when did that occur?
- A. Fourth quarter, first quarter -- fourth quarter of 2014, the first quarter of 2015, somewhere in that neighborhood.
- Q. Okay. Now, after the BlueWave contract was terminated, was it your understanding that HDL offered some of the BlueWave sales representatives jobs at HDL?
- A. Yes.
- Q. Is it typical in your experience for a company to offer

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somebody a job who they believe has committed any kind of fraud?

- Generally, as a corporate business lawyer, I would say that's correct.
- That they would or they would not? 0.
- They would not. Α.
- Now, did you -- were you aware of negative publicity in Q. the media with respect to HDL as a result of the DOJ investigation?
- Yes. Α.
- In your experience, did that hurt HDL? Q.
- Yes, it did. Α.
- And do you generally recall a Wall Street Journal article Q. being published that was critical of HDL in September of 2013?
- Α. 2014, yes.
- I'm sorry. Now, if you thought that HDL was 0. Okay. 2014. violating any law while you were employed at HDL, you would have told HDL to stop the practice; correct?
- Yes. Α.
- Did you believe that HDL was violating the Okay. Anti-Kickback Statute before June 25th, 2014, with respect to its P&H fees?
- They were operating in an environment with risk and uncertainty prior to the release of the OIG advisory opinion as to fraud.

11:51AM	1	Q. Did you advise HDL to stop P&H fees before June 25th,
11:51AM	2	2014?
11:51AM	3	A. Disclosed the risk. I disclosed the risk.
11:51AM	4	<b>Q.</b> Okay. But did you advise them did you advise HDL to
11:51AM	5	stop paying P&H fees?
11:51AM	6	A. I did not.
11:51AM	7	<b>Q.</b> Okay. To your knowledge, did any lawyer advise HDL to
11:51AM	8	stop paying P&H fees before June 25th, 2014?
11:51AM	9	A. I can't speak to how many lawyers they might have talked
11:51AM	10	to, but I can tell you that Ropes & Gray, as the primary
11:51AM	11	outside counsel, didn't tell them to stop.
11:51AM	12	Q. Were you part of any conspiracy to have HDL file false
11:51AM	13	claims to the federal government?
11:51AM	14	A. No.
11:52AM	15	MR. GRIFFITH: Your Honor, no further questions.
11:52AM	16	Thank you.
11:52AM	17	THE COURT: Thank you.
11:52AM	18	Cross-examination by the government, Mr. Shaheen?
11:52AM	19	MR. SHAHEEN: Your Honor, may I have just 20 seconds
11:52AM	20	real quick to check on something?
11:52AM	21	THE COURT: Yes.
11:52AM	22	(Pause.)
11:52AM	23	MR. SHAHEEN: Thank you, Your Honor.
11:52AM	24	CROSS-EXAMINATION
11:52AM	25	BY MR. SHAHEEN:

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- Q. Hello, Mr. Sbertoli. How are you?
- How are you, Mr. Shaheen? Α. Fine.
- Good. Thank you. Q.

How would you describe your practice as a lawyer?

- Currently? Α.
- Before you arrived at HDL. Q.
- Capital markets, securities, mergers and acquisitions, general business like that.
- I don't think I heard health care in there. You were not a practicing health care attorney prior to your arrival at HDL; is that correct?
- That's correct. My experience was limited to financings for medical device companies and tax-exempt bond issues for 501(c)(3) health care organizations.
- And when you came on, I think you testified just a couple Q. moments ago that one of your primary focuses was to raise capital for HDL; correct?
- Α. That's correct.
- And that would have fell into your expertise that you had developed in the prior 20 years of your practice; correct?
- Yes.
- And I think you also testified that you really didn't come Q. on to the investigative side of things until Derek Kung, HDL's general counsel at the time, left the company in December of 2013; correct?

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L	1	:	5	5	Α	М	23
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- A. That's correct.
- Q. You talked about risk. You said you disclosed the risks.

Was it your understanding that up through the special fraud alert and up through the moment that HDL stopped paying P&H, that there were risks associated with that practice?

- A. Yes.
- **Q.** I think you also mentioned risk assessments when you were talking about your discussions with potential financing. Do you recall that?
- A. I do.
- Q. Was there a risk assessment done in regards to whether or not HDL should continue to pay P&H?
- A. Nothing formal, but it was discussed.
- **Q.** I think -- do you recall testifying at your deposition that HDL was hesitant to stop paying P&H because it was afraid its referrals would drop or decrease?
- A. If you show me that, I'll validate it, yeah.

MR. SHAHEEN: Your Honor, may I approach?

THE COURT: You may.

MR. SHAHEEN: Thank you. Thank you.

May I approach the witness, Your Honor?

THE COURT: You may.

## BY MR. SHAHEEN:

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11:55AM

**Q.** I'll direct you in just a second, but I want to ask a couple of questions first.

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- A. Sure.
- Q. And I sort of touched upon this moments ago, but the risk persists -- the risk with paying P&H persisted up until the time that HDL stopped paying P&H; is that correct?
- A. I'll give you an analogy. Risk moves up and down the spectrum, whether you're providing financing for an investment or if you're evaluating items from a risk management standpoint. So it could be red means stop, orange means a lot of risk, yellow, green. That's how I look at risk in any other professions.
- **Q.** And there was risk associated with paying P&H up until the time it stopped; correct?
- A. Correct.
- **Q.** And that's true even after HDL revised its P&H agreements, correct, in November of 2013?
- A. Yes.
- Q. And, now, if you would turn to page 27 of your deposition.

  And if you'll just let me know when you get there.
- A. I'm there.
- Q. Okay. And I asked the question, "Is it fair to say" -and I'm on Line 5.
- A. Uh-huh.
- Q. "Is it fair to say that HDL was concerned that, if they stopped paying P&H, that referrals would drop or decrease?"

  And then can you read out your response.

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- A. I said, "I think that's a fair statement."
- Q. And my question to you is, when you were doing these informal risk assessments, was it true that, on one side, there was the risks associated with continuing to pay P&H and, on the other side, there was the risks associated with losing business and losing referrals on the other side?

Was that part of the analysis?

- A. That was a consideration.
- **Q.** You testified moments ago that you arrived at HDL in the spring of 2013; correct?
- A. Yes.
- **Q.** And so you were not present when Larry Freedman warned that the government would take the position that the P&H payments were blatant kickbacks; is that correct?
- A. That's what I recall, because I think that was 2012.
- **Q.** I think that 's correct. So you would not have been there?
- A. Correct.
- Q. And you also were not there when Mr. Kung presented his memo to the board in August 30th, 2012; correct?
- A. Correct.
- Q. And you talked about risk assessment. And the analogy you gave me was red, yellow, green -- or red, orange, green; correct.
- A. Correct.

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11:59AM

**Q.** And Mr. Kung associated the payment of -- paying -- I'm sorry.

Mr. Kung associated the practice of paying P&H with a red flag. That's the highest level of risk; correct?

- A. That would be a high level based on whatever his scale was, I would think.
- Q. And you weren't there when he recommended that HDL should terminate the practice of paying P&H; correct?

MR. GRIFFITH: Objection, Your Honor. That misstates the evidence.

**THE COURT:** Overruled. Cross-examination. Please continue.

THE WITNESS: Can you repeat the question, please, Mr. Shaheen.

### BY MR. SHAHEEN:

- Q. You were not there when Mr. Kung in his memo recommended that HDL terminate the practice of paying P&H; correct?
- A. Correct.
- Q. Likewise, you were not there in the spring of 2013 -- or you were not involved with this part of HDL's ongoing business in the spring of 2013 when Ropes & Gray advised that HDL needed to move away from paying P&H; correct?
- A. That's correct.
- Q. One of the documents that Mr. Griffith showed to you involved something called a waiver. Do you recall what that

was about? 1 11:59AM Partial waiver of attorney-client privilege. 2 Α. 11:59AM And up until -- well, was there a waiver of 3 Q. 11:59AM 4 attorney-client privilege at some point? 11:59AM 5 Α. Yes. 11:59AM And was that waiver partial? 6 11:59AM Q. 7 with the Department of Justice, I believe so. 11:59AM we've got two fields going on. One of the things I reviewed 8 11:59AM 9 before testifying here was the partial waiver provided to me 11:59AM 10 through the HDL bankruptcy trust as to certain topics because I 11:59AM 11 still have attorney-client privilege at the loss of that 12:00PM 12 So that both waivers, they were partial waivers. entity. 12:00PM 13 MR. SHAHEEN: Your Honor, may I grab an exhibit off 12:00PM 14 the table? 12:00PM 15 THE COURT: You may. 12:00PM 16 Now may I approach the witness? MR. SHAHEEN: 12:00PM 17 THE COURT: You may. 12:00PM 18 BY MR. SHAHEEN: 12:00PM 19 There's an orange sticker at the bottom of that. 12:00PM does say Plaintiffs' Exhibit 1616, correct, on the front page? 20 12:00PM 21 Little orange sticker. 12:00PM 22 Α. Yes. 12:00PM 23 That's 1616; right? Q. 12:00PM 24 Α. Yes, it is. 12:00PM

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12:00PM

Q.

Thanks.

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Does that refresh your recollection as to when the partial waiver that I'm talking about was entered into?

A. Yes.

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12:00PM

- Q. And what time period did that partial waiver apply to?
- A. I don't know.
- Q. And again --
- A. If you can show me, it's in this agreement.
- Q. Yes. Right there, that first line.
- A. And you want me to state that for the record?
- Q. Yeah, what were the time periods that the waiver applied to?
- A. From November 25th, 2008, to December 29, 2012.
- Q. And when was that limited waiver entered into?
- A. April 28th, 2014.
- **Q.** And so, prior to that, the Department of Justice had in its possession the letter that HDL had relied on or claimed to have relied on from LeClairRyan; correct?

MR. GRIFFITH: Objection, Your Honor. He can't speak to whatever the --

THE COURT: Overruled. Don't suggest an answer to a witness.

Please proceed.

#### BY MR. SHAHEEN:

**Q.** Did the United States have in its possession, or was it your understanding that the United States had in its

12:01PM	1	possession, the April 27, 2012, memo from Michael Ru
12:01PM	2	A. I don't know.
12:01PM	3	Q. But at least up through April of 2014, the Unit
12:02PM	4	did not have in its possession a large portion of
12:02PM	5	attorney-client communications; is that correct?
12:02PM	6	A. That is correct.
12:02PM	7	Q. And even after that time frame, the United Stat
12:02PM	8	have in its possession any attorney-client communica
12:02PM	9	October of 2012; correct?
12:02PM	10	A. Correct.
12:02PM	11	Q. And so before that limited waiver was entered i
12:02PM	12	United States didn't know that Larry Freedman had ad
12:02PM	13	that P&H payments would be viewed as blatant kickbac
12:02PM	14	correct?
12:02PM	15	MR. GRIFFITH: Your Honor, I object.
12:02PM	16	THE COURT: Overruled. This is cross-exam
12:02PM	17	Please continue.
12:02PM	18	THE WITNESS: Could you repeat the question
12:02PM	19	BY MR. SHAHEEN:
12:02PM	20	Q. Sure. So prior to the entry of that when th
12:02PM	21	entered into that limited waiver, the United States
12:02PM	22	know that HDL had been advised by Larry Freedman tha
12:02PM	23	government would view P&H as a blatant kickback; is
12:02PM	24	correct?
12:02PM	25	MR. GRIFFITH: Same objection, Your Honor.

Michael Ruggio? e United States of t? d States did not nunications after ered into, the had advised HDL ickbacks; s-examination. uestion, please. hen the parties tates did not an that the k; is that

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THE COURT: Overruled.

THE WITNESS: I really can't speak or recall as to what you may have received or known as to anything specific like that.

#### BY MR. SHAHEEN:

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- **Q.** Well, you were involved in the discussion to waive the attorney-client privilege as to some of those documents; correct?
- A. Correct.
- **Q.** And you just don't recall what the government had in its possession before and after the waiver?
- A. I don't know what you may have had before versus what you had after, exactly.
- **Q.** How would the states have come into the possession of attorney-client communications prior to the entry of the waiver?
- A. A qui tam whistle-blower, for example.
- **Q.** Did HDL withhold unflattering attorney-client communication, Mr. Sbertoli?
- A. Withhold? From whom?
- Q. From the United States.
- A. Not to my knowledge.
- Q. Can we pull up Plaintiffs' Exhibit Number 1277.
- Mr. Sbertoli, can you tell me -- if we just focus in on the top there -- who is this email from?

12:04PM	1	A. From me.
12:04PM	2	Q. And when is it sent?
12:04PM	3	A. August of 2015.
12:04PM	4	<b>Q.</b> And to whom do you send it?
12:04PM	5	A. Jason Harbour, the bankruptcy counsel for HDL.
12:04PM	6	Q. And who's cc'd on that?
12:04PM	7	A. Tyler Brown and Laura Hoey. Tyler Brown being the lead
12:04PM	8	bankruptcy counsel for HDL; Laura being with Ropes & Gray.
12:04PM	9	Q. And can you read for me just the last sentence of the
12:04PM	10	first paragraph.
12:04PM	11	A. It says, "We held back and retained the privilege on some
12:04PM	12	that were unflattering."
12:04PM	13	MR. SHAHEEN: Thank you, Your Honor. I have no
12:04PM	14	further questions right now.
12:04PM	15	THE COURT: Thank you.
12:04PM	16	Mr. Ashmore?
12:04PM	17	MR. ASHMORE: Thank you, Your Honor.
12:04PM	18	CROSS-EXAMINATION
12:04PM	19	BY MR. ASHMORE:
12:05PM	20	Q. Mr. Sbertoli, I'm Beattie Ashmore. I represent Tonya
12:05PM	21	Mallory. How are you?
12:05PM	22	A. Fine. Thank you.
12:05PM	23	Q. We've never met, but we may be staying at the same hotel.
12:05PM	24	A. I hope I'm going home, but it
12:05PM	25	THE COURT: He's asking you questions right now.

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                          THE WITNESS:
                                        Excuse me.
12:05PM
           2
                                        Fair enough. Fair enough.
                          MR. ASHMORE:
12:05PM
           3
               BY MR. ASHMORE:
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           4
                    The HDL board meetings that Mr. Griffith asked you about,
               Q.
12:05PM
               who -- who was on the board of HDL when you first joined it,
           5
12:05PM
               HDL?
           6
12:05PM
                     In March of 2013, it was Tonya Mallory, Joe McConnell, and
           7
               Α.
12:05PM
               Russ Warnick.
           8
12:05PM
           9
                    Those three were the board members?
12:05PM
               Q.
          10
                    Correct.
               Α.
12:05PM
          11
                    They were the founders?
               Q.
12:05PM
          12
               Α.
                    Yes.
12:05PM
                    They owned most, if not all, of HDL; is that fair?
          13
               Q.
12:05PM
          14
               Α.
                    Most.
12:05PM
          15
                    Sure.
                          And they ran HDL; correct?
               Q.
12:05PM
          16
               Α.
                    Yes.
12:06PM
          17
                    It's the board that ran HDL; correct?
               Q.
12:06PM
          18
               Α.
                    Yes.
12:06PM
          19
                    That's not unusual. That's how corporations operate;
               0.
12:06PM
          20
               correct?
12:06PM
          21
               Α.
                    Correct.
12:06PM
          22
                    Sure. Let me -- let me clear up a few points.
               Q.
12:06PM
                          Ropes & Gray, what -- what's your knowledge of
          23
12:06PM
          24
               Ropes & Gray, the reputation, their capabilities?
12:06PM
          25
                    My experience with them is they're very capable and
12:06PM
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1 experienced. 12:06PM They're really good lawyers; right? 2 Q. 12:06PM From my perspective, yes. 3 Α. 12:06PM 4 All right. And they were hired in large part to get an Q. 12:06PM answer from the Department of Justice concerning P&H fees; is 5 12:06PM that correct? 6 12:06PM I wasn't at HDL when they were hired, so I don't have any 7 12:06PM knowledge of that. 8 12:07PM 9 Okay. During -- while you were there, what was their 12:07PM 10 primary purpose? 12:07PM 11 Resolve the situation in a manner favorable to Health 12:07PM 12 Diagnostic Laboratory. 12:07PM 13 And part of that, the largest part of that is converse 12:07PM 14 with the Department of Justice and find out if HDL can pay P&H 12:07PM 15 fees; isn't that correct? 12:07PM 16 Α. Yes. 12:07PM That was -- that was their job, was it not? 17 12:07PM Q. One of many, I would say. 18 Α. 12:07PM 19 Sure, one of many. That's fair. 12:07PM 20 And you participated in at least one meeting with the 12:07PM 21 Department of Justice; is that correct? 12:07PM 22 Α. Yes. 12:07PM 23 So Ropes & Gray and you met with the Department of Q. 12:07PM 24 Justice; is that correct? 12:07PM 25

Α.

12:07PM

Yes.

12:07PM	1	Q. And was it Ms. Strawn and Mr. Leventis that you met with?
12:07PM	2	A. Among many others, yes.
12:07PM	3	Q. Sure. Many others.
12:07PM	4	And you say many others. I mean, how many people
12:07PM	5	would participate in this particular meeting?
12:07PM	6	A. A small number representing HDL and 15 to 20
12:08PM	7	representatives of the government.
12:08PM	8	Q. 15 to 20 government representatives. That's your
12:08PM	9	testimony?
12:08PM	10	A. Yeah.
12:08PM	11	<b>Q.</b> Okay. And did you walk out of that meeting with an
12:08PM	12	answer?
12:08PM	13	A. To what question?
12:08PM	14	Q. Did you walk out of that meeting with an understanding
12:08PM	15	strike that.
12:08PM	16	Did those 15 to 20 people tell HDL to stop paying P&H
12:08PM	17	fees?
12:08PM	18	A. Yes.
12:08PM	19	Q. To stop right then and right there?
12:08PM	20	A. Yes.
12:08PM	21	<b>Q.</b> Okay. And when was that meeting?
12:08PM	22	A. It was a series of meetings running sometime April through
12:08PM	23	June where we repeatedly heard the position of the Department
12:08PM	24	of Justice.
12:08PM	25	THE COURT: What year was that, sir?

1 12:08PM 2 12:08PM 3 12:08PM 4 12:08PM 5 12:08PM 6 12:08PM 7 12:08PM 8 12:08PM 9 12:08PM 10 12:08PM 11 12:09PM 12 12:09PM 13 12:09PM 14 12:09PM 15 12:09PM 16 12:09PM 17 12:09PM 18 12:09PM 19 12:09PM 20 12:09PM 21 12:09PM 22 12:09PM 23 12:09PM 24 12:09PM

THE WITNESS: I'm sorry?
THE COURT: What year?
THE WITNESS: Oh, 2014.

THE COURT: Thank you.

#### BY MR. ASHMORE:

- **Q.** And was that before or after the special fraud alert came out?
- A. Before.
- Q. How -- was it -- can you define for us -- do you remember when that meeting might have occurred?
- A. They -- the Department of Justice took a position on process and handling fees at some point. I want to say, like, after discovery and certain interrogatories were provided to them to complete the responsibilities associated with the subpoena.

After they had all the information, they expressed the opinion that P&H fees were violations of the health care regulatory and legal requirements.

- Q. It's important for me to understand when that happened.
- A. I would be speculating on a date if I threw one out, Counsel, but sometime after the January email that I think was presented into evidence and before the OIG advisory fraud alert came out.
- Q. And that was expressed to Ropes & Gray?
- A. Yes.

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- 25 12:11PM

- Q. They were at that meeting. And so you returned. And then what happened?
- when you say "returned," I'm not sure -- maybe I didn't hear the question.
- Let me ask a better question. Your testimony is you were told by Department of Justice to stop paying P&H fees. did not stop paying P&H fees; is that correct?
- That's correct. Α.
- Okay. And why is that?
- There was no official guidance. There was uncertainty and a need for more clarity on the part of HDL.
- So it was still undecided by the Ropes & Gray lawyers as to whether or not P&H fees were properly paid; is that correct?
- Yes. Α.
- Until when? Until the special fraud alert came out; Q. correct?
- Correct. Α.
- Every business has risk; correct? Q.
- Yes. Α.
- And in your analogy, you used colors, red and orange and yellow; correct?
- Correct. Α.
- Now, the Kung memo does nothing more than to state that Q. there are risks involved; correct?
- I don't recall. I have not read or seen it in a very long

1 time. 12:11PM Fair enough. I'll move on. 2 Q. 12:11PM You were hired in part to raise capital; is that 3 12:11PM 4 correct? 12:11PM 5 Yes. Α. 12:11PM And that was in an effort to effectuate Project Twilight; 6 12:11PM Q. 7 is that correct? 12:11PM That was one element, I think. 8 Α. 12:11PM 9 True. And that was -- that was to follow Ropes & Gray's 12:11PM Q. 10 advice to move away from P&H fees; correct? 12:11PM 11 It would lower risk, yes. Α. 12:11PM 12 Sure. And that was what HDL was doing while you were Q. 12:11PM 13 there, moving away from the payment of P&H fees; correct? 12:11PM 14 Correct. Α. 12:12PM 15 Tonya Mallory got fired; is that correct? Q. 12:12PM 16 That's my understanding. Α. 12:12PM 17 Okay. And when that happened, did HDL turn out the lights 12:12PM Q. 18 and bolt the door? 12:12PM 19 No. Α. 12:12PM They kept operating? 20 Okay. 12:12PM Q. 21 Α. Yes. 12:12PM 22 Russ and Joe kept running HDL? Q. 12:12PM 23 Α. Correct. 12:12PM 24 Q. And if she left at some time, would you agree, disagree, 12:12PM 25 she left July 2014? Is that -- does that sound right to you? 12:12PM

12:12PM	1	A. No.
12:12PM	2	Q. Okay. Help me out there. When do you think she left?
12:12PM	3	A. September 2014.
12:12PM	4	Q. September 2014. And HDL continued to operate for how
12:13PM	5	long?
12:13PM	6	A. September 29th, 19 I'm sorry 2015.
12:13PM	7	Q. So for another year?
12:13PM	8	A. Yes.
12:13PM	9	Q. So a year after Tonya Mallory left, HDL was still ongoing
12:13PM	10	and run by Russ Warnick and Joe McConnell?
12:13PM	11	A. And the board of directors of HDL, yes.
12:13PM	12	Q. And who was on the board after she left?
12:13PM	13	A. Noel Bartlett, Bob Galen joined. There were four
12:13PM	14	directors. And then after HDL filed for bankruptcy protection
12:13PM	15	on or about June 7th, an independent director named John Young
12:13PM	16	was added.
12:13PM	17	Q. Well, I want to make clear. Mr. McConnell and Mr. Warnick
12:13PM	18	stayed on the board?
12:13PM	19	A. Yes.
12:13PM	20	MR. ASHMORE: That's all I have, Your Honor. Thank
12:13PM	21	you.
12:13PM	22	THE COURT: Thank you. Anything on redirect?
12:14PM	23	MR. GRIFFITH: No, Your Honor.
12:14PM	24	THE COURT: Very good. You may step down. Thank
12:14PM	25	you, sir.

12:14PM	1	(Witness excused.)
12:14PM	2	THE COURT: How long is our next witness?
12:14PM	3	MR. GRIFFITH: I said this guy wasn't going to be
12:14PM	4	that long. I think he'll be comparable to what we
12:14PM	5	THE COURT: Okay. Ladies and gentlemen, let's break
12:14PM	6	for lunch. Be back in an hour or as soon thereafter as you
12:14PM	7	can.
12:14PM	8	(Whereupon the jury was excused from the courtroom.)
12:15PM	9	THE COURT: Please be seated. Do we have any
12:15PM	10	evidentiary issues we need to take up or any other issues we
12:15PM	11	need to take up?
12:15PM	12	MR. LEVENTIS: No issues right now, Your Honor.
12:15PM	13	Thank you.
12:15PM	14	THE COURT: Very good. Thank you.
12:15PM	15	(Recess.)
1:27PM	16	THE COURT: Please be seated.
1:27PM	17	Any matters we need to address from the government?
1:27PM	18	MR. SHAHEEN: None from the government, Your Honor.
1:27PM	19	MR. LEVENTIS: There are some exhibits we'd like to
1:27PM	20	talk about, Your Honor.
1:27PM	21	THE COURT: Sure. Let's do it.
1:27PM	22	MR. SHAHEEN: I was going to let them say it.
1:27PM	23	THE COURT: Yeah. Okay. What we got?
1:27PM	24	MR. GRIFFITH: So, Your Honor, we're calling the
1:27PM	25	former CEO of Singulex, not this witness, but the next witness.

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His name is Philippe Goix, G-o-i-x.

THE COURT: Yes, sir.

MR. GRIFFITH: And I provided to the government a number of documents that are in our exhibit list, and we were trying to -- you know, trying to get them preadmitted, but there's an issue on a couple -- at least a couple. And I'll let them identify which ones.

THE COURT: Okay. What are the issues?

MS. SHORT: Yeah, Your Honor. So there are a couple of issues. I think there are several documents that were handed to us this morning where I do not believe the witnesses that Bluewave intends to call can lay a proper foundation for the documents. Some of the documents postdate their employment with Singulex.

THE COURT: Okay.

MS. SHORT: So these -- but those, I think we'll deal with them during the course of their testimony. But there may be an objection as to foundation.

THE COURT: Right.

MS. SHORT: Those, we can deal with. I wanted to make the Court aware that we have some objections.

THE COURT: Right. I've got that. Okay.

MS. SHORT: The second issue is a little bit broader or a little more delicate. Both of these gentlemen are former -- well, there's a second Singulex former employee.

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They're both executives with Singulex during their employment, but they have long since left the company.

THE COURT: Yes.

MS. SHORT: Singulex the company has not waived attorney-client privilege. They reached a settlement with the Department of Justice a couple of years ago. They did not waive privilege in the context of that settlement. They have not waived privilege since.

During at least Mr. Goix's deposition, there were several questions. And I did raise the notion that the question might solicit attorney-client privileged communications. I don't represent Singulex, but there's nobody here to represent Singulex.

THE COURT: Well, let me say of course the government doesn't own the privilege.

MS. SHORT: And neither do these gentlemen.

THE COURT: The client owns the privilege, and, you know, if -- if -- I'm not here to enforce a privilege not asserted. So, to the extent these guys come in and violate the privilege, that's between them and Singulex. That's not this Court's business.

You know, I take the view as the old Statute of Elizabeth, that the Court is entitled to every man's evidence -- I apologize for the sexist reference -- but the old law is that, you know, every person's evidence is available to

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the Court. That's obviously not always true. There are privileges, but they must be asserted. And if Singulex hasn't asserted the privilege, I'm not going to assert it on their behalf and the government can't assert it on their behalf.

MS. SHORT: Understood. There's one document in particular that I believe counsel intends to introduce for the proposition contained in an email that refers to an advisory letter from an outside attorney that Singulex purportedly had, but, again, the government hasn't seen this. It has not --

THE COURT: Singulex reportedly -- you haven't seen it -- reportedly had an opinion; right? Is that what the claim is?

MS. SHORT: Well, all I know is there's an email that counsel wants to introduce. And the line -- first line of the email says, "Please see the attached advisory letter from our outside compliance expert and attorney."

And it comes from another Singulex employee, and it is copied to --

THE COURT: Do we know what the content of that is?

MS. SHORT: I have no idea what the content of that

letter --

THE COURT: Does it address process and handling or any other issue?

MR. GRIFFITH: It does, Your Honor.

**THE COURT:** Do we have the opinion letter?

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MR. GRIFFITH: We don't, but, Your Honor, that's
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              prima fascia evidence that -- that the client has waived the
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              privilege, number one.
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                         MS. SHORT:
                                     Oh, there's --
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                         THE COURT:
                                    No, no, that's not the issue of
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              privilege. I thought we were talking about the --
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                                    This is hearsay.
                         MS. SHORT:
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                         THE COURT:
                                    -- hearsay. I mean, first of all, why is
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              it relevant? How is it relevant here?
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                         MR. GRIFFITH: Well, Mr. Goix -- Singulex and
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              Mr. Goix are being -- are alleged co-conspirators.
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                         THE COURT: They're not parties here. We're not
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              getting into that. They're not able to -- we're dealing with
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              the knowledge of these defendants. Were they provided a copy
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              of the letter? Were they provided a copy of this letter
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              referred to in the email?
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1:32 P M
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                         MR. GRIFFITH: I think -- I think he's going to
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              testify yes, Your Honor.
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1:32 P M
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                         THE COURT: Who -- Dent and Johnson were provided the
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              letter?
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         21
                                         Excuse me?
                         MR. GRIFFITH:
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                         THE COURT: Dent and Johnson were provided a copy of
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              the lawyer's opinion?
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                         MR. GRIFFITH: I thought you were talking about
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              Mr. Goix.
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THE COURT: No. I don't care. Mr. Goix is not a party here. His state of mind is not relevant to the case. The only reason hearsay would come in with these other folks is -- Mr. Dent and Mr. Johnson, to the extent they received information that affected their state of mind, that's relevant for that reason. But Mr. Goix's state of mind is of no consequence to the Court, and I'm not going to allow hearsay on that point.

Now, if you've got some other ground, I'd be glad to hear it, but -- the basis for admissibility, but that's hearsay.

MR. GRIFFITH: Well, I understand your ruling, Your Honor, but we do think it relevant to show co-conspirators -- I mean, if the reverse were true and he was told that it was illegal, you know, they would be bringing it in here to -- to -- as evidence of knowledge --

THE COURT: All I'm going to tell you is you can't have an unavailable letter come in from a lawyer who's not involved in this case and have that come in, and then somebody report what the lawyer said. Huh-uh. That's hearsay, not admissible. I've ruled.

What else?

MR. GRIFFITH: Well, he's not reporting what the lawyer said.

THE COURT: What's he reporting?

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MR. GRIFFITH: He's just reporting that he relied on counsel, and counsel advised him --

MS. SHORT: That's not this email, Your Honor.

THE COURT: Let me see the email.

MS. SHORT: This is my only copy.

THE DEPUTY CLERK: Okay.

THE COURT: So somebody named Jeff Anderson wrote somebody named Eddie Bishop.

MR. GRIFFITH: Jeff Anderson being a lawyer at Singulex.

THE COURT: Okay. To Eddie Bishop, and then somebody named Nate Lebowitz sent this to Eddie Bishop. What are you trying to show? Are you trying to get an opinion in by this? This is ridiculous. I mean, first of all it's misleading.

You know, Mr. Griffith, I've been a little troubled by your constant references to Ropes & Gray's opinion when I know and you know from issues about Ms. Hoey testifying that the lawyer said you don't want to put her on the stand. I mean, we got to be careful about what we're suggesting to the jury. It's one thing to say that somebody didn't say something. That's fine. But you were trying to imply that they have affirmative opinion, and I don't know how to read what that lawyer said. He said don't put Ms. Hoey on the stand. You know, just we got -- we're officers of the court here. We can't misrepresent something to the jury.

But as to this, I sustain the government's objection 1 1:37PM 2 as to Bluewave 80. It's hearsay. 1:37PM MS. SHORT: Thank you, Your Honor. Those were the 3 1:37PM 4 issues that we wanted to raise with you. 1:37PM 5 THE COURT: Anything further? 1:37 P M MR. GRIFFITH: Did you say there are no other issues 6 1:37 P M 7 on those exhibits or --1:37PM 8 No, sir. You need to lay the foundation. MS. SHORT: 1:37 P M 9 MR. GRIFFITH: Okay. 1:38 P M 10 MR. LEVENTIS: Thank you, Your Honor. 1:38PM 11 THE COURT: Yes. Let's bring in the jury. 1:38 P M (whereupon the jury entered the courtroom.) 12 1:38PM 13 Please be seated. THE COURT: 1:37PM 14 BlueWave, call your next witness. 1:37PM 15 MR. GRIFFITH: Your Honor, BlueWave calls Joe 1:37PM 16 Anastasia. 1:37 P M 17 THE DEPUTY CLERK: Please place your left hand on the 1:38PM Bible and raise your right. State your full name for the 18 1:38PM 19 record, please. 1:38 P M 20 Joseph David Anastasia. THE WITNESS: 1:38 P M 21 THE DEPUTY CLERK: Can you spell your last name for 1:38PM 22 the record? 1:38 P M 23 THE WITNESS: A-n-a-s-t-a-s-i-a. 1:38PM 24 THE DEPUTY CLERK: Thank you. 1:38PM 25 (Witness sworn.) 1:38PM

1:38PM	1	THE DEPUTY CLERK: Thank you. You may be seated.
1:38PM	2	JOSEPH DAVID ANASTASIA,
1:38PM	3	a witness called on behalf of the defendants, being first duly
1:38PM	4	sworn, was examined and testified as follows:
1:38PM	5	DIRECT EXAMINATION
1:38PM	6	BY MR. GRIFFITH
1:38PM	7	Q. Good afternoon, Mr. Anastasia.
1:38PM	8	A. Hello.
1:38PM	9	Q. My name is Joe Griffith. I represent BlueWave Healthcare
1:38PM	10	Consultants, Inc., Brad Johnson, and Cal Dent. Okay?
1:38PM	11	A. Uh-huh.
1:38PM	12	Q. We're just going to ask you some questions here today.
1:38PM	13	Let's start out with a little bit of background information.
1:38PM	14	Where are you from?
1:38PM	15	A. I'm from Richmond, Virginia, originally from the Boston
1:38PM	16	area.
1:38PM	17	Q. Okay. And starting with college, give us your educational
1:38PM	18	background.
1:39PM	19	A. I went to school at Virginia Tech. That's how I ended up
1:39PM	20	in Virginia, because I met my wife there. Majored in
1:39PM	21	economics. Went back up to Boston to work after college for a
1:39PM	22	couple of years, then moved to Richmond in 2007.
1:39PM	23	Q. Okay. And when before you got to HDL when did you
1:39PM	24	join HDL?
1:39PM	25	A. I joined HDL in October of 2009. Prior to that, I had

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So Aerotek Scientific was a company I worked in staffing. worked for. We would place folks likes chemists, phlebotomists, people in R&D, scientists, general staffing.

- Q. Okay. And so you joined -- and when did you join HDL?
- It was October 2009, I believe.
- And so what was your job at HDL?
- I was hired as the client services manager. At that time it was still a very small startup. I was the tenth employee. So I had been unemployed, and it was an opportunity at a So I've never done the startup thing before, so I figured I'd give it a try.

So my primary role was client services manager. of just rolled with the punches, helped out with the sales team, helped out, you know, with the patients in the health care, just any kind of customer service duty you can think of. And so when you say customer service, did that 0. Okay. involve any interaction with physicians?

I would, you know, mainly through telephone, if Α. Sure. they needed something, they'd call; I'd speak to them. you know, one of the reps needed me to go to a local facility to pick up specimens or something, I could do that.

This was still when we were very small, so it was kind of really close by. We were working with VCU. So I would go over there and pick up samples sometimes.

But as far as face-to-face interactions with the

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doctors, it was pretty minimal, just usually over the phone speaking to their staff.

- **Q.** And what type of issues would you deal with in terms of doctors and their customer service?
- A. Mainly repeating related to getting patient results, ordering supplies, just, you know, general things.
- **Q.** And how -- how frequent did you interact with client physicians?
- A. Well, specifically with the physicians, not as much. Mainly with their office managers and staff around them. I would go out -- depending on which time frame you're talking about, later on in HDL, when we started to release kind of some new products as far as being able to order online, new capabilities -- not really products -- I would go out and, you know, help train their staff on how to do -- place an order online or, you know, display some of the new -- what's the best way to put it? -- some of the new service offerings we had that were value-added, basically through our patient portal and things like that.
- Q. Okay. And did your role at HDL evolve?
- A. Yes. So from that time, October 2009 -- by the time I left, I was VP of operations, so that was about five and a half years later.
- **Q.** Okay. And what was different at the time that you left in terms of your role at HDL?

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A. So my main responsibilities before I left, since I started off in the customer service role, I basically grew myself into several different departments.

So we had sales support. So they would support the sales reps out in the field and also take supply orders. And then we had client services, which was also under me, and they would mainly deal with calls from physicians and scheduling health coach consultations for them. And then just more general calls from the practice.

And then I also had the logistics group, so fulfilling supply orders. And then we had strategic initiatives group that focused on health and wellness programs for corporate clients. So I was in charge of that participant support team.

- **Q.** Okay. And so you mentioned that you had a support group for the sales reps?
- A. Yes.
- Q. Okay. And did -- and HDL had sales reps in Virginia which were not affiliated with BlueWave; correct?
- A. That's correct.
- **Q.** And DC as well?
- A. Yes.
- **Q.** Okay. And -- and so what -- what type of interaction did you have with the sales reps?
- A. The internal ones to HDL?

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- Q. well, let's break it down, internal and external.
- A. The internal reps, much more interaction with because they were local. They were in and out of the lab a lot, picking up supplies. Rather than call, they would ask me a question face-to-face. So much more face-to-face interaction, just trying to give them what they need so they can get out there in the field.

And as far as the Bluewave group, mainly just over the phone. Didn't have lot of face time with them.

- **Q.** Okay. And what were the issues with BlueWave sales reps that you would typically deal with?
- A. You mean from the customers or the reps themselves?
- Q. The reps themselves.
- A. Oh --
- Q. You said you gave sales reps support.
- A. Sure, sure. So the main things they would need is just kind of if they were new to HDL, were just getting on board and learning what our processes were for signing up a new customer. Who to go to for what. So they would get assigned a specific sales support person by the region they were selling in. And that sales support person's main job was to help onboard new customers, get them built into our system.

So the issues that they would work with the sales team on is getting missing pieces of information for new account forms, rep forms, getting everything built into our

In the beginning,

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system so we could ship out supplies. Did you -- did you have anything to do with their Q. Okay. actual marketing, in-the-field marketing? Α. No. And you were familiar with the fact that HDL offered P&H fees to physicians who wanted to -- to enter into a contract with HDL for those type services; correct? Yes, I'm familiar with the P&H. Α. Okay. And what -- did you have any role in monitoring the payments of P&H fees? It was more of a kind of collaborative effort Somewhat. between a couple of different departments. everything was kind of more manual, and then we developed some automated processes. But, in general, you know, there would be a download of a file out of our laboratory information system that would go over to the accounting system, and from there the P&H payments would go out for qualifying samples. And did y'all keep weekly, monthly records on this, on the Q. P&H fee payments?

20 That's the accounting group. I'm not sure if they have 1:47PM 21 them. I didn't maintain them myself, though, no. 1:47PM 22 Do you know what percentage of the physicians who ordered 0. 1:47PM 23 lab tests from HDL actually were paid or reimbursed P&H fees 1:47PM 24 for their services? 1:47PM 25 I don't know the percentage, no. 1:47PM

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- **Q.** Did HDL have a system for ensuring that P&H fee requests were for an adequate number of tubes?
- A. Yes. There was more than one tube, more than one test.

  Again, this is kind of the automated report we billed from LIS.

  So if --
- **Q.** What is LIS?
- A. The laboratory information system.
- **Q.** Okay.
- A. So it's just kind of the back-end software that tracks all the orders in the lab. Yeah.
- **Q.** And why was that important?
- A. Because the P&H contracts stated that it was more than one tube, more than one tube, because the P&H was meant to be reimbursement for the time spent of their staff, processing, and packaging all the specimens.

So the time and motion studies that we had done or that had been done, basically, were for drawing four vials of blood and running our panel. So if you were to only order, you know, one test and draw one vial of blood, obviously, doesn't take as much time, and you don't want people to try to game the system. So that report was there to catch it.

THE COURT: Mr. Griffith, let me just ask this, raise the issue.

So if somebody ordered one test, would there be a process and handling fee?

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THE WITNESS: No. It had to be more than one tube, more than one test.

**THE COURT:** To be paid anything?

THE WITNESS: Yes. That was the requirement.

THE COURT: Thank you. Go ahead.

## BY MR. GRIFFITH:

- Q. Now, did HDL reimburse doctors P&H fees on every claim that was requested for one?
- A. No, not if it didn't qualify.
- **Q.** And what was the qualification? Was it just what you just explained to the judge?
- A. Yes, exactly.
- **Q.** So while you were at HDL, did you receive any compliance training?
- A. Yes. We had -- as the company grew, we actually had a pretty good training system. When I first started, we used some online modules. But from there, we had basically folks focused on learning objectives and ongoing training annually.
- **Q.** And what type of training did this involve?
- A. So there was kind of a mix, depending on your level in the company, whether it was, you know, either face-to-face for, I guess, more advanced things that you might encounter. But pretty much everybody had a -- based off the area they worked in, had modules online. You know, it would be like going through a slide show. And they talked to you about, you know,

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whatever the topic was, and there would be a quiz at the end. So that's how it was administered. It was all online learning management. Q. And did -- while you were there, did HDL hire a compliance officer? Α. Yes. Okay. And who was that? Q. Kathy Johnson. Α. Okay. And did she -- while you were there, did she 0. develop a compliance program? She worked with human resources on that program. Α. Yes. Did the compliance training involve any health 0. care-related topics? It's covered, you know, the inducements, all that kind of stuff related to, you know, the -- physician --The Anti-Kickback Statute? 0. Yeah, the Anti-Kickback Statute. Yeah. It was pretty Α.

much the whole gamut of anything that is required.

- 0. Right. Like Stark laws and HIPAA?
- Yeah, all that. PHI, HIPAA, everything.
- Had you received any similar-type training in your prior employment?
- It wasn't required. Α. No.
- Q. Now, did there come a time when you became aware that HDL was conducting -- was conducting a time and motion

study? 1 1:51PM 2 Α. 1:51PM 3 Okay. Q. 1:51PM 4 1:52 P M Yes. 5 Α. 1:52PM 6 0. okay. 1:52 P M 7 for the study? 1:52 P M 8 1:52PM 9 1:52 P M 10 1:52 P M 11 1:52 P M 12 1:52 P M 13 1:52PM 14 1:52 P M 15 1:52 P M 16 1:52PM 17 0. 1:52 P M 18 1:52 P M 19 1:53PM 20 1:53PM 21 1:53PM 22 hiccups. 1:53PM 23 Okay. 0. 1:53PM 24 doctors for this particular time and motion study? 1:53PM 25 Α. No. 1:53PM

That was probably around 2011 or so. Did you -- did you help provide a list of doctors to HDL folks who were involved in this? Did -- how did you determine which doctors to use The company that they were using to do the time and motion study, I believe, was out of the DC area. geographically looking at which doctors were around there because they had requested -- they had a list of, basically, criteria, I recall, as far as, you know, just location. think they got a mix of doctors that have been, you know, with HDL for a long time and then some newer clients, because if you've been doing it a long time, then you might be more proficient at processing as opposed to a newer client. was that your experience, that newer physicians or physician practices took more time to process and handle blood? I really wasn't in the physician offices when that was I mean, just from the phone calls and dealing with customer service issues, usually new clients have a few I mean, I could assume that, but I don't know it. Did Latonya Mallory tell you how to select the

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- **Q.** Did she tell you who to select for the time and motion study?
- A. No. Actually didn't really interact with Tonya regarding the time and motion study. Her name was Shahrzad. She was in one of our data analytics groups, and she was kind of managing the project. So I gave her the information.
- **Q.** Did Brad Johnson have any input on the doctors that you selected for this time and motion study?
- A. No.

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- Q. How about Cal Dent?
- A. No.
- Q. Now, you were still at HDL when the P&H fee reimbursement program was terminated; right?
- A. Yes, that's correct.
- **Q.** Okay. And did -- were you involved with the communications to the doctors regarding the termination of P&H?
- A. Yes. We sent out letters pretty much with the position statement from OIG and all of that. And then, you know, if they had questions, they could call me.
- Q. Well, did -- did some physicians say that they were going to discontinue testing?
- A. No, I didn't get any calls specifically saying they were going to discontinue testing. We did see a dip in some sample volume for a period, but I think I only received kind of one aggravated call from somebody, but it was more so along the

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lines of the government getting in their business kind of deal. It was just one physician. I don't know. But, in general, no.

- And was it -- was the dip, in your experience, about Q. 10 percent?
- Yeah, initially. And then it kind of leveled out from It didn't continue to fall.
- Now, so at least initially that meant that Okay. 90 percent of the physician clients were still ordering the lab tests?
- And the ones that we lost, I don't even know if it was directly related to P&H. Mainly, it was just kind of the straw that broke the camel's back. You have to understand physician relationships are pretty fragile. So they don't have to deal with something they don't want to deal with. And this was, again, you know, after our competition out there walking in with these letters, telling physicians to leave HDL because they're doing things that are illegal and this proves it. So a lot of it had to do with that.

MR. GRIFFITH: Okay. Can we bring up Exhibit M4, Mallory 4. All right.

Your Honor, this is already in evidence.

THE COURT: Very good. Thank you.

## BY MR. GRIFFITH:

Mr. Anastasia, this appears to be an email from you dated January 21st, 2014.

- 1 1:56PM 2 1:56PM 3 1:56PM 4 1:56PM 5 1:57PM 6 1:57PM 7 1:57PM 8 1:57PM 9 1:57PM 10 1:57PM 11 1:57PM 12 1:57PM 13 1:57PM 14 1:57PM 15 1:57PM 16 1:57PM 17 1:57PM 18 1:57PM 19 1:57PM 20 1:57PM 21 1:57PM 22 1:57PM 23 1:57PM 24 1:58PM 25 1:58PM
- A. Uh-huh.
- Q. Do you see that?
- A. Yes.
- **Q.** And it's to Tonya Mallory; correct?
- A. That's correct.
- Q. Okay. And so it says, "just so you have the information. There are 5,390 unique custom panels in our system."
- A. Uh-huh.
- Q. Do you see that?
- A. Yes.
- Q. Explain to us what that -- what that means.
- A. So when a new physician -- or it can be any physician, if they're an existing customer or not, we call the group of tests they order a panel. Usually a physician has a baseline panel and a follow-up panel. Your baseline is the first one you get done, typically has the genetics; and then the follow-up doesn't have genetics because they don't change. But it's usually the same body of tests.

In general, HDL gave physicians freedom to put together any grouping of tests they like. So they created their own panels. Then over time, as physicians continued to use us more and we released more tests, those panels would continue to either grow or shrink. Some physicians would make up their own metabolic panels with groupings of tests because they didn't like the standard panel.

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So by this saying there's 5300 unique custom panels, that means that if -- when the requisition form, which is a lab order, hits the -- they essentially would be entered, they have to, you know, pull up that specific panel for that physician, and then that's the order that is placed.

So we had around 5300 unique panels in the system.

- **Q.** Okay. And did -- to your -- this was dated January of 2014.
- A. Uh-huh.
- **Q.** While you were at HDL, did you -- did HDL continue to have more unique custom panels ordered after this date?
- A. Oh, yes. It was kind of, actually, an operational challenge because of having so many unique panels in there and so many versions you have to control. You know, the people entering the order have to make sure they select the right one because that doctor could have changed his panel from last week. So we were looking for a way on the operations side to try to come up with a panel that we could always order and then append tests to that so that it would make it easier on the accessioners, because 5300 panels is a lot to look through to try to find the right one for a doctor.
- **Q.** And so weren't the number of physician or physician practices that HDL had approximately 3500?
- A. Practices?
- Q. Yeah.

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2:01PM

- A. Yeah, that sounds about right.
- Q. Okay. And were you able -- with respect to these unique custom panels, did that give you any -- did y'all use that for any kind of research in terms of what was popular or what was effective?
- A. Yeah, there was analytical work done on that. Not in my department, but yeah.
- Q. Okay. So let's pull up BlueWave 255.

Also in evidence, Your Honor.

So, Mr. Anastasia, not going to go over this in detail because we've already seen this. The jury has already seen this. But this is an email from Kathy Johnson and you and others regarding a call regarding a revised process and handling agreement.

Do you recall that?

- A. Yeah, vaguely. I don't recall this specific email, but

  I -- I do recall it being revised in this group meeting, yeah.
- **Q.** And so I'm just curious. Were you typically in the group of email chains when there were discussions of P&H fees and P&H fee agreements?
- A. I wouldn't say P&H specifically. Really, anything that would have an effect on our customer, because the folks on this email are really -- it's myself, and then there's our sales support manager, customer service. So just -- so they're equipping them to know to deal with, you know, their sales team

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and the calls they might get.
          1
2:01PM
          2
                   Okay. So let's go to Plaintiffs' Exhibit 7009.
              Q.
2:01PM
                         MR. GRIFFITH: Your Honor, may I approach?
          3
2:02PM
          4
                         THE COURT:
                                    You may.
2:02PM
          5
              BY MR. GRIFFITH:
2:02PM
                   Can you take -- that's a real thick email. Just take a
          6
2:02PM
              second to glance at the -- at the content of the email.
          7
2:02PM
          8
                   Okay.
              Α.
2:03PM
          9
                   Okay. Are you generally familiar with that document?
2:03PM
         10
                   Yeah.
                           I recall Anna being hired as a consultant to go out
2:03PM
         11
              and speak to physicians to kind of --
2:03PM
                   Let's stop. Tell us generally what -- what is the email
         12
              0.
2:03PM
         13
              about generally? Give us the date, from whom, to whom, and
2:03PM
              what's it about.
         14
2:03PM
         15
                   Sure.
                           It's from Tonya to Joe McConnell, Russ, Michael
2:03PM
         16
              Payne, Ali Baedke, Stacey Barnes, myself, Satya, Michael
2:03PM
         17
              Woodard, Leslie Strickler, Paul Spicer, Barry Hodge, Janet
2:03PM
              Vicario, and Saba Zafari, and copied was Cal and Brad.
         18
2:04PM
         19
              0.
                   Okay.
2:04PM
                   The subject is "Report please read."
         20
2:04PM
         21
              Q.
                   Okay.
2:04PM
         22
                                     I'm sorry. Report what?
                         THE COURT:
2:04PM
         23
                         MR. GRIFFITH: "Report please read."
2:04PM
         24
                         THE COURT:
                                     Good.
                                             Thank you.
2:04PM
         25
              BY MR. GRIFFITH:
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And you read, actually, the second header in the email; 1 Q. 2 right? 2:04PM Yeah. 3 Α. 2:04PM 4 Q. The top email is from you dated February 28th to Tracy --2:04PM 5 Α. Tracy. 2:04PM Borowski? 6 Q. 2:04PM 7 Α. Yes. 2:04PM 8 Just basically forwarding that email. 0. 2:04PM 9 Yeah, yeah. I'm sorry. Yeah, so I forwarded it on to 2:04PM 10 Tracy because it was customer service billing-related stuff in 2:04PM 11 here. 2:04PM So -- and was Tracy Borowski in customer service? 12 0. 2:04PM 13 She's in charge of billing. Α. 2:04PM 14 Q. Billing? 2:04PM 15 Α. Yeah. 2:04PM So explain -- and so there's an attachment to this 16 0. Okay. 2:04PM 17 email; correct? 2:04PM 18 Α. Yes. 2:05PM And generally, because it's a lot of pages --19 0. Okay. 2:05PM 20 Yeah. 2:05PM 21 -- I don't see page numbers, but it looks like it's about Q. 2:05PM 22 Generally explain to the jury what this report is. 80 pages. 2:05PM 23 Well, Anna McKean was hired as a kind of third-party 2:05PM 24 consultant to go out and talk to physicians, basically as a way 2:05PM 25 to improve customer service, kind of find out what we were 2:05PM

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2:07PM

doing that, you know, they weren't happy with and where we could improve.

So there was some stuff related to billing. interacted with billing quite a bit, and Tracy wasn't on the initial distribution, so I sent it over to her so she could take a look at it.

- And so -- and who was the author of this report? Q.
- Α. Anna McKean.
- Right. Who was she?
- At that time she was -- I think she had her own consulting business, but prior to that, she was the chief operating officer at PartnerMD, which is a concierge medical group. And then later on HDL hired Anna to head up the strategic initiatives group and focus on population health and wellness.
- Okay. Now, what was your understanding of the purpose of Q. obtaining this report?
- To improve customer service. Α.
- To your knowledge -- and I want to put on the ELMO Q. okay. if we can. But to your knowledge was this document ever used for any type of marketing purposes to doctors?
- Α. No.

THE DEPUTY CLERK: Mr. Griffith, hit the button to turn it on on this -- yeah, right there.

> MR. GRIFFITH: Thank you.

BY MR. GRIFFITH:

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Q. And so I'm just going to show -- this page is numbered.

But this is page -- if you can go to page -- you can see it on the screen, but if you go to the page 23.

A. Uh-huh.

"Question:

advanced testing.

**Q.** This appears to be questioning doctors who had -- who had attended a seminar provided by HDL.

Is that how you understood it where it says,

Did you think the program was informative and

provided information that was helpful? Why and why not?"

A. Yes. We did start to -- because the testing was advanced and we had a lot of questions from physicians, we started doing continuing -- CMEs, which is continuing medical education, classes and things like that later on. And then we also would hold, you know, talks where we'd have either the chief medical

Q. Okay. And so -- and this -- on this particular page, if you look at Dr. Spiers, for instance, he says, "Informative, very interesting, and reflects what I've heard in other lectures but in a more palatable, easier-to-grasp-on-first-pass style.

officer, Joe McConnell, or somebody give a talk about the

Do you see that?

A. Yes.

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2:09PM

Q. So they were just looking for input, apparently, from the doctors as to their assessment of the CMEs; correct?

2:09PM	1	A. Correct. Yeah, so we could tweak them if they were not
2:09PM	2	working.
2:09PM	3	Q. And that was just part of the report. That wasn't the
2:09PM	4	entire report; right?
2:09PM	5	A. No.
2:09PM	6	Q. Okay. And so Miss Anna apparently interviewed doctors;
2:10PM	7	correct?
2:10PM	8	A. Yes.
2:10PM	9	Q. And she wrote summaries of her interviews; correct?
2:10PM	10	A. Yes.
2:10PM	11	Q. And this appears to be an interview with a
2:10PM	12	Dr. Matthew Acampora dated 11/3/2010. Do you see that?
2:10PM	13	A. Yes.
2:10PM	14	Q. And you did not instruct Ms. McKean on what to ask or what
2:10PM	15	to report, did you?
2:10PM	16	A. No. Actually, I think I don't even know if I was aware
2:10PM	17	she was out doing this study. I think it was kind of blind so
2:10PM	18	we wouldn't, you know, be able to skew the results in any way
2:11PM	19	from a customer service standpoint.
2:11PM	20	Q. Okay. So I point this out if you look in the middle,
2:11PM	21	"Sees two ways to sell HDL. Number 1, great test, believes the
2:11PM	22	test has good science behind it, spokespeople and founders have
2:11PM	23	high integrity, tremendous respect."
2:11PM	24	Do you see that part?
2:11PM	25	A. Yes.

1 2:11PM 2 2:11PM 3 2:11PM 4 2:11PM 5 2:11PM 6 2:11PM 7 2:11PM 8 2:11PM 9 2:11PM 10 2:11PM 11 2:12PM 12 2:12PM 13 2:12PM 14 2:12PM 15 2:12PM 16 2:12PM 17 2:12PM 18 2:12PM 19 2:12PM 20 2:12PM 21 2:12PM 22 2:13PM 23 2:13PM 24 2:13PM 25 2:13PM

**Q.** And then, Number 2, it says, "Positive ROI for physician -- being able to use higher coding for consultation visits, including 99214."

Did -- did you in any way ask that physician to provide information regarding return on investment?

- A. No.
- **Q.** To your knowledge, did anybody at HDL talk to this physician about a return on investment?
- A. No.
- **Q.** Okay. And on page 18 of the report, there's a section called "generating a positive ROI."

Do you see that on the bottom?

- A. Yes.
- Q. And it says, "As physicians struggle with increasing overhead and lower reimbursement -- insurance reimbursement amounts, the costs of providing the HDL test compared to the revenue that they -- that they can generate must be taken into account."

Do you see that?

- A. Yes.
- **Q.** Okay. And do you see all the calculations that she made?
- A. I do.
- **Q.** And the assumptions that she made?
- A. Yes.
- Q. Did HDL have anything to do, to your knowledge, with

2:13PM	1	asking her to formulate these questions or formulate these
2:13PM	2	assumptions?
2:13PM	3	A. Not to my knowledge, no.
2:13PM	4	Q. Okay. To your knowledge, did HDL use this report in any
2:13PM	5	way in its marketing materials?
2:13PM	6	A. No, not to my knowledge.
2:13PM	7	Q. Okay. Mr. Anastasia, that's all I have for you. There
2:13PM	8	will be some other questions, I'm sure.
2:13PM	9	THE COURT: Thank you, Mr. Griffith.
2:13PM	10	Government, examination?
2:13PM	11	MR. SHAHEEN: Your Honor, we have no questions.
2:13PM	12	Thank you.
2:13PM	13	THE COURT: Mr. Ashmore?
2:14PM	14	MR. ASHMORE: No questions, Your Honor.
2:14PM	15	THE COURT: Sir, you may step down.
2:14PM	16	Let me ask you, actually, one or two questions to
2:14PM	17	follow up what you were telling us
2:14PM	18	THE WITNESS: Sure.
2:14PM	19	THE COURT: about Mr. Anastasia, about the
2:14PM	20	vials. You said with one vial there would be no process and
2:14PM	21	handling fee paid; is that correct?
2:14PM	22	THE WITNESS: If my recollection serves me, yeah,
2:14PM	23	more than one tube, more than one test. Both of those had to
2:14PM	24	be met.
2:14PM	25	THE COURT: Had to happen?

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So one vial, would it only apply to one test or could you draw blood for multiple tests in one vial?

THE WITNESS: Multiple.

THE COURT: So if a physician ordered multiple tests, but only those tests required one vial, that physician got no process and handling fee?

THE WITNESS: That's correct.

THE COURT: How about if it required two vials?

THE WITNESS: Then they would --

THE COURT: The full? Would they get the full process and handling?

THE WITNESS: Right.

THE COURT: And why would it be that there would be nothing for one -- if you know, for one vial for the test that would only fill up one vial?

THE WITNESS: I don't know. I mean, that's -- I don't know why -- how they arrived at the amount or the number of tubes. We did have one -- I think the reason we created this report -- actually, it's coming back to me -- is we had a physician that we had actually mistakenly, because it was a man -- sent double payment on a sample because he sent in a urine test separate from the blood.

THE COURT: And tried to get two?

THE WITNESS: Right, right. So we implemented this to cut that out. So it was kind of a failsafe. But then we

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came up with that policy there.

THE COURT: And what -- you mentioned about the standard HDL panel. You said there were 5,000 unique panels. What percentage would have done just the standard panel, as you described it?

THE WITNESS: Very small. The way our new account forms worked is they would have a -- a panel on it, like a suggested panel. I think the chief medical officer --

THE COURT: We've seen that.

THE WITNESS: Yeah. So the physician is free to scratch out and add tests. So --

THE COURT: Either -- could remove tests?

THE WITNESS: Yeah, remove tests or add tests. If a physician was brand new to HDL, just wanted to try it, then they might go with the standard panel.

THE COURT: What percentage would you estimate ordered the standard panel? What percentage of those total tests were standard panel?

THE WITNESS: I'd say probably between 15 to 20 percent maybe.

THE COURT: Thank you.

Any questions occasioned by the Court's questions?

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

THE COURT: Mr. Griffith?

MR. GRIFFITH: No, Your Honor.

2:16PM	1	THE COURT: Mr. Ashmore?
2:16PM	2	MR. ASHMORE: No, sir.
2:16PM	3	THE COURT: Very good. You may step down.
2:16PM	4	(Witness excused.)
2:16PM	5	THE COURT: Call your next witness.
2:16PM	6	MR. GRIFFITH: Your Honor, BlueWave calls Philippe
2:17PM	7	Goix.
2:17PM	8	THE DEPUTY CLERK: Please place your left hand on the
2:17PM	9	Bible and raise your left hand. Place your left hand on the
2:17PM	10	Bible and raise your right.
2:17PM	11	State your full name for the record, please.
2:17PM	12	THE WITNESS: Philippe Goix.
2:17PM	13	THE DEPUTY CLERK: Can you spell your name for the
2:17PM	14	record, please.
2:17PM	15	THE WITNESS: P-h-i-l-i-p-p-e; Goix, G-o-i-x.
2:17PM	16	THE DEPUTY CLERK: Thank you.
2:17PM	17	(Witness sworn.)
2:18PM	18	THE DEPUTY CLERK: You may be seated. There's a step
2:18PM	19	over there, so be careful. Just go right there.
2:18PM	20	THE WITNESS: Over there?
2:18PM	21	THE DEPUTY CLERK: Yes, sir.
2:18PM	22	PHILIPPE GOIX, PH.D.,
	23	a witness called on behalf of the defendants, being first duly
2:18PM	24	sworn, was examined and testified as follows:
2:18PM	25	DIRECT EXAMINATION

2:18PM	1	BY MR. GRIFFITH:
2:18PM	2	Q. Good afternoon, Mr. Goix.
2:18PM	3	A. Good afternoon.
2:18PM	4	Q. Mr. Goix, we've met before. I'm Joe Griffith.
2:18PM	5	A. Yes.
2:18PM	6	Q. Okay. And I represent Cal Dent and Brad Johnson and
2:18PM	7	BlueWave in this matter.
2:18PM	8	A. I understand.
2:19PM	9	<b>Q.</b> Okay. And just so we get it right out in the open, you
2:19PM	10	have a very heavy French accent; correct?
2:19PM	11	A. That's correct.
2:19PM	12	Q. Okay. And you're from France originally?
2:19PM	13	A. Yes.
2:19PM	14	Q. And if we have any communications problems, I want you to
2:19PM	15	please stop me, ask me to clarify the best we can. And we may
2:19PM	16	have to do the same thing with you because we may not be able
2:19PM	17	to understand you. No offense intended, but we just want to
2:19PM	18	make sure everything is clear.
2:19PM	19	A. It's a shame, because I've been in this country for 28
2:19PM	20	years.
2:19PM	21	THE COURT: Mr. Griffith, he's clear. You, I don't
2:19PM	22	know.
2:19PM	23	MR. GRIFFITH: Okay. Don't know how to take that,
2:19PM	24	Your Honor. I'll take it as a compliment.
2:19PM	25	BY MR. GRIFFITH:

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- Q. So Mr. Goix, it's Philippe Goix; correct?
- A. Correct.
- **Q.** Okay. So give us a little bit of information about your background, starting in college.
- A. Yeah, so I -- you know, I was born in France. I earned a Ph.D. in physics and -- in 1988.

And I was invited by UC Berkeley to do a two-year fellowship after my Ph.D. So I did a fellowship at UC Berkeley.

I was then hired as a full-time, tenured scientist at CNRS in France for -- for -- for forever, but I got an opportunity to come back to work at Sandia National Labs, where I am a scientist. 15 years of scientist background, I earn an MBA from the University of San Francisco, and then I started -- I live in the Bay Area for 28 years. And I started several companies.

And started Guava Technologies. The company was sold to Merck Millipore. And then I started -- I was hired at Singulex to be Singulex. And I kept going and building companies.

- Q. Okay. And approximately when did you join Singulex?
- A. I was hired by Singulex in September 2004.
- Q. Okay. And did you -- did you start a company before Singulex?
- A. I did.

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- **Q.** Okay. And what was that called?
- A. Guava Technologies.
- **Q.** Okay. And what was that company?
- A. This company had a technology platform that performs single-cell analysis. And it's a cell analysis platform that was sold to pharmaceutical companies and medical school to do research.
- **Q.** Okay. And what happened to Guava Tech?
- **A.** Guava was sold by Merck -- to Merck Millipore. And it had application for HIV monitoring and cancer research. And the product are still in existence and sold today.
- **Q.** And so what was your role when you started with Singulex?
- A. I was hired as a CEO of Singulex. At that time, the company was based in St. Louis in Missouri. And, again, the technology was a single-molecule detection technology. And my role was to -- they had no revenue, 10 employees. And my role was to commercialize this technology for lifestyles and health care markets.
- **Q.** Okay. And how did you -- what did you do to commercialize the products that Singulex had?
- A. It's several steps. Number one steps, understand the technology and make sure it works. So there is a development stage by which you -- and it took about two years to really take the technology that has absolutely no revenue, was not sold, and build it for it to work, then market the technology

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to the research market. And the research market is either medical school and pharmaceutical company that wants to do research with that technology.

- Q. okay. Did -- at some point, did Singulex develop a lab component?
- So what was very important is -- and I took --Yes. personally, I was selling the technology to the pharmaceutical companies and medical school and the top researcher in the country, Harvard, UCSF, Stanford, the top pharmaceutical companies, you know, that invested heavily in -- value market research. And we simply asked them, you know, how -- how they used this technology, what do they need the technology for?

And we developed applications for that technology that was -- that was the first stage of the company. And there was clinical application for that technology and -- in the cardiovascular space. And some of the technology we developed enabled detection of -- of troponin, which is a heart attack marker. So if you have a heart attack, your heart produces that marker called troponin. And it was used in the past in the emergency room when someone has a heart attack. confirm that there's a heart attack, you do that -- that detection, the test for troponin.

what we did with this technology, we were able to measure that protein, troponin, in a very, very small concentration -- in a very low concentration in the blood and

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detect that protein in normal people. So, before, it was thought that -- it was a major invention, by the way. Before we thought that you have troponin in the blood only when you have a heart attack. We changed that. And it took us about two years to do the research to show, even if you don't have heart attack, you -- your -- you have troponin in your blood. So the clinical application for that is -- in other words, we can use that test to help a doctor assess the risk of someone to develop a heart attack within, you know, the near future.

And that was -- that was the reason -- that I was very excited about this opportunity, because I think we can change the way you manage people with cardiovascular disease.

So we developed a lab -- a laboratory to offer to make this test, you know, available to the physician and the cardiologist.

- **Q.** Okay. And so how did Singulex come to market this product?
- A. It's extremely challenging. You know, when you have a company and you have a platform that has huge value in the marketplace, the key is how you commercialize that. And in many ways, that's what I was hired for, is to find a business model where I can get that test out, get it in the hand of the cardiologist, the physician, build the publication that are required by the top medical researcher in the country.

We had a lot of publication that shows that, yes, we

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could detect that troponin; yes, it was very important information to measure that -- that test in normal people; and yes, you can draw a clinical value out of an increase of troponin at the very small level, and -- and have -- as a warning test, as almost a smoke detector. Many of the cardiologist, customer of ours, you know, see that test, like, as a smoke detector. If there is smoke, there is a danger of fire. So you need to treat heavy.

However, you know, troponin by itself is just one test. It can be elevated for many, many reasons. So it was very important that we partner with other lab to integrate a broader content so the physician can really, you know, put all the pieces, you know, of the puzzles together.

And so, you know, I was actively looking for a partner in the lab business. And across the street, literally, from where Singulex was, there was a company called Berkeley -- Berkeley HeartLab. You may have heard of that company. And that lab had developed very interesting infrastructure around, you know, a comprehensive cardiovascular panel.

And Berkeley HeartLab was -- you know, got sold by -to Quest eventually. And so we had an opportunity to really
have a lot of talented individual that had this experience in
the lab business to build the lab business around the
technology we developed.

Q. Okay. And so did I understand you to say, did some of the

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folks from Berkeley come to work for you at Singulex?

- A. Yes.
- **Q.** Were -- who in particular do you recall that worked at Berkeley came to work at Singulex?
- A. Gary Tom and part of his team; Frank Ruderman was a former CEO of Berkeley HeartLab and the chief marketing officer of Berkeley HeartLab in a sense; and many other people.
- Q. Okay. And so when -- when did these -- like, Frank Ruderman, Gary Tom, generally, what time frame did they come to work at Singulex?
- A. It's been a while. 2009, 2010.
- Q. Okay. So when you said you were looking for lab partners, was that the initial foray into marketing that you did? Did you seek out a lab partner?
- A. Well, at first, I mean, I -- we hired Frank Ruderman. And so -- and then we -- Frank has -- has spent nearly 10 years to build Berkeley HeartLab. So we benefited tremendously from his experience. And he really taught us how to build this panel, you know, what type of things worked -- what works, what didn't work -- understanding the billing piece of the business.

And, you know, so before we started to really, you know, look for a laboratory, which there is no such thing as laboratory to do what we wanted, we wanted a marketing strategy to help tie what we were building with a cardiovascular, you know, business.

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So to answer your question is, first, we build the marketing strategy. You know, we build all the pieces that we needed. And then, ultimately, we build -- we build the lab.

- Q. Okay. Well, did -- did you -- did Singulex enter into any --
- A. I want to make a correction, because we had the lab -- a laboratory, of course, before, but it was not a CLIA laboratory. A CLIA --
- **Q.** Yeah, what is a CLIA laboratory?
- A. It's a -- it's a laboratory that is regulated for clinical laboratory tests.
- **Q.** And so did you end up partnering or contracting with any other labs?
- A. We tried. We were looking at some labs that could add value, you know, and deliver a menu -- deliver the tests that we needed complementary to troponin I, but we didn't find, really, a good partner.

So after all -- maybe six months of research of looking at the right partner and then six months of developing the marketing strategy and bringing the right people, we -- and it was very apparent to us the right strategy was to build the CLIA lab, which we did.

- **Q.** Okay. Did you go -- at any point, did you enter into an agreement with HunterLabs?
- A. Yes.

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- **Q.** Okay. And what was -- what was the purpose of that agreement?
- A. If I recall, it's -- again, it's long time ago.

When we were formulating our strategy, we knew that around this market of troponin I that has a unique value, we needed to have a panel, if you will, of clinically approved tests, and -- because, you know, we didn't have the laboratory, we expected Hunter, who is a local laboratory in California, to deliver what we didn't have in-house in order to move rapidly.

MR. GRIFFITH: Your Honor, may I approach?

THE COURT: You may.

## BY MR. GRIFFITH:

- Q. Do you recognize that?
- A. Yes, I do.
- Q. Okay. And what is it?
- A. It's a service agreement.
- Q. With whom?
- A. With Hunter.
- **Q.** With HunterLaboratories?
- A. Yeah, HunterLab.

MR. GRIFFITH: Your Honor, we'd move this,

BlueWave 63, into evidence.

THE COURT: Is there an objection?

MS. SHORT: No objection.

THE COURT: Very good.

Mr. Ashmore? 1 2:35PM 2 MR. ASHMORE: No objection, Your Honor. 2:35PM Bluewave 63 admitted without objection. 3 THE COURT: 2:35PM BY MR. GRIFFITH: 4 2:35PM 5 Now, HunterLabs did -- was a -- was it also in -- was it 2:35PM in the cardiovascular space? 6 2:36PM 7 Α. Yes. 2:36PM And -- and what -- and don't go into detail, but just kind 8 0. 2:36PM 9 of generally, what did HunterLabs do for you, for Singulex? 2:36PM 10 I'm not sure we came back -- what they did really for us. 2:36PM 11 They provided -- and Frank Ruderman actually introduced us to 2:36PM this laboratory. I didn't know this laboratory before. 12 2:36PM 13 the expectation that this laboratory could provide, you know, 2:36PM 14 some biomarker tests for us so we can get to the market and 2:36PM 15 integrate our troponin I to the panel we would offer to the 2:36PM 16 customer. 2:36PM 17 And to -- when you say that HunterLabs was in the Q. 2:36PM 18 cardiovascular space --2:37PM 19 Α. Yes. 2:37PM 20 Do you know what kind of test that they offer? 2:37PM 21 I don't quite recall, but, I mean, I think it's in the 2:37PM 22 exhibit. 2:37PM And if you look at the date of the agreement, it's 23 Q. Okay. 2:37PM March 12th, 2010; correct? 24 2:37PM 25 Α. Correct. 2:37PM

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**Q.** Okay. And so --

You can bring that down.

And so, ultimately, several months later, Singulex entered into a contract -- a sales representation contract with BlueWave Healthcare: is that correct?

A. Yes. Correct.

MR. GRIFFITH: And please pull up BlueWave 92, which is in evidence. And if you just pull out the first paragraph.

## BY MR. GRIFFITH:

- Q. So the -- does this appear to be the sales agreement --
- A. Yes.
- Q. -- between Singulex and BlueWave?
- A. Correct.
- Q. Okay. And it's dated June 1st, 2010?
- A. Correct.
- **Q.** And did you execute this agreement?
- A. Yes.
- Q. Okay. And so how did this agreement -- how did you negotiate this agreement? How did it come to fruition?
- A. Again, you know, Frank Ruderman and Gary Tom and other in the company knew Brad and -- Brad Johnson. So I had had an opportunity to meet with Brad Johnson and, you know, explain to him what our challenges were to market this product.

Clearly, you know, talking about the Hunter solution was not a viable solution. So we were looking for a

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sophisticated, you know, sales force that understood what we were doing and help us to get to the market. So we met -- I met with Brad, and then we -- you know, we started to discuss, you know, how we could work together.

- Q. Okay. And were there negotiations --
- A. It was a lot of negotiation.
- **Q.** Well, did you and Singulex -- excuse me -- employ an attorney to represent Singulex in these negotiations?
- A. Yes.
- **Q.** And who was that attorney?
- A. Ballard and Spahr firm, Ms. Mullany was the --
- Q. Mary Mullany.
- A. Mary Mullany was the -- in charge, was recommended to me, really well recommended to me by my board and some of my consultant with expertise in compliance, in that space.

  Remember, I was not an expert in that space. So, throughout, I had to really bring the best advice. And, you know, Ballard had a great reputation, so we hired them.
- Q. So -- and I don't want to go into what the attorneys -- what you discussed with your attorneys in any detail, but is it -- is it a fair statement that Mary Mullany of Ballard Spahr negotiated this contract, this sales contract, BlueWave 92, on your behalf?
- A. It was correct. I had people on my team, my HR executive, I had a pretty comprehensive team, and Mary was clearly the --

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the gatekeeper or the adviser, the -- you know, the -- she was controlling the original. I would never have signed a document that was not validated and approved by Mary Mullany.

Q. If you go to the second page, just starting with that -if you'd pull out b.

And this provision, I think everybody can read it, but I'll just read it out loud.

"Provide processing and handling fees to physicians in the range of \$18 to \$21 and processing and handling fees to the outside labs in the range of \$18 to \$25, provided that any fee change shall be mutually agreed by the parties."

Did I read that correctly?

- A. Yes.
- **Q.** Okay. And so did Ms. Mary Mullany review that particular provision?
- A. Yes.
- Q. Okay. Did she have any problems with that provision?
- A. No, once we signed it.
- Q. Okay. Let's go to e, please, which says, "provide zero-balance billing in the territory for Medicare, Medicaid, PPOs, POSs, and HMOs except as otherwise mutually agreed to by the company and the contractor."

Do you see that?

A. Yes.

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Q. And did Miss Mary review that provision?

2:43PM	1	A. Yes.
2:43PM	2	Q. Did she have any concerns or objection to that provision?
2:43PM	3	A. No, once we signed it.
2:43PM	4	Q. Okay. What was your understanding as to excuse me
2:43PM	5	as to the specialization of Ms. Mullany?
2:43PM	6	A. What do you mean?
2:43PM	7	Q. In terms of law. Was she a health care lawyer?
2:44PM	8	A. She's a health care lawyer, compliance lawyer, yeah.
2:44PM	9	<b>Q.</b> And if you go down to paragraph 5, this is the
2:44PM	10	compensation provision; is that right?
2:44PM	11	A. Yes.
2:44PM	12	<b>Q.</b> Okay. And it appears that the contractor shall be paid a
2:44PM	13	commission equal to 24 percent of the revenue collected by the
2:44PM	14	company in the sales territory; is that right?
2:44PM	15	A. Yes.
2:44PM	16	Q. And there was some other provision as well, but 24 percent
2:44PM	17	was the overriding percentage throughout most of the contract;
2:44PM	18	correct?
2:44PM	19	A. Yes.
2:44PM	20	Q. And did Ms. Mullany review that provision?
2:44PM	21	A. Yes.
2:44PM	22	Q. And did she have any objections or concerns with that?
2:44PM	23	A. Not when we signed it. We obviously negotiated this
2:45PM	24	number, and
2:45PM	25	Q. Well, and when you signed it, was it had she reviewed

it? 1 2:45PM 2 Yeah, and many others in the company. Α. 2:45PM And were you worried at any -- in any way that it was 3 Q. 2:45PM 4 unlawful in any fashion? 2:45PM 5 Absolutely not. Α. 2:45PM Do you recall whether or not BlueWave was represented by 6 Q. 2:45PM 7 counsel during the negotiations on this contract? 2:45PM 8 Α. Yes. 2:45PM 9 Okay. Do you recall who? 2:45PM 10 No, I don't. Α. 2:45PM 11 And you presented the contract to the board? 0. Okay. 2:45PM 12 Yes. 2:45PM 13 And did the board approve the contract? Q. Okay. 2:45PM 14 The board approved the contract. Α. 2:45PM 15 Q. Okay. 2:46PM 16 I just want to say one comment about this contract. 2:46PM 17 know, I want you -- everybody to put myself in where we were. 2:46PM 18 We were in the early stage company. We had great clinical 2:46PM value -- validation for our technology, and we wanted to access 19 2:46PM 20 the best expertise to sell this product. And BlueWave -- what 2:46PM 21 I like about BlueWave on that particular contract, they believe 2:46PM 22 in the technology, so they can defer the compensation to --2:46PM 23 once we would -- on commission. And to -- I just want to make 2:46PM 24 one point. Is to launch technology and the product line is --2:46PM 25 from scratch takes a lot of effort. And they -- they did spend 2:46PM

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- a lot of time with us.
- Q. Okay. Thank you.

Now, did Singulex offer P&H fees to physicians?

- A. We -- we -- we have to make that available.
- **Q.** Okay.
- A. Yeah.
- **Q.** And do you recall the amount of the P&H fees that Singulex paid -- offered to -- as reimbursement to physicians initially?
- A. I think it's about -- I mean, I'd reviewed before. It's about -- it was \$20.
- Q. And was it at \$20 in the initial stages?
- A. Yes.
- Q. Okay. And did Singulex come to change the amount of P&H fee reimbursement down to \$10?
- A. Yes.
- **Q.** Okay. And why was that?
- A. We wanted to make sure that, you know -- and at that time there was not a hard number of what we should pay on that. And so we wanted to be conservative and make sure that we pay for what it was worth. We didn't have a time and motion study to help analyze exactly how much it would take to draw the blood. So you would -- you would -- you would pay a fair market value for someone to draw the blood. And that's where -- that's what the P&H is for. So we said \$10 was the lowest number among all the number we looked at.

- Q. Okay. And did Singulex have an attorney review the P&H
  control to the part of the part
  - A. Yes.
  - **Q.** And was that Ms. Mullany?
  - A. Yeah.

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- **Q.** Okay. And did Ms. Mullany have any objections or concerns regarding the P&H fee agreement?
- A. No.
- **Q.** Did Singulex have any attorneys on staff?
- A. We -- we had -- yeah, I believe two. Two attorney on staff at that time.
- **Q.** Okay.
- A. Yeah.
- **Q.** And you said it was a -- it was a team effort to review the sales contract with BlueWave; correct?
- A. It was my whole team.
- Q. Okay. And did you also have your whole team review the P&H fee agreement?
- A. Yes.
- Q. Did any -- did any of the internal lawyers that you had at Singulex have any problems with the P&H fee agreement in terms of legality?
- A. No. Once we reviewed everything, you know, we didn't have clear guidance. And so we'd done the best estimate to come up with this \$10, and we were comfortable with it.

2:50 P M <b>1</b>	<b>Q.</b> Okay
2:50 P M <b>2</b>	study?
2:50 P M <b>3</b>	A. Yes.
2:50 P M <b>4</b>	<b>Q.</b> Okay
2:50 P M <b>5</b>	motion st
2:51PM <b>6</b>	A. Abso
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2:51PM <b>9</b>	BY MR. GR
2:51PM <b>10</b>	Q. Can
2:51PM <b>11</b>	A. Yeah
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2:52PM <b>15</b>	Q. But
2:52PM <b>16</b>	A. Yeah
2:52PM <b>17</b>	
2:52PM <b>18</b>	Exhibit 5
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2:52PM <b>22</b>	
2:52PM <b>23</b>	objection
2:52PM <b>24</b>	BY MR. GR
2:52PM <b>25</b>	Q. If y

- So you mentioned something about a time and motion
- Did, in fact, Singulex employ a firm to do time and udy?
- olute, yes.

MR. GRIFFITH: Your Honor, may I approach?

THE COURT: You may.

## RIFFITH:

- you look at this and tell me what it is.
- n. This is the result of a report that assess the cost ming a time and motion study. And it was a range, you assess the time it takes for somebody to draw the It's not precise.
- did you see that document --
- n. I saw that document, yes.

MR. GRIFFITH: Your Honor, I would move BlueWave's 5 into evidence.

> THE COURT: Any objection?

No, sir. MS. SHORT:

MR. ASHMORE: No objection.

THE COURT: Very good. Bluewave 55 admitted without ١.

### RIFFITH:

 $\sigma$ ou can bring up 55, please.

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On the second page. Second page. There you go. And if you can just look at the bottom segment, the bottom three lines.

So when you said that there was a range of the dollar amounts in this particular study, there is -- the last three lines reflect the range which you understood to be the P&H fees?

- A. Yes.
- **Q.** Appropriate?
- A. Yeah.
- Q. And was this -- and were these time and motion studies circulated within Singulex to the whole team?
- A. Yes.

MS. SHORT: Your Honor, may we approach for just a
moment?

THE COURT: You may.

(Whereupon the following proceedings were held at the bench out of the hearing of the jury:)

MS. SHORT: I don't mind this witness testifying about what Singulex did, but I believe the evidence that has been presented to date is that BlueWave never saw this time and motion study, so I don't know how this goes to the defendants' state of mind.

THE COURT: How would that be? I was waiting for that connection.

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MR. GRIFFITH: Well, Your Honor, BlueWave was told that they had a time and motion study, and this reflects that a time and motion study was, in fact, performed by --

THE COURT: Did they tell them the result?

MR. GRIFFITH: And the United States has done a report. Their expert has done an analysis on the time and motion studies that Singulex did.

THE COURT: The question is normally the report would not come -- that would be hearsay, that report, but for the fact it's the state of mind. So I was expecting you to connect that information to one of the defendants.

If they only knew that the -- there was a time and motion study, he can testify to that, because that's their state of mind. But the result, if they weren't informed, then he shouldn't be able to testify to that, because you're coming in as an exception to hearsay because of the state of mind. Do you see the problem? I was expecting you, frankly, to make that connection, that they were told that result. If they were, I think it is admissible. If they were not, then I would sustain their objection.

MR. GRIFFITH: We'll ask him.

THE COURT: Okay. Fair enough.

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

THE COURT: Mr. Griffith, please lay a foundation.

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2	:	5	7	Ρ	M	24
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## BY MR. GRIFFITH:

- Q. So, Mr. Goix, when you got these time and motion studies, were -- you were still in a sales contract agreement with BlueWave: is that correct?
- A. Yes.
- Q. Okay. And the BlueWave-Singulex contract had in it, as we saw, that P&H fees were going to be paid; correct?
- A. Uh-huh. Yes.
- Q. You have to say yes. Okay.

And there was also a compliance provision --

- A. Yes.
- **Q.** -- in the contract.

And so when you obtained the information regarding the P&H studies, was -- were Cal and Brad and BlueWave informed that you had these studies?

- A. Yes.
- Q. Okay.

THE COURT: Did they tell you the result of the studies? Did you give them the specific numbers?

THE WITNESS: Personally, we had -- I'm sorry. This is again, you know, six years in the making. But, you know, we had quarterly meeting with Brad and Cal, quarterly. Every quarter they came.

We -- and, again, this is my recollection. Okay? It's not -- we started to launch the product. We realized

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that, you know, the P&H we set it at \$10. We realized we needed to validate it. We didn't have hot data.

So every quarter the new question, where is the P&H? Do we have those studies? We started to invest money in the study. It took a certain time to do. I don't recall how long. It took some time.

And when it was available, they were the first to know because they were asking always time.

THE COURT: Overrule the objection.

MR. GRIFFITH: Thank you.

THE COURT: Mr. Griffith, we've been going about an hour and a half. Is this a good time to break?

MR. GRIFFITH: It would be a great time.

THE COURT: Ladies and gentlemen, let's take our afternoon break.

(whereupon the jury was excused from the courtroom.)

THE COURT: Please be seated. Are there any matters we need to address?

Is that sort of the type of issues, Ms. Short, you were talking about?

MS. SHORT: Well, to be candid, Your Honor, there are a couple of issues. I think the way -- I think there's a misunderstanding perhaps both by Mr. Griffith and the witness as to what this document is. So I can -- I can deal with it on --

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THE COURT: It came in -- it was admitted without objection, so I don't know why we're arguing about it now.

MS. SHORT: Yes, Your Honor.

THE COURT: I mean, I think your objection would be late.

MS. SHORT: These are the types of issues that I'm concerned about.

THE COURT: I'm all ears when you got one, but once we admit it, it's in, and we're not going to relitigate those issues.

MS. SHORT: And that's fine. There are -- for this particular document, I'm less concerned, but there are a number of documents we were handed this morning where there's either no date on the document or the date on the document is post Mr. Goix's time with Singulex.

THE COURT: Why don't y'all do this? I'm getting ready to take a break. See if y'all can talk it out. If not, I'm glad to take it up one at a time just to keep the trial moving.

MS. SHORT: Yes, exactly.

THE COURT: Very good. Take a 10-minute break.

(Recess.)

THE COURT: Please be seated.

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

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3:17PM

MR. COOKE: Your Honor, one thing. I'm sorry. It's a concern about the concern that the Court expressed, and now may not be the time to bring it up, but at some point I would like a minute to address that with the Court.

THE COURT: What is that?

MR. COOKE: About how your concern about how we've been characterizing Ropes & Gray. The Court has an affidavit from Laura Hoey. I think you may be reading too much into what her lawyer was saying when he said we don't want to call her. What her affidavit says is almost exactly what it's been characterized as.

THE COURT: I would like to look at it. Let's do it at the end of the day. I'd love to look at it. Let me look at it, because I can tell you, I haven't seen it.

MR. COOKE: Right. We talked about it at the hearing about the subpoena. You remember, I commented that, "Well, she doesn't mention in there that they redid the P&H agreements in October," and you said, "Well, that'll make things interesting" or something to that effect.

THE COURT: To be honest with so many documents, I don't remember. I just remember counsel saying you don't want to call her, and that got my attention.

MR. COOKE: Well, and neither of us is calling her.

I think she's one of those witnesses that kind of falls where
neither --

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THE COURT: I inferred from that that she would not give your view a ringing endorsement. I just wanted to make sure that you weren't mischaracterizing her position.

MR. COOKE: We'll pull the affidavit.

THE COURT: But I would like to see the affidavit.

That will help me. Thank you.

Let's bring in the jury.

(Whereupon the jury entered the courtroom.)

THE COURT: Please be seated.

Mr. Griffith, please continue, sir.

MR. GRIFFITH: Thank you, Your Honor. Excuse me.

### BY MR. GRIFFITH:

- Q. So, Mr. Goix, when you were talking about the P&H fee reimbursement that y'all had decided to offer, was -- in your experience, was it more cost-effective to offer P&H fees as reimbursement to doctors as opposed to hiring a phlebotomist?
- A. I don't think I can really answer that question. It really depends on the situation at that time. And -- I mean, if you had once -- if you have one sample a day coming to a practice, it doesn't make sense to hire a phlebotomist for that.
- Q. Well, at the time could Singulex -- at the time in 2010, when you entered into a contract with BlueWave, could Singulex have afforded to get -- to place phlebotomists in doctors' offices?

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              Α.
                   No.
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                   Why not?
              Q.
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                   When you start a product, a company that is starting in
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              the marketplace, you cannot afford to hire, you know, people
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              for everything you do. You leverage your resources for what
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              you're good at, and you try to find partner that knowledgeable
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              in the area you don't know much, and then you cannot afford
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              hiring people. And I will explain, as a CEO for this company,
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              that's very personal, and I don't want to add too much of your
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              time is --
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                   Well, I think the gist of what you're saying is it's just
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              too expensive?
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                    It's way too expensive, and we don't have a lot of cash at
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              that point.
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                           I didn't mean to cut you off, but --
              Q.
                   Okay.
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         16
                   Okay.
                           I apologize.
              Α.
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                   If you need to explain, I want you to, but I think we
              Q.
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         18
              can --
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                   Thank you.
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              Α.
                                I apologize.
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                    Did Singulex at the time in 2010 have a sales force of its
              0.
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              own?
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                         In the laboratory business; right?
              Α.
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                    In the laboratory business?
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              Α.
                    No.
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Was Singulex a full-service lab?

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3:22PM

Q.

No?

3:22PM	1	A. What do you mean by that?
3:22PM	2	Q. Well, did it as compared to HDL?
3:22PM	3	A. No.
3:22PM	4	Q. Was Singulex's offerings more limited than the offerings
3:22PM	5	that HDL provided
3:22PM	6	A. Yes.
3:22PM	7	Q in terms of lab tests?
3:22PM	8	A. Yes.
3:23PM	9	MR. GRIFFITH: Your Honor, may I approach?
3:23PM	10	THE COURT: You may.
3:23PM	11	BY MR. GRIFFITH:
3:23PM	12	Q. I'm going to hand you what's marked as BlueWave
3:23PM	13	Exhibit 149. Can you tell us what it is and look at the
3:23PM	14	signature page?
3:23PM	15	A. Again this is a proposal for a time and motion study.
3:23PM	16	Q. From whom?
3:23PM	17	A. From Grant Thornton.
3:23PM	18	Q. Dated?
3:23PM	19	A. June 20th, 2012.
3:23PM	20	Q. And who is it signed by on behalf of Singulex?
3:23PM	21	A. Philippe I did sign it. I don't have a signature page
3:23PM	22	here. Yeah, signed by me.
3:23PM	23	Q. You signed it?
3:24PM	24	A. Yep.
3:24PM	25	MR. GRIFFITH: Okay. Your Honor, I'd move BlueWave

149 into evidence. 1 3:24PM 2 THE COURT: Any objection? 3:24PM No objection. 3 MS. SHORT: 3:24PM 4 MR. ASHMORE: No objection. 3:24PM 5 THE COURT: Very good. Bluewave 149 admitted without 3:24PM objection. 6 3:24PM 7 BY MR. GRIFFITH: 3:24PM 8 And so can you bring up 149, please. 3:24PM 9 So, Mr. Goix, we're not going to go over this in any 3:24PM 10 detail but just want to confirm that the date was June 20th, 3:24PM 2012; right? 11 3:24PM Right. 12 Α. 3:24PM 13 And Jeff Anderson is -- is identified as the recipient on 3:24PM 14 behalf of Singulex. Who is Jeff Anderson? 3:24PM 15 Α. He was my contract manager. 3:24PM Okay. And the subject is "Singulex, Inc. Time and Motion 16 0. 3:24PM 17 Study." 3:24PM 18 Do you see that? 3:24PM 19 Yes. Α. 3:24PM 20 And so was Grant Thornton one of the firms that you hired 3:25PM 21 to conduct a time and motion study? 3:25PM 22 Α. Yes. 3:25PM 23 Now, did Grant Thornton produce results of their time and 0. 3:25PM 24 motion study to you? 3:25PM 25 Well, you've got to show me the exhibit. I mean it --3:25PM

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- Q. But, I mean, just generally did they?
- A. Yeah. That's what they were hired for. Yeah.
- **Q.** Okay. I'm going to show you what's marked as BlueWave Exhibit Number 74. Do you recognize that?
- A. Do you have a date on it?
  Yeah. Yeah.
- **Q.** And what is that document?
- A. It's, I believe -- it's the communication for procedure for the time and motion study.
- MR. GRIFFITH: Your Honor, I'd move into evidence Bluewave 74.
  - MS. SHORT: Objection. Hearsay.

## BY MR. GRIFFITH:

- Q. Did you provide this information to the defendants, Cal and Brad? Did you discuss this -- the information that's contained in this --
- A. Not necessarily me personally in that level of detail, but someone working for my company did.
- **Q.** Okay.

THE COURT: Well, if he can testify -- he's talking hearsay. Somebody must have told him that.

MR. GRIFFITH: No, he said somebody did provide the information.

THE COURT: How does he know that? Did someone tell you they did?

1	THE WITNESS: We are talking about it's 2012, July
2	2012. Somebody did that, I'm sure, because I
3	THE COURT: Sustained. Hearsay.
4	MR. GRIFFITH: Okay.
5	BY MR. GRIFFITH:
6	Q. Mr. Goix, did you receive other time and motion studies
7	from Grant Thornton? And
8	A. Probably yes.
9	Q. Okay. Did did you, in fact, relay did you, in fact,
10	relay the results of any of the time and motion studies to
11	either Brad Johnson or Cal Dent?
12	A. I believe so.
13	<b>Q.</b> Okay.
14	THE COURT: He needs to identify which ones he
15	specifically told them.
16	MR. GRIFFITH: Okay.
17	THE COURT: Was it more than one?
18	MR. GRIFFITH: Yes, Your Honor.
19	THE COURT: He needs to identify one or more which he
20	did, and then
21	BY MR. GRIFFITH:
22	Q. I'm going to show you what's marked as BlueWave Exhibit
23	Number 44 144. I'm sorry. And if you would look at the
24	second page on.
25	A. The second page to the end?
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Q. Yeah. And what are -- what are the second pages through the end?

- A. Yes. The communication for that motion study. Yeah.
- **Q.** And did you relay this information to either Brad or Cal?
- A. I am sure that either Michael Bell or Jeff Anderson communicated that to Brad or Cal.
- Q. But did you?
- A. Personally, I don't think I got to that level of detail.
- **Q.** Okay. But did you relay any level of detail -- I mean, you had quarterly meetings with them?
- A. Yeah. So I -- to make it clear. Okay? P&H was clearly -- the valuation of this P&H was on our mind. It was on the mind of every member of the team, including Brad and Cal. They were all over that. Everybody, as a team, trying to do the best thing for his teammate, was that motion study, we hired multiple team to do it. Took some time. It took some money to do it. And we did it.

I was all over that because I was fighting an SEC document for the company to go IPO. That was part of the divisions package. So I was not getting in that level of detail.

- Q. But did you -- but -- but not necessarily the details.
  Did you reveal the results of the time and motion study to Brad and Cal?
- A. Sure.

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THE COURT: And what did you reveal?

THE WITNESS: You know, it's a six-year -- I think we were with -- we validated. I'm sure we communicated -- it's hard to --

THE COURT: But did you give them the numbers?

THE WITNESS: Oh, yeah.

THE COURT: I overrule the objection.

MR. GRIFFITH: I move BlueWave 144 into evidence.

MS. SHORT: Same objection.

MR. ASHMORE: No objection.

THE COURT: BlueWave 144 admitted over the objection of the government.

MR. GRIFFITH: Your Honor, with the Court's indulgence, can I revisit BlueWave 74 and just verify that he -- because he -- because I want to ask whether he provided the information, not the detail --

THE COURT: Show him the document and ask him if he specifically provided that information personally to one of the defendants.

### BY MR. GRIFFITH:

- Q. This was BlueWave 74, which we went over previously. Did you provide Mr. Dent or Mr. Johnson with the -- not all the details but with the summary information that is contained in that report?
- **A.** You mean personally?

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Q. Yes. Handing that to them? No, no. Just telling them --Yeah. We -- we had conversation, and, again, six or seven I guarantee you we had conversation. This is the years ago. complete communication of the P&H study that validated the number or the process that is here, because -- I mean, I'm prolonging my answer because, A, it's six or seven years ago. But I'm certain that the whole team was involved in getting So they were asking, I'm sure, you know, where were we in that process and all that. And did you reveal the information? Yeah, the information was provided to them. I'm certain of it. MR. GRIFFITH: Your Honor, I would re-move BlueWave 74 into evidence. THE COURT: In light of the testimony, I overrule the government's objection. MS. SHORT: Thank you. MR. ASHMORE: No objection. THE COURT: Very good. BlueWave 74 admitted over the objection of the government. MR. GRIFFITH: Your Honor, may I approach? THE COURT: You may. BY MR. GRIFFITH:

3:34PM	1	Q. Mr. Goix, can you look at BlueWave 81?
3:35PM	2	A. Yes.
3:35PM	3	Q. And tell me if you recognize it.
3:35PM	4	A. I do.
3:35PM	5	<b>Q.</b> Okay. And what is it?
3:35PM	6	A. This is a Singulex BlueWave quarterly meeting agenda,
3:35PM	7	and
3:35PM	8	Q. What's the date?
3:35PM	9	A. The date was February 21st, 2013.
3:35PM	10	<b>Q.</b> Okay. Thank you.
3:35PM	11	MR. GRIFFITH: Your Honor, move BlueWave 81 into
3:35PM	12	evidence.
3:35PM	13	THE COURT: Is there objection?
3:35PM	14	MS. SHORT: No, sir.
3:35PM	15	MR. ASHMORE: No objection.
3:35PM	16	THE COURT: Very good. BlueWave 81 admitted without
3:35PM	17	objection.
3:35PM	18	BY MR. GRIFFITH:
3:36PM	19	Q. Okay. So I think you testified earlier that you you
3:36PM	20	had quarterly meetings with Brad and Cal?
3:36PM	21	A. Yes.
3:36PM	22	Q. And when you were talking about excuse me your team,
3:36PM	23	were the people listed where it says "Singulex attendees," was
3:36PM	24	that the team? Were those the members of the team to which you
3:36PM	25	were referencing?
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- A. Yes.
- **Q.** Okay. And what was the purpose of these quarterly meetings?
- A. It's very important. Very important meeting. Those quarterly meeting is -- was the purpose to really get the Singulex team and the BlueWave team on the same page on the quarterly basis.

And we started this meeting, I believe, as soon as the collaboration started in 2010 and '11. And I -- I had the process, you know, because required a high level of management to manage this contract due to its importance. So I brought my chief commercial officer, my chief financial officer, director of marketing, you know, the director of billing, and my chief medical officer. And we spent whatever it takes to go through everything that we need to go through to be on the same page and according to the contract we have.

- **Q.** Okay. And was it important to exchange information with Cal and Brad?
- A. It was -- it was very important. It was a two-way street. First of all, when you launch a product, you think you're launching a product but you need feedback. So we got a lot of feedback from Cal and Brad on how to, you know, improve our offering, our service. There was a lot of -- a lot of feedback.

But, for us, it was also very important. And I

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	7	Μ	Ρ	8	3	:	3
	8	Μ	Ρ	8	3	:	3
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considered it one of my key tasks to train the team on the value of our technology as we are going. So there was a lot of education, providing, you know, marketing information to help and support the record.

- **Q.** So let's move away from that real quick. The contract, the sales contract that Singulex had with BlueWave had a provision for an audit?
- A. Yes.
- **Q.** Okay. And did Singulex -- and the audit was to seek a compliance review by someone -- by a firm who specialized in the Anti-Kickback Statute?
- A. Yes.
- Q. Did there come a time when you entered into a contract to have such an audit --
- A. Yes.
- **o.** -- performed?
- A. Uh-huh.

MR. GRIFFITH: Your Honor, may I approach?
THE COURT: You may.

#### BY MR. GRIFFITH:

- Q. I'm showing you BlueWave 150. Can you identify it?
- A. Yes. So it says "BlueWave Healthcare Consulting Independent Compliance Review," March 26th, 2012.
- Q. Did you sign that?
- A. Let me make sure. I probably would sign it, yeah.

3:39PM	1	Yes.
3:39PM	2	MR. GRIFFITH: Your Honor, I'd move BlueWave 150 into
3:39PM	3	evidence.
3:39PM	4	THE COURT: Any objection?
3:39PM	5	MS. SHORT: No objections.
3:40PM	6	MR. ASHMORE: No objection.
3:40PM	7	THE COURT: BlueWave 150 admitted without objection.
3:40PM	8	BY MR. GRIFFITH:
3:40PM	9	<b>Q.</b> All right. So let's look at the date. The date is
3:40PM	10	March 26th, 2012?
3:40PM	11	A. Yes.
3:40PM	12	Q. Okay. And who was Navigant Consulting?
3:40PM	13	A. It was an audit firm consulted by one member of my team.
3:40PM	14	Q. Well, who was Ms. Jean C. Hemphill, Esq.?
3:40PM	15	A. Jean is the manager of the Ballard Spahr legal team,
3:40PM	16	compliance team.
3:40PM	17	Q. Was that the same firm that Mary Mullany was in?
3:40PM	18	A. Yes. She was working with Mary.
3:40PM	19	Q. And and so had you had you asked Ballard Spahr to
3:41PM	20	find someone to conduct a compliance audit?
3:41PM	21	A. Yeah, that was yes. Yeah.
3:41PM	22	Q. Let's go to the second page and the first I guess the
3:41PM	23	second full paragraph.
3:41PM	24	A. Uh-huh.
3:41PM	25	Q. So this paragraph says, "The sales agreement between

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BlueWave and Singulex provides for an annual compliance audit of BlueWave's sales practices by an independent third party who specializes in Anti-Kickback laws and Stark Laws. will serve as Singulex's independent auditor to perform a compliance review of BlueWave's sales practices, with an emphasis on training materials, client interaction, anti-kickback, Stark Law, HIPAA, and other relevant federal and state regulatory compliance."

Do you see that?

- Α. Absolutely.
- And was that -- was that your understanding of the scope 0. that -- of work under which Navigant was going to undertake?
- Α. Yes.
- And did, in fact, Navigant issue a report? Q.
- I believe so. Α.
- Let's go to Bluewave 142, which is, I believe, already 0. admitted into evidence.

Do you recall, Mr. Goix, receiving this report conducted by Navigant in or around September 2012?

- Α. Yes.
- Okay. Q.

Let's go to the second page. All right. And the second -- second paragraph, pull it out, please.

And so this report says, "The sales agreement initiated in 2010 between BlueWave and Singulex provides for an

1 3:43PM 2 3:43PM 3 3:43PM 4 3:43PM 5 3:43PM 6 3:43PM 7 3:44PM 8 3:44PM 9 3:44PM 10 3:44PM 11 3:44PM 12 3:44PM 13 3:44PM 14 3:44PM 15 3:44PM 16 3:44PM 17 3:44PM 18 3:44PM 19 3:44PM 20 3:44PM 21 3:44PM 22 3:45PM 23 3:45PM 24 3:45PM 25 3:45PM

annual compliance audit of BlueWave's sales practices by an independent third party who specializes in anti-kickback and Stark Laws."

Do you see that?

- A. Yes.
- **Q.** And was it your understanding that Navigant was an independent third party who specialized in the Anti-Kickback Statute and Stark Laws?
- A. Yes.
- **Q.** Okay.

Let's go to the next page, please. And can you pull out the third set of -- yeah, there you go.

And on this page, it says, "In order to assess any potential risks, the following documents were reviewed."

And on the bottom, it has this -- the "Singulex process and handling agreement between Singulex and physicians."

Do you see that?

- A. Yes.
- **Q.** And was it your understanding that, in fact, Navigant reviewed the process and handling fees -- fee agreements between physicians and Singulex?
- A. Yes.
- Q. Okay.

Take that off. Now go to the next page.

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And if you'll just please review the overview -- just read it silently to yourself, the overview of Bluewave. And just let me know when you get done.

- A. Yeah.
- **Q.** Okay. In the overview, was there any indication that Navigant had found any violations of the Anti-Kickback Statute in anything that it had reviewed?
- A. No.
- **Q.** And at any time did Navigant tell you or Singulex that it had found any Anti-Kickback Statute violations or concerns?
- A. No.

MR. GRIFFITH: Let's go back to the second page -- or maybe it's the third page and pull out that same section.

# BY MR. GRIFFITH:

- Q. If you look at the next-to-the-last bullet, it says "representative contracts." Do you see that?
- A. Yeah.
- **Q.** Did you provide Navigant with a copy of the sales agreement between BlueWave and Singulex?
- A. Not me personally, but my chief financial officer did.
- **Q.** Okay. And at any time did Navigant inform you or anybody at Singulex that they had any concerns regarding the legality of the sales agreement between BlueWave and Singulex?
- A. No.

MR. GRIFFITH: Your Honor, may I approach?

3:48PM	1	THE COURT: You may.
3:48PM	2	BY MR. GRIFFITH:
3:48PM	3	Q. I'm handing you BlueWave 143.
3:48PM	4	A. Yeah.
3:48PM	5	Q. And do you recognize that?
3:49PM	6	A. I I recognize what it is.
3:49PM	7	Q. Yes.
3:49PM	8	A. Yeah.
3:49PM	9	Q. Did you receive that and review that?
3:49PM	10	A. Not me, but my a member of my team, my CFO, my
3:49PM	11	contract, yeah.
3:49PM	12	Q. Okay. Well, what is it?
3:49PM	13	A. It's a sample collection processing and handling model.
3:49PM	14	Q. And who performed it?
3:49PM	15	A. Pace.
3:49PM	16	Q. And does it have what type of without saying what it
3:49PM	17	is, what type of information is contained in there?
3:49PM	18	A. It's a time and motion study, yeah.
3:49PM	19	<b>Q.</b> Okay. And did you reveal the results of this particular
3:49PM	20	time and motion study to Brad or Cal?
3:49PM	21	A. Again, not me, but probably my a member of my team did.
3:49PM	22	Q. Okay.
3:50PM	23	MS. SHORT: Your Honor, I object. Lacks foundation.
3:50PM	24	THE COURT: Sustained.
3:50PM	25	MR. GRIFFITH: Your Honor, may I approach?

3:50PM	1	THE COURT: You may.
3:50PM	2	BY MR. GRIFFITH:
3:50PM	3	Q. Mr. Goix, do you recognize BlueWave Exhibit Number 82?
3:50PM	4	A. Yes.
3:50PM	5	<b>Q.</b> Okay. And what is it?
3:51PM	6	A. It's a presentation made by Dr. Lebowitz.
3:51PM	7	<b>Q.</b> Okay. And who was Dr. Lebowitz?
3:51PM	8	A. One of our lead doctor cardiologists in New Jersey.
3:51PM	9	Q. Okay. And what is this document specifically?
3:51PM	10	A. It's it explain the value of scientific and medical
3:51PM	11	value of advanced lipid testing.
3:51PM	12	Q. And was this something that Singulex used in its
3:51PM	13	marketing?
3:51PM	14	A. Absolutely.
3:51PM	15	<b>Q.</b> Okay. And did you relay this information to Mr. Dent and
3:51PM	16	Mr. Johnson?
3:51PM	17	A. Yes.
3:51PM	18	<b>Q.</b> Okay.
3:51PM	19	MR. GRIFFITH: Your Honor, I move BlueWave 82 into
3:51PM	20	evidence.
3:51PM	21	THE COURT: Any objection?
3:51PM	22	MS. SHORT: No objection.
3:51PM	23	MR. ASHMORE: No objection.
3:51PM	24	THE COURT: BlueWave 82 admitted without objection.
3:52PM	25	BY MR. GRIFFITH:

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Q. So let's go to the second page. Well, first of all, who --

THE COURT: Is his testimony to provide the substance of the report or the report itself to the defendants?

MR. GRIFFITH: Your Honor, I'm just going to go over the -- I'm not going over the report; I'm just going to ask him to summarize basically the overview of the report. The report's very long.

THE COURT: Well, the question is -- it's only relevant regarding state of mind.

MR. GRIFFITH: Right.

THE COURT: So the question is, what -- if he provided the report to one of the defendants, fine. If he didn't, only specifically what he said, what he told them.

MR. GRIFFITH: Well, he said he --

# BY MR. GRIFFITH:

- **Q.** Didn't you provide this report to the defendants?
- A. Yeah, the purpose of such a report is to help BlueWave, you know, sell the product. So, absolutely, I did share that.

THE COURT: That's fine. Please proceed.

# BY MR. GRIFFITH:

- Q. All right. So let's go to the second page.
- A. I need to see the date. I don't have the date. 2010. Sorry.
- Q. Yeah.

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3:53PM

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Would you just pull that out.

And, just to put it in context, would the doctor here relay this information to other doctors?

- A. Correct.
- **Q.** Okay. And I'm just going to let everybody just read the bullet points. We don't need to go over them one by one.

MS. SHORT: Objection, Your Honor.

MR. GRIFFITH: Okay. Well, then I can -- would you like to read each bullet point?

THE COURT: Well, no. I mean, you're examining your witness. You can do as you wish, Mr. Griffith.

#### BY MR. GRIFFITH:

Q. Well, let's go over them then real quickly. The first bullet point, "statins are completing their second decade."

was that something that you knew?

- A. Yeah.
- Q. Okay. "Statins represent a major advance" --

THE COURT: Well, what he knew was not important. What he told the -- or provided the defendant. And if you've established he gave the report, fine.

MR. GRIFFITH: Okay.

THE WITNESS: Did -- did --

THE COURT: We're not allowing this testimony to come in for the truth of the matter; it's offered for the -- for what the defendants knew.

Understood, Your Honor. 1 MR. GRIFFITH: 3:54PM 2 So let's go to the next page. 3:54PM 3 BY MR. GRIFFITH: 3:54PM 4 Q. And was this information also provided to Mr. Dent and 3:54PM Mr. Johnson? 5 3:54PM Yes. This -- to make it clear -- and I don't want to 6 3:54PM 7 repeat what's in the report, obviously -- when you market a 3:55PM product like this, you stay outside. You let a different 8 3:55PM speaker that is credible in the field -- in this case, a 9 3:55PM cardiologist -- make a presentation to an audience. And that's 10 3:55PM 11 what it is. 3:55PM 12 0. Okay. 3:55PM 13 MR. GRIFFITH: Your Honor, may I approach? 3:55PM 14 THE COURT: You may. 3:55PM 15 BY MR. GRIFFITH: 3:55PM I'm going to show you this real quick and ask you, did you 16 3:55PM 17 ever provide this -- before you go into it, did you ever 3:55PM 18 provide this information to Mr. Dent or Mr. Johnson? 3:55PM 19 Α. Yes. 3:55PM 20 And so what is this? Okay. 3:55PM 21 This is a Singulex code of business conduct and ethics. 3:56PM 22 And did you have this or something similar in place 0. 3:56PM 23 during your tenure at Singulex? 3:56PM 24 Α. Yes. 3:56PM 25 Q. Okay. 3:56PM

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MR. GRIFFITH: Your Honor, I'd move BlueWave 89 into
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3:56PM
          2
               evidence.
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                         THE COURT:
                                      Yes.
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                         Any objection?
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                         MS. SHORT:
                                      No objection.
3:56PM
                         MR. ASHMORE: No objection, Your Honor.
          6
3:56PM
          7
                                     Admitted without objection, BlueWave 89.
                         THE COURT:
3:56PM
          8
                         MS. SHORT:
                                      Your Honor, could we take down the
3:56PM
              previous exhibit?
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3:56PM
         10
                         THE COURT:
                                      Yes.
3:56PM
         11
                                      Thanks.
                         MS. SHORT:
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                                        Your Honor, may I approach?
                         MR. GRIFFITH:
3:57PM
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                         THE COURT:
                                      You may.
3:57PM
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              BY MR. GRIFFITH:
3:57PM
         15
              Q.
                    Do you recognize that?
3:57PM
         16
                    Yes, I do.
3:57PM
         17
                    Okay. And what is it?
              Q.
3:57PM
         18
                    It's the -- it's some clinical data.
              Α.
3:57PM
         19
              0.
                    Okay. Did you provide this information to Mr. Dent or
3:57PM
         20
                   Johnson?
              Mr.
3:57PM
         21
              Α.
                    Yes.
3:57PM
         22
              Q.
                    Okay.
3:57PM
         23
                                       And, Your Honor, I move --
                         MR. GRIFFITH:
3:57PM
         24
                                     I don't know what "clean code data" is.
                         THE COURT:
3:57PM
         25
              What is that?
3:57PM
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THE WITNESS: It's the data that show -- it's an important data set, actually. It's -- it's the data that show that our technology can measure the concentration of troponin that is responsible for heart --

THE COURT: State of mind goes to the issues in context in which their state of mind is relevant. I don't believe that is an issue in the state of mind. That's my concern.

MR. GRIFFITH: Well, Your Honor, we would just say that they were selling these tests. These -- this information goes to the validity of the tests. I mean --

THE COURT: But that's hearsay. You're offering -- I overrule it as hearsay if it's offered for that purpose.

# BY MR. GRIFFITH:

- Q. Okay. Well --
- A. Do I need to --
- Q. No, never mind. Thank you.

Mr. Goix, on this Exhibit 91, did -- was this a marketing material?

- A. Yeah.
- **Q.** Okay. Did BlueWave use this BlueWave 91 document in their marketing efforts?
- A. Yes.
- Q. Okay.

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3:58PM

THE COURT: Can I speak to counsel for a second?

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(whereupon the following proceedings were held at the bench out of the hearing of the jury:)

THE COURT: Mr. Griffith, let me explain. State of mind evidence goes to whether they thought something was lawful. If they told them it was lawful, that's relevant. You are now trying to get substantive medical efficacy evidence in through hearsay. I'm going to sustain the objection. Don't do it again.

MR. GRIFFITH: Okay.

THE COURT: State of mind is, did they think it was legal? Did they tell them it was legal? Time and motion studies are relevant to that, because that goes to their state of mind, but this stuff is just efficacy evidence you're trying to get in through --

MR. GRIFFITH: But they -- there's also the state of mind of whether they were offering medically necessary tests.

And this goes -- and we're offering it to show state of mind that this information underpins the medical --

THE COURT: I'm not going to have medical experts testifying about hearsay, number one.

MR. GRIFFITH: I get it.

THE COURT: But the other part is proper. Okay.

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

THE COURT: Objection sustained.

MR. GRIFFITH: Your Honor, bear with me one second. 1 4:02PM 2 Given your ruling, I'm trying to weed out some --4:02PM 3 THE COURT: Yes, sir. 4:02PM MR. GRIFFITH: -- information. 4 4:02PM 5 THE COURT: I understood what you were doing. 4:02PM MR. GRIFFITH: Your Honor, I'm down to three 6 4:02PM 7 documents. And it might be quicker just for me to hand them up 4:02PM 8 to you and let you look at them. 4:02PM 9 **THE COURT:** I'd be glad to look at them, yes, sir. 4:02PM 10 Hand them to Ms. Ravenel. 4:03PM 11 Mr. Griffith, what's the purpose of Bluewave 176, the 4:03PM 12 specimen collection instructions? What would you be offering 4:03PM 13 that for? 4:03PM 14 MR. GRIFFITH: That is just to show the marketing 4:03PM 15 materials that the defendants were using --4:03PM 16 THE COURT: Okay. 4:03PM 17 MR. GRIFFITH: -- from Singulex. 4:03PM 18 THE COURT: And this is the order form? 4:03PM 19 MR. GRIFFITH: Yes, Your Honor. 4:03PM 20 THE COURT: 214? 4:03PM 21 And BlueWave 177 is their collection handling policy 4:03PM at Singulex? 22 4:03PM 23 MR. GRIFFITH: Right. 4:03PM 24 THE COURT: All those would be fine. 4:03PM 25 MR. GRIFFITH: May I approach? 4:04PM

4:04PM	1	THE COURT: Yes.
4:04PM	2	BY MR. GRIFFITH:
4:04PM	3	Q. Exhibit BlueWave 176, what is that?
4:04PM	4	A. It's a specimen collection instruction procedure.
4:04PM	5	<b>Q.</b> Okay. And is that the specimen collection procedure for
4:04PM	6	Singulex?
4:04PM	7	A. Yeah.
4:04PM	8	<b>Q.</b> Okay.
4:04PM	9	MR. GRIFFITH: Your Honor, I'd move BlueWave 176 into
4:04PM	10	evidence.
4:04PM	11	THE COURT: Any objection?
4:04PM	12	MS. SHORT: No objection.
4:04PM	13	MR. ASHMORE: No objections.
4:04PM	14	THE COURT: Very good.
4:04PM	15	BlueWave 176, is that what it is?
4:04PM	16	MR. GRIFFITH: Yes, Your Honor.
4:04PM	17	THE COURT: Admitted without objection.
4:04PM	18	BY MR. GRIFFITH:
4:04PM	19	Q. And what is BlueWave 214?
4:04PM	20	A. It's the test requisition.
4:04PM	21	Q. And what is a lab test requisition form?
4:04PM	22	A. It's a documentation that is filled by the physician on
4:04PM	23	the tests they want to perform.
4:05PM	24	Q. All right.
4:05PM	25	MR. GRIFFITH: Your Honor, we'd move BlueWave 214 in.

1	THE COURT: Any objection?
2	MS. SHORT: No objection.
3	MR. ASHMORE: No objection.
4	THE COURT: BlueWave 214 admitted without objection.
5	BY MR. GRIFFITH:
6	Q. And BlueWave 177, what is that?
7	A. A specimen collection and handling policy and procedure
8	for the Singulex panel.
9	Q. And what is the date of that effective date?
10	A. June 1st June 1st, 2012.
11	Q. Okay.
12	MR. GRIFFITH: Your Honor, I move BlueWave 177 into
13	evidence.
14	THE COURT: Any objection?
15	MS. SHORT: Hearsay, Your Honor.
16	MR. ASHMORE: No objection, Your Honor.
17	THE COURT: BlueWave 177 admitted over the objection
18	of the government.
19	BY MR. GRIFFITH:
20	Q. And we just a few quick questions. Was there another
21	audit report done of BlueWave in 2013 to your recollection?
22	A. In 2013?
23	Q. '13.
24	A. I would assume so.
25	Q. Okay. Do you know one way or another?
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10	М	Ρ	7	0	:	4
11	М	Ρ	7	0	:	4
12	М	Ρ	7	0	:	4
13	М	Ρ	7	0	:	4
14	M	Ρ	8	0	:	4
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19	М	Ρ	8	0	:	4
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22	М	Ρ	8	0	:	4
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25	М	Ρ	9	0	:	4

- A. I'm not a hundred percent sure, but I would say, yes, I assume so.
- **Q.** Mr. Goix, did you conspire with Brad Johnson or Cal Dent or BlueWave to violate the Anti-Kickback Statute?
- A. No.

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- **Q.** Did you conspire with BlueWave, Brad Johnson, or Cal Dent to violate the False Claims Act?
- A. No.
- **Q.** Do you believe that Singulex filed any false claims to the federal government?
- A. No.
- **Q.** Do you believe that Brad Johnson or Cal Dent caused any false claims to be filed with the government?
- A. No.

MR. GRIFFITH: Thank you.

**THE COURT:** Cross-examination by the government?

#### **CROSS-EXAMINATION**

#### BY MS. SHORT:

- Q. Good afternoon, Mr. Goix. How are you?
- A. I'm good.
- Q. Good. I'm Jennifer Short. I represent the United States in this matter. Just a couple of questions.

I believe you testified that you were hired as Singulex's CEO in order to raise capital, commercialize the company, and bring it to an initial public offering; is that

right? 1 4:09PM 2 Α. Correct. 4:09PM And the shorthand for initial public offering is 3 okay. Q. 4:09PM 4 IPO? 4:09PM 5 Correct. Α. 4:09PM That's when a company goes from being held by a few 6 4:09PM 7 shareholders to being traded on the stock market; is that 4:09PM 8 right? 4:09PM 9 Yes. Α. 4:09PM 10 And you mentioned that you hired Ballard Spahr. 4:09PM 11 true Ballard Spahr was hired to represent you through that IPO 4:09PM 12 process; isn't that right? 4:09PM 13 Yeah, but in a certain function; right? They were not my 4:09PM legal counsel for the IPO. They were focusing on compliance. 14 4:09PM 15 Q. Correct. 4:09PM They were hired to help me with the -- you know, the 16 4:09PM 17 compliance of the BlueWave contract. That was their --4:09PM 18 well, you testified earlier that --Q. 4:09PM 19 Α. Because we had those -- just to clarify, in my board, I 4:09PM 20 had a secretary of the board. And Latham & Watkins was the law 4:09PM 21 firm that drove the IPO process for Singulex --4:09PM 22 0. Okay. 4:10PM 23 -- from a legal standpoint. 4:10PM 24 You spoke earlier about Mary Mullany at Ballard Spahr; 0. 4:10PM 25 correct? 4:10PM

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- Yeah, I hired Mary Mullany to help me with the BlueWave contract.
- And -- okay. Ms. Mullany is a securities law Right. Q. specialist, isn't she?
- I didn't hire -- I mean, it's good to know, but that's not why I hired her for; that was, you know, helping me with the compliance issue and negotiating the BlueWave contract.
- Latham & Watkins was my legal counsel. Latham & Watkins was on the SEC documents. Alan Mendelson was my legal counsel on the SEC document. And they had me draft the document, yeah.
- I understand you hired another law firm to help with the 0. IPO process, but Ms. Mullany, you understand, is a securities law specialist; correct?
- So -- and that's very important, because, when I started, you know, I moved Singulex from St. Louis, Missouri, to San Francisco Bay Area. I hired my corporate legal counsel, Alan Mendelson, who is my -- he's the -- he works at Latham & Watkins. And that is the company that drove the IPO process for Singulex.
- Okay. You understand that Ms. Mullany is not a health care attorney; correct?
- Well, I --Α.
- All right. Ο.
- Okay. So I may have misspoke in that letter. attorney that was driving the BlueWave contract and the

compliance issue. 1 4:11PM And I believe you testified earlier that you were 2 Q. 4:11PM introduced to Bluewave, specifically to Brad Johnson, through 3 4:11PM 4 Gary Tom; is that right? 4:12PM 5 That's correct. Α. 4:12PM And Mr. Tom had been a Berkeley HeartLab employee; is that 6 0. 4:12PM 7 right? 4:12PM 8 Α. Yes. 4:12PM 9 And Mr. Johnson was also a Berkeley HeartLab employee; is Q. 4:12PM 10 that right? 4:12PM 11 Mr.? Α. 4:12PM 12 Mr. Johnson. 0. 4:12PM 13 Yes. 4:12PM 14 In fact, it was BlueWave, wasn't it, who sent the initial Q. 4:12PM 15 draft sales agreement to Singulex; isn't that right? 4:12PM I don't recall. 16 I --Α. 4:12PM 17 They were -- but isn't it right that BlueWave was the one 0. 4:12PM 18 who provided Singulex with the provisions that we looked at 4:12PM earlier, regarding process and handling fees, zero-balance 19 4:12PM 20 billing, those provisions came from BlueWave, not from 4:12PM

I don't recall who -- you know, there was a contract.

hired Mary Mullany and Ballard Spahr, which is big firm, to

help me to manage and negotiate the contract.

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24

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Q.

4:12PM

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4:13PM

Singulex; correct?

Okay.

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4:14PM

are advanced tests.

I don't know who started with the provision. Α. Q. Okay. I don't --Α. Q. You yourself have no experience in commercializing the type of test that you were offering to the market through Singulex; isn't that right? That's -- I was new in this area. Α. Uh-huh. 0. And so I hired the best resources I could to get that. Is it fair to say, Mr. Goix, that BlueWave had some Q. significant leverage over Singulex in those contract negotiations? You know, what -well, because of their sales experience; right? Q. Α. Yeah. Right? So I think --0. There are not many sales force that understand that Α. market. Yeah. I think your words during -- I believe it was 0. during your deposition that you said Bluewave had the channels and the leverage to get Singulex to the market; is that right? So -- yeah, I said that. If I said that, I did. Α. mean by that is the knowledge. These are complex tests.

They were cardiovascular tests.

need -- you know, I could not hire Quest or LabCorp or any of

4:14PM	1	those labs to help me commercialize this test because, you
4:14PM	2	know, they are they are specialized in the routine
4:14PM	3	routine tests. We are specializing in advanced testing.
4:14PM	4	So I believe Brad and Cal at that time were the most
4:14PM	5	knowledgeable executive in the sales area marketing to help me
4:14PM	6	with this test. Yes, I do. So yeah.
4:14PM	7	Q. They had the relationships; correct?
4:14PM	8	A. They did have relationship as well.
4:14PM	9	MS. SHORT: All right. Thank you very much.
4:14PM	10	THE COURT: Mr. Ashmore?
4:14PM	11	MR. ASHMORE: Thanks, Your Honor.
4:14PM	12	CROSS-EXAMINATION
4:14PM	13	BY MR. ASHMORE:
4:15PM	14	Q. Mr. Goix, I'm Beattie Ashmore. I represent Tonya Mallory.
4:15PM 4:15PM	14 15	Q. Mr. Goix, I'm Beattie Ashmore. I represent Tonya Mallory. How are you?
4:15PM	15	How are you?
4:15PM	15 16	How are you?  A. I'm good. How are you?
4:15PM 4:15PM 4:15PM	15 16 17	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?
4:15PM 4:15PM 4:15PM 4:15PM	15 16 17 18	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?  A. Yes, I do.
4:15PM 4:15PM 4:15PM 4:15PM 4:15PM	15 16 17 18 19	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?  A. Yes, I do.  Q. Who is he?
4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM	15 16 17 18 19 20	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?  A. Yes, I do.  Q. Who is he?  A. He's a well-known scientist in testing and involved with
4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM	15 16 17 18 19 20 21	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?  A. Yes, I do.  Q. Who is he?  A. He's a well-known scientist in testing and involved with Berkeley HeartLab. Yeah.
4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM 4:15PM	15 16 17 18 19 20 21 22	How are you?  A. I'm good. How are you?  Q. Good. Do you know Russ Warnick?  A. Yes, I do.  Q. Who is he?  A. He's a well-known scientist in testing and involved with Berkeley HeartLab. Yeah.  Q. He worked at Berkeley HeartLab?

work with him personally at that time. 1 4:15PM 2 Fair enough. Just -- I don't know, so I'm asking. Q. 4:15PM Yeah. 3 Α. 4:15PM 4 Q. But -- so he was a consultant for Singulex? 4:15PM 5 To help, yeah, my chief operating officer with the lab, I Α. 4:15PM believe, with some tests. 6 4:15PM 7 And you knew him when he was at HDL? Q. 4:15PM 8 They all worked at the Berkeley HeartLab. Α. 4:15PM 9 Berkeley. 0. 4:15PM 10 And it turns out that Berkeley HeartLab was located within 4:16PM 11 500 yards from where we were at in Singulex in California. 4:16PM 12 Let me state the obvious. HDL and Singulex are two 0. 4:16PM 13 entirely different entities; correct? 4:16PM 14 Α. Yes. 4:16PM 15 Owned by different people; correct? Q. 4:16PM 16 Yeah. Α. 4:16PM 17 Run by different people; correct? Q. 4:16PM 18 Α. Yes. 4:16PM 19 0. Okay. Nothing to do with each other? 4:16PM 20 No. 4:16PM 21 Can I describe them as friendly competitors? Q. 4:16PM 22 I don't think I met Tonya. I'm -- and I met Russ Yeah. Α. 4:16PM 23 Warnick way after this matter. 4:16PM 24 Now, you testified earlier Singulex changed its 0. Sure. 4:16PM

processing and handling from \$20 down to \$10; correct?

25

4:16PM

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- A. Correct.
- Q. And I believe you said something to the effect that there was not a hard number. Do you remember saying that?
- A. No.
- Q. Essentially.
- A. Yeah.
- Q. Sure. And what did you mean by that?
- A. Well, when you try to listen to how you come up with \$20 or \$15, \$16, \$10, and you start to nickel-and-dime every penny that is done, and then you have to go under which state? How you pay from the test? Who is performing the test? It's complicated.
- Q. Sure.
- A. So we came up with a number, which I think can -- came from the Berkeley HeartLab experience, and then we -- personally, with my team and the advice I got, because I'm not an expert in this field, I wanted to be conservative.
- Q. Sure. And were you aware of what other blood tests were paying in terms of P&H?
- A. We did that. We did the survey. We basically got five or six companies at that time. We knew that.
- Q. Singulex uses just one tube; is that correct?
- A. I don't recall.
- Q. Okay. Do you know when Singulex quit paying the processing and handling fees?

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I don't recall exactly.
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                   Any guesstimate? Can you give me a --
              Q.
4:18PM
                   It's 2017. '14?
                                      Actually, I was out of Singulex, you
          3
              Α.
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          4
              know, in 2013, so --
4:18PM
                         MR. ASHMORE: Okay. All right. That's all I have,
          5
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              Your Honor.
          6
4:18PM
          7
                                    Thank you. Anything on redirect,
                         THE COURT:
4:18PM
              Mr. Griffith?
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          9
                                        No, Your Honor.
                         MR. GRIFFITH:
4:18PM
         10
                         THE COURT:
                                     You may step down. Thank you, sir.
4:18PM
         11
                                      (Witness excused.)
4:18PM
                                     Call your next witness.
         12
                         THE COURT:
4:18PM
         13
                         MR. COOKE:
                                     I'd call Tony Carnaggio.
4:18PM
         14
                                           (Pause.)
4:19PM
         15
                                     Maybe we'll just call whoever comes in
                        MR. COOKE:
4:19PM
              the door. There he is.
         16
4:19PM
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                                            Right here, sir. Please place
                         THE DEPUTY CLERK:
4:20PM
              your left on the Bible and raise your right. State your full
         18
4:20PM
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              name for the record, please.
4:20PM
         20
                         THE WITNESS: Thomas Anthony Carnaggio.
4:20PM
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                         THE DEPUTY CLERK: Can you spell your last name?
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                         THE WITNESS: C-a-r-n-a-g-g-i-o.
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                         THE DEPUTY CLERK:
                                            Thank you.
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                                       (Witness sworn.)
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                                            Thank you. You may be seated
                         THE DEPUTY CLERK:
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	Ī	
4:20PM	1	right over there.
4:20PM	2	THOMAS ANTHONY CARNAGGIO,
4:20PM	3	a witness called on behalf of the defendants, being first duly
2:18PM	4	sworn, was examined and testified as follows:
	5	DIRECT EXAMINATION
	6	BY MR. COOKE:
4:20PM	7	Q. Thank you, Mr. Carnaggio. Would you state your full name,
4:20PM	8	please.
4:20PM	9	A. Thomas Anthony Carnaggio.
4:20PM	10	Q. And we've recently met, and you know that I represent
4:20PM	11	BlueWave and the BlueWave defendants, Mr. Dent and Mr. Johnson.
4:20PM	12	Were you aware of that?
4:20PM	13	A. Yes.
4:20PM	14	Q. Okay. And what do you do for a living?
4:21PM	15	A. I'm a sales representative.
4:21PM	16	Q. For who?
4:21PM	17	A. True Health Diagnostics.
4:21PM	18	Q. Were you formerly a sales representative contractor with
4:21PM	19	BlueWave?
4:21PM	20	A. Yes, I was.
4:21PM	21	Q. Where do you live?
4:21PM	22	A. Irmo, South Carolina.
4:21PM	23	Q. Irmo, South Carolina?
4:21PM	24	A. Yes, sir.
4:21PM	25	Q. Where did you grow up?

4:21PM	1	Α.	Columbia, South Carolina.
4:21PM	2	Q.	Where did you go to school?
4:21PM	3	Α.	Columbia High.
4:21PM	4	Q.	And then where did you go after that?
4:21PM	5	Α.	University of South Carolina.
4:21PM	6	Q.	Did you graduate?
4:21PM	7	Α.	I did, yes, sir.
4:21PM	8	Q.	What did you do after that?
4:21PM	9	Α.	Went to work for Zeus.
4:21PM	10	Q.	And what year was that?
4:21PM	11	Α.	That was 2000 and
4:21PM	12	Q.	1?
4:21PM	13	Α.	Something like that, yeah, because I graduated in 2000.
4:21PM	14	Yes.	
4:21PM	15	Q.	All right. And what did you do at Zeus?
4:21PM	16	Α.	We sold Teflon tubing.
4:21PM	17	Q.	And what did you do in 2004?
4:21PM	18	Α.	I went to work for a medical foods company called Pan
4:22PM	19	Amer	rican Labs.
4:22PM	20	Q.	What's a medical foods company?
4:22PM	21	Α.	It's prescription-grade supplements that the products
4:22PM	22	that	they had were for lowering homocysteine levels and for
4:22PM	23	diab	petic neuropathy.
4:22PM	24	Q.	How long did you do that?
4:22PM	25	Α.	Three years.

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- Q. Did you sell on commission?
- A. There was commission-based, yes.
- **Q.** And at some point did you meet Cal Dent?
- A. Yes, sir.
- Q. When did you meet him?
- A. Somewhere towards the -- somewhere around 2007.
- **Q.** As a result of that meeting, did you go to work for Berkeley HeartLab?
- A. Yes, sir, I did.
- **Q.** All right. Tell us about that, please.
- A. Cal and I worked together. We networked together when I was with the -- when I was with Pan American Labs and worked really well together. And I would -- I would set him up with some -- put him in front of some of the customers that I had because some of the diagnostics that he sold identified homocysteine on the test report which, in turn, I had a product that lowered homocysteine. So we just networked together and, you know, we would discuss those things with the providers.
- **Q.** And so at some point did you decide to come work at Berkeley?
- A. Yes, I did.
- Q. How long did you work there?
- A. About two years.
- Q. Did you receive compliance training at Berkeley?
- A. I believe I did, yes.

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- Did you learn about process and handling fees? Q.
- Yes, I did. Α.
- Did you learn what the purpose of the processing and Q. handling fees was?
- Yes, sir. Α.
- What was it? if you can describe it your own words.
- It was for the time and energy that it takes to draw the Α. blood, spin it down, fill out the paperwork, and then package it up and ship it out.
- And were there other ways that you could get the blood --Q. conceivably get blood to the laboratory?
- Is there other ways to get blood to the laboratory?
- Yeah, other than having the doctor's staff do it. Were Q. there other ways that a laboratory could do that?
- There were some draw sites, I guess, yeah, that the Α. patients could go to.
- How about supplying a phlebotomist? Was that a way? Q.
- You could supply the phlebotomist, yes. Correct. Yes. Yes, we could supply the phlebotomist, yes. I'm sorry. didn't understand the question.
- Could you pay another laboratory to process and handle the specimens?
- Yes, you could. Α.
- was there a compliance attorney named Jonathan Wolin at Q. Berkeley?

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- A. Yes, there was.
- Q. Did you provide compliance training?
- A. Yes, I believe he did. Yes.
- **Q.** During the time that you were there, were you ever instructed that you're not supposed to pay a doctor for referrals?
- A. Yes. You couldn't pay a doctor for referrals, correct.
- **Q.** Were you ever told that paying process and handling fees at fair market value was illegal?
- A. No.
- Q. Were you ever told that it was even a gray area?
- A. No, sir.
- **Q.** Why? Where did they explain to you the dividing line between what you could do and what you couldn't do?
- A. You could pay the practice, but you couldn't pay a physician. That's just what -- that's what we were trained about. There were some -- I guess, some laws that forbid, you know, paying physicians directly.
- **Q.** And were you allowed to pay the practice an exorbitant amount to try to entice them to order more tests?
- A. No, sir. My understanding was that the process and handling was deemed to be fair market value.
- **Q.** Do you know how Berkeley determined what fair market value was?
- A. No, sir, I do not.

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- **Q.** Do you know whether they had legal opinion letters to support their process and handling fees?
- A. I seem to remember that there had been discussions about that, yes.
- **Q.** What about zero-balance billing? Did Berkeley do that at some point?
- A. No, sir, Berkeley didn't have zero-balance billing.
- Q. Okay. During the time that you were there?
- A. That I was there, correct.
- **Q.** Have you ever heard of zero-balance billing by other laboratories?
- A. Yes, sir.
- Q. Other laboratories besides HDL and Singulex?
- A. Yes, sir.
- Q. Okay. Did anybody ever tell you that that was illegal?
- A. No, sir. Not at the time, no, sir.
- **Q.** Did anybody ever tell that you it was illegal to sell on commission?
- A. No. sir.
- Q. Do you remember pro formas ever being used at Berkeley?
- A. Yes, sir, I do.
- Q. Tell us -- tell us what role pro forma -- first of all, what is a pro forma?
- A. It's basically a calculation looking at, you know, a number of, I guess, samples versus how much human resource

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would be, like a phlebotomist versus number of samples.

So it's a -- it's looked at -- at Berkeley it was more for, if they were opening up centers, that they had the justification to be able to do that.

- **Q.** Well, was the -- what exactly were you told about proformas and whether you could provide those at Berkeley?
- A. I don't recall all the -- all the instructions that came along with pro formas, but I just do remember seeing them.
- **Q.** Was a pro forma used to help persuade a doctor to order your tests?
- A. I never -- I never used that, so I can't speak to that.
- Q. You made a reference to making a decision whether to use a phlebotomist or to do the processing and handling fees.

How would it be helpful in that regard?

- A. You give them options on whether or not they could either -- you know, you can either pay the practice a process and handling fee or you could supply a phlebotomist or, you know, some folks didn't take either.
- Q. Were you ever told, while you were at Berkeley, that it was illegal to talk about money to doctors at all?
- A. No, sir, I never -- never heard that.
- **Q.** Did you ever hear that it was illegal to answer questions that doctors might ask you about the financial aspects of testing?
- A. No, sir.

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- **Q.** Did you find that sometimes doctors would ask questions, like "How much might this cost me?" or questions along those lines?
- A. Yeah. They would ask questions about the cost of the -you know, how much the patients, you know, were going to have
  to pay, and they would ask for, you know, how much time and
  effort it would take to draw the blood, things of that nature,
  yes.
- **Q.** Did you find that oftentimes physicians' practice was busy, their staff was busy?
- A. Very much so, yes.
- **Q.** And they were busy before they started doing testing with HDL or Singulex?
- A. Yes, sir.
- Q. So tell us about how you came to work with BlueWave.
- A. At the end of 2009 and on January of 2010, myself, Cal, Brad, Burt Lively, and Richard Yunger, we had seen over the course of the last year our commissions continually steadily had gone down with Berkeley HeartLab because they kept restructuring the commission. And so we just made a concerted effort that we felt like there were other opportunities out there; and, henceforth, HDL was one of those opportunities. So in January we left Berkeley HeartLab.
- Q. Were you familiar with HDL at that time?
- A. Vaguely, yes.

4:29PM	1	Q. How about Singulex?
4:29PM	2	A. Hadn't heard of Singulex at that time, no.
4:29PM	3	Q. Did you know Tonya Mallory before you left Berkeley?
4:29PM	4	A. Not really. I heard the name, but I'd never met her.
4:30PM	5	Q. Did you form a company along with Cal Dent?
4:30PM	6	A. I did, yes.
4:30PM	7	Q. What was the name of the company?
4:30PM	8	A. Hisway of South Carolina.
4:30PM	9	Q. And did that company become a contractor with BlueWave?
4:30PM	10	A. Yes, it did.
4:30PM	11	Q. Did but you were not an owner of BlueWave; is that
4:30PM	12	right?
4:30PM	13	A. I was not an owner of BlueWave, no.
4:30PM	14	Q. But you were an owner of Hisway?
4:30PM	15	A. That is correct.
4:30PM	16	Q. Did Hisway have a code of ethics and compliance?
4:30PM	17	A. Yes, we did.
4:30PM	18	MR. COOKE: May I approach, Your Honor?
4:30PM	19	THE COURT: You may.
4:30PM	20	BY MR. COOKE:
4:30 P M	21	Q. Does that appear to be it?
4:30PM	22	A. Yes, sir.
4:30PM	23	MR. COOKE: I would offer this as
4:30PM	24	THE COURT: What's the number?
4:30PM	25	MR. COOKE: BW209.

We

Is there an objection? 1 THE COURT: 4:30PM 2 No, Your Honor. MR. LEVENTIS: 4:30 P M No, sir. 3 MR. ASHMORE: 4:30 P M 4 THE COURT: Bluewave 209 admitted without objection. 4:30 P M 5 BY MR. COOKE: 4:31PM Could we bring it up for a second, 209, just to --6 0. 4:31PM 7 And I notice this is dated January 4, 2012. Is that 4:31PM 8 when this was formally adopted? 4:31 P M 9 Α. Yes. 4:31PM 10 Did you follow the principles of ethics that were set out 4:31PM 11 there? 4:31PM 12 Yes, sir. Α. 4:31PM 13 why did you think it was important to have a code of Q. 4:31PM 14 ethics? 4:31PM 15 Because that's the way that we ran our business. Α. 4:31PM 16 always liked to stay aboveboard. 4:31PM 17 Who is we? Q. 4:31PM Myself and Cal. 18 Α. 4:31PM Did you -- I won't make this a leading question. 19 0. 4:31 P M 20 what, if anything, did you find about Cal's integrity 4:31PM 21 in doing business with him? 4:31PM 22 Cal is -- has some of the best character of any individual 4:31PM 23 I've ever met in my life. He's been a mentor to me. 4:31PM 24 0. Did he ever in any way try to encourage you to skirt the 4:32 P M 25 law or to come close to the line or to press the line of the 4:32 P M

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law in any way? No, sir. Α. Did you receive compliance training at BlueWave? Α. Yes, sir. what did you feel like the sense was? Was it one of these 0. things where they tell you one thing but they kind of wink and suggest that maybe there's an easier way to do things? that the mentality of BlueWave? No, sir. They were very adamant about things that they put in place and processes to make sure that we held fast to the trainings that we had. Did you do ride-alongs with Cal? 0. Yes, sir. Α. Did you ever do any with Brad? Q. Α. Yes, I did. Would you tell the jury in your own words what you 0. observed and how they conducted themselves on the ride-alongs that you accompanied them on? Cal was more of a clinically based person to sell. a God-given gift to be able to retain information. things that I really admired about him, he used to read one to two clinical trials a day, and he could really quote them verbatim, whereas Brad was more relational as far as his sales techniques. So both were very effective.

Did they -- what would they talk to the doctors about when

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they came into the office?

- A. About what they were currently -- the diagnostics they were currently using. And, you know, most of the times with Cal, it was more of a case study-based scenario. So we would bring a case study in and show the doctor the lipid panels and things we're currently utilizing and the diagnostics HDL provided and how you could pick up on a lot of disease that you typically wouldn't with a traditional lipid panel.
- **Q.** How often would they use process and handling fees as an incentive to the doctor to order tests?
- A. Those conversations usually didn't take place until the very end of the presentations, and that was really the physician sparked those.
- **Q.** And what would they tell the doctor about process and handling fees?
- A. It was to offset the time and energy that the phlebotomist used to draw it, spin it down, package it up, fill out the paperwork, and ship it.
- **Q.** Did you ever hear either Brad or Cal use the availability of processing and handling fees as an attempt to influence a doctor to order tests?
- A. No, sir.

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- **Q.** Well, how did they convince a doctor to order tests?
- A. The clinical utility of the tests -- like I said, we would spend -- we'd go into an office, and they'd say, "You've got 15

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minutes," and we'd end up being there for an entire hour just going over the clinical data, looking at the case study, and talking to physicians about -- about the utility of the tests.

- **Q.** Well, these doctors were not already customers of yours when you'd come in, typically; right?
- A. Can you repeat that question, please.
- Q. Am I correct that most of these doctors that you would visit with them were not already HDL or Singulex customers?
- A. That is correct.
- Q. So how could you convince a doctor who maybe is either using another laboratory or is not using advanced lipids at all to -- to become a customer?
- A. A lot of the physicians would openly admit that -- you know, one of the things that the data would state was that half the patients would still go on to have heart attacks and strokes when they traditionally would have a very nice, beautiful lipid panel, and still 50 percent of those patients go on and have events. So there's something missing.

And so utilizing the case study, you would show where patients who had been treated goal. With their traditional lipid panels, there were still a lot of lipid proteins that are not traditionally utilized that would pick up on a lot of risk.

- Q. Did you find that they were able to answer the questions the doctors would ask about the clinical utility?
- A. Yes, sir.

```
Especially Cal?
          1
              Q.
4:36PM
          2
                    Absolutely.
              Α.
4:36PM
                    All right. Did he actually have documentation to support
          3
              Q.
4:36PM
          4
              the --
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          5
                    Yes, he did.
              Α.
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                    -- tests?
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              0.
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                         And you did receive compliance training?
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          8
                    Yes, sir.
              Α.
4:36PM
                                     Your Honor, may I approach?
          9
                         MR. COOKE:
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         10
                         THE COURT:
                                      You may.
4:36PM
         11
              BY MR. COOKE:
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                    I'm going to ask you to look at that and see if that looks
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              like an email addressed to a lot of people and see if you're in
4:36PM
         14
              there.
4:36PM
         15
              Α.
                    Okay.
4:36PM
         16
                 Are you on there?
              0.
4:36PM
         17
                    Oh, am I on here?
                                        I'm sorry.
              Α.
4:36PM
         18
                    Probably should have told you ahead of time I was going to
              Q.
4:37PM
         19
              ask you that question.
4:37PM
         20
                    I see everybody else on here. I should be on here.
                                                                            I'm
4:37PM
         21
              looking.
4:37PM
         22
                    Well, I will tell you what. Why don't we move on?
              Q.
4:37PM
         23
                    Yes, I see myself.
              Α.
4:37PM
         24
              Q.
                    Okay. Good.
                                  Where?
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         25
                    I was down on the bottom.
              Α.
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4:37PM

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MR. COOKE: Offer -- it's actually marked as Plaintiffs' Exhibit 1269.

THE COURT: Is there objection?

MR. LEVENTIS: No objection, Your Honor.

MR. ASHMORE: No objection.

THE COURT: Plaintiff 1269 admitted without objection.

MR. COOKE: And can you get that one up there, John?

BY MR. COOKE:

Q. This shows a -- an announcement of a legal conference call on Friday, December 21st, 2012, at 2 p.m. central time. And here's an agenda: P&H draw fee. No-balance billing. How to present anti-kickback. Registered dietician, what can they to? How to offer? And the \$372 amount.

Do you know what that refers to, the \$372?

- A. I believe that's the Sunshine Act. You couldn't exceed that much on any particular provider per year.
- **Q.** And does this look like a fairly typical agenda that you might have on one of these compliance training conference calls?
- A. Yes, sir.
- Q. And who typically would present the program for those?
- A. Sometimes it was Cal. Sometimes it was Brad. Depending on what it was, sometimes it was someone within the lab.
- Q. Would there ever be an attorney presenting?

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Sometimes it could have been an attorney, yes.
          1
              Α.
4:39PM
                   And, again, on any of these calls, was there ever a sense
          2
              Q.
4:39PM
              that, you know, we just have to do this for the record, but
          3
4:39PM
          4
              it's not really serious stuff?
4:39PM
          5
                   No, they're very serious.
4:39PM
                   Can you recall ever being called down for getting too
          6
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          7
              close to the line or for anything along those lines when you
4:39PM
              were with Cal or Brad?
          8
4:39PM
          9
                   I was corrected fairly often just because sometimes I
4:39PM
         10
              would misquote things and Cal would bring it to my attention.
4:39PM
         11
              He'd say, "Hey, you know, you said this. It might have been
4:39PM
              better if you would have said this." So --
         12
4:39PM
         13
                   All right. And did you ever use process and handling fees
4:39PM
         14
              as a selling inducement in your presentations?
4:39PM
         15
              Α.
                   No, sir.
4:39PM
         16
                   Do you ever recall delivering a process and handling check
4:39PM
         17
              in person?
4:40PM
                   I don't recall doing that.
         18
              Α.
4:40PM
         19
              0.
                   Let me just -- I'm going to show you --
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         20
                                     May I approach again, Your Honor?
                         MR. COOKE:
4:40PM
         21
                         THE COURT:
                                     Yes.
4:40PM
         22
              BY MR. COOKE:
4:40PM
         23
                   This is just an email that's come up in the course of this
4:40PM
         24
              case.
4:40PM
         25
                   Okay.
              Α.
4:40PM
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21	М	Ρ	1	4	:	4
22	М	Ρ	1	4	:	4
23	М	Ρ	1	4	:	4
24	М	Ρ	1	4	:	4
25	М	Ρ	1	4	:	4

- Q. Do you remember seeing that?
- A. I saw it not too long ago.
- **Q.** Okay. Does it jog your memory at all?
- A. I don't recall it. I mean, this is -- if it was a scenario, the reasons, I mean, it was a one-off scenario.
- Q. But that is an email from you?
- A. Yes, it is.

MR. COOKE: I would offer that into evidence.

THE COURT: What number is it?

MR. COOKE: I'm sorry. It's Plaintiffs' 1224.

THE COURT: Any objection?

MR. LEVENTIS: No objection, Your Honor.

MR. ASHMORE: No objection.

THE COURT: Plaintiffs' 1224 admitted without objection.

MR. COOKE: Can we go ahead and bring it up.

# BY MR. COOKE:

Q. All right. Now, it says, "Hey, Keren." This was back in October of 2011.

"Hey, Keren. I know we discussed separating the P&H log by each doctor for this practice."

It's Colonial Family Practice. Where were they? Do you remember?

- A. They were in Sumter, South Carolina.
- Q. "But I need to make sure the first P&H check gets sent to

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4:41PM

my home so I can hand-deliver it to the docs. When are the checks typically sent?"

Can you think of any reason why on that occasion you'd have had to deliver the check?

- A. They went through some construction at one point in time. And when you said Colonial Family, I mean, it could have been they weren't getting their mail. It could have been that something -- several different reasons why. But it wasn't something that I typically did. So if the physician had asked me to do it, then I didn't see a reason not to.
- **Q.** Okay. But would you, like, have a celebration by hand-delivering the P&H checks or anything like that?
- A. No.
- **Q.** Okay.

Do you remember any situations where questions in the field might be raised about whether you could pay P&H fees?

- A. I don't recall any situations in the field coming to light about paying P&H fees, no.
- **Q.** All right. We're going to talk about Heritage Medical in iust a little while.
- A. Okay.

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4:43PM

- **Q.** But before I get to that, I'm wondering if you can remember ever being asked for a pro forma from a -- from a doctor.
- A. I mean, the one that you showed me earlier, I don't really

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4:44PM

recall seeing a -- or the pro forma is -- usually, when discussions happened, it was just pro forma that you could do in your head. But it was really -- Berkeley HeartLab had one, but there was nothing that we carried around with us for the doctor's office to show them. I don't recall that.

Q. Let me show you an exhibit that's already in evidence. It's United States Exhibit 1004. And this is just a -- it's an email from you to Nancy Netter.

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

Do you remember that?

- A. I don't -- I don't typically recall that email, no.
- Q. Okay. No, but do you remember Dr. Netter?
- A. Oh, absolutely. Yes, I know Dr. Netter.
- Q. Can you tell us anything about Dr. Netter that would explain why you were asked to forward a pro forma to Dr. Netter?
- A. I don't recall the actual email, but I know that she ended up with a phlebotomist in her office. So maybe she was looking at it from the standpoint of -- you know, as far as putting a phlebotomist in her office.
- Q. Was there anything in your training up to that point that had suggested to you that you're not allowed to talk to a

4:45PM	1	doctor about something like that?
4:45PM	2	A. No.
4:45PM	3	Q. So what you said was that she wound up hiring a having
4:45PM	4	the lab put a phlebotomist in her office?
4:45PM	5	A. That's correct. Uh-huh.
4:45PM	6	Q. And, again, had you seen that happen with other
4:45PM	7	laboratories and in other situations?
4:45PM	8	A. Sure.
4:45PM	9	Q. It's fairly common?
4:45PM	10	A. Yes.
4:45PM	11	Q. And so would sometimes a doctor have to try to figure out
4:45PM	12	whether it would make more sense to have a phlebotomist versus
4:45PM	13	using their own staff?
4:45PM	14	A. Sure. Yep.
4:45PM	15	<b>Q.</b> During the time that you were at Berkeley, or anywhere
4:45PM	16	else, did anybody in your legal training tell you that you
4:45PM	17	can't talk about money at all to a doctor who asks a question?
4:45PM	18	A. No, sir.
4:45PM	19	Q. Did you believe you were violating the Anti-Kickback
4:45PM	20	Statute in some way by or any law by sending
4:45PM	21	accommodating that request for a pro forma?
4:45PM	22	A. No, sir.
4:46PM	23	MR. COOKE: Would you put up Mallory 44.
4:46PM	24	BY MR. COOKE:
4:46PM	25	Q. Do you know what this is?

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- Yes, sir. Α.
- What is it? Q.
- It's a new account form. Α.
- Q. Okay. And how would you use that?
- For when a physician wanted to -- wanted to sign up for -with -- with HDL for their diagnostics, or they wanted to change, either add or subtract, tests from their current panels.
- And did you explain to the doctors how they would go about indicating the tests that they wanted?
- Yeah, they -- yes. They would usually do that after going through the case study and they decided that they wanted to utilize the diagnostics. Then they would be able to pick which diagnostics they wanted to use. And then they would sign off on it, and we'd create the requisitions.
- Did you have a minimum number of tests that a doctor was 0. required to order?
- No, sir. Α.
- were doctors allowed to select whatever combinations they 0. wanted?
- Yes, sir. Α.
- Could they create their own panels? Q.
- Α. Yes.
- Q. Did they do that?
- Yes, they did. Α.

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- **Q.** How well received were these HDL and Singulex tests by the -- by your customers?
- A. They were received well. That's how they became customers, yeah.
- Q. Did you ever have anybody express appreciation to you for --
- A. Oh, there was -- there was -- they would have stories all the time. The physicians would contact us, especially when we had test reviews, and they would sing praises about the diagnostics and how -- how clinical -- how they were able to use them in the clinical setting and save people's lives.

That happened all the time.

- **Q.** Did any of them ever suggest to you that these tests were shams or fake tests or anything like that?
- A. Not to my knowledge.
- **Q.** I hate to put you on the spot like this, but were you successful in selling these tests?
- A. I think -- I think we were successful as a company, yes.
- Q. And how about in your territory? Did you do pretty well?
- A. Yes.
- Q. Let's talk about Dr. Mayes. Do you know Dr. Mayes?
- A. Yes.
- Q. Do you know the Heritage Medical Practice?
- A. I do.
- Q. Is that where you practiced, at Hilton Head?

	1	A Voc
4:48PM	1	A. Yes.
4:48PM	2	Q. And was it so they were your customer?
4:48PM	3	A. They were initially a Berkeley HeartLab customer, which
4:48PM	4	was at the time, they were not my responsibility; they were
4:49PM	5	someone else's. But, yes, they were an HDL customer.
4:49PM	6	Q. And when did they become an HDL customer?
4:49PM	7	A. Sometime, I believe, in 2011 or 2012.
4:49PM	8	Q. Did you know Michael Mayes?
4:49PM	9	A. I didn't know him personally, no.
4:49PM	10	Q. Did you know did you ever deal with him?
4:49PM	11	A. I met with him a few times.
4:49PM	12	Q. Do you did he ever happen to mention to you that he had
4:49PM	13	secretly filed a lawsuit?
4:49PM	14	A. No, he did not.
4:49PM	15	Q. Did he ever mention to you that he was secretly recording
4:49PM	16	telephone conversations with you?
4:49PM	17	A. No, sir, he did not.
4:49PM	18	Q. Have you had occasion to hear that telephone conversation?
4:49PM	19	A. I have.
4:49PM	20	Q. And do you recall him asking you about your tests?
4:49PM	21	A. Yeah. He did ask about some of the clinical utility for
4:49PM	22	the tests, yes.
4:49PM	23	Q. Did he ask you some questions about process and handling
4:49PM	24	fees?

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4:49PM

Yes, he did.

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- And what did you tell him? Q.
- I answered his question about the processing and handling. Α.
- Okay. Q.

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- Α. He asked about HDL and Singulex, and I answered the question.
- Did you talk about the medical utility of the tests? Q.
- Α. Absolutely. Uh-huh.
- Is what's on that recording pretty typical of the way you 0. would have answered a doctor's questions whether you knew you were recorded or not?
- Α. Yes.
- Did you notice that -- any part of your conversation that didn't make it onto the recording?
- One of the things that we typically talk about, especially when doctors ask about processing and handling, is that there's always opportunities there, meaning they can either utilize processing and handling, a phlebotomy option is also there. And, once again, some practices just didn't take processing and handling at all. So you really had three different options.
- was that at the very end of your conversation?
- Yes, sir. Α.
- And did that make it onto the audiotape? Ο.
- I didn't hear it. Α.
- So was the audiotape cut off before your conversation Q. ended?

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- A. I'm not a hundred percent sure, but it seems that way.
- **Q.** Okay. Do you remember attending a meeting at the request of the Heritage practice?
- A. Yeah. There were a few meetings, yes.
- Q. Do you remember one in the spring of 2013? Do you remember one where Cal Dent came and Dr. Hollins came?
- A. Yes.
- Q. Tell the jury in your own words what happened then, please.
- A. Doctor -- the practice had requested a cardiologist come down and talk to them about some of the clinical utility of the tests. Dr. Hollins had been a long-time customer. He was also a lipidologist. And so he came down and did a presentation for the group. I believe they had been testing for a little while when that happened.
- **Q.** Do you remember anybody asking a question of anybody about process and handling fees?
- A. It seems like there was a question asked of Dr. Hollins, and I think they reverted it -- I think they reverted that back to Cal.
- Q. And what did Cal say?
- A. He said that -- I think it had already been discussed and they had been set up. So I don't think that the processing and handling question that he had -- that they had asked, he didn't really -- I think that they had already addressed it with the

4:52PM	1	practice manager.
4:52PM	2	Q. Did either Dr. Hollins or Mr. Dent say anything at that
4:52PM	3	meeting to suggest that P&H fees were should be considered
4:52PM	4	an enticement to order more tests?
4:52PM	5	A. No, sir.
4:52PM	6	<b>Q.</b> Did you say anything like that?
4:52PM	7	A. No, sir.
4:52PM	8	Q. Let me show you Plaintiffs' Exhibit 1571, which I think is
4:52PM	9	already in evidence.
4:53PM	10	MR. LEVENTIS: No, but I don't object.
4:53PM	11	THE COURT: Do we have 1571 in?
4:53PM	12	THE DEPUTY CLERK: No.
4:53PM	13	MR. COOKE: I'm going to show it to him.
4:53PM	14	BY MR. COOKE:
4:53PM	15	Q. Okay. Is that an email from you to Michelle at Heritage
4:53PM	16	Medical Partners?
4:53PM	17	A. Yes.
4:53PM	18	MR. COOKE: I would offer Plaintiffs' 1571?
4:53PM	19	MR. LEVENTIS: No objection, Your Honor.
4:53PM	20	MR. ASHMORE: No objection.
4:53PM	21	THE COURT: Plaintiffs' 1571 admitted without
4:53PM	22	objection.
4:53PM	23	BY MR. COOKE:
4:53PM	24	Q. This is dated August 17, 2012. "Hey Michelle, here's the
4:54PM	25	P&H position letter. Let me know if Dr. Mayes has any further

questions." 1 4:54PM 2 So I was -- back in 2012, was Dr. Mayes asking you 4:54PM 3 for your legal justification for process and handling fees? 4:54PM 4 Α. Yes, sir. 4:54PM 5 Go ahead and show the second page, just MR. COOKE: 4:54PM so we can see what you sent. 6 4:54PM 7 BY MR. COOKE: 4:54PM And is this the May 1st, 2010, HDL position statement? 8 0. 4:54PM 9 Α. Yes, sir. 4:54PM 10 Is that what you were provided to give to anybody who had Q. 4:54PM 11 a question about process and handling fees? 4:54PM 12 Yes, sir. Α. 4:54PM 13 You currently work for True Health? Q. 4:54PM 14 Α. T do. 4:54PM 15 And do they sell the same tests that HDL sold? Q. 4:54PM 16 They do. A lot of the same, yes. Correct. Α. 4:54PM 17 All right. And is there still a demand for those tests? Q. 4:54PM 18 Yes, sir. Α. 4:55PM Did you also sell for Singulex? 19 0. 4:55PM 20 I did, yes, sir. 4:55PM 21 And did you encourage doctors to order both HDL and 4:55PM 22 Singulex tests so they could get an extra P&H fee? 4:55PM 23 No, sir. Α. 4:55PM 24 How many of your customers would typically order both HDL Q. 4:55PM 25 and Singulex tests together? 4:55PM

I don't know the exact number. It might have been, as a 1 4:55PM 2 percentage, maybe a smaller percentage, maybe 30 percent, 4:55PM something around there. 3 4:55PM 4 Q. Do you believe that your customers stopped ordering tests 4:55PM 5 from HDL and Singulex because they were no longer being paid 4:55PM process and handling fees? 6 4:55PM 7 No, sir. Α. 4:55PM 8 Why don't you think so? 0. 4:55PM 9 So a lot of physicians were -- I'll just use the word 4:55PM 10 "scared" when they -- when there was information out there 4:55PM 11 where they talk about fraud and anti-kickback and Stark. And a 4:56PM lot of the doctors just kind of took a step back and said, "I 12 4:56PM 13 don't want to have anything to do with that." 4:56PM 14 Are a lot of the doctors, though, that used HDL now using 4:56PM 15 the tests with your current employer, True Health? 4:56PM 16 Yes, sir. Α. 4:56PM 17 Just a moment. 0. 4:56PM 18 (Pause.) 4:56PM 19 BY MR. COOKE: 4:56PM 20 Do you happen to know, when you were at Berkeley HeartLab, 4:56PM 21 whether there were some areas in the country where there's --4:56PM 22 zero-balance billing was offered? 4:56PM 23 Yes, sir. Α. 4:56PM Do you know -- do you happen to know whether there is even 24 0. 4:56PM 25 such a thing as balance billing for Medicare? 4:57PM

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- A. I don't believe there is, no.
- Q. Okay. Did you -- during any of the time that you worked for Berkeley or at -- at Bluewave, did you ever even hear that there might be a difference in whether you could balance bill TRICARE versus Medicare?
- A. No. sir.
- **Q.** Did you ever, ever try to skirt the law, break the law, bend the law in any way to try to increase your sales?
- A. No, sir.
- **Q.** For any reason at all?
- A. No, sir.

MR. COOKE: Thank you.

THE COURT: Mr. Leventis, how long do you think your cross is going to be?

MR. LEVENTIS: I was afraid you were going to ask me. I was looking at the time, Your Honor.

THE COURT: Yes, I want to be respectful of my jury.

MR. LEVENTIS: Absolutely.

THE COURT: It's been a long day.

Ladies and gentlemen, let's call it a day. I just think I'm asking too much of y'all. Y'all are paying great attention, but it's 5:00.

I had hoped, when we started the trial, we would finish by Friday. We're not going to do that. As much as we try -- you see we bring one witness in right after another --

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it's -- we're just not going to be able to do it. I'm hoping to finish Monday, could be Tuesday. But we're going to keep pushing hard, and I'm pushing the lawyers when y'all aren't here to keep this thing moving. But they're all working hard. You can see that. And we're just doing the best we can.

So I'm breaking my statement to you earlier that I told you I was going to try to get it done in two weeks. course, we had MLK day, so we missed a day. But I had still hoped to do it, but we're not going to be able to do it.

So we're going to break for the day. I'll see you at 9:00 tomorrow morning. Travel safely. Do not discuss the case with anyone.

Mr. Carnaggio, wait just one second.

(Pause.)

THE COURT: Very good. Please be seated.

Mr. Carnaggio, you're going to feel kind of lonesome tonight because you're on the witness stand and nobody can talk They're not being unfriendly to you. Once you're on to you. the stand, no one is really to communicate with you about dealing with the case. Okay? So you'll probably be a little lonesome tonight. 0kay?

THE WITNESS: Okay.

THE COURT: Very good. You're able to leave for the day. You can leave that, yes, sir.

(Witness excused.)

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THE COURT: Let me -- Mr. Cooke referenced to me the affidavit of Ms. Hoey, which I frankly did not remember. It's, for the record, 503-16 that was filed with the Court earlier.

And it makes reference to the -- to the Kung letter of 8/30/12, August 30, 2012, which is an exhibit in the trial, but it's also on the docket at 500-12. And the issue was a concern I had raised on whether Ropes & Gray and Ms. Hoey's opinions were being suggested to the jury to be contrary to what they were. And I had made referral to the fact that her very fine counsel had raised questions in an earlier hearing that suggested to me that the opinion would not be indicating that they thought that the -- that process and handling fees were unlawful.

I've now reviewed the Hoey affidavit again. And I do remember it now that I've looked at it. Let me just highlight some of the parts that concern me.

Paragraph 5. "As part of our work, Ropes & Gray reviewed numerous documents, including an April 2012 letter to HDL president and chief executive officer Latonya Mallory from Michael F. Ruggio, Esq., of LeClairRyan, referred to as the Ruggio letter; an August 30, 2012, memorandum to the HDL board of directors from Derek W.H. Kung, Esq., the general counsel of HDL." And she refers to that as the Kung memorandum.

Paragraph 6. "Ropes & Gray generally concurred with the advice conveyed in the Kung memorandum regarding HDL's

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practice of making certain process and handling fee payments to physician practices."

Then she goes on in paragraph 7 and says,
"Specifically, in or about spring of 2013, Ropes & Gray advised
HDL's board of directors, A." And first point under A is "the
practice of paying process and handling fees was a red flag
from the Office of Inspector General of the Department of
Health and Human Services, OIG, that led to increased scrutiny
of HDL's business practices by OIG and the Department of
Justice.

"B. HDL's" -- this is what she's conveying she told the board. "HDL's continued payment of processing and handling fees posed a high-risk level of risk that the Department of Justice could consider the payments to constitute violations of the Anti-Kickback Statute and the Stark Law and could initiate criminal proceedings under the Anti-Kickback Statute or civil claims under the False Claims Act against HDL based on the payment of the P&H fees.

"C. The conclusions set forth in the Ruggio letter that HDL payments of P&H fees were within safe harbor exceptions under the Anti-Kickback Statute and False Claims Act was not correct, and HDL continued payment of P&H fees did not fall within any recognized safe harbor to the Anti-Kickback Statute.

"D. In view of the risk posed by the continued

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payment of P&H fees and the absence of a safe harbor exception, Mr. Kung's recommendation that HDL should consider alternatives that would permit HDL to terminate these payments was prudent, and HDL should therefore seek to phase out the practice of paying P&H fees."

And "E. Going forward, HDL could no longer rely on the Ruggio letter as a basis for the advice of counsel or good-faith defense in any criminal or civil proceedings about those practices brought by the Department of Justice."

Now, that is very different from what's being communicated to the jury. And I am concerned about it. I'm going to tell you that right now, Mr. Cooke. I think that -- I've re-read the Kung letter and specifically the exception on processing and handling fees. And she says she told them that she agreed with that.

I am very concerned that we could be creating a false impression about at least what Ms. Hoey said to the board, and I think we need to be careful how we represent that.

MR. COOKE: Well, Your Honor, I think that is, in many ways, a focal point of the case, a fulcrum of the case.

And, with all due respect, we have gone to great lengths to emphasize their advice to, quote, move away from processing and handling fees, which is exactly --

THE COURT: That markedly understates. I have a responsibility under 403 not to have the jury misled.

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That markedly misstates the advice she has summarized in her affidavit. And I am just very concerned -- now, if your client has a different memory about that, you know, that's one thing. But you've been representing what they -- and you've referred me to this affidavit. And this affidavit -- I -- frankly, when I saw it -- I mean, I had kind of an impression what her opinion was, but I didn't remember the affidavit. When I looked it over, I kind of know where that impression came from.

And I am concerned. You know, you're -- this is -this scienter requirement is a very unusual -- we all know that
none of us have tried -- outside of this statute have ever
tried a case in which so much hearsay came in, but for a
limited purpose. And that's for the purpose of the state of
mind of the defendants.

But it's being represented, really, by counsel that she thought this was fine and that the adjustment -- the change in the process and handling policy reflected a belief that that was lawful. We all know -- we represent clients. I'm not that far from practicing to know this. You represent clients, and you did the best where you were. You advocated for your client. That's what you did. And if you -- in your heart of hearts, you might not really totally agree with what they're doing, but they have a right to be represented and passionately and zealously represented. But that doesn't mean they believe

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it.

And I'm just concerned that the jury is being misled by these -- frankly, not by the evidence offered by your clients but, frankly, by comments by counsel, leading questions by counsel.

So I'm going to -- you know, I'm concerned about it.

I started -- and, frankly, you directed me to these, and I'm
more concerned after I read them again.

MR. COOKE: May I be heard?

THE COURT: You may.

MR. COOKE: Your Honor, we strongly disagree.

First of all, as I pointed out at the hearing regarding the subpoena, we thought it was very curious that Ms. Hoey neglected any mention of what happened after that meeting, that she neglected mention of the fact that they had redrafted the --

THE COURT: You think this document is misleading?

MR. COOKE: I think it's incomplete. And, with all due respect, we do not see a distinction between saying that they should seek to phase out the practice of paying P&H fees and saying we should move away from P&H fees. I --

THE COURT: I think the whole tone of this is different. And I think if you're going to represent again what Ropes & Gray -- unless you have another counsel who takes a different view, I think you need to call her as a witness if

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you want to represent what she says. Call her as a witness.

MR. COOKE: I don't think we've represented what she said other than what's in the documents, Your Honor.

**THE COURT:** I think it is misleading, what has been going on here. And I think -- we don't have a means to ask our jury, but I think the jury would -- at least what I'm hearing in this, is very different from her affidavit.

And I can understand you would feel like that maybe the affidavit, for her own reasons -- you and I both know what those could be; right?

> MR. COOKE: Yes.

-- might be tailored in some way? THE COURT:

MR. COOKE: Yes.

THE COURT: But, you know, this is her sworn statement. And you're welcome to call her, put her on the stand, and have her testify. I will tell you, if she testified what was in her affidavit, you'd be in real trouble with the jury.

Well, Your Honor, we intend to stick with MR. COOKE: what the evidence shows, but I would also point out to the Court that the question is going to be the scienter of my clients.

Correct. And I have no problem with your THE COURT: clients getting on the stand and stating what they understood. They have a right to do that under the AKS. And, you know,

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Ms. Dent's already had a chance to do that. And that's fair game.

what I don't want is a suggestion that that is the view of Ms. Hoey or Ropes & Gray. That's their view. They can say why they had that view. Okay? They're welcome to do that. But to sit there and represent that some third party who is absent here had a view which I think, at least according to the affidavit, is simply untrue.

MR. COOKE: Maybe I missed something that we said, but speaking for myself, I don't -- or Mr. Griffith, I don't think either one of us has purported to speak on behalf of Ms. Hoey. We have commented on what the evidence shows and what our clients perceived. They were not parties to the Kung memo. You heard the testimony they never saw that. Their one little window into this was that one meeting in June and then what their lawyers conveyed to them about the conversations.

THE COURT: There's, of course, evidence in already about what happened at that June meeting. Okay? Ms. Flippo testified to that. Mr. Pace testified to that. Frankly, that testimony is more consistent with this affidavit than what your questions are.

I just want you to be careful, Mr. Cooke, about the questions you're asking. They're communicating to me -- it's a kind of a subtle way you're sliding in -- or at least it's giving the impression of that -- that Ropes & Gray has an --

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took a position contrary to what is represented by Ms. Hoey's affidavit.

MR. COOKE: I think it's very important that we do and that we be allowed to convey to the jury the perspective that these gentlemen had, because it's their scienter --

THE COURT: Well, their testimony is fine, but you're asking questions of third parties. Maybe it won't come up again. I'm concerned about it. That is subtly suggesting to the jury that Ropes & Gray embraced process and handling fees. And according to at least -- I have a question. Right? All I know is I have this Kung -- is Kung going to be a witness?

MR. COOKE: No.

THE COURT: Okay. You got his -- his opinion.

Obviously, that reflects, as you say, Mr. Dent and Mr. Johnson said they didn't know about it. That would only reflect on Mallory. Hoey, I mean, she is -- she is representing also Mallory, but she attends this meeting; correct? She attends this June meeting --

MR. COOKE: Yes.

THE COURT: -- which everyone's present.

MR. COOKE: Yes.

THE COURT: You know, we joke that wouldn't you like to have been a fly on the wall at that meeting. Everybody wants to know. But her account of what she says here is -- is just not consistent with the suggestion -- for instance, let me

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give you the one that's troubled me the most, that their participation at a Department of Justice meeting or their participation in revising a policy reflected the fact that they embraced processing and handling fees.

we all know you represent the client where they are. If your client tells you, "I just can't move away from a process and handling fee," you're going to do the best for your client. You're going to try to move them in the right direction. We all had clients like this. You try to move your client the best you could.

That doesn't mean that you personally -- that's your And, in fact, what Ms. Hoey says here that, being behind closed doors, she said the practice is a red flag. agrees with the Kung document, which is a very damaging document; that the Ruggio letter, which was being promoted, should not be used, should not be relied on, could not be relied anymore as a basis for an advice-of-counsel defense.

Y'all are asserting a good-faith and an advice-of-counsel defense here. He just -- you know, I think you ought to be very careful going forward about -- about what you're representing to be Ropes & Gray's position. What is Mr. Dent and Mr. Johnson and Bluewave's position? They have a right to assert and you have a right to argue.

MR. COOKE: And, Your Honor, I think I'm appreciating the distinction that you're making. I would like to make a

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point on that too.

I -- I think I have been careful to not suggest that merely because Ropes & Gray is advocating, that means that they are endorsing fees. But what it does show is that the government had not made up its mind yet, that this was -- that the line, the speed limit, had not yet been set.

THE COURT: It's not -- that's different, and -- but that's not the way it's coming across, Mr. Cooke. It is coming across that Ropes & Gray did not think processing and handling fees were unlawful. And I think the reason her very fine counsel came here and said "You don't want to call them" was because she would get on the stand and say that.

And -- and that's just, you know -- I think you just need to be very careful when you represent anything suggesting the view of Ropes & Gray. I do not seek to restrain in any way the right of your defendants to get on the stand or you to argue and close their personal scienter. That is their right to assert and the government's right to cross-examine them.

MR. COOKE: Could we -- can we make the distinction between -- we think it's important in this case that all of these legal opinions -- not a single one was making reference to what the law was. They all refer to the position that we think the government is going to take. And turns out they were right. They were right about what the position the government is going to take. But I think that's an important -- it's an

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important but subtle distinction.

THE COURT: Then put them on the stand. I don't think that -- I frankly think that they were being politic with their own clients. They were being --

MR. COOKE: Well, they were wrong.

THE COURT: If you read her statement, she was telling them -- as you read this, she was making it very clear that she -- this was deeply concerning to her, as did Mr. Kung. And the fact that your clients had a good-faith belief in this has nothing to do with this necessarily.

But to represent what their view is is problematic here. And I think it -- I just don't want you to mislead the jury. You tell me you haven't meant to do that. I'm just telling you what it's coming out that way, that you're representing a view of Ropes & Gray.

And I'm just going to tell you, if you do it again and I hear an objection, I'm going to sustain it and I may instruct the jury on it. So I want you to be careful about this.

MR. COOKE: I'll be careful. But I'm also worried about closing too because I can't overemphasize how important it is for me to be able to convey to the jury what information was filtered through to these gentlemen, because they're going to have to decide that they acted knowingly and willfully.

THE COURT: What they testify, what they knew. We

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had this whole thing. Mr. Griffith and I were thrumming around, trying to get what -- what they knew about, for instance, time and motion study. That's important because that goes to their believe that they could do it as long as it's fair market value. That's important stuff. That's fair.

But when you start representing not what Dent and Johnson believe or Mr. Ashmore doing, what Ms. Mallory knew, but then arguing what Ropes & Gray believed, I think here you're treading on misleading the jury.

MR. COOKE: And I'm duly admonished on that, Your Honor. I apologize if it came across that way. I'm trying to convey to the jury what these guys were hearing and how they reasonably intended --

THE COURT: And I think -- I think that -- and I'm not trying -- and I want to say again because I know

Mr. Johnson still has to testify. I'm not trying to prevent what he says and what he, in good faith, believed. That is his right to get up there and say that. But don't get up and say what Ropes & Gray believed unless they specifically said something to you contrary to this.

I haven't heard -- what evidence I've heard -- I mean Mr. Pace was in the meeting and Ms. Flippo was in the meeting. They really didn't convey a suggestion that Ropes & Gray thought this was just fine and was just -- you just had to finesse the government. I didn't hear that.

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MR. COOKE: I don't think we tried to say that, but if we did, we won't do it again.

THE COURT: Does the government have any response, Mr. Leventis?

MR. LEVENTIS: No, we agree, Your Honor. The difficulty is standing up and objecting when he's asking the question. I'm afraid the jury is going to think we're trying to hide something.

THE COURT: I voice it, of course, outside the presence of the jury. I'm very reluctant to say anything in front of the jury. I raised it -- you know, Mr. Cooke and I go back a lot of years, and he was concerned that I felt this way. And I wanted -- I thought we ought to air it out during -- while the other witness was up, I had Ms. Caruana pull for me the Hoey and Kung affidavits so -- the affidavit and the letter, the memorandum, because I wanted to look at them because my impression was this wasn't accurate. And these reinforce that to me.

So I just say exercise care when you're talking about Ropes & Gray, not just --

Mr. Ashmore, do you have any thoughts?

MR. ASHMORE: Your Honor, I'm similarly situated, so I hear you. I understand.

We do have, Your Honor, Ms. Mallory's Exhibit 87.

And that's Ms. Hoey, the slide presentation to the Department

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of Justice. That happened May 15th, 2014. She lauds about Mike Ruggio. And I just -- I hear you, Your Honor. I'm not trying to beat a dead horse.

THE COURT: Once your client advocates -- your lawyer advocates in your favor, they're doing their job. You and I -- listen, we all represented people who, if you had asked us privately, we might not have taken that view. But they have a right to be represented and to make the best argument in their situation.

what I read in Ropes & Gray, they did that. They weren't being unethical about it, but when they got behind closed doors, they told the defendants in this case something else. And if they're talking about their scienter, that is what they got, their legal advice. That was in a closed meeting. And that's pretty important. I mean that's some -- that's very relevant to the case.

And to then get up and start talking about, well, didn't they -- first of all, your clients weren't at the Department of Justice meeting. They were not there. This is late in the process. They weren't relying on it to do process and handling fees. And to use it is really to suggest something else, which is that this was Ropes & Gray's personal views. And we know from Ms. Hoey's affidavit, that wasn't what she told them privately. Right? I mean that's the bulk.

Anything further anyone wishes to address on this?

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

THE COURT: Very good. 9:00 tomorrow morning.

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

## **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. Héss, CRR, FCRR, RMR Official Court Reporter