

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA

THE UNITED STATES OF
AMERICA, ET AL.

versus

BLUEWAVE HEALTHCARE
CONSULTANTS, INC., ET AL.

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Case No. 9:14-cv-230

January 30, 2018

REPORTER'S OFFICIAL TRANSCRIPT OF THE JURY TRIAL - DAY ELEVEN
HELD BEFORE THE HONORABLE RICHARD M. GERGEL
UNITED STATES DISTRICT JUDGE
January 30, 2018

Appearances:

For the United States
of America

U.S. Department of Justice
Civil Division
BY: Elizabeth Strawn, Esq.
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
Consultants, Inc.

Joseph P. Griffith Law Firm
BY: Joseph P. Griffith, Jr.
Seven State Street
Charleston, SC 29401
843.225.5563

For Bluewave Healthcare
Consultants, Inc.

Barnwell, Whaley, Patterson
and Helms
BY: Morris Dawes Cooke, Jr., Esq.
Christopher M. Kovach, Esq.
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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computer-aided transcription software.

8 : 4 4 A M 1 (Call to order of the Court.)

8 : 4 4 A M 2 **THE COURT:** Good morning. Please be seated.

8 : 4 5 A M 3 Okay. Let's first begin, and let's address any
8 : 4 5 A M 4 Rule 50 motions for a directed verdict.

8 : 4 5 A M 5 **MR. COOKE:** Thank you, Your Honor.

8 : 4 5 A M 6 **THE COURT:** And I will say right now that all of your
8 : 4 5 A M 7 arguments are protected that you have previously made, and we
8 : 4 5 A M 8 need not occupy ourselves this morning with things which have
8 : 4 5 A M 9 previously been addressed by this court and denied by pretrial
8 : 4 5 A M 10 directive at the stage of the -- at the end of the government's
8 : 4 5 A M 11 case. Everything you would have had on record, you are
8 : 4 5 A M 12 protected. And I -- I assume, for purposes of your motion,
8 : 4 5 A M 13 you -- they're incorporated.

8 : 4 5 A M 14 **MR. COOKE:** Thank you, Your Honor. And with that in
8 : 4 5 A M 15 mind, what I propose is to not try to argue or cite the record
8 : 4 6 A M 16 but simply put on the record the grounds for the motion. And
8 : 4 6 A M 17 I'll just go through them quickly and --

8 : 4 6 A M 18 **THE COURT:** Yes, sir.

8 : 4 6 A M 19 **MR. COOKE:** -- the Court can rule.

8 : 4 6 A M 20 First of all, we would move for a directed
8 : 4 6 A M 21 verdict as to all claims. The Anti-Kickback Statute is -- if
8 : 4 6 A M 22 liability were to be imposed based on the facts of this case,
8 : 4 6 A M 23 that the statute would be unconstitutionally vague so as to not
8 : 4 6 A M 24 reasonably put defendants on notice that they were violating
8 : 4 6 A M 25 it. No reasonable person would understand --

8 : 4 6 A M 1 **THE COURT:** That's fine. I understand that. You
8 : 4 6 A M 2 don't need to go any further. I understand the concept that a
8 : 4 6 A M 3 constitutionally vague statute would be unconstitutional if
8 : 4 6 A M 4 true. Okay.

8 : 4 6 A M 5 **MR. COOKE:** To not impute the actions of contractors
8 : 4 6 A M 6 to BlueWave, Dent, or to Johnson. All the evidence -- in fact,
8 : 4 6 A M 7 the plaintiffs' allegation is that all their sales
8 : 4 6 A M 8 representatives were independent contractors.

8 : 4 7 A M 9 **THE COURT:** Mr. Cooke, I get it. I get the concept.
8 : 4 7 A M 10 Go ahead.

8 : 4 7 A M 11 Third?

8 : 4 7 A M 12 **MR. COOKE:** There was no evidence of damages for
8 : 4 7 A M 13 waiver of copays and deductibles; and, therefore, any claims
8 : 4 7 A M 14 based on waiver of copays and deductibles should be dismissed
8 : 4 7 A M 15 for that reason.

8 : 4 7 A M 16 **THE COURT:** Okay. Keep going.

8 : 4 7 A M 17 **MR. COOKE:** There is no evidence of any violation of
8 : 4 7 A M 18 the Anti-Kickback -- any claims resulting from a violation of
8 : 4 7 A M 19 the Anti-Kickback Statute because the plaintiffs did not put in
8 : 4 7 A M 20 any evidence of fair market value of the processing and
8 : 4 7 A M 21 handling fees and is thus left to a subjective determination on
8 : 4 7 A M 22 a case-by-case basis.

8 : 4 7 A M 23 And there is no testimony that any of the
8 : 4 7 A M 24 actions of sales agents that appeared to use process and
8 : 4 7 A M 25 handling fees as a sales tool resulted in any claims being

8 : 4 7 A M 1 made.

8 : 4 7 A M 2 THE COURT: I get it. Keep going.

8 : 4 7 A M 3 MR. COOKE: Okay. There can be no violation of
8 : 4 7 A M 4 Anti-Kickback Statute if there's a reasonable interpretation of
8 : 4 8 A M 5 an ambiguous rule.

8 : 4 8 A M 6 we would also cite the pronouncements of the
8 : 4 8 A M 7 attorney general, the most recent -- I think it just came out
8 : 4 8 A M 8 last week or perhaps this week even of -- that you cannot use
8 : 4 8 A M 9 administrative guidance as a basis to impose substantive
8 : 4 8 A M 10 liability.

8 : 4 8 A M 11 There's no evidence that the process and
8 : 4 8 A M 12 handling fee was a double payment or higher than fair market
8 : 4 8 A M 13 value. And, in fact, the -- the processing and handling
8 : 4 8 A M 14 agreements expressly provided that the doctors could not obtain
8 : 4 8 A M 15 double recovery. And there's been no testimony in the record
8 : 4 8 A M 16 as to what claims, if any, the doctor made for reimbursement
8 : 4 8 A M 17 and thus no basis for claiming double recovery.

8 : 4 8 A M 18 Damages are speculative because the plaintiffs'
8 : 4 8 A M 19 damages expert included tests from Virginia and the District of
8 : 4 8 A M 20 Columbia where Bluewave defendants did not participate; and,
8 : 4 9 A M 21 therefore, the jury has no basis under which to award damages
8 : 4 9 A M 22 should it find liability.

8 : 4 9 A M 23 we would assert, as I mentioned last night, that
8 : 4 9 A M 24 the Court should find as a matter of law that the process and
8 : 4 9 A M 25 handling fees do fall within the safe harbor based upon the

8 : 4 9 A M 1 analogous Stark regulation which specifically addresses a
8 : 4 9 A M 2 per-click scenario and would hold that this -- because the
8 : 4 9 A M 3 amount per click remains fixed, that that meets the aggregate
8 : 4 9 A M 4 fixed-in-advance requirement.

8 : 4 9 A M 5 There's no evidence of deceptive or untruthful
8 : 4 9 A M 6 speech; and, therefore, imposing violation of the Anti-Kickback
8 : 4 9 A M 7 Statute would violate the First Amendment protection for
8 : 4 9 A M 8 commercial speech -- for truthful commercial speech.

8 : 4 9 A M 9 And to the extent that there was any evidence of
8 : 4 9 A M 10 any deceptive speech, there's no evidence that that caused any
8 : 5 0 A M 11 claims to be made -- any false claims to be made.

8 : 5 0 A M 12 Medical necessity. As a matter of law, if
8 : 5 0 A M 13 there's a difference of medical opinion, there cannot be a
8 : 5 0 A M 14 finding that the -- that -- against medical necessity. And
8 : 5 0 A M 15 also it's undisputed in the evidence that the physicians are
8 : 5 0 A M 16 the ones to determine medical necessity, not -- not BlueWave's
8 : 5 0 A M 17 and not even HDL's.

8 : 5 0 A M 18 There was a recent decision in District of
8 : 5 0 A M 19 Columbia, United States ex rel. Groat versus Boston Heart
8 : 5 0 A M 20 Diagnostics that makes that finding.

8 : 5 0 A M 21 **THE COURT:** Very familiar with it. I've read it.

8 : 5 0 A M 22 **MR. COOKE:** I suspected as much.

8 : 5 0 A M 23 There's a -- I think you said you were going to
8 : 5 0 A M 24 defer the equitable claims. But for the record, we would move
8 : 5 0 A M 25 that there was no evidence of any payments made to Bluewave or

8 : 5 0 A M 1 unjust enrichment.

8 : 5 0 A M 2 Anyway, I think those are the grounds.

8 : 5 0 A M 3 And we also would contend that the government
8 : 5 1 A M 4 has abandoned its claims for which it did not establish either
8 : 5 1 A M 5 causation or -- or damages, and that would include the --
8 : 5 1 A M 6 certainly the claims based on waiver of copays and deductibles
8 : 5 1 A M 7 and may include process and handling based on the slides that
8 : 5 1 A M 8 we were provided last night. It doesn't appear that they're
8 : 5 1 A M 9 putting up damages for process and handling fees, but that
8 : 5 1 A M 10 remains to be seen.

8 : 5 1 A M 11 **THE COURT:** Okay. Let me -- first of all, I'm aware
8 : 5 1 A M 12 of all of these arguments. I have seen them in some variety
8 : 5 1 A M 13 all throughout this case. And I do find that a reasonable
8 : 5 1 A M 14 jury -- with the evidence taken in the light most favorable to
8 : 5 1 A M 15 the nonmoving party, a reasonable jury could find for the
8 : 5 1 A M 16 government. And thus all of these are denied.

8 : 5 1 A M 17 I do want to -- because this issue of the Stark
8 : 5 2 A M 18 Act came up, and I have a couple of observations.

8 : 5 2 A M 19 Number one, throughout, Bluewave has taken the
8 : 5 2 A M 20 position it does not -- neither party asserted an affirmative
8 : 5 2 A M 21 defense of safe harbor. It's waived into that.

8 : 5 2 A M 22 But more than that, the Stark reference is --
8 : 5 2 A M 23 it's just not correct. As I read it -- and I'll let the
8 : 5 2 A M 24 government say if I'm misreading this. Just straighten me out
8 : 5 2 A M 25 on this.

8 : 5 2 A M 1 But they're addressing compensation for
8 : 5 2 A M 2 physicians in a situation like with a hospital. And they said
8 : 5 2 A M 3 you don't have to have the fixed number of their salary; you
8 : 5 2 A M 4 could base it on the number of hours they work or the number of
8 : 5 2 A M 5 patients they saw per unit. But the statute -- the Stark Act
8 : 5 2 A M 6 makes clear it can never be based on the value of referrals.
8 : 5 2 A M 7 That is explicitly prohibited by the Stark Act, which is
8 : 5 2 A M 8 exactly what is prohibited here under -- under the laws at
8 : 5 2 A M 9 issue here.

8 : 5 2 A M 10 It's prohibiting -- at least the safe harbor
8 : 5 3 A M 11 addresses the issue of paying for referrals. Both of them are
8 : 5 3 A M 12 prohibited.

8 : 5 3 A M 13 Someone from the government, is that a correct
8 : 5 3 A M 14 interpretation?

8 : 5 3 A M 15 **MS. STRAWN:** It is, Your Honor. And the key
8 : 5 3 A M 16 difference between the safe harbors, they're not analogous.

8 : 5 3 A M 17 **THE COURT:** They're not.

8 : 5 3 A M 18 **MS. STRAWN:** There's some similarities, sure. But
8 : 5 3 A M 19 they are different statutes, different regulations, different
8 : 5 3 A M 20 definitions.

8 : 5 3 A M 21 The key difference between Prong Number 5 of
8 : 5 3 A M 22 each is the word "aggregate." And it's because of the word
8 : 5 3 A M 23 "aggregate" that per-click or per-unit compensation cannot meet
8 : 5 3 A M 24 Prong 5 of the AKS safe harbor. But that one is absent in the
8 : 5 3 A M 25 Stark safe harbor.

8 : 5 3 A M 1 So under some circumstances, a per-unit
8 : 5 3 A M 2 compensation may fall -- may meet the Stark Prong 5. And
8 : 5 3 A M 3 that's why there's additional definitions that explain the
8 : 5 3 A M 4 circumstances under which they may fall into a Stark safe
8 : 5 3 A M 5 harbor. But that's just not applicable to this case, Your
8 : 5 3 A M 6 Honor.

8 : 5 3 A M 7 THE COURT: All right. I agree with that view.

8 : 5 3 A M 8 Okay. And, you know, the issue of fair market
8 : 5 4 A M 9 value, we'll get into this a little bit, because I didn't agree
8 : 5 4 A M 10 with the government's recent proposed charge that you could
8 : 5 4 A M 11 have an AKS violation if the -- if -- unless there's some other
8 : 5 4 A M 12 theory under the AKS, you couldn't simply have it if they paid
8 : 5 4 A M 13 fair market value. Because they paid fair market value, then
8 : 5 4 A M 14 this -- there's no -- there's no -- it's just reimbursement.
8 : 5 4 A M 15 And I don't think that's what it's intended to do.

8 : 5 4 A M 16 However, the government alleges that the service
8 : 5 4 A M 17 had already been paid for. And I don't think anybody would
8 : 5 4 A M 18 argue that, if that were true, that would be double payment.
8 : 5 4 A M 19 That wouldn't be allowed.

8 : 5 4 A M 20 And, you know, as I mentioned a little bit late
8 : 5 4 A M 21 yesterday, I said, you know, the -- in the Boston Heart case --
8 : 5 4 A M 22 which thank y'all. I mean, I had had this theory in my head,
8 : 5 4 A M 23 but I thought the judge in DC really nailed it when he said,
8 : 5 4 A M 24 you know, there's a whole problem with promoting tests --
8 : 5 5 A M 25 undertaking a scheme to promote tests that are medically

8 : 5 5 A M 1 unnecessary. And that's a good bit of this case is that there
8 : 5 5 A M 2 was this alleged scheme.

8 : 5 5 A M 3 Now, the defendants deny it. The government
8 : 5 5 A M 4 asserts it. There's evidence in the record. That's for the
8 : 5 5 A M 5 jury to decide. But I do think, as we get into discussion on
8 : 5 5 A M 6 fair market value -- I might add, however, there is evidence
8 : 5 5 A M 7 the government offered that this was exceeding fair market
8 : 5 5 A M 8 value. Dr. Mayes talked about his partners deducting their
8 : 5 5 A M 9 costs and were taking thousands of dollars home every month.
8 : 5 5 A M 10 But that's a whole -- that's issues for the jury.

8 : 5 5 A M 11 The absence of no evidence of double payment,
8 : 5 5 A M 12 no, both government -- both Medicare and TRICARE payments said
8 : 5 5 A M 13 that it was all bundled. That's an issue for the jury
8 : 5 5 A M 14 ultimately, whether they believe that's actually the law.
8 : 5 5 A M 15 There's -- there was -- obviously, other HeartLabs and this
8 : 5 6 A M 16 HeartLab were charging process and handling fees. That's up
8 : 5 6 A M 17 for the jury to see whether that is actually correct.

8 : 5 6 A M 18 I thought the government did adequate on
8 : 5 6 A M 19 damages. I'm not concerned about that. I don't believe the
8 : 5 6 A M 20 government has abandoned any claims. There are a number of
8 : 5 6 A M 21 claims of evidence that went to state of mind, but a lot of
8 : 5 6 A M 22 this case is the state of mind. And a lot of evidence -- my
8 : 5 6 A M 23 goodness, a lot of evidence came in on both sides that we never
8 : 5 6 A M 24 would see in a trial.

8 : 5 6 A M 25 I mean, Mr. Cooke is smiling because we all know

8 : 5 6 A M 1 we often try a lot of cases, never -- I mean, but it came in
8 : 5 6 A M 2 properly. It wasn't even close. I mean, the defendants
8 : 5 6 A M 3 pointed to things in 2005 and 2007. It goes to their state of
8 : 5 6 A M 4 mind. Whether that ultimately met the standards under the AKS
8 : 5 6 A M 5 and under FCA is for the jury to decide.

8 : 5 6 A M 6 So BlueWave's motion for a directed verdict is
8 : 5 6 A M 7 the same as I indicated yesterday. I think there's reasonable
8 : 5 7 A M 8 evidence in the record.

8 : 5 7 A M 9 Mr. Ashmore, do you wish to add anything to
8 : 5 7 A M 10 yours?

8 : 5 7 A M 11 **MR. ASHMORE:** Your Honor, simply to join into those
8 : 5 7 A M 12 arguments also made this morning by Mr. Cooke and stand on my
8 : 5 7 A M 13 previously made arguments.

8 : 5 7 A M 14 **THE COURT:** Yes, sir. And for the same reason, that
8 : 5 7 A M 15 motion is denied.

8 : 5 7 A M 16 **MR. ASHMORE:** Thank you so much.

8 : 5 7 A M 17 **THE COURT:** Okay. I now want to go to the proposed
8 : 5 7 A M 18 jury charge, and I'm going to ask first the government to
8 : 5 7 A M 19 advise me of any objections the government has to the jury
8 : 5 7 A M 20 charge.

8 : 5 7 A M 21 **MR. TERRANOVA:** Your Honor, the United States wants
8 : 5 7 A M 22 to focus on the two primary issues that Your Honor predicted
8 : 5 8 A M 23 the parties would like to discuss. And that concerns
8 : 5 8 A M 24 remuneration, and the second one is advice of counsel. A few
8 : 5 8 A M 25 smaller things, but those two are the principal concerns that

8 : 5 8 A M 1 we want to raise with Your Honor.

8 : 5 8 A M 2 THE COURT: Okay.

8 : 5 8 A M 3 MR. TERRANOVA: With respect to the first,
8 : 5 8 A M 4 remuneration, I believe that the parties have made this much
8 : 5 8 A M 5 more complicated than it needed to be. And, in fact, I'll take
8 : 5 8 A M 6 a good portion of the blame here.

8 : 5 8 A M 7 Remuneration under the AKS includes money. That
8 : 5 8 A M 8 is perfectly clear from the statutory text itself, which
8 : 5 8 A M 9 references in cash or in kind. And the remuneration that the
8 : 5 8 A M 10 United States alleges was provided here was the \$20 process and
8 : 5 8 A M 11 handling fees -- the money -- and the commission payments.
8 : 5 8 A M 12 Again, the money.

8 : 5 9 A M 13 So there's no dispute, I don't think, that the
8 : 5 9 A M 14 remuneration element of the Anti-Kickback Statute has been met.
8 : 5 9 A M 15 What is disputed are different elements of the Anti-Kickback
8 : 5 9 A M 16 Statute: The purpose, the intent to induce.

8 : 5 9 A M 17 Defendants are arguing to the jury that they had
8 : 5 9 A M 18 a different reason; it wasn't to induce the doctors, but it was
8 : 5 9 A M 19 to reimburse them.

8 : 5 9 A M 20 THE COURT: Well, let me do this. Tell me where you
8 : 5 9 A M 21 think the charge is wrong. I get all these arguments.

8 : 5 9 A M 22 MR. TERRANOVA: Sure.

8 : 5 9 A M 23 THE COURT: Tell me where it's wrong.

8 : 5 9 A M 24 MR. TERRANOVA: So, Your Honor, we would request that
8 : 5 9 A M 25 the final two sentences of the remuneration definition be

8 : 5 9 A M 1 removed and that "in cash or in kind" be added after the
8 : 5 9 A M 2 "direct or indirect language."

8 : 5 9 A M 3 And I think the second-to-the-last sentence,
8 : 5 9 A M 4 which reads, "Remuneration includes transfers of items or
8 : 5 9 A M 5 services for free, payment for services already paid for by
9 : 0 0 A M 6 another, or payment for more than fair market value," I think
9 : 0 0 A M 7 that's accurate. However, it is confusing to the jury because
9 : 0 0 A M 8 what is not at issue in this case is an argument that
9 : 0 0 A M 9 defendants transferred items or services. So centrifuges would
9 : 0 0 A M 10 be an item. We're not saying that those items that were
9 : 0 0 A M 11 transferred are the remuneration.

9 : 0 0 A M 12 And likewise for services, we're not saying that
9 : 0 0 A M 13 the dietician services that were provided for free by the
9 : 0 0 A M 14 defendants is the remuneration. We're saying that money is the
9 : 0 0 A M 15 remuneration. And --

9 : 0 0 A M 16 **THE COURT:** But if -- you know, what I'm struggling
9 : 0 0 A M 17 with is the -- is the language. Let me go to it here.

9 : 0 1 A M 18 **MR. TERRANOVA:** Your Honor may be referring to the
9 : 0 1 A M 19 Civil Monetary Penalties Act, 42 USC 1320a-7a.

9 : 0 1 A M 20 **THE COURT:** Right. I'm looking it up. Give me a
9 : 0 1 A M 21 second. And it refers to -- let me pull it up because I --

9 : 0 1 A M 22 **MR. TERRANOVA:** Sure.

9 : 0 2 A M 23 **THE COURT:** Of course, in my massive stuff, I can't
9 : 0 2 A M 24 seem to find that particular statutory reference, the
9 : 0 2 A M 25 definition of -- of "remuneration."

9 : 0 2 A M 1 Mr. Barber, you got that handy, by any chance?

9 : 0 2 A M 2 MR. TERRANOVA: Your Honor, I just have a highlighted
9 : 0 2 A M 3 version that I'd be happy to hand up.

9 : 0 2 A M 4 THE COURT: Okay. For some reason, I just didn't,
9 : 0 2 A M 5 you know -- surprise, surprise, you guys have given me so much
9 : 0 2 A M 6 stuff. Hold on just a second.

9 : 0 2 A M 7 Give me your highlighted one just for a moment,
9 : 0 2 A M 8 if I could, please, sir. It's around here somewhere. I'm not
9 : 0 2 A M 9 sure where I put it --

9 : 0 2 A M 10 Right. It -- you know, we've got sort of two
9 : 0 2 A M 11 suggestions in the statute about things that could be
9 : 0 3 A M 12 remuneration. Of course, we know that remuneration is anything
9 : 0 3 A M 13 of value. Okay. But then we have further guidance.

9 : 0 3 A M 14 It includes a kickback, a bribe, or a rebate
9 : 0 3 A M 15 under the AKS. Under 1320a-7b(b)(i), it defines it that way.

9 : 0 3 A M 16 And then in 1320a-7a(i)(6), it additionally
9 : 0 3 A M 17 addresses remuneration. And it's, again, not an exclusive
9 : 0 3 A M 18 list. It's examples again. And it says, "The waiver of
9 : 0 3 A M 19 coinsurance and deductible amounts or any part thereof" and
9 : 0 3 A M 20 "transfers of items or services for free or for other than fair
9 : 0 3 A M 21 market value."

9 : 0 3 A M 22 Now, the question is, does that mean, if it's
9 : 0 3 A M 23 for fair market value, then it's not remuneration? That's the
9 : 0 4 A M 24 question. The government asserts, oh, no, it can also include
9 : 0 4 A M 25 within fair market value.

9 : 0 4 A M 1 I told my law clerks it reminded me of a joke in
9 : 0 4 A M 2 which a guy gets up and he says, "I'm in the change business;
9 : 0 4 A M 3 4 quarters for a dollar, 10 dimes for a dollar, 20 nickels for
9 : 0 4 A M 4 a dollar."

9 : 0 4 A M 5 Somebody says, "well, how do you make a living
9 : 0 4 A M 6 on that?"

9 : 0 4 A M 7 And he says, "On volume." Okay. And obviously
9 : 0 4 A M 8 there's no -- there's no money in it; it's just an exchange.

9 : 0 4 A M 9 And the question is, did Congress, by putting in
9 : 0 4 A M 10 that language for other than fair market value, intend to
9 : 0 4 A M 11 communicate that concept?

9 : 0 4 A M 12 I think it did. I mean, and I believe, if I'm
9 : 0 4 A M 13 not wrong, your original charge did not include that language.

9 : 0 4 A M 14 Am I right about the government's original
9 : 0 4 A M 15 charge on remuneration?

9 : 0 4 A M 16 **MR. TERRANOVA:** The government's original charge,
9 : 0 4 A M 17 Your Honor, I think is quite close to the first three sentences
9 : 0 5 A M 18 of Your Honor's definition of "remuneration," which is what the
9 : 0 5 A M 19 law is and what we believe is correct.

9 : 0 5 A M 20 Just to step back on the statute that I just
9 : 0 5 A M 21 provided Your Honor, that's the civil monetary penalties law,
9 : 0 5 A M 22 which is a different section of the U.S. code than the
9 : 0 5 A M 23 Anti-Kickback Statute.

9 : 0 5 A M 24 **THE COURT:** There's actually a reference to -- to the
9 : 0 5 A M 25 statute as well.

9 : 0 5 A M 1 **MR. TERRANOVA:** And that's important for a few
9 : 0 5 A M 2 reasons. The first of all is that the definition of
9 : 0 5 A M 3 "remuneration" in civil monetary penalties law is specific to
9 : 0 5 A M 4 this section. It's remuneration for this section.

9 : 0 5 A M 5 And under the Anti-Kickback Statute, Congress
9 : 0 5 A M 6 provided exceptions to what constitutes remuneration in the
9 : 0 5 A M 7 statute. And in 1987 it passed a law that gave -- that
9 : 0 5 A M 8 required Health and Human Services to pass safe harbors, which
9 : 0 5 A M 9 it did, promulgated regulations in 1991.

9 : 0 6 A M 10 And so those safe harbors, which are in
9 : 0 6 A M 11 42 CFR 1001.952, those define what is not remuneration.

9 : 0 6 A M 12 And in 1972, just history -- in 1972, the
9 : 0 6 A M 13 Anti-Kickback Statute did not include the word "remuneration."
9 : 0 6 A M 14 It was added in 1977 to broaden the scope of the Anti-Kickback
9 : 0 6 A M 15 Statute.

9 : 0 6 A M 16 "Remuneration" means to pay an equivalent for
9 : 0 6 A M 17 service. And the leading case in this series, United States
9 : 0 6 A M 18 versus Bay State Ambulance -- that's a First Circuit case,
9 : 0 6 A M 19 874 F. 2d 20. In there, the very same argument that the
9 : 0 6 A M 20 defendants are making now was raised and rejected. And this
9 : 0 6 A M 21 has been followed by numerous circuits regarding the
9 : 0 6 A M 22 Anti-Kickback Statute.

9 : 0 6 A M 23 And they held giving a person an opportunity to
9 : 0 6 A M 24 earn money may well be an inducement to that person to channel
9 : 0 6 A M 25 potential Medicare payments toward a particular recipient. And

9 : 0 7 A M 1 the Court there --

9 : 0 7 A M 2 THE COURT: You know, I said this a little bit
9 : 0 7 A M 3 yesterday. I think y'all are blurring the line between a
9 : 0 7 A M 4 medical necessity claim and an AKS claim, and I know they
9 : 0 7 A M 5 overlap. I mean, potentially you could have both, correct, for
9 : 0 7 A M 6 the same conduct.

9 : 0 7 A M 7 But -- so if you're out there and you're
9 : 0 7 A M 8 marketing these tests and you're urging people, among a variety
9 : 0 7 A M 9 of things, think about your office visits afterwards. If you
9 : 0 7 A M 10 order all these tests, you know, in doing -- in marketing --
9 : 0 7 A M 11 even marketing it within fair market value but trying to induce
9 : 0 7 A M 12 them to order medically unnecessary tests, that is a scheme, a
9 : 0 7 A M 13 conspiracy, a violation causing to present a medically
9 : 0 7 A M 14 unnecessary -- a false claim.

9 : 0 8 A M 15 And that's why that Boston Heart case is -- was
9 : 0 8 A M 16 interesting to me --

9 : 0 8 A M 17 MR. TERRANOVA: Right.

9 : 0 8 A M 18 THE COURT: -- because it articulated that. And the
9 : 0 8 A M 19 judge had it dead wrong initially, that the labs had to
9 : 0 8 A M 20 second-guess the doctors. That just could not happen. You
9 : 0 8 A M 21 cannot hold a lab liable for that. You would be -- how could
9 : 0 8 A M 22 you do that; right? Have to make an independent judgment? I
9 : 0 8 A M 23 mean, they're not trained to do that. The lab's not set up for
9 : 0 8 A M 24 that.

9 : 0 8 A M 25 So it was dead wrong. The theory was correct.

9 : 0 8 A M 1 You know, I got to say I think it's a pretty
9 : 0 8 A M 2 close question. I'm going to give you that. I just -- there's
9 : 0 8 A M 3 something about paying somebody for something that they have to
9 : 0 8 A M 4 do, they have to perform, and they do it within their costs. I
9 : 0 8 A M 5 mean, that to me is -- is -- I've always thought about the
9 : 0 8 A M 6 difference between remuneration and reimbursement.

9 : 0 8 A M 7 And I want to tell you something, Mr. Terranova.
9 : 0 9 A M 8 I think when you have a statute like this, you're holding
9 : 0 9 A M 9 people triple damages for liability. You know, you need to
9 : 0 9 A M 10 look at these kind of definitions of what conduct actually does
9 : 0 9 A M 11 it. I think if they did what you claim they did, there is a
9 : 0 9 A M 12 scheme to engage and to order unnecessary tests. I think
9 : 0 9 A M 13 that's it.

9 : 0 9 A M 14 Now, you would say, "Oh, I agree with you but I
9 : 0 9 A M 15 also argue that -- that it -- that it should include tests
9 : 0 9 A M 16 within fair market value."

9 : 0 9 A M 17 Let me just hear Mr. Cooke's response to that,
9 : 0 9 A M 18 just for a second. And, Mr. Terranova, I'll give you a chance
9 : 0 9 A M 19 to reply.

9 : 0 9 A M 20 **MR. GRIFFITH:** Your Honor, we agree with your -- with
9 : 0 9 A M 21 what you've got in the -- in your instructions and so don't
9 : 1 0 A M 22 really have anything to add to it. We think that's a fair --

9 : 1 0 A M 23 **THE COURT:** I'm just struggling with this. I mean,
9 : 1 0 A M 24 you understand that -- that the theory that medical necessity
9 : 1 0 A M 25 is the issue, arguably the issue, there's a little bit of

9 : 1 0 A M 1 challenge for your clients because you don't have to have a
9 : 1 0 A M 2 willful violation for that. Okay. It's a knowing violation
9 : 1 0 A M 3 because it's a straight-up FCA claim. You see what I mean?

9 : 1 0 A M 4 **MR. GRIFFITH:** Correct. We agree with that.

9 : 1 0 A M 5 **THE COURT:** Everything has eight different dimensions
9 : 1 0 A M 6 to this case. Every time you do one thing, it has a
9 : 1 0 A M 7 consequence somewhere else.

9 : 1 0 A M 8 Okay. Let me -- Mr. Terranova, let me -- first
9 : 1 0 A M 9 of all, Mr. Ashmore, do you have something you wish to add,
9 : 1 0 A M 10 sir?

9 : 1 0 A M 11 **MR. ASHMORE:** No, Your Honor. Mr. Terranova did --
9 : 1 0 A M 12 he was forthright before. He said, "I think that's accurate,"
9 : 1 0 A M 13 and so I'm perfectly --

9 : 1 0 A M 14 **THE COURT:** Okay. Mr. Terranova, give me again the
9 : 1 0 A M 15 citation of the case that you were pointing to, and I will -- I
9 : 1 0 A M 16 looked at a couple of cases that y'all had cited, but let me go
9 : 1 0 A M 17 back and look at -- I will look at that again.

9 : 1 0 A M 18 what's the --

9 : 1 0 A M 19 **MR. TERRANOVA:** Sure. The Bay State Ambulance case
9 : 1 0 A M 20 is 874 F. 2d 20. That's the First Circuit.

9 : 1 1 A M 21 **THE COURT:** And what's the page number that's --

9 : 1 1 A M 22 **MR. TERRANOVA:** I believe it's 29 through 30
9 : 1 1 A M 23 approximately. And the second one in the same line is United
9 : 1 1 A M 24 States versus Greber. This is a Third Circuit case,
9 : 1 1 A M 25 760 F. 2d 68. And the discussion there begins on page 71.

9 : 1 1 A M 1 **THE COURT:** Okay. Let me -- let me look again. I'm
9 : 1 1 A M 2 going to be -- you know, I remember one time I was trying a
9 : 1 1 A M 3 very important case, and I made an argument. And the judge
9 : 1 1 A M 4 said to me, "Mr. Gergel, do you really want me to rule with you
9 : 1 1 A M 5 on this?"

9 : 1 1 A M 6 **MR. TERRANOVA:** I understand.

9 : 1 1 A M 7 **THE COURT:** You know what I'm saying?

9 : 1 1 A M 8 **MR. TERRANOVA:** Yes.

9 : 1 1 A M 9 **THE COURT:** And I looked at him, and I said, "I
9 : 1 2 A M 10 withdraw my request." I got a \$10 million verdict that was
9 : 1 2 A M 11 bulletproof. Okay.

9 : 1 2 A M 12 So I'm just saying to you, do you really --

9 : 1 2 A M 13 **MR. TERRANOVA:** Yeah. And I think that issue will
9 : 1 2 A M 14 come up with the advice-of-counsel defense.

9 : 1 2 A M 15 **THE COURT:** Yeah.

9 : 1 2 A M 16 **THE FOREPERSON:** So we'll get to that.

9 : 1 2 A M 17 But with respect to remuneration, the protection
9 : 1 2 A M 18 that the Anti-Kickback Statute provides to defendants is in the
9 : 1 2 A M 19 to induce purpose and in the knowledge and willfulness
9 : 1 2 A M 20 requirements. Those are the elements that defendants are
9 : 1 2 A M 21 relying on --

9 : 1 2 A M 22 **THE COURT:** I'm just having a -- I'm going to read
9 : 1 2 A M 23 your cases. I'm having a conceptual problem saying someone got
9 : 1 2 A M 24 paid for something in which they were just being paid back a
9 : 1 2 A M 25 service. Just conceptually to me, I'm struggling with that.

9 : 1 2 A M 1 And I don't -- I don't recognize some force to
9 : 1 2 A M 2 your argument. Okay. But it strikes me that it's really a
9 : 1 2 A M 3 better FCA argument because, if you're part of a scheme to --
9 : 1 3 A M 4 all of this, as I hear the government's case -- and I reread
9 : 1 3 A M 5 your complaints today really just from the beginning of this --
9 : 1 3 A M 6 was that they were pushing these unnecessary tests.

9 : 1 3 A M 7 And so in any regard, I've heard enough on that
9 : 1 3 A M 8 issue. Let's talk about advice of counsel. What do you -- I
9 : 1 3 A M 9 don't have an advice-of-counsel charge.

9 : 1 3 A M 10 Do you want one?

9 : 1 3 A M 11 **MR. TERRANOVA:** We do.

9 : 1 3 A M 12 But briefly, if I may, Your Honor, the last
9 : 1 3 A M 13 point just on the conceptual nature of it, if a salesman or
9 : 1 3 A M 14 laboratory goes into a physician's office and says, "Doctor, I
9 : 1 3 A M 15 will offer you a job as long as you direct all of your Medicare
9 : 1 3 A M 16 patients to me. My laboratory will run extensive, very
9 : 1 3 A M 17 expensive testing on you. I'll give you this job. You have to
9 : 1 3 A M 18 do work for the job. I'm going to pay you fair market value
9 : 1 3 A M 19 for the work," that still violates the Anti-Kickback Statute,
9 : 1 3 A M 20 which is designed to prevent laboratories and others from
9 : 1 3 A M 21 providing monetary inducements.

9 : 1 4 A M 22 And as the Bay State Ambulance case says, even
9 : 1 4 A M 23 providing a person an opportunity to earn money is a violation
9 : 1 4 A M 24 of the statute.

9 : 1 4 A M 25 **THE COURT:** So the question -- I got to go read this

9 : 1 4 A M 1 case. But are they earning money when they're being
9 : 1 4 A M 2 reimbursed? That's my question. Are they -- if their actual
9 : 1 4 A M 3 costs are below or are greater than -- equal to or greater than
9 : 1 4 A M 4 that number, are they earning anything?

9 : 1 4 A M 5 MR. TERRANOVA: Okay.

9 : 1 4 A M 6 THE COURT: That's my struggle.

9 : 1 4 A M 7 I've heard enough on this. Let me go back and
9 : 1 4 A M 8 read this case. Talk to me about advice of counsel.

9 : 1 4 A M 9 MR. TERRANOVA: Real quick, if I may, just one last
9 : 1 4 A M 10 point on the "fair market value" definition.

9 : 1 4 A M 11 THE COURT: Yes.

9 : 1 4 A M 12 MR. TERRANOVA: If Your Honor would -- we would
9 : 1 4 A M 13 object to that definition. We believe that it should include
9 : 1 4 A M 14 additional language which made sure that the amount has not
9 : 1 4 A M 15 been adjusted to include the additional value which one or both
9 : 1 4 A M 16 of the parties has attributed to the referral of business
9 : 1 4 A M 17 between them.

9 : 1 5 A M 18 THE COURT: I don't understand that.

9 : 1 5 A M 19 MR. TERRANOVA: So this is -- this is a definition
9 : 1 5 A M 20 that's both in the anti-kickback safe harbors and in the Stark
9 : 1 5 A M 21 Law. And the purpose behind it is that if HDL is paying
9 : 1 5 A M 22 doctors for services, HDL may be willing to pay a lot more
9 : 1 5 A M 23 money because one of the things it's paying for is the fact
9 : 1 5 A M 24 that these doctors are going to send business to them. So it's
9 : 1 5 A M 25 not a true arm's length negotiation because HDL is taking into

9 : 1 5 A M 1 account the strategic value of getting referrals from these
9 : 1 5 A M 2 physicians. And so that's an element. That's an important
9 : 1 5 A M 3 element --

9 : 1 5 A M 4 THE COURT: Say that again. I'm still struggling.
9 : 1 5 A M 5 what are you asking me to add? what's the language?

9 : 1 5 A M 6 MR. TERRANOVA: That the -- that the amount has not
9 : 1 5 A M 7 been adjusted, so -- adjusted up or down to include the
9 : 1 5 A M 8 additional value which one or both of the parties has
9 : 1 6 A M 9 attributed to the referral of business between them. And this
9 : 1 6 A M 10 is --

9 : 1 6 A M 11 THE COURT: Is that suggesting that, if they did it
9 : 1 6 A M 12 for a loss so they could get the order, that that should be
9 : 1 6 A M 13 considered in fair market value?

9 : 1 6 A M 14 MR. TERRANOVA: Not quite. It would be if HDL says,
9 : 1 6 A M 15 normally, I would pay someone \$2 to do a five-minute process
9 : 1 6 A M 16 and handling, but because you're a physician and you're
9 : 1 6 A M 17 referring to me, I'm willing to pay a lot more money.

9 : 1 6 A M 18 THE COURT: well, that would go to the market value
9 : 1 6 A M 19 and so forth. I mean, that's argument, it seems to me, is the
9 : 1 6 A M 20 price of what a seller is willing to accept and a buyer is
9 : 1 6 A M 21 willing to pay. You're saying that they're exceeding that.

9 : 1 6 A M 22 There's not a lot of evidence you've put up
9 : 1 6 A M 23 that -- you know, I haven't heard a price. Y'all didn't call
9 : 1 7 A M 24 your fair market value expert. So I'm left with Dr. Mayes'
9 : 1 7 A M 25 testimony on your side and these various people who talked

9 : 1 7 A M 1 about it on the defendants' side.

9 : 1 7 A M 2 MR. TERRANOVA: And I would just say one order of
9 : 1 7 A M 3 Your Honor, that is Docket Number 527 at page 4, Your Honor
9 : 1 7 A M 4 does refer to the fair market value standard and it does
9 : 1 7 A M 5 include the language that I just read.

9 : 1 7 A M 6 THE COURT: I'm sorry. Docket?

9 : 1 7 A M 7 MR. TERRANOVA: 527, page 4, that Anti-Kickback
9 : 1 7 A M 8 Statute safe harbors also define fair market value.

9 : 1 7 A M 9 THE COURT: Okay. Okay. Okay. Talk to me about
9 : 1 7 A M 10 advice of counsel.

9 : 1 7 A M 11 MR. TERRANOVA: Yes, Your Honor.

9 : 1 7 A M 12 So this is an area where we believe Your Honor
9 : 1 7 A M 13 was correct that no reasonable jury could find that defendants
9 : 1 7 A M 14 have established an advice-of-counsel defense. However, there
9 : 1 7 A M 15 is still a reference in the proposed instructions to advice of
9 : 1 8 A M 16 attorneys, advice of counsel. So the concern here is --

9 : 1 8 A M 17 THE COURT: This is in the good-faith discussion?

9 : 1 8 A M 18 MR. TERRANOVA: Correct. The concern here is that
9 : 1 8 A M 19 the jury will be --

9 : 1 8 A M 20 THE COURT: Fix on that?

9 : 1 8 A M 21 MR. TERRANOVA: They'll be allowed to consider advice
9 : 1 8 A M 22 of counsel without actually applying the requirements of the
9 : 1 8 A M 23 advice-of-counsel defense, so it gets around completely the
9 : 1 8 A M 24 requirements that a party needs to meet to establish that
9 : 1 8 A M 25 defense.

9 : 1 8 A M 1 So the jury is given no guidance as to what to
9 : 1 8 A M 2 consider. And this issue was specifically raised and addressed
9 : 1 8 A M 3 in another circuit case decided in 2011. This is United States
9 : 1 8 A M 4 v. Joshua, and the cite is 648 F.3d 547. That's a Seventh
9 : 1 8 A M 5 Circuit case. And --

9 : 1 8 A M 6 **THE COURT:** What page number?

9 : 1 8 A M 7 **MR. TERRANOVA:** The page number is 554 --

9 : 1 9 A M 8 **THE COURT:** Hold on just a second.

9 : 1 9 A M 9 **MR. TERRANOVA:** -- to 555. And we do have a copy to
9 : 1 9 A M 10 hand up, Your Honor, if needed.

9 : 1 9 A M 11 **THE COURT:** You can hand it to Ms. Ravenel, if you
9 : 1 9 A M 12 wish.

9 : 1 9 A M 13 **MR. TERRANOVA:** And the Court --

9 : 1 9 A M 14 **THE COURT:** Hold on just a minute. You're getting
9 : 1 9 A M 15 ahead of me here. Thank you.

9 : 1 9 A M 16 So you object to me making a reference to
9 : 1 9 A M 17 attorneys' opinions?

9 : 1 9 A M 18 **MR. TERRANOVA:** Yes. We think it should be one of
9 : 1 9 A M 19 two solutions: Either there is an explicit statement that
9 : 2 0 A M 20 defendants cannot rely on advice of counsel or, the option that
9 : 2 0 A M 21 we prefer, that the jury is instructed on the advice-of-counsel
9 : 2 0 A M 22 defense as we listed, and --

9 : 2 0 A M 23 **THE COURT:** So how would I instruct them under your
9 : 2 0 A M 24 theory? What would I say to them?

9 : 2 0 A M 25 **MR. TERRANOVA:** So this is --

9 : 2 0 A M 1 **THE COURT:** Because, you know, this statement cuts
9 : 2 0 A M 2 both ways. I'm telling them to look at all the opinions
9 : 2 0 A M 3 received regardless of the source. Of course that invites the
9 : 2 0 A M 4 jury to consider the opinions coming in by the email, over the
9 : 2 0 A M 5 transom, all these different things people say things for,
9 : 2 0 A M 6 which I think is correct.

9 : 2 0 A M 7 **MR. TERRANOVA:** It is.

9 : 2 0 A M 8 **THE COURT:** I think that all goes to whether they're
9 : 2 0 A M 9 in good faith. I do find, as a matter of law, they are not --
9 : 2 0 A M 10 this does not remotely approach advice of counsel, but we let
9 : 2 0 A M 11 all this evidence in -- I let it in -- that's not we; I did it
9 : 2 1 A M 12 because I thought it was relevant to the state of mind because
9 : 2 1 A M 13 I think that, frankly, is the heart of this case is state of
9 : 2 1 A M 14 mind. And the defendants have a right to provide a robust
9 : 2 1 A M 15 defense.

9 : 2 1 A M 16 And if I were sitting on the defense side, I
9 : 2 1 A M 17 might say, Judge, could you just leave that sentence out? And
9 : 2 1 A M 18 if you both think I should leave it out, I might do that. I'm
9 : 2 1 A M 19 trying to help the jury. I mean, we could just simply -- just
9 : 2 1 A M 20 say "the totality of the evidence presented" and leave out that
9 : 2 1 A M 21 last sentence and then let you guys argue what that means.

9 : 2 1 A M 22 Mr. Cooke, what's your take on that one, or
9 : 2 1 A M 23 Mr. Griffith?

9 : 2 1 A M 24 **MR. GRIFFITH:** Your Honor, we think you've got it
9 : 2 1 A M 25 right in your instructions. The -- I mean you've already ruled

9 : 2 1 A M 1 that there's no advice-of-counsel defense. And we're not --

9 : 2 2 A M 2 **THE COURT:** But the information Mr. Johnson and
9 : 2 2 A M 3 Mr. Dent and Ms. Mallory have is relevant to their state of
9 : 2 2 A M 4 mind.

9 : 2 2 A M 5 **MR. GRIFFITH:** It is, and it goes to good faith.

9 : 2 2 A M 6 **THE COURT:** And, you know, some would say -- I mean,
9 : 2 2 A M 7 it does invite this whole willful ignorance issue; right? I
9 : 2 2 A M 8 mean, you got to sort all that out. But there is no question
9 : 2 2 A M 9 that they had lots of opinions out there. You know, you could
9 : 2 2 A M 10 say they're a bunch of shills for the industry who were out
9 : 2 2 A M 11 there giving the opinions their clients wanted. Okay?

9 : 2 2 A M 12 I mean, that's all argument to me. And they
9 : 2 2 A M 13 certainly had exposure. There's going to be a lot of debate
9 : 2 2 A M 14 about -- I think the jury to sort out what happened in that
9 : 2 2 A M 15 June 2013 meeting, because I think that -- according to some of
9 : 2 2 A M 16 the testimony we have, the Ropes & Gray lawyers told them that
9 : 2 2 A M 17 the Ruggio opinion wasn't worth the paper it was written on, it
9 : 2 3 A M 18 was wrong, and they were at high risk. It was a red flag.
9 : 2 3 A M 19 Mr. Kung told them that. Mr. Pace told them that. That's for
9 : 2 3 A M 20 the jury to resolve whether, under those circumstances, they
9 : 2 3 A M 21 had good faith. I mean, that's sort of the case to me.

9 : 2 3 A M 22 **MR. GRIFFITH:** We agree with that, Your Honor.

9 : 2 3 A M 23 **THE COURT:** And, you know, I do see -- I have -- I
9 : 2 3 A M 24 had wondered whether you would want me to take the last
9 : 2 3 A M 25 sentence out because it invites the look at all the evidence.

9 : 2 3 A M 1 But I think that's what the law is. And for me not to mention
9 : 2 3 A M 2 the advice of lawyers is to ignore about half the testimony on
9 : 2 3 A M 3 both sides coming in. I mean, that's what y'all were fighting
9 : 2 3 A M 4 over. And you're asking me -- with regard to the jury, my own
9 : 2 3 A M 5 inclination is, if you both said leave it out, I perhaps would
9 : 2 3 A M 6 defer to you; but I think -- for guiding my jury, I think I
9 : 2 3 A M 7 need to mention that. And, frankly, it cuts both ways is my
9 : 2 3 A M 8 view.

9 : 2 3 A M 9 **MR. GRIFFITH:** We want it in, Your Honor. We think
9 : 2 4 A M 10 you have to look at the totality of the circumstances,
9 : 2 4 A M 11 including all --

9 : 2 4 A M 12 **THE COURT:** You know, I keep pushing y'all, don't
9 : 2 4 A M 13 make me part of your closing argument. I'm going to give it to
9 : 2 4 A M 14 the jury, and you guys go at it. I mean, that's what I'm
9 : 2 4 A M 15 trying to do here. I'm inclined to leave it the way it is. I
9 : 2 4 A M 16 hear the force. I get it. I'm not going to direct them there
9 : 2 4 A M 17 is no advice of counsel. I'm just not going to charge it. I
9 : 2 4 A M 18 wouldn't do the negative. I wouldn't say, "By the way, there
9 : 2 4 A M 19 was this claim, and I have found as a matter of law that they
9 : 2 4 A M 20 can't assert it." No, I'm just not going to charge it. It's a
9 : 2 4 A M 21 request to charge; I deny the charge.

9 : 2 4 A M 22 **MR. TERRANOVA:** And just one more explanation about
9 : 2 4 A M 23 why we would request a charge that's on Docket 847 on page 6.
9 : 2 4 A M 24 These are attorney opinions and statements that are being
9 : 2 4 A M 25 offered in evidence. And, like expert testimony, there are

9 : 2 4 A M 1 special protections that are needed when those types of
9 : 2 4 A M 2 statements are presented in evidence to a jury. Juries may be
9 : 2 5 A M 3 more likely to over-rely on attorney statements, just like they
9 : 2 5 A M 4 may -- like --

9 : 2 5 A M 5 THE COURT: That cuts both ways, Counsel.

9 : 2 5 A M 6 MR. TERRANOVA: It does.

9 : 2 5 A M 7 THE COURT: That's --

9 : 2 5 A M 8 MR. TERRANOVA: Absolutely.

9 : 2 5 A M 9 THE COURT: Let me say this: If they believe that
9 : 2 5 A M 10 Mr. O'Connor came in and told them what -- there is evidence in
9 : 2 5 A M 11 the record saying they told them? It's a killer. If the jury
9 : 2 5 A M 12 believes that, it's a killer.

9 : 2 5 A M 13 MR. TERRANOVA: That's correct.

9 : 2 5 A M 14 THE COURT: That's why I asked y'all, had you
9 : 2 5 A M 15 calculated? Early on, I said, "Have y'all calculated this from
9 : 2 5 A M 16 the June meeting?" I mean, I know y'all made a motion for
9 : 2 5 A M 17 summary judgment from that time forward, and I just said I'm
9 : 2 5 A M 18 not going to grant summary judgment in an intent case. I just
9 : 2 5 A M 19 don't think you can get there.

9 : 2 5 A M 20 But I recognize that was a powerful moment in
9 : 2 5 A M 21 this, and if the jury is inclined -- the defendants account
9 : 2 5 A M 22 differently for that meeting. They say they heard something
9 : 2 5 A M 23 else, thus my caustic comment, "wouldn't you love to have been
9 : 2 6 A M 24 a fly on the wall?" I would have loved to have a transcript of
9 : 2 6 A M 25 that meeting because I think it's pretty important.

9 : 2 6 A M 1 I -- I think this gets it about right. I mean,
9 : 2 6 A M 2 there's nothing perfect about these. So I'm going to leave
9 : 2 6 A M 3 that.

9 : 2 6 A M 4 Mr. Terranova, any other objections to the
9 : 2 6 A M 5 Court's charge?

9 : 2 6 A M 6 **MR. TERRANOVA:** The one issue that we weren't -- were
9 : 2 6 A M 7 not clear about is whether Your Honor intended to instruct the
9 : 2 6 A M 8 jury on presenting false statements or claims -- false
9 : 2 6 A M 9 statements or records material to a --

9 : 2 6 A M 10 **THE COURT:** I thought that's in there.

9 : 2 6 A M 11 **MR. TERRANOVA:** Yeah, there is some language in
9 : 2 6 A M 12 there, but we just wanted to make sure that that's what Your
9 : 2 6 A M 13 Honor intended to do. And if so --

9 : 2 6 A M 14 **THE COURT:** I'm going to say what's here is exactly
9 : 2 6 A M 15 what I'm going to say. I list that as one of the ways, and one
9 : 2 6 A M 16 of them is presenting a false claim, another is a false
9 : 2 6 A M 17 statement, and a third is conspiracy. I say them all.

9 : 2 6 A M 18 **MR. TERRANOVA:** Okay. Understood.

9 : 2 6 A M 19 **THE COURT:** Okay. Bluewave, objections from
9 : 2 7 A M 20 Bluewave?

9 : 2 7 A M 21 **MR. GRIFFITH:** Your Honor, starting off -- and you've
9 : 2 7 A M 22 already indicated this, but just for the record, to the extent
9 : 2 7 A M 23 that we've already provided our proposed jury instructions --

9 : 2 7 A M 24 **THE COURT:** By the way, I'm going to go through each
9 : 2 7 A M 25 jury instruction and rule on it and explain why I'm ruling

9 : 2 7 A M 1 against you.

9 : 2 7 A M 2 MR. GRIFFITH: I did want to make sure we're
9 : 2 7 A M 3 protected on the record.

9 : 2 7 A M 4 THE COURT: Absolutely. I'm going to explain. And I
9 : 2 7 A M 5 take it that, to the extent any charge is inconsistent with
9 : 2 7 A M 6 that, you're objecting. You want that charge. I get that.

9 : 2 7 A M 7 MR. GRIFFITH: Exactly. Just on the record, I want
9 : 2 7 A M 8 to do that. And I will materially cut back on what I need to
9 : 2 7 A M 9 discuss today. Several times -- I mean, throughout the charge,
9 : 2 7 A M 10 you used the preponderance of the evidence standard.

9 : 2 7 A M 11 THE COURT: You're protected on that. I'm not
9 : 2 7 A M 12 charging --

9 : 2 7 A M 13 MR. GRIFFITH: And just for the record, we believe
9 : 2 7 A M 14 from FCA it should be clear and convincing.

9 : 2 8 A M 15 THE COURT: I know your arguments.

9 : 2 8 A M 16 MR. GRIFFITH: And for the AKS, it should be beyond a
9 : 2 8 A M 17 reasonable doubt.

9 : 2 8 A M 18 THE COURT: And I have previously ruled on that.

9 : 2 8 A M 19 MR. GRIFFITH: Right. And we object to the
9 : 2 8 A M 20 presenting aspect of the False Claims Act in terms of we
9 : 2 8 A M 21 believe that the record is only caused to be presented and not
9 : 2 8 A M 22 a -- and not a presentation in terms of the False Claims Act.

9 : 2 8 A M 23 THE COURT: well, you're guilty if you presented or
9 : 2 8 A M 24 caused to be presented the -- and I explained then that the
9 : 2 8 A M 25 claim -- the government asserts that defendant Mallory

1 presented and defendant -- BlueWave defendants caused to be
2 presented. So is there a problem with that?

3 **MR. GRIFFITH:** well, to the extent that BlueWave did
4 not have anything to do with the presentation of claims, all
5 BlueWave did was --

6 **THE COURT:** I think that's clear, but I'm going to
7 leave it to you for argument if you wish to make that point.

8 **MR. GRIFFITH:** Okay.

9 **THE COURT:** It's certainly correct.

10 **MR. GRIFFITH:** And so our understanding, only HDL was
11 actually presenting the claims.

12 **THE COURT:** Right, presenting or causing to be
13 presented. That's why I said, now, here's what the government
14 says HDL did and here's what the government says BlueWave did.
15 And I would think, as part of your argument, you would --
16 closing argument may well explain that further. But that's
17 what the charge says.

18 **MR. GRIFFITH:** Okay. Then, again, I know you ruled
19 on this, but you cite the one-purpose test. And we would --

20 **THE COURT:** I've ruled. Keep going.

21 **MR. GRIFFITH:** Your Honor, on page 14 --

22 **THE COURT:** Let me get there.

23 **MR. GRIFFITH:** On the last paragraph, you say "a
24 defendant who acts with a good-faith belief that his or her
25 conduct is lawful does not willfully violate the Anti-Kickback

9 : 3 0 A M 1 Statute."

9 : 3 0 A M 2 THE COURT: Let me find -- where are we now, page 14?

9 : 3 0 A M 3 MR. GRIFFITH: Page 14, bottom paragraph.

9 : 3 0 A M 4 THE COURT: Okay. For some reason -- yes. Okay.
9 : 3 0 A M 5 First sentence of that paragraph, yes, sir.

9 : 3 0 A M 6 MR. GRIFFITH: If you note, Your Honor, you only
9 : 3 0 A M 7 address the Anti-Kickback Statute. And we believe that it's
9 : 3 0 A M 8 appropriate -- we believe that good faith goes to knowledge --
9 : 3 0 A M 9 the knowledge element of the False Claims Act in addition to
10 the -- what you've cited here.

9 : 3 0 A M 11 THE COURT: Let's talk about that. This is a little
9 : 3 0 A M 12 tricky here because the False Claims Act sets forth a --
9 : 3 1 A M 13 different ways in which one would be knowingly liable. You can
9 : 3 1 A M 14 have actual knowledge. Obviously, if you have actual
9 : 3 1 A M 15 knowledge, there's not a good faith. You could be deliberately
9 : 3 1 A M 16 ignorant. And then you should -- and then reckless disregard.
9 : 3 1 A M 17 All of those are incompatible with good faith. Okay? I
9 : 3 1 A M 18 mean -- and it's the government's burden to prove those.

9 : 3 1 A M 19 The question is, should I additionally -- you
9 : 3 1 A M 20 see, it gets complicated because I'm defining -- you know, the
9 : 3 1 A M 21 government has this burden to prove this. And you're now
9 : 3 1 A M 22 asking me -- they don't have the burden to prove the absence of
9 : 3 1 A M 23 good faith. Good faith, obviously, they have to prove
9 : 3 2 A M 24 deliberate -- actual knowledge, deliberate ignorance, or
9 : 3 2 A M 25 reckless disregard. If those are present, you don't have good

9 : 3 2 A M 1 faith. It just seems to me it's more confusing to the jury.
9 : 3 2 A M 2 Do you understand what I'm saying there?

9 : 3 2 A M 3 MR. GRIFFITH: well, I think -- I think I understand.

9 : 3 2 A M 4 THE COURT: You can't have -- it's the government's
9 : 3 2 A M 5 burden -- this is not an affirmative defense for y'all under
9 : 3 2 A M 6 this. As I view you it, you don't have a burden to prove it;
9 : 3 2 A M 7 the government has the burden to prove the state of mind.

9 : 3 2 A M 8 MR. GRIFFITH: Right.

9 : 3 2 A M 9 THE COURT: So the question is, clearly, if you have
9 : 3 2 A M 10 actual knowledge, you can't have a good faith belief because
9 : 3 2 A M 11 you have knowledge. If you were deliberately ignorant, what it
9 : 3 2 A M 12 takes to do that, to be deliberately ignorant, is the absence
9 : 3 2 A M 13 of good faith. I mean, you have to be willfully trying -- you
9 : 3 2 A M 14 have to be deliberately and intentionally avoiding information.
9 : 3 2 A M 15 And reckless disregard includes acts -- reckless disregard
9 : 3 2 A M 16 includes conduct that entails such an unjustifiably high risk
9 : 3 3 A M 17 of running afoul of the standard that it cannot be said to be
9 : 3 3 A M 18 doing so was either known or so obviously it should have been
9 : 3 3 A M 19 known. Mere negligence is not sufficient.

9 : 3 3 A M 20 Boy, that's not good faith. I mean, so I
9 : 3 3 A M 21 have -- I hear what you're saying. I'm just trying to figure
9 : 3 3 A M 22 out how you fit good faith into that, because I'm -- it's
9 : 3 3 A M 23 almost -- I mean, I don't want to shift the burden to the
9 : 3 3 A M 24 defendants here. I'm trying to -- the government has got to
9 : 3 3 A M 25 prove this. I get argument.

9 : 3 3 A M 1 So what would you have me add, Mr. Griffith?

9 : 3 3 A M 2 **MR. GRIFFITH:** That good faith applies to the
9 : 3 3 A M 3 knowledge element of the False Claims Act. And that would
9 : 3 3 A M 4 encompass all three standards: actual knowledge, deliberate
9 : 3 3 A M 5 indifference, and a reckless disregard.

9 : 3 3 A M 6 I mean, I think it's pretty black letter law
9 : 3 3 A M 7 that good faith is applicable to the knowledge standard of the
9 : 3 4 A M 8 False Claims Act.

9 : 3 4 A M 9 **THE COURT:** But a finding of -- would you agree with
9 : 3 4 A M 10 me a finding of actual knowledge is not compatible with good
9 : 3 4 A M 11 faith? Do we agree with that? You have actual knowledge.
9 : 3 4 A M 12 It's not compatible; right?

9 : 3 4 A M 13 **MR. GRIFFITH:** I agree conceptually.

9 : 3 4 A M 14 **THE COURT:** Yeah. And if you were deliberately
9 : 3 4 A M 15 ignorant, that is not -- that is not conceptually consistent
9 : 3 4 A M 16 with good faith. I mean, you couldn't meet that standard, be
9 : 3 4 A M 17 deliberately ignorant and be acting in good faith.

9 : 3 4 A M 18 **MR. GRIFFITH:** Agreed, Your Honor, but I think the --

9 : 3 4 A M 19 **THE COURT:** I couldn't include that without saying if
9 : 3 4 A M 20 you determine that the defendant, one or more defendants was --
9 : 3 4 A M 21 had actual knowledge, was deliberately ignorant, and/or was --
9 : 3 5 A M 22 had showed reckless disregard, that cannot be good faith. I
9 : 3 5 A M 23 mean, you can't have those and have good faith. They're not
9 : 3 5 A M 24 compatible. And I don't want to mislead the jury that the
9 : 3 5 A M 25 government could prove that and you could say, oh, well, I had

9 : 3 5 A M 1 a good faith. These definitions are incompatible with it.

9 : 3 5 A M 2 So you're inviting me to say something which,
9 : 3 5 A M 3 frankly, I left out because the second sentence of that, you
9 : 3 5 A M 4 know, I thought it was kind of unnecessary. You're going to
9 : 3 5 A M 5 get both sentences if you get it in there. Do you hear what
9 : 3 5 A M 6 I'm saying? You're going to get that second sentence, which
9 : 3 5 A M 7 says that if you find one of these elements that meet the
9 : 3 5 A M 8 standard of knowingly, that's not good faith. Do you really
9 : 3 5 A M 9 want that?

9 : 3 5 A M 10 MR. GRIFFITH: So you're going to put the second
9 : 3 6 A M 11 sentence in --

9 : 3 6 A M 12 THE COURT: If -- if -- I mean, you can't just say,
9 : 3 6 A M 13 "Oh, I did have actual knowledge" or "I was deliberately
9 : 3 6 A M 14 ignorant" or "I had reckless disregard," but "I did it in good
9 : 3 6 A M 15 faith." No, you can't do that. The government's burden to
9 : 3 6 A M 16 prove is -- meets one of those states of mind.

9 : 3 6 A M 17 So it's potentially confusing just to say "good
9 : 3 6 A M 18 faith." So if you want me to do it, I'm going to have to add
9 : 3 6 A M 19 the second sentence to explain that, if you determine that it
9 : 3 6 A M 20 is -- if you determine that one of these states of mind, the
9 : 3 6 A M 21 government has proven it by a preponderance of the evidence,
9 : 3 6 A M 22 cannot be good faith.

9 : 3 6 A M 23 So do you want me to do that?

9 : 3 6 A M 24 MR. GRIFFITH: Your Honor, if you're going to qualify
9 : 3 6 A M 25 it like that, we're just going to leave it the way it is.

9 : 3 6 A M 1 THE COURT: It's not qualified; that's what the law
9 : 3 6 A M 2 is.

9 : 3 7 A M 3 Mr. Ashmore, do you have anything you wish to
9 : 3 7 A M 4 add to that?

9 : 3 7 A M 5 MR. ASHMORE: Not that particular argument, Your
9 : 3 7 A M 6 Honor.

9 : 3 7 A M 7 THE COURT: Government, what's y'all's thought about
9 : 3 7 A M 8 this?

9 : 3 7 A M 9 MR. TERRANOVA: We agree that it would be confusing
9 : 3 7 A M 10 to add this reference to good faith because it seems like there
9 : 3 7 A M 11 are two different standards the jury has to decide when there's
9 : 3 7 A M 12 only one under the False Claims Act.

9 : 3 7 A M 13 THE COURT: Right. And I'd have to explain that --
9 : 3 7 A M 14 as I've said, that if they find one of these -- and I left -- I
9 : 3 7 A M 15 will tell you, Mr. Ashmore, in a couple of breaths, I had it in
9 : 3 7 A M 16 my head to do it when I had both sentences, and I ultimately
9 : 3 7 A M 17 said, you know, I think the simpler way is to put the standards
9 : 3 7 A M 18 up and let the parties argue.

9 : 3 7 A M 19 MR. GRIFFITH: Okay.

9 : 3 7 A M 20 THE COURT: So I'm not locked into that. If you --
9 : 3 7 A M 21 but you're going to get both sentences.

9 : 3 7 A M 22 MR. GRIFFITH: Then we'll leave it the way it is,
9 : 3 7 A M 23 Your Honor.

9 : 3 7 A M 24 THE COURT: I thought -- I frankly thought that it
9 : 3 7 A M 25 would just be better for everybody to let y'all argue this.

9 : 3 7 A M 1 The government has the burden. I've set forth what that burden
9 : 3 7 A M 2 is.

9 : 3 7 A M 3 Okay. I'm just going to leave it the way it is.
9 : 3 7 A M 4 what else you got?

9 : 3 7 A M 5 **MR. GRIFFITH:** Your Honor, I -- but in that same
9 : 3 7 A M 6 paragraph that leads into page 15 --

9 : 3 8 A M 7 **THE COURT:** Let me go back to that.

9 : 3 8 A M 8 **MR. GRIFFITH:** Okay.

9 : 3 8 A M 9 **THE COURT:** Okay.

9 : 3 8 A M 10 **MR. GRIFFITH:** And you're talking about good faith.
9 : 3 8 A M 11 And in the last sentence, you reference legal opinions and
9 : 3 8 A M 12 advice --

9 : 3 8 A M 13 **THE COURT:** Yes.

9 : 3 8 A M 14 **MR. GRIFFITH:** -- regardless of its source. And we
9 : 3 8 A M 15 had discussed previously industry practices as being evidence
9 : 3 8 A M 16 of good faith. And we would like --

9 : 3 8 A M 17 **THE COURT:** If you're going to get me into all of
9 : 3 8 A M 18 that, I'm going to take the sentence out. I'm not getting into
9 : 3 8 A M 19 an argument on the facts. I just thought, generally
9 : 3 8 A M 20 speaking -- and, you know, I'm rethinking whether the last
9 : 3 8 A M 21 sentence should even be there. If you invite me to start
9 : 3 8 A M 22 adding these other things, I'm probably going to take it all
9 : 3 8 A M 23 out, frankly.

9 : 3 8 A M 24 **MR. GRIFFITH:** we would probably have you --

9 : 3 8 A M 25 **THE COURT:** I mean, it just strikes me that, in

1 fairness to the defendants, I should say that the totality of
2 the evidence mentions these opinions everybody is talking
3 about. In fairness to the government, it's all of them.
4 That's what I'm trying to do in a balanced statement.

5 **MR. GRIFFITH:** Okay. And then, under the
6 presentment -- on that same page, 15 --

7 **THE COURT:** And let me just say about industry
8 practice, I feel like I'm getting into commenting on the
9 evidence, which I try to avoid doing. And you're just -- you
10 know, that's for y'all for argument.

11 So the list would be very long. You wouldn't
12 stop -- start -- you would end at industry practices. That's
13 one you want to talk about. But there would be others, and I
14 just think that's for argument. So --

15 **MR. GRIFFITH:** Okay. And on the presentment of false
16 claims, you've got three elements listed. You don't have
17 materiality.

18 **THE COURT:** I've ruled as a matter of law that
19 materiality is -- is present. I have thought about putting it
20 in and telling the jury that I found it as a matter of law.
21 That's another way to do it. I think that would probably be
22 adverse to the defendants and not particularly necessary. I'm
23 giving the jury enough information here. I have already ruled
24 as a matter of law that -- that it is present.

25 So I'm declining to -- I'm not putting it in.

9 : 4 0 A M 1 If I put it in, I'm going to have to say that's an element of
9 : 4 0 A M 2 the statute, but I have already ruled as a matter of law that
9 : 4 0 A M 3 such payments would be material. I don't think you want me to
9 : 4 0 A M 4 do that.

9 : 4 0 A M 5 MR. GRIFFITH: No, we don't, Your Honor.

9 : 4 0 A M 6 THE COURT: I didn't think so.

9 : 4 0 A M 7 MR. GRIFFITH: So then on the next page, 16 -- and
9 : 4 0 A M 8 this is -- I'd just point out to the Court, on the last
9 : 4 1 A M 9 paragraph it says, "United States alleges that certain
9 : 4 1 A M 10 defendants who did not themselves present claims to Medicare or
9 : 4 1 A M 11 TRICARE violated the False Claims Act by causing others to
9 : 4 1 A M 12 present false or fraudulent claims or statements."

9 : 4 1 A M 13 THE COURT: Yes.

9 : 4 1 A M 14 MR. GRIFFITH: I'm not sure presenting a statement is
9 : 4 1 A M 15 an accurate instruction in the law right there.

9 : 4 1 A M 16 THE COURT: Presenting a statement is what the
9 : 4 1 A M 17 statute says, doesn't it?

9 : 4 1 A M 18 MR. GRIFFITH: No. The statute says --

9 : 4 1 A M 19 THE COURT: Submitting? You want me to add --

9 : 4 1 A M 20 MR. GRIFFITH: I would just leave out "or
9 : 4 1 A M 21 statements."

9 : 4 1 A M 22 THE COURT: well, no, that's an element. That's part
9 : 4 1 A M 23 of the thing, is your -- having them make their false
9 : 4 1 A M 24 certification.

9 : 4 1 A M 25 MR. GRIFFITH: Okay.

9 : 4 1 A M 1 **THE COURT:** If you want me to -- let's look at what
9 : 4 1 A M 2 the statute says here. "Knowingly, willfully making or causing
9 : 4 2 A M 3 to make any false statement; knowingly or willfully causing to
9 : 4 2 A M 4 be made any false statement of a material -- material fact."

9 : 4 2 A M 5 I think it's fine.

9 : 4 2 A M 6 Okay. What else?

9 : 4 2 A M 7 **MR. GRIFFITH:** Okay. And then later on in that
9 : 4 2 A M 8 paragraph, it says that "You may find that United States has
9 : 4 2 A M 9 shown causation even if you find that HDL and Singulex, the
9 : 4 2 A M 10 laboratories who submitted the claims to the United States, did
9 : 4 2 A M 11 not know that the claims, records, or statements were false."

9 : 4 2 A M 12 **THE COURT:** Right.

9 : 4 2 A M 13 **MR. GRIFFITH:** And we just believe that's an
9 : 4 2 A M 14 incorrect statement, that if the entity that's involved in the
9 : 4 2 A M 15 presentment of the claim doesn't know that it's a false claim,
9 : 4 2 A M 16 we don't know how we can be held responsible.

9 : 4 2 A M 17 **THE COURT:** Here's how it could be: If you took the
9 : 4 2 A M 18 view of the evidence that Bluewave, without the knowledge of
9 : 4 2 A M 19 HDL, was inducing referrals with improper remuneration or
9 : 4 3 A M 20 improperly encouraging the submission of unnecessary tests,
9 : 4 3 A M 21 and -- and HDL said "We didn't know about it," and the -- and
9 : 4 3 A M 22 the Bluewave defendants and -- and Bluewave defendants caused
9 : 4 3 A M 23 to be presented knowing -- knowingly caused to be presented
9 : 4 3 A M 24 such a claim, yeah, they would be liable even though the lab
9 : 4 3 A M 25 wouldn't be liable. That would state a claim.

9 : 4 3 A M 1 So I respectfully disagree with your
9 : 4 3 A M 2 interpretation of the law.

9 : 4 3 A M 3 MR. GRIFFITH: Okay. And then on the next page, 17,
9 : 4 3 A M 4 under the false or fraudulent claim, Your Honor, it says that
9 : 4 3 A M 5 "the United States alleges that certain of the claims
9 : 4 3 A M 6 defendants presented or caused to be presented were false
9 : 4 3 A M 7 because those claims were presented in violation of the
9 : 4 4 A M 8 Anti-Kickback Statute."

9 : 4 4 A M 9 And we would ask that you insert "knowingly and
10 willfully."

9 : 4 4 A M 11 THE COURT: No, I'm not -- do I do all the other
9 : 4 4 A M 12 elements of AKS? No. I've already defined earlier what the
9 : 4 4 A M 13 AKS elements were.

9 : 4 4 A M 14 Part of this, folks, is that we don't so lawyer
9 : 4 4 A M 15 up the statement that the jury can't understand it. I'm trying
9 : 4 4 A M 16 to do it in a way -- this is as complex a charge as I have ever
9 : 4 4 A M 17 given. I suspect it's as complex a charge as y'all have ever
9 : 4 4 A M 18 worked on. And I'm trying to do my best to simplify it. And
9 : 4 4 A M 19 inserting unnecessary language, there's a legion of all those
9 : 4 4 A M 20 elements. So I decline to do that.

9 : 4 4 A M 21 what else?

9 : 4 4 A M 22 MR. GRIFFITH: On the next page.

9 : 4 4 A M 23 THE COURT: Yes.

9 : 4 4 A M 24 MR. GRIFFITH: Your Honor, on the very first
9 : 4 4 A M 25 sentence, it says, "United States alleges that all defendants

9 : 4 5 A M 1 knowingly made or caused to be made or used false or fraudulent
9 : 4 5 A M 2 claims." And we -- we believe that's incorrect.

9 : 4 5 A M 3 THE COURT: How's that?

9 : 4 5 A M 4 MR. GRIFFITH: well, there's two components of the
9 : 4 5 A M 5 False Claims Act. And this is under the false statements.
9 : 4 5 A M 6 "Made or caused to be made or used" is under the second prong,
9 : 4 5 A M 7 not the first -- not the false claim. If you look at -- I
9 : 4 5 A M 8 think it was a(1) is the false and a(2) is the false records
9 : 4 5 A M 9 and statements.

9 : 4 5 A M 10 THE COURT: Knowingly or willfully makes or causes to
9 : 4 5 A M 11 be made a false statement, causes --

9 : 4 5 A M 12 MR. GRIFFITH: Yeah, but this says "claim."

9 : 4 5 A M 13 THE COURT: Hold on. This is only the claims part,
9 : 4 5 A M 14 this one here. It says "acting knowingly."

9 : 4 5 A M 15 You want me to add "or statements" --
9 : 4 5 A M 16 "fraudulent claims or statements"?

9 : 4 6 A M 17 MR. GRIFFITH: well, we'd like you to take out
9 : 4 6 A M 18 "claims" and just say "statements or records." Because when
9 : 4 6 A M 19 you say made or -- we thought that you were addressing the
9 : 4 6 A M 20 false statements --

9 : 4 6 A M 21 THE COURT: No, I'm doing both.

9 : 4 6 A M 22 MR. GRIFFITH: Okay.

9 : 4 6 A M 23 THE COURT: Here we're talking about the claims. I
9 : 4 6 A M 24 could put "false or fraudulent claims or false statements."
9 : 4 6 A M 25 You want me to add that? If you want me to add that, I'll

9 : 4 6 A M 1 add --

9 : 4 6 A M 2 MR. GRIFFITH: well --

9 : 4 6 A M 3 THE COURT: -- "fraudulent claims or false
9 : 4 6 A M 4 statements" -- "and/or false statements."

9 : 4 6 A M 5 MR. GRIFFITH: well, we think -- I think it would be
9 : 4 6 A M 6 incorrect under that -- even if you add that.

9 : 4 6 A M 7 THE COURT: why?

9 : 4 6 A M 8 MR. GRIFFITH: Because -- because there's no
9 : 4 6 A M 9 reference to presentation. I think you're conflating a(1) and
10 a(2). And --

9 : 4 7 A M 11 THE COURT: Okay. We're going to separate -- I'm
9 : 4 7 A M 12 going to -- I'm going to have two sentences here rather than
9 : 4 7 A M 13 one, one addressing the claims. We merged them too with "false
9 : 4 7 A M 14 statements" to eliminate any confusion. We tried to reduce
9 : 4 7 A M 15 that to one sentence.

9 : 4 7 A M 16 I see your point. We'll do two sentences.

9 : 4 7 A M 17 Yes, sir? What else?

9 : 4 8 A M 18 MR. GRIFFITH: Your Honor, that would be -- that
9 : 4 8 A M 19 would be it at this time. We'd also ask if we can propose an
9 : 4 8 A M 20 instruction on independent contractor. I mean, I have -- we
9 : 4 8 A M 21 have one. I mean, it's short. But we think in light of the
9 : 4 9 A M 22 evidence that's been presented --

9 : 4 9 A M 23 THE COURT: The idea that we present these things
9 : 4 9 A M 24 ahead of time is that we -- the answer is yes, I will look at
9 : 4 9 A M 25 it. Okay.

9 : 4 9 A M 1 But let me fuss just a moment that, you know,
9 : 4 9 A M 2 we've had multiple opportunities. You had a deadline to get
9 : 4 9 A M 3 your proposed charges in. But hand it up, and let's show it to
9 : 4 9 A M 4 the government.

9 : 4 9 A M 5 MR. COOKE: Your Honor, can I butt in on that one?

9 : 4 9 A M 6 THE COURT: Yes, sir.

9 : 4 9 A M 7 MR. COOKE: We would actually ask the Court to charge
9 : 4 9 A M 8 the jury that the sales representatives were independent
9 : 4 9 A M 9 contractors. And we do have a charge that says that if they're
9 : 4 9 A M 10 a conspirator, then their acts could be imputed to the
9 : 4 9 A M 11 principals.

9 : 4 9 A M 12 THE COURT: Right.

9 : 4 9 A M 13 MR. COOKE: But I think that should be offset by the
9 : 4 9 A M 14 Court instructing, as a matter of law, that they were, in fact,
9 : 4 9 A M 15 independent contractors. And absent a finding that they were
9 : 4 9 A M 16 conspirators, their acts would not be imputed to the
9 : 4 9 A M 17 defendants, because the plaintiffs actually allege that they're
9 : 5 0 A M 18 independent contractors.

9 : 5 0 A M 19 One testified that every element that goes to
9 : 5 0 A M 20 determining independent contractor was met. And rather than
9 : 5 0 A M 21 give them a complicated instruction on all the elements of
9 : 5 0 A M 22 independent contractor, we would ask the Court to simply
9 : 5 0 A M 23 instruct them that they are independent contractors and --

9 : 5 0 A M 24 THE COURT: You see, it's alleged that there's a
9 : 5 0 A M 25 scheme, acting through independent contractors to order

9 : 5 0 A M 1 unnecessary tests and to offer unlawful remunerations under the
9 : 5 0 A M 2 AKS.

9 : 5 0 A M 3 You can't create -- you can't immunize yourself
9 : 5 0 A M 4 from your conduct by having these people set up an array of
9 : 5 0 A M 5 corporations to act through to protect them from liability. I
9 : 5 0 A M 6 have not yet looked at this. I want to, but I'm worried you're
9 : 5 0 A M 7 going to open a Pandora's box that I now will have to charge
9 : 5 1 A M 8 those additional issues.

9 : 5 1 A M 9 But I'm not going to do it independently. If
9 : 5 1 A M 10 you want me to do that, I've got to go further and explain why
9 : 5 1 A M 11 that conduct is potentially relevant because they're not free
9 : 5 1 A M 12 to -- I don't want to suggest that, as long as you put "LLC"
9 : 5 1 A M 13 after your name, you could commit crimes and get away with it
9 : 5 1 A M 14 and the people directing you and training you and encouraging
9 : 5 1 A M 15 you and compensating you for it have no liability. That is not
9 : 5 1 A M 16 the law.

9 : 5 1 A M 17 So if you want to open this Pandora's box, I
9 : 5 1 A M 18 will have to go further. Do you want me to do that?

9 : 5 1 A M 19 **MR. COOKE:** well, think you've already done that with
9 : 5 1 A M 20 your conspiracy charge.

9 : 5 1 A M 21 **THE COURT:** I've said that they're part of the
9 : 5 1 A M 22 conspiracy. You can include the language it's just the people
9 : 5 1 A M 23 that worked here. Okay?

9 : 5 1 A M 24 If you want me to go further than that -- I
9 : 5 1 A M 25 haven't discussed it, I haven't addressed it. I could see the

9 : 5 1 A M 1 reason you would want the initial charge, but it would be
9 : 5 1 A M 2 inaccurate to leave it hanging out there as one simple
9 : 5 2 A M 3 statement because I would have to add on top of that that, if
9 : 5 2 A M 4 you determine that they were acting pursuant to the direction,
9 : 5 2 A M 5 advice, authority, whatever of their principals that they or
9 : 5 2 A M 6 their -- the people who they were contracting, that that
9 : 5 2 A M 7 liability could be imputed.

9 : 5 2 A M 8 MR. COOKE: I think that's fair. I mean, that's
9 : 5 2 A M 9 fair. In other words, if the --

9 : 5 2 A M 10 THE COURT: Let me see.

9 : 5 2 A M 11 MR. COOKE: If the principal endorses the conduct or
9 : 5 2 A M 12 participates in the conduct, then it would be -- I think that's
9 : 5 2 A M 13 a fair instruction and -- but I think you could cover it if you
9 : 5 2 A M 14 gave the charge right before your conspiracy charge because it
9 : 5 2 A M 15 would go right into explaining the exception.

9 : 5 2 A M 16 THE COURT: What's the government's thought?

9 : 5 2 A M 17 MR. TERRANOVA: Your Honor, I don't think this
9 : 5 2 A M 18 Instruction Number 57 is an accurate statement of the law.

9 : 5 2 A M 19 Here the independent contractors were acting as
9 : 5 2 A M 20 Bluewave's agents and also their co-conspirator. So under both
9 : 5 3 A M 21 theories, they would be liable for violations of the
9 : 5 3 A M 22 Anti-Kickback Statute.

9 : 5 3 A M 23 And, moreover, this argument that independent
9 : 5 3 A M 24 contractors are somehow exempt or the liability is not attached
9 : 5 3 A M 25 to the principal is flatly contradicted by the safe harbors

9 : 5 3 A M 1 that were set up by OIG. This -- this argument was
9 : 5 3 A M 2 specifically put to them in 1991 to create a safe harbor for
9 : 5 3 A M 3 independent contractors. And OIG said, "we continue to reject
9 : 5 3 A M 4 this approach because of the existence of widespread abuse of
9 : 5 3 A M 5 practices by sales persons who are independent contractors,
9 : 5 3 A M 6 and, therefore, are not under appropriate supervision and
9 : 5 3 A M 7 control.

9 : 5 3 A M 8 So they're trying to create a new safe harbor
9 : 5 3 A M 9 that OIG rejected in 1991, and the cite for this is
9 : 5 3 A M 10 56 Fed. Reg. 35952.

9 : 5 3 A M 11 **THE COURT:** So you're introducing a term called
9 : 5 3 A M 12 "vicarious liability." Okay. And, you know, there's actually
9 : 5 4 A M 13 a very interesting case. I don't have it at my fingertips. It
9 : 5 4 A M 14 talks about independent contractors in the AKS who are actually
9 : 5 4 A M 15 independent contractor agents -- they call them that -- versus
9 : 5 4 A M 16 those like you'd go hire a guy to build your pool in your
9 : 5 4 A M 17 backyard and you have no -- and then they really analyze very
9 : 5 4 A M 18 differently.

9 : 5 4 A M 19 I'm not going to -- I'm not crazy about the idea
9 : 5 4 A M 20 of introducing the term "vicarious liability." That's a new
9 : 5 4 A M 21 term. If you want me to do something -- and I'll take a
9 : 5 4 A M 22 thought about how to do this. I see your point.

9 : 5 4 A M 23 But you're inviting the other side of that
9 : 5 4 A M 24 argument, as the government just said, that they're
9 : 5 4 A M 25 co-conspirators who are acting pursuant to their direction and

9 : 5 4 A M 1 training. Then the defendants are potentially liable as -- you
9 : 5 4 A M 2 know, are potentially responsible. It's not imputed to them as
9 : 5 5 A M 3 they're co-conspirators, of course -- I guess it is.

9 : 5 5 A M 4 Let me ask you this: Is the -- beyond
9 : 5 5 A M 5 co-conspirator, is there any other way in which the defendants
9 : 5 5 A M 6 are potentially liable for the conduct of the -- of the
9 : 5 5 A M 7 independent contractors, Mr. Terranova?

9 : 5 5 A M 8 **MR. TERRANOVA:** Yes, as agents. And that -- it goes
9 : 5 5 A M 9 to the standard instruction that Your Honor sometimes gives,
9 : 5 5 A M 10 liability of corporations.

9 : 5 5 A M 11 Here Bluewave Corporation set up and has its
9 : 5 5 A M 12 agents that they trained, they sit with, tell them how to sell
9 : 5 5 A M 13 a product. And folks go out and sell them.

9 : 5 5 A M 14 **THE COURT:** That's the whole thing. They certainly
9 : 5 5 A M 15 would fall into this category -- I can find a case that talks
9 : 5 5 A M 16 about independent contractors issues. They're not
9 : 5 5 A M 17 freestanding. They may be independent contractors for some
9 : 5 5 A M 18 purposes. But they're trained by them, they are monitored and
9 : 5 5 A M 19 supervised by them, daily reports of their behavior.

9 : 5 6 A M 20 If you want me to get into this -- I'm not going
9 : 5 6 A M 21 to use -- I'm going telling you right now I'm not using the
9 : 5 6 A M 22 term "vicarious liability." That's introducing a new legal
9 : 5 6 A M 23 concept.

9 : 5 6 A M 24 I would say to the -- I could say to the jury
9 : 5 6 A M 25 that a party is responsible for those with whom they contract

9 : 5 6 A M 1 to the extent that they direct, advise, conspire with,
9 : 5 6 A M 2 et cetera.

9 : 5 6 A M 3 Do you really want me to make that charge?

9 : 5 6 A M 4 MR. COOKE: Well, in a way, but can I -- can I --

9 : 5 6 A M 5 THE COURT: I don't think you want me to, but I'm
9 : 5 6 A M 6 open to thinking about it because you're asking me to do the
9 : 5 6 A M 7 first half and not the second half. And I think you're
9 : 5 6 A M 8 probably -- everybody's better off just arguing it. But if you
9 : 5 6 A M 9 want me to do it, I will think about it.

9 : 5 6 A M 10 MR. COOKE: I do, and let me just say why. Let me
9 : 5 6 A M 11 give an example. Kyle Martel. Kyle Martel, as we brought out
9 : 5 6 A M 12 in testimony, sent things that nobody at Bluewave knew about --
9 : 5 6 A M 13 or that at least the defendants didn't know about -- and that
9 : 5 7 A M 14 they were not consistent with company policy.

9 : 5 7 A M 15 THE COURT: That is the defendants' theory.

9 : 5 7 A M 16 MR. COOKE: The jury could disagree with that. They
9 : 5 7 A M 17 could say, I think that he really did know what he was doing
9 : 5 7 A M 18 and you were winking at him and telling him to do it.

9 : 5 7 A M 19 If that's true, then we've -- what's the
9 : 5 7 A M 20 word? -- adopted and endorsed? We've ratified his conduct
9 : 5 7 A M 21 and --

9 : 5 7 A M 22 THE COURT: Ratified, adopted.

9 : 5 7 A M 23 MR. COOKE: Anything. Participated in.

9 : 5 7 A M 24 THE COURT: Participated in. And you're going to get
9 : 5 7 A M 25 all this -- if you get it, do you really want this?

9 : 5 7 A M 1 **MR. COOKE:** well, let me explain. I think -- because
9 : 5 7 A M 2 if you just leave it as it is, I think the jury believes that
9 : 5 7 A M 3 they're all employees; and, therefore, what they did we're
9 : 5 7 A M 4 responsible for.

9 : 5 7 A M 5 That's not the law. That's -- the government
9 : 5 7 A M 6 wants to have it both ways. They don't want to give us the
9 : 5 7 A M 7 safe harbor because they're independent contractors and it
9 : 5 7 A M 8 lacks that control, but they don't want to recognize the
9 : 5 7 A M 9 legal --

9 : 5 7 A M 10 **THE COURT:** Mr. Cooke, you have a point. The
9 : 5 8 A M 11 problem, of course, for you is that it has to be a balanced
9 : 5 8 A M 12 statement. I don't mind telling them they are independent
9 : 5 8 A M 13 contractors and that the defendants would not be responsible
9 : 5 8 A M 14 for conduct of independent contracts to which they were -- in
9 : 5 8 A M 15 which they had not participated.

9 : 5 8 A M 16 However, if they ratified, adopted, participated
9 : 5 8 A M 17 in, and/or directed the activity, they could be -- that
9 : 5 8 A M 18 knowledge could -- that conduct could be imputed to them or
9 : 5 8 A M 19 co-conspirators.

9 : 5 8 A M 20 **MR. COOKE:** That's exactly right.

9 : 5 8 A M 21 **THE COURT:** You're okay with that?

9 : 5 8 A M 22 Government okay with that, something along those
9 : 5 8 A M 23 lines?

9 : 5 8 A M 24 **MR. TERRANOVA:** Something along those lines, I think,
9 : 5 8 A M 25 would be -- would be fine.

9 : 5 8 A M 1 "Participated" may be a stronger requirement
9 : 5 8 A M 2 than is appropriate under the law of agency. If they train
9 : 5 8 A M 3 these folks -- even if they don't participate, if they train
9 : 5 8 A M 4 them, go out and sell tests like this and people do it --

9 : 5 9 A M 5 **THE COURT:** Okay. What we're going to do in just a
9 : 5 9 A M 6 minute is I'm going to give both sides a little time to think
9 : 5 9 A M 7 about a proposed charge on this. I'm going to go back to
9 : 5 9 A M 8 chambers and work on it myself.

9 : 5 9 A M 9 I think Mr. Cooke has sort of a point here that
9 : 5 9 A M 10 could be addressed. It's just, like a lot of these charges,
9 : 5 9 A M 11 they're two -- it's a two-edged sword; everybody gets benefit
9 : 5 9 A M 12 and cut in the same charge, right. Maybe it's the right charge
9 : 5 9 A M 13 if that's true.

9 : 5 9 A M 14 But I'm open to it. I'm open to thinking about
9 : 5 9 A M 15 it, and I want to go back and work on it.

9 : 5 9 A M 16 Anything further?

9 : 5 9 A M 17 **MR. GRIFFITH:** No, Your Honor.

9 : 5 9 A M 18 **THE COURT:** Mr. Ashmore?

9 : 5 9 A M 19 **MR. ASHMORE:** Thank you, Your Honor. The adverse
9 : 5 9 A M 20 inference charge, Your Honor, I would argue does not apply to
9 : 5 9 A M 21 Ms. Mallory.

9 : 5 9 A M 22 **THE COURT:** Okay. Tell me what page. We got to go
9 : 5 9 A M 23 to a page.

9 : 5 9 A M 24 This is the Fifth Amendment argument?

9 : 5 9 A M 25 **MR. ASHMORE:** That's right, Your Honor. And that's

9 : 5 9 A M 1 page 24. I would ask that a distinction be drawn excluding
9 : 5 9 A M 2 Ms. Mallory from that.

9 : 5 9 A M 3 That was Kyle Martel that asserted the Fifth.
9 : 5 9 A M 4 He's an independent contractor for Bluewave. There is no close
1 0 : 0 0 A M 5 personal or business relationship with Tonya Mallory, Your
1 0 : 0 0 A M 6 Honor, and I think it's grossly unfair to extend his Fifth
1 0 : 0 0 A M 7 Amendment assertions all the way to Tonya Mallory.

1 0 : 0 0 A M 8 **THE COURT:** What happens if he's a co-conspirator?

1 0 : 0 0 A M 9 **MR. ASHMORE:** Well, Your Honor, I just don't think
1 0 : 0 0 A M 10 there's any evidence in the record to establish that.

1 0 : 0 0 A M 11 **THE COURT:** I disagree.

1 0 : 0 0 A M 12 Okay. If he's a co-conspirator, is it a proper
1 0 : 0 0 A M 13 charge?

1 0 : 0 0 A M 14 **MR. ASHMORE:** I again say no, Your Honor. It's just
1 0 : 0 0 A M 15 he -- the standard is there's got to be a close business and
1 0 : 0 0 A M 16 personal relationship --

1 0 : 0 0 A M 17 **THE COURT:** A co-conspirator.

1 0 : 0 0 A M 18 **MR. ASHMORE:** -- between the person asserting the
1 0 : 0 0 A M 19 Fifth and my client.

1 0 : 0 0 A M 20 **THE COURT:** Okay. I think there is evidence to
1 0 : 0 0 A M 21 support that they were in a conspiracy. And it says, "And if
1 0 : 0 0 A M 22 you find that such witness was a member of a conspiracy to
1 0 : 0 0 A M 23 violate the False Claims Act, you may, but are not required, to
1 0 : 0 0 A M 24 infer such a refusal that the witness's answer would have been
1 0 : 0 0 A M 25 unfavorable to the interest of any co-conspirator."

1 That is black letter law, folks. So I qualify
2 it. I think in the absence of conspiracy, I think you're
3 right. That's why I qualified it that way.

4 Okay. Anything else?

5 MR. ASHMORE: One final thing, Your Honor.

6 THE COURT: Yes, sir.

7 MR. ASHMORE: And that is the advice-of-counsel
8 defense, and I've heard you -- your statements, and I need you
9 to change your mind on that, Judge.

10 THE COURT: Yes, sir.

11 MR. ASHMORE: And here is why. Tonya Mallory has
12 constantly and consistently sought the advice of counsel from
13 the inception of the formation of HDL.

14 And, Your Honor, I would refer you to -- to
15 Mallory exhibits. And I have four in particular that I'll
16 briefly discuss. It's 31, 3, 7, and 29.

17 THE COURT: Yes.

18 MR. ASHMORE: And, Your Honor, just to summarize, 31,
19 this is in 2010. This is Dennis Ryan at LeClairRyan, some
20 250-person firm who was always involved.

21 October 25th, 2010, we are on solid ground with
22 the OIG advisory opinion that Pat is sending. She sought and
23 gained guidance from them concerning the P&H fees and the
24 agreement. That's Defendant 31.

25 Defendants' 3, in 2011, this is Tonya Mallory to

1 Patrick Hurd -- I believe he was a health care expert at
2 LeClairRyan -- and Dennis Ryan. This is Latonya Mallory to her
3 lawyers, "You guys have reviewed this document" -- she's
4 referring to the P&H agreement.

5 "You guys have reviewed this document in the
6 past and did not have an issue with it then. However, in light
7 of this new possible interpretation, criticism of the same
8 document, I'd like you to take a look at it again. Could you
9 please review this document and please tell me what should be
10 changed?" Again, seeking their advice.

11 Defendants' Exhibit 7, this is in 2012. This
12 is -- this is the Ruggio opinion, Your Honor. "Tonya, attached
13 is our time and motion study legal analysis letter. Please let
14 me know if you have any questions."

15 And then, finally, Your Honor, the revised P&H
16 agreement. This is in 2013, Defendants' Exhibit 29, Derek Kung
17 to Tonya Mallory. "I've attached the most recent draft of the
18 revised P&H agreement. I don't think there is anything
19 controversial."

20 She constantly included her lawyers, Your Honor,
21 the HDL lawyers, her own personal lawyer, seeking their advice,
22 is the P&H agreement permissible? Is it illegal?

23 She -- I can't overstate how many times she
24 conversed with the lawyers. And I think it's been established
25 throughout the course of this trial; she sought, gained, and

1 followed the advice of her lawyers.

2 **THE COURT:** well, there are several difficulties.
3 One of the essential elements is you must make full disclosure.
4 And there is the defendants' burden on advice of counsel to
5 show that. There is no evidence of full disclosure.

6 There's a mountain of evidence that has come in
7 that there was a scheme, a plan to promote the sales of these
8 laboratory studies using efforts to encourage mass orderings,
9 to induce people to -- physicians to make mass purchases of
10 medically unnecessary tests. Defendant has not shown that this
11 was revealed to the -- to the lawyers.

12 I again say that, had they been told this, they
13 would have told her that was clearly illegal. Even the ones
14 who were trying -- who may have been making mistakes like
15 Ruggio never -- there's no evidence he ever got this
16 information.

17 And when -- I was struck by both Mr. Johnson and
18 Mr. Dent's examination -- cross-examination on these issues of
19 these documents where the salesmen are -- are offering, you
20 know, if you do so many tests, you make this much money, you
21 get these office visits. They say, oh, that would be wrong.
22 Everybody knew this was wrong.

23 So to say that she was acting on advice of
24 counsel, she doesn't -- she never squarely presents the
25 question with full disclosure. And for that reason, advice of

1 counsel is not appropriate.

2 Also the first letter in which it directly is
3 addressed without full disclosure, formal opinion -- it is
4 actually an opinion -- is Ruggio's letter, which is two years
5 and four months after.

6 And within four months, she knew from Kung that
7 that was wrong. And -- and by early January, Pace had been
8 hired, told her it was wrong and that it was a red flag, that
9 the whole company could be jeopardized. She had taken action
10 to move away from it pursuant to that advice.

11 So to say that she relied on counsel as a
12 complete defense for this whole scenario, for all those reasons
13 it's not an appropriate defense. I understand what you're
14 saying. I allowed it to come in for good faith, and I think
15 you -- I frankly think that, in some ways, you're better off
16 with that because it's not your burden as a practical matter.

17 But it doesn't fit. It doesn't matter whether
18 it helps you or hurts you. It doesn't fit, advice of counsel,
19 which is an extraordinary defense if you think about it.

20 You broke the law. You met all the statutory
21 requirements. You relied on a lawyer who gave you bad advice,
22 and you are completely exonerated. That just doesn't fit the
23 facts here.

24 So for those reasons and others that don't occur
25 to me as I sit here, off the top of my head, I don't think it's

1 an appropriate defense here. However, I have charged the --
2 the defense of good faith.

3 MR. ASHMORE: I understand, Your Honor.

4 THE COURT: Yes. And not charged the defense as an
5 issue on state of mind. Okay.

6 MR. GRIFFITH: Your Honor, may I just briefly --

7 THE COURT: Yes.

8 MR. GRIFFITH: -- just join in Mr. Ashmore's --

9 THE COURT: Well, you're not even close. Okay? I
10 mean, y'all had nobody. Okay?

11 MR. GRIFFITH: Your Honor --

12 THE COURT: You had nice Mr. Sellers, okay, who said,
13 "I know nothing. I did nothing." Okay.

14 MR. GRIFFITH: And specifically with the Fifth
15 Amendment -- and we had addressed that pretrial, and I just
16 want to make sure --

17 THE COURT: Sure. Y'all are protected. Everybody
18 adopted -- all the defendants adopt each others'.

19 MR. ASHMORE: Thank you, Your Honor.

20 THE COURT: Okay. Let me walk through, if I could --
21 the rules mandate that I do this. And if I need to stop and
22 say more fully -- because I've explained a lot of this, but I
23 want to go through these.

24 First I'm going to go through the government's
25 request to charge 1.1 as substantially charged; 2.1 as

1 substantially charged; 2.2, substantially charged.

2 I have two of them that are numbered 2.2,
3 substantially charged; one, for the record, being for claim
4 defined and one being burden of proof.

5 So 2.3, substantially charged; 2.4,
6 substantially charged; 2.5, substantially charged; 2.6, charged
7 but left out the example. It was common in the evidence.

8 2.7, deliberate ignorance, I used the Tuomey
9 charge affirmed by the Fourth Circuit; 2.8, reckless disregard
10 is substantially charged.

11 2.9, materiality, I had already ruled. And as
12 we discussed earlier, we're not charging it at all.

13 2.10, substantially charged; 2.11, substantially
14 charged; 2.12, substantially charged; 2.13, substantially
15 charged; 2.14, substantially charged; 2.15, substantially
16 charged; 2.16, substantially charged.

17 3.1, substantially charged; 3.2, substantially
18 charged; 3.3, substantially charged; 3.4, substantially
19 charged; 3.5, substantially charged; 3.6, substantially
20 charged.

21 4.1, paragraph 1, substantially charged. Did
22 not think the second paragraph was appropriate. It was a
23 comment on the facts.

24 5.1, advice of counsel, I've already discussed,
25 did not charge for the reasons stated. 5.1, substantially

1 charged; 5.2, substantially charged.

2 6.1, substantially charged.

3 And then as to the late request for the charge
4 regarding fair market value, I have -- I did not charge it.
5 There are actually several there. This was Docket 847.

6 The Fifth Amendment, substantially charged.

7 Remuneration, I'm going to go back and we're
8 going to look at that further, but I did not charge it as
9 requested.

10 Safe harbor, substantially charged. Advice of
11 counsel, did not charge.

12 Okay. Now let me go through the -- the request
13 of charge by BlueWave.

14 Number 1, substantially charged.

15 Number 2 is a -- one of the things that was
16 asked was to charge AKS first. I thought it actually made
17 sense. I had it the other way, and I charged it at the
18 defendants' request.

19 Number 3, I've already done the Medicare program
20 and TRICARE, and 3 and 4 and didn't charge. I felt with all
21 the evidence that's come in since then, it was unnecessary.

22 Number 5, substantially charged; Number 6,
23 substantially charged; Number 7, charged until the last two
24 sentences. It goes to the materiality issue, which I've ruled
25 to the contrary.

1 Number 8, I've already ruled to the contrary
2 that one purpose -- the one-purpose rule at Docket 268 at 10.

3 Number 9, remuneration, charged in part. A lot
4 of it was comment on evidence. Did not -- did not think that
5 required an explicit quid pro quo. Did not mention about that.
6 It would be confusing.

7 Number 10, did not charge, clear and convincing.

8 11, did not charge beyond a reasonable doubt.

9 Number 12, did not charge because of my ruling
10 at 795 of materiality, Docket Number 795.

11 Number 13, substantially charged; 14,
12 substantially charged; 15, substantially charged.

13 16, I substantially charged this. 17, I charged
14 the first part. The last -- that sentence, "Flawed reasoning
15 and disputed legal issues arising from vague provisions," I
16 thought that sounded like closing argument, but what do I know?
17 Did not charge that. The first part, I did.

18 Number 18, substantially charged.

19 19 is the materiality issue. I've already ruled
20 at Docket Number 795.

21 Docket number -- Request Number 20, that's the
22 good-faith issue. We're going to -- I'm going to look further
23 in just a minute but did not charge it as requested.

24 Number 21, did not charge affirmative -- did not
25 charge advice of counsel. Same for 22, as previously

10:13 AM 1 explained.

10:13 AM 2 Number 23, substantially charged; 24,
10:13 AM 3 substantially charged.

10:13 AM 4 25 set forth the elements of the FCA, I thought,
10:13 AM 5 lied about compliance. I don't think that needs to be in my
10:13 AM 6 charge, but we laid out the elements but did not charge as
10:13 AM 7 requested there.

10:13 AM 8 26, too fact-specific, laid out the basic
10:14 AM 9 elements, didn't think it was necessary. It sounded like
10:14 AM 10 argument. Number 26, declined to charge.

10:14 AM 11 27 sounds like argument to me. I've laid out
10:14 AM 12 the elements of the statute, so I declined to charge it.

10:14 AM 13 28, this is essentially argument. I've already
10:14 AM 14 laid out issues of medical necessity.

10:14 AM 15 29, I've already charged state of mind, talking
10:14 AM 16 about unreasonable. It's confusing to the jury and not the
10:14 AM 17 standard. It was basically argument.

10:14 AM 18 Number 30, I did not charge. It's argument.

10:14 AM 19 31 is argument. Did not charge.

10:14 AM 20 32, I've argued that this is not an element of
10:14 AM 21 the FCA or AKS, and I did not charge it.

10:15 AM 22 33, did not charge. It mentions that OIG
10:15 AM 23 advisory opinions are not admissible. I ruled they were,
10:15 AM 24 although I don't think they were offered. I can't remember if
10:15 AM 25 it's in, but it's not correct.

1 Asked for a charge in 34 about -- that the
2 advisory opinions are not relevant. I don't -- I don't charge
3 that. And, frankly, the -- the defendants' claim that all they
4 wanted to know was what the law was -- and getting an advisory
5 opinion could be a way to do it. So it is potentially in
6 these -- for these facts potentially relevant. I decline to
7 charge it.

8 35, substantially charged. 36, I've already
9 ruled to the contrary at Docket Number 738.

10 Number 37 is this issue about safe harbor.
11 we've discussed that earlier, and I'm not -- I don't think
12 there's enough claims for safe harbor. It has not been
13 asserted, and it doesn't meet the standard. I decline to
14 charge it. Does not fall -- the law does not support it. It
15 falls within the provisions of the safe harbor here.

16 Number 38, I've substantially -- let me review
17 this again.

18 (Pause.)

19 **THE COURT:** It suggests you can't have a violation of
20 these -- of the False Claims Act if you gave value for
21 services, and it ignores the fact that it may have already been
22 paid by somebody else. Also if there's no medical necessity.
23 So I think it's incorrect, and I don't charge it.

24 39, same reason. Decline to charge.

25 40, substantially charged.

10:17 AM

1 41, substantially charged.

10:17 AM

2 42, clear and convincing, didn't charge. I did
3 mention that you can't have speculative damages.

10:17 AM

4 43, I think it was a confusing statement. I
5 decline to charge. I think it would confuse the jury.

10:17 AM

6 44, it's not correct if there was a
7 co-conspirator. The action of one conspirator, if you join in
8 the conspiracy, would be. So I have not charged that.

10:17 AM

9 Reasonable doubt, Number 45, I decline to charge
10 that. I've already previously ruled.

10:17 AM

11 Number 46, laches, I've already ruled at Docket
12 Number 693 to the contrary.

10:17 AM

13 47, the payment to relators is not a standard
14 here. The parties were -- the defendant was entitled to
15 cross-examine Dr. Mayes and did on that point. Specific
16 amounts are not proper.

10:18 AM

10:18 AM

17 Number 48, substantially charged.

10:18 AM

18 49, substantially charged.

10:18 AM

19 50, substantially charged. And the verdict form,
20 we'll get to in a minute, I think prevents double damages.

10:18 AM

21 51, substantially charged.

10:18 AM

22 52, talking about industry practice constitutes good
23 faith. I think just simply saying that as it does is not a
24 correct statement of the law. It's totality.

10:18 AM

10:18 AM

25 I decline to charge 52.

10:18 AM

1 53, duty to mitigate does not apply under the False
2 Claims Act.

3 54, not charged because it is argumentative.

4 And then I had additional requests about the --
5 Number 56.

6 I didn't have a 55. Was there a 55, or do you guys
7 just count uniquely? I have Jury Instruction 54 and then a 56.
8 Is there a 55?

9 **MR. GRIFFITH:** Your Honor, there was. I thought it
10 was filed. Let me make sure. I think it's -- it was ECF824-1.
11 I can hand you a --

12 **THE COURT:** Okay. I need to look at that. Docket --
13 what is it?

14 **MR. GRIFFITH:** 824-1.

15 **THE COURT:** I'll look at that in a minute. That's
16 why I ask these things.

17 56, I decline to charge. It's not -- there's no
18 claim here by the government that the lab is responsible for
19 determining -- second-guessing the doctor's medical necessity,
20 that there was a scheme to induce the ordering of unnecessary
21 tests. And I simply cite United States v. Groat -- ex rel
22 Groat v. Boston Heart Diagnostics, which was provided at 846-2
23 by the defendants as supporting the proposition earlier
24 discussed here; that is, the scheme that is the problem.

25 The one -- Docket Number 55 is listing all the

1 different factors, and I decline to do that. I don't think
2 it's necessary. I think the general charge is appropriate and
3 sufficient.

4 Then I had just a few from -- anything on
5 Mallory. There was one at docket -- it requests, Number 1,
6 about not producing evidence. And I found the government did
7 produce the necessary evidence. All the others -- unless I'm
8 missing something, Mr. Ashmore, all the others were sort of
9 commentary on other people's requested charge. Am I right
10 about that?

11 **MR. ASHMORE:** That's correct. We're joining in
12 Bluewave's and objecting to the government's in general.

13 **THE COURT:** Okay. Did I leave any out, fail to
14 address any of the charges?

15 **MR. TERRANOVA:** None for the government, Your Honor.

16 **MR. GRIFFITH:** Just 57 that we just handed up
17 earlier, which we discussed earlier today.

18 **THE COURT:** Yes. I will address 57 after our break
19 here.

20 Okay. Verdict form. Any objections to the
21 verdict form?

22 **MR. TERRANOVA:** Not for the government, Your Honor.

23 **MR. GRIFFITH:** No, Your Honor.

24 **MR. ASHMORE:** No, sir.

25 **THE COURT:** Okay. Very good. At last, agreement on

1 something.

2 MR. COOKE: Something's wrong.

3 THE COURT: Okay. Let me go retreat for a few
4 minutes. I want to think about a couple of these issues. I
5 think you need to email me any issue on the independent
6 contractor in the next few minutes because I'm going back to
7 chambers. I'm trying to meet the deadline of starting at 11.

8 How about length of argument? What's the --
9 what's folks' estimation of how long each party's --

10 MR. SHAHEEN: Your Honor, I did a dry run the other
11 night. And it was about an hour and 15 minutes.

12 THE COURT: Okay. Hold on just a second here.

13 MR. SHAHEEN: I've been told to talk slower, though,
14 so it may be --

15 THE COURT: Yeah, you're -- because down here in the
16 south, you got to slow down. The government is about an hour
17 and a quarter.

18 Okay. How about -- who's going to make close?

19 MR. COOKE: I'm doing it for the BlueWave defendants,
20 Your Honor, and I'm thinking probably an hour and a half.

21 THE COURT: Okay.

22 MR. COOKE: But you've seen me be wrong before.

23 THE COURT: We're going to have a little electric
24 probe set up to get your response.

25 Mr. Ashmore?

1 **MR. ASHMORE:** Your Honor, a guess would be somewhere
2 between 45 minutes and an hour and a half. I have to comment
3 on Mr. Cooke saying he was going to stay at his chair, and he
4 worked all the way up to the podium.

5 **THE COURT:** He could not resist being in the
6 spotlight.

7 And then how about for reply? Any estimation on
8 that?

9 **MR. LEVENTIS:** I guess we'll just --

10 **THE COURT:** Play it by ear.

11 **MR. LEVENTIS:** Play it by ear, Your Honor.

12 **THE COURT:** Well, you know, here we go, guys. Two
13 hours -- I mean, if I get them at 11, I'm bringing in lunch for
14 the jury, so we may have, like, 30 minutes for lunch, just so
15 they can get something down. And I'm going to try to avoid
16 breaking up arguments. So, you know, between breaks and lunch
17 and all of that, I'm going to try to get in as many arguments
18 as we can.

19 I mean, they may not get it until late
20 afternoon. You know, they do say that brevity has its rewards.
21 Y'all might want to think about that.

22 And I will say this also: As much as y'all
23 think that -- that you need to explain to the jury everything
24 over and over again, this has been a very attentive jury. Have
25 y'all noticed that? I mean, this has been pretty impressive

1 for a case as complicated as this. You know, they have been
2 unusually attentive.

3 So, you know, don't think you need to reexplain
4 them things that are obvious because I think they -- I think
5 they -- I think they understand the basic facts here. I think
6 it's how they should apply those to the law and what the
7 facts -- you know, that's the gravamen of the case.

8 Okay. Let me go spend a few minutes thinking
9 about these other issues.

10 (Recess.)

11 **THE COURT:** Please be seated. Would you please give
12 the copies to counsel.

13 Folks, let me address these issues that we had
14 outstanding. First of all, on page 13, we -- we took the
15 words -- y'all didn't ask, but we looked over it. When we
16 describe remuneration, it's transfers of items or services for
17 free. That has not really been an issue here, so I took it
18 out. It's just some unnecessary language.

19 Now, to the issue about fair market value. I
20 read the government's cases. I recognize there could be a
21 scenario. Let's take one.

22 Somebody offers to hire someone else's son for
23 fair market value as an inducement. That would obviously -- so
24 there are scenarios where you could have a fair market value
25 and an unlawful inducement.

1 But, in this particular situation, I just
2 find -- give weight to the language of Congress here about more
3 than fair market value. I think it's a very close question.
4 I'll give the government that, but under these circumstances,
5 I'm going to keep the language as I stated it.

6 As to the issue on page 14 about good faith,
7 I've thought about taking out the sentence; but I think, in all
8 fairness, it's the way to do it. I think it's a -- it's a
9 reasonable statement. I did think about it, but I think
10 everybody kind of wants it in, and I think that's reasonable.

11 I made a small change on page 18 just to make
12 clear that -- that false claims and false statements were
13 slightly different, put them both in there. And we, of course,
14 make that clear in other parts of the -- of the -- in other
15 parts of the charge.

16 The largest change is on independent
17 contractors. I was asked to charge this, and I -- this is what
18 I would say: "You have heard evidence that sales
19 representatives for defendant Bluewave Healthcare Consultants
20 were independent contractors. The defendants in this case are
21 not automatically liable for the conduct of Bluewave
22 independent contractors; however, should you find that the
23 Bluewave independent contractors and one or more of the
24 defendants were part of a conspiracy to violate the False
25 Claims Act, you may impute the conduct of the Bluewave

1 independent contractors to any defendant who was part of the
2 conspiracy.

3 "Further, if you find that one or more Bluewave
4 independent contractors engaged in conduct in violation of the
5 False Claims Act, you may impute that unlawful conduct to any
6 defendant who directed, participated in, adopted, and/or
7 ratified that unlawful conduct."

8 Now, does anyone object to that charge? First
9 for the government?

10 **MR. TERRANOVA:** Your Honor, we would just reiterate
11 our prior point regarding agency, but I think, with respect --

12 **THE COURT:** This is not -- I'm not going to charge on
13 agency here.

14 **MR. TERRANOVA:** And with respect to conspiracy, we
15 think this is accurate, although Latonya --

16 **THE COURT:** I can't hear you, Mr. Dent.

17 **MR. TERRANOVA:** Latonya Mallory may have a concern
18 about this final sentence. "If you find that one or more of
19 the Bluewave contractors, then you may impute it to any
20 defendant."

21 **THE COURT:** well, it could be if she -- if she
22 directed, participated in, adopted, and/or ratified it, she
23 would be liable.

24 **MR. TERRANOVA:** Understood.

25 **THE COURT:** That's -- and if she isn't, she's not

1 liable.

2 Okay.

3 MR. GRIFFITH: No objection.

4 THE COURT: Very good.

5 MR. ASHMORE: I join in Mr. Terranova's objection,
6 Your Honor; but other than that, no objection.

7 THE COURT: Well, it is correct, Mr. Ashmore, that if
8 she -- but she's only liable --

9 MR. ASHMORE: I understand.

10 THE COURT: -- if she directed, participated in;
11 she's not liable otherwise.

12 MR. ASHMORE: Yes, sir.

13 THE COURT: Okay. That's the charge. Let's bring in
14 the jury.

15 MR. LEVENTIS: Your Honor, I'm sorry. This should
16 just take a second. I just want to make sure, for closing
17 arguments, two things that came up during the trial.

18 One is this idea of a secret lawsuit. We think
19 that's misleading and unnecessary. The --

20 THE COURT: Argument.

21 MR. LEVENTIS: Okay. And then the second one is
22 discussing --

23 THE COURT: Explain -- you know what you can do? You
24 can explain why it's a secret lawsuit. Okay? It is
25 technically correct. It's just -- has an element that is

1 potentially misleading about it. Okay? And you get to -- if
2 he gets up and says it, then you're free to say, "Let me
3 explain to you what the law is. There's no participation by
4 Dr. Mayes in the secrecy. He's following federal law." Okay?

5 So attributing it to him is ridiculous. So, I
6 mean, but I'm not going to tell them not to use hyperbole.
7 Isn't that what closing argument is anyway?

8 what else you got?

9 **MR. LEVENTIS:** All right. Thank you, Your Honor.

10 The second one is this idea of Fifth Amendment
11 and why someone would have pled the Fifth Amendment. I want to
12 make sure we stay away from --

13 **THE COURT:** Right. I mean, I think we may be having
14 a little bit of a problem where one of the defendants, not a
15 lawyer, said, "Oh, there was a suggestion, you know, that he
16 just -- he was scared."

17 And Mr. Cooke, one time, sort of got there. And
18 I snapped him back and I never heard about it again.

19 And, Mr. Cooke, I'm confident you won't do that
20 during the closing argument; correct?

21 **MR. COOKE:** Now that he's planted it in my brain, who
22 knows?

23 **THE COURT:** You just know the whip is coming from the
24 bench if you do that. How about that?

25 **MR. COOKE:** Logistically, are you thinking that

11:30 AM 1 you'll break for lunch after the plaintiffs' closing?

11:30 AM 2 THE COURT: That's my thought, yes, sir.

11:30 AM 3 MR. COOKE: Okay. Good.

11:30 AM 4 THE COURT: And I have lunch brought in, about 30
11:30 AM 5 minutes. And we're trying to keep this thing going, but we got
11:30 AM 6 to do it within reason.

11:30 AM 7 And, folks, there's a capacity that everybody
11:30 AM 8 has, right, to -- to absorb information. And I don't want
11:30 AM 9 people -- an exhausted jury not to hear what everybody has to
11:30 AM 10 say.

11:30 AM 11 MR. COOKE: Right. I was actually in favor of that,
11:30 AM 12 because I'm going to actually use some paper exhibits, and I
11:30 AM 13 thought it would be good to have a few minutes --

11:30 AM 14 THE COURT: I would -- let me just say this: when
11:30 AM 15 you get real enthusiastic about what you might say, I'm going
11:30 AM 16 to keep them here through your argument. Okay? So if you keep
11:30 AM 17 them too long, you'll have to suffer the consequences of
11:30 AM 18 keeping them too long. Do you understand what I'm saying?

11:30 AM 19 MR. COOKE: I understand.

11:30 AM 20 THE COURT: If they begin frowning at you, take the
11:30 AM 21 hint.

11:30 AM 22 MR. COOKE: I've always known that; it just hasn't
11:31 AM 23 stopped me up until this point.

11:31 AM 24 THE COURT: And you're shameless; right?

11:31 AM 25 Okay. Let's bring in the jury.

1 (Whereupon the jury entered the courtroom.)

2 THE COURT: Please be seated. I can barely say good
3 morning because it's 11:30, but I want y'all to know we have
4 been here since 8:30 this morning working. We were trying to
5 do this so you would not be sitting back there. I kept you
6 back there about 32 minutes, and I was counting every minute I
7 was doing it. I respect and appreciate so much of your service
8 here, but it's important what we did; everybody has been
9 working hard.

10 what you're going to do is you're going to hear
11 argument. First, the government as the plaintiff carries the
12 burden of proof and goes first. Then you will hear from
13 counsel for the defendants, and then the government will have a
14 right to reply.

15 And I'm going to -- we're going to break, try to
16 keep our -- around the time. I hate breaking up attorneys'
17 arguments, but we're going to try to stay on sort of the same
18 schedule we have. And Ms. Ravenel has ordered lunch. Y'all
19 probably know that. So you won't go out of the courthouse;
20 you'll be able to eat lunch right here so we will lose as
21 little time as possible.

22 with that, closing argument for the government.

23 MR. SHAHEEN: Thank you, Your Honor. Good morning.

24 JURY: Good morning.

25 MR. SHAHEEN: It's a privilege to get to turn the

1 lecturn this way and get to face y'all. As my first act of
2 having that privilege, I want to thank you all for the
3 dedication and the time that you've devoted to this case. And
4 I say that on behalf of all my colleagues here as well.

5 This is a case where the evidence shows that
6 defendants are guilty of knowingly and willfully implementing
7 two separate but intertwined kickback schemes in order to
8 induce doctors to order tests from HDL and Singulex. I'm going
9 to talk today about how the evidence demonstrates that the
10 defendants violated the Anti-Kickback Statute and the False
11 Claims Act. But before we discuss specific exhibits, I want to
12 walk through the facts that the parties agree upon.

13 For instance, it is undisputed in this case that the
14 Bluewave sales reps were the face of the labs. They were the
15 ones in the field. They visited doctors' offices across the
16 country, and they pitched these tests to the doctors.

17 It is undisputed that the physicians who received the
18 P&H payments submitted claims -- or referred tests to HDL and
19 Singulex and that HDL and Singulex then referred those claims
20 on to Medicare and TRICARE, two taxpayer-funded federal health
21 care agencies.

22 It is undisputed that Medicare and TRICARE paid those
23 claims. In fact, during the 4.5 years that HDL and Singulex --
24 that these schemes were ongoing, Medicare and TRICARE paid HDL
25 and Singulex \$585.7 million.

1 It is also undisputed that HDL and Singulex paid
2 physicians more than \$52.6 million in exchange for their
3 referrals.

4 And, finally, it is undisputed that HDL and Singulex
5 paid the Bluewave defendants \$244 million in commissions for
6 the referrals they generated.

7 The question you need to answer is why? why did
8 defendants decide to pay \$52.6 million to get the doctors to
9 order tests?

10 It was not to get the blood to the labs as defendants
11 would have you believe. There were other viable and
12 potentially legal ways to do that. No, the reason defendants
13 paid the physicians \$52.6 was because defendants knew that the
14 only way to compete with the more established blood labs was to
15 pay kickbacks. But they didn't just pay kickbacks; they paid
16 significantly more than their competitors in order to get those
17 physicians to switch labs and refer to HDL and Singulex.

18 You recall Burt Lively's testimony that Berkeley
19 tests were virtually identical to HDL's test. It was like
20 pulling the emblem off of a Ford and slapping a Chevy sticker
21 on it. Mr. Lively was right. Berkeley and HDL were, for all
22 intents and purposes, offering the same tests. So how was
23 Bluewave able to convert almost all of its old Berkeley
24 customers to HDL customers? HDL may have been offering the
25 same test, but it also offered twice the P&H payment that

1 Berkeley was paying. They paid twice the kickback.

2 Moreover, HDL removed the one barrier that prevented
3 Berkeley physicians from widespread ordering by waiving copays
4 and deductibles for patients.

5 Mr. Dent testified that Bluewave went out with an
6 absolute vengeance to get as much business as we absolutely
7 could to establish our business. And, frankly, it was very
8 easy picking.

9 why? What made it such easy picking? It was because
10 the Bluewave sales reps were out in the field telling
11 physicians they could make tens of thousands, even hundreds of
12 thousands, of dollars of profit each year by referring tests to
13 HDL and Singulex.

14 And did these schemes work? You bet they did. The
15 labs flourished and defendants became multimillionaires.
16 Bluewave and defendants Dent and Johnson were showered in
17 riches to the tune of more than \$244 million. Similarly, HDL
18 went from a dream sketched out on the back of a napkin in 2008
19 to a lab that raked in more than a billion dollars in revenue
20 and hundreds of millions of dollars in profit in just a few
21 years.

22 Now, defendants would have you believe that these
23 astronomical profits were all just a result of their hard work
24 and a superior product. Now, if that was really the case, why
25 did HDL's revenues plummet after it stopped paying these

1 kickbacks? More to the point, why did HDL have to declare
2 bankruptcy less than a year after it stopped paying these
3 kickbacks? The answer to both of those questions is simple.
4 Defendants' businesses were built on blood money kickbacks, and
5 when those blood money kickbacks stopped, so too did the
6 referrals and so too did the money.

7 Now, as part of this closing statement, I plan to
8 highlight many of the key pieces of evidence the United States
9 presented throughout the trial. But before we go through that
10 evidence, I want to give you some context.

11 This is a civil case. And this is very important
12 because it dictates the burden of proof. In this case, the
13 United States needs to prove its case by a preponderance of the
14 evidence. You will see the scales up there. And that's the
15 easiest way to think about this. If the evidence tilts even
16 the slightest bit, just by one tiny iota, in favor of the
17 United States, then that's sufficient and you should find the
18 defendants liable for violating the Anti-Kickback Statute and
19 the False Claims Act.

20 So the next question is, what does the United States
21 need to prove by a preponderance of the evidence? Well, the
22 evidence in this case shows that defendants broke the law by
23 violating the Anti-Kickback Statute and the False Claims Act.
24 The Court will instruct you on the law, but as we match up the
25 evidence to each of the requirements highlighted there, I will

1 go through them step by step and sort of give you a little bit
2 of a definition.

3 Before we deep dive into how the evidence shows that
4 the defendants violated the Anti-Kickback Statute, remember
5 that there are two statutes at issue: the Anti-Kickback
6 Statute and the False Claims Act. But because this is a
7 kickback case, any claim coming into Medicare or TRICARE as a
8 result of the kickback is also a false -- fraudulent claim
9 under the False Claims Act.

10 So let's turn to how the evidence fits within this
11 case within the Anti-Kickback Statute. And the easiest way to
12 do that, I think, is to match up the evidence with the terms
13 highlighted there. That defendants acted knowingly and
14 willfully, that they offered or paid remuneration, and that
15 their purpose was to induce providers.

16 And as I do this, we'll walk through several
17 exhibits, and I will identify for you their number so that,
18 when you go back into the room to deliberate, you'll have those
19 accessible. You won't have the benefit of these slides. So if
20 you want to write them down, that would be fine.

21 Let's start with remuneration. What is remuneration?
22 It simply means something of value. Defendant Dent testified
23 about gift cards, cruises, hunting trips. Sometimes
24 remuneration schemes can be incredibly complicated. But in
25 this instance, it's just good old-fashioned money. And no one

1 disputes the fact that defendants aspired to and actually paid
2 good old-fashioned money to physicians.

3 If we go back to the five steps of the P&H kickback
4 scheme that Mr. Hines developed -- at least he developed a
5 demonstrative -- the evidence shows the defendants paid
6 physicians more than \$52 million in P&H between 2010 and 2014.

7 Now, I know it probably seems like a long time ago,
8 but think back to Mr. Hines's testimony from day one, when he
9 showed you how he combed through HDL's and Singulex's files and
10 he matched those files up with specific claims in the Medicare
11 and TRICARE database. He also went through their banking
12 records. And he determined that \$52.6 million was paid to
13 physicians in exchange for their referrals.

14 Think about that for a moment. \$52.6 million. HDL
15 and Singulex had to pay \$52.6 million to get physicians to
16 order these tests.

17 Mr. Hines also explained how certain practices and
18 physicians' practices -- including the Keowee Practice, where
19 Dr. Alam, one of defendants' witnesses, practiced -- raked in
20 hundreds of thousands of dollars between 2010 and 2014. In
21 fact, just the 20 physicians listed on that chart right there
22 brought in more than \$7.2 million in remuneration in less than
23 4.5 years.

24 The evidence is clear here. Defendants paid
25 remuneration to the physicians for every sample that was

1 referred.

2 So that covers the first part of the Anti-Kickback
3 Statute. Let's move on to the second.

4 The second requirement is the defendants paid the
5 remuneration to induce physicians to order tests. I want to
6 pause here and draw your attention to some important language
7 in the instructions and the law.

8 We have the burden of showing by a preponderance of
9 evidence that one reason defendants paid the money was to
10 induce physicians to order tests. We do not have the burden,
11 nor are we required to show you, that any single doctor was, in
12 fact, induced to order these tests by the payments. So any
13 testimony you heard from doctors telling you how they were not
14 influenced by the kickbacks is irrelevant. You can of course
15 draw your own conclusions about physicians who received
16 hundreds of thousands of dollars in order to order these tests.

17 And you should remember that both Dr. Alam and
18 Dr. Hollins, defendants' own witnesses, talked about how they
19 used the P&H payments to pay bills and then to distribute as
20 profits. I think Dr. Hollins used the term "bonus."

21 But to be clear, under the law and the instructions
22 you will be given, all you need to decide is whether the
23 defendants paid the kickbacks to induce the referrals. And
24 that decision should be cut and dry. The evidence shows that
25 defendants knew from the very beginning of their negotiations

1 that the P&H payments were a critical door-opener. Their
2 language, not mine.

3 The evidence shows that Bluewave sales reps touted
4 the fact that physicians could generate thousands of dollars of
5 revenue from P&H fees each year. The evidence shows that
6 defendants distributed pro formas showing doctors how much they
7 could make by referring tests to HDL and Singulex. And the
8 evidence shows that in 2010 defendant Mallory commissioned an
9 internal study to determine how best to sell HDL's tests. And
10 the report revealed that selling doctors on the return on
11 investment was a critical component of the sales pitch.

12 And, finally, the evidence shows that, when
13 physicians were told that they could not receive P&H fees,
14 defendants immediately began looking for other ways to get the
15 same amount of money to their customers. These defendants
16 offered and paid doctors cash in exchange for referrals.
17 Common sense tells us that the defendants paid the doctors to
18 get them to order tests. And that's inducement under the AKS.

19 Sorry. I have a cold.

20 If we go back to 2009, the evidence shows that the
21 P&H kickback was a critical component of defendants'
22 negotiations before they signed the contract. And the reason
23 it was critical was because the defendants needed the kickbacks
24 to sell the tests. Let's look at Exhibit 1248. This is the
25 email exchange between defendants that occurred a couple of

1 days after that initial meeting at the airport Marriott in
2 Atlanta. And in this email exchange, defendant Mallory
3 summarizes her understanding of the terms that the parties had
4 discussed at that meeting. One of those terms is that HDL will
5 pay the P&H kickback.

6 Let's step back for a moment here and think of the
7 significance of this, because kickbacks were one of just a
8 handful of terms that the lab needed to work out with its sales
9 force in order to get them on board. The defendants went into
10 business together to sell HDL's tests to doctors. And
11 defendants knew that one of the key tools they needed to sell
12 these tests was for the lab to pay doctors money for their
13 referrals.

14 Simply put, defendants weren't going to be able to
15 get the doctors to sign up without the kickbacks since these
16 tests, as you heard from Dr. Trost, were medically unnecessary.

17 Turning to Exhibit 1293. This is an email
18 communication from defendants Dent and Johnson responding to
19 the previous exhibit we just looked at. It is sent just three
20 days after that previous exhibit. In this email communication,
21 defendants Dent and Johnson add comments to Ms. Mallory's list
22 of items. And in one of those comments, they note that they
23 want the kickback to be larger, at 18 to \$21. Of course they'd
24 prefer it to be higher. What's more effective in inducing
25 referrals than a \$15 kickback? An 18 to \$21 kickback. The

1 more you pay, the larger and more significant the inducement.

2 Turning to Plaintiffs' Exhibit 1288, this is an
3 exhibit from March of 2010 -- an email from March of 2010.
4 Mallory is emailing the other defendants. This is right before
5 they execute the sales agreement. In this email, defendant
6 Mallory writes, "I realize that P&H is a critical door-opener."
7 Defendants knew that without P&H, the sales reps might not even
8 make it through the door.

9 Now, ultimately, in the HDL's sales agreement, HDL
10 agreed that one of the obligations it owed to Bluewave, its
11 outside sales force, was to pay the doctors a kickback. And I
12 want to make this point abundantly clear. This was a sales
13 agreement, and the provisions in the agreement pertained to
14 sales. The P&H payment is a sales tool. That's why it's in
15 this agreement. If it wasn't a sales tool, it wouldn't need to
16 be there.

17 And I want to make one more point. Defendants have
18 spent much of their case telling you how important it is to get
19 blood to the lab, and they've acknowledged that there are
20 multiple ways to do that. They talk about draw sets, placing
21 phlebotomists, mobile phlebotomists. We've heard it from
22 several of their witnesses. All of those are, in fact, viable
23 and potentially legal ways to get the blood to the lab, but
24 there's nothing in the contract or the negotiations or the
25 back-and-forth in these emails referring to any of those

1 practices because those practices don't induce referrals.

2 P&H fees, that's a critical door-opener. They induce
3 referrals. And why? Because the doctors make money from them.

4 The same is true of the Singulex agreement. There's
5 a provision in there for P&H payments. There's no provision in
6 there for mobile phlebotomists. There's no provision in there
7 for in-office phlebotomists. There's no provision in there for
8 draw sets. It's about P&H. P&H induces referrals.

9 Beyond your common sense and the negotiations that we
10 just highlighted, there are emails, testimony, even an
11 undercover surveillance video showing that the sales reps, at
12 the direction of the defendants, used the P&H payments to
13 induce physicians to refer HDL lab tests to Medicare and
14 TRICARE.

15 The defendants trained the sales representatives to
16 market the kickbacks that they had conspired to include in
17 these agreements. And the sales reps were acting on behalf of
18 the defendants when they touted the money that doctors could
19 earn from the P&H.

20 In fact, the evidence shows that defendants
21 themselves used these very same tactics to sell tests to
22 customers. All three of them used pro formas or advocated for
23 the use of pro formas. Moreover, all three of them encouraged
24 sales reps to use these pro formas. "Do the math. Show the
25 doctors what they can make."

1 Now, you know that the sales reps were deploying the
2 defendants' strategy because of Mr. Cornwell's testimony that
3 sales reps were trained by defendants Dent and Johnson on how
4 to sell the tests. Likewise, you know from Anna McKean's memo
5 and from Paul Mincey's testimony that defendant Mallory was
6 also in favor of selling HDL's tests by touting the revenue
7 doctors could generate.

8 And you know that defendants actively targeted
9 money-hungry doctors who would be susceptible to the lure of
10 the P&H payments.

11 Let's look at Exhibit 1162. This is an email from
12 June of 2010 from BlueWave sales rep Kyle Martel. He's
13 pitching a physician practice. Kyle Martel was BlueWave's
14 second-most successful salesman. And he earned almost
15 \$6 million in commissions in less than four and a half years
16 with BlueWave. You may also remember Mr. Martel as one of the
17 witnesses -- as the witness that chose to assert his Fifth
18 Amendment rights rather than answer any of my questions.

19 In this email, we see Mr. Martel close his sales
20 pitch with what boils down to "Refer to us and you'll make
21 \$2,000 a week."

22 He writes, "With regards to business opportunity, I
23 have a process and handling fee of \$20. In estimation, the
24 practice has the potential to draw close to a hundred panels a
25 week. Therefore, a hundred panels a week would result in a

1 revenue stream for the office of \$2,000 per week." And then he
2 does the math.

3 This pitch is not about how good HDL's tests are.
4 This isn't about clinical studies or case studies. It's "refer
5 to us because you'll make \$100,000 a year." Ladies and
6 gentlemen, this is using the P&H kickback to induce referrals.

7 Remember Mr. Blasko, how he sold the test. We saw
8 the video. And I want to play just a snippet, not all 30
9 minutes. Just a snippet of it again to remind you of what it's
10 like to sit in a Bluewave sales pitch.

11 **MR. BLASKO:** This is something else that's not in
12 here. There's an economic thing to this.

13 **DR. SABIDO:** well, this and the other thing, that I
14 wanted to speak to you privately.

15 **MR. BLASKO:** I know. I didn't want to talk in there.
16 Okay. We need -- we give you a processing and handling fee.
17 That's what we call it. There's no Stark violations here.
18 Here's -- here's our letter to support it. I put that in,
19 \$20 -- \$20 a patient.

20 **DR. SABIDO:** Oh, that's the way it works?

21 **MR. BLASKO:** Yep.

22 **DR. SABIDO:** We make \$20 for each patient? Medicare,
23 Medicaid, the same?

24 **MR. BLASKO:** The same. Everything \$20.

25 **DR. SABIDO:** And how --

11:55 AM 1 MR. BLASKO: 300 a month, 300 tests.

11:55 AM 2 DR. SABIDO: 300 tests a month.

11:55 AM 3 MR. BLASKO: Times 20. You do the math.

11:55 AM 4 (Video ends.)

11:55 AM 5 MR. SHAHEEN: I got some docs, 300 tests a month, 300
11:55 AM 6 times 20. You do the math. That's what it's like to sit in a
11:56 AM 7 Bluewave sales presentation.

11:56 AM 8 This pitch wasn't about the -- I mean, this
11:56 AM 9 pitch was not about medical -- I'm sorry. This pitch was not
11:56 AM 10 about the clinical utility of the test. It was not about case
11:56 AM 11 studies. It was about the economic component.

11:56 AM 12 This is evidence that one purpose of Bluewave
11:56 AM 13 offering P&H was to induce the doctor on the video to order
11:56 AM 14 tests.

11:56 AM 15 This is inducement, ladies and gentlemen.

11:56 AM 16 Do you want to see it again?

11:56 AM 17 Moving on to Exhibits 1158 and 1035, we saw
11:56 AM 18 these yesterday. These are two pro formas that were being
11:56 AM 19 distributed in October and December of 2012, more than --
11:56 AM 20 roughly three years into the scheme, by two Bluewave sales reps
11:57 AM 21 that defendant Dent -- I mean -- I'm sorry -- defendant Johnson
11:57 AM 22 admitted training.

11:57 AM 23 what are they doing? These pro formas show
11:57 AM 24 doctors how referring tests to HDL could generate revenues of
11:57 AM 25 \$145,000 to \$175,000 per year. And that's just the P&H, folks.

1 There's several hundred thousand additional dollars referenced
2 here to be made when doctors include all of the additional
3 follow-up visits and tests that they can bill.

4 This, ladies and gentlemen, is using the P&H
5 kickbacks to induce referrals.

6 The concepts that we saw in those two documents,
7 they should look familiar to you. And that's because they're
8 just like the pro forma that defendant Johnson -- that
9 defendant Johnson asked Mr. Lively to send to Lori Mallory back
10 in 2010.

11 Let's look at Exhibit 1099. That is that
12 pro forma. Mr. Lively was BlueWave's third most successful
13 sales rep and a partner of defendant Johnson. He brought in
14 \$5.4 million in commissions in less than five years. In the
15 pitch, defendant Johnson and Mr. Lively are selling the test by
16 telling doctors that referring to HDL will result in \$777,600 a
17 year in additional revenues with net profits, net profits
18 totaling just shy of \$550,000. And that includes \$200,000 in
19 profits just from the P&H fees.

20 Let me repeat that. He's telling physicians
21 that they will generate more than a half a million dollars a
22 year by referring tests to HDL. That \$550,000, that's meant to
23 induce referrals.

24 And as if writing it out weren't enough,
25 Mr. Lively goes on to include a handy spreadsheet where he

1 breaks down the calculations for the doctors.

2 Ladies and gentlemen, doctors can do basic math.
3 And for those that can't, they have phones with calculators
4 that can do multiplication. Doctors don't need this, but the
5 sales reps gave it to them because it showed them how much they
6 could make, all by referring tests to HDL, a half a million
7 dollars a year. This was using the P&H kickback to induce
8 referrals.

9 This is Plaintiffs' Exhibit Number 1004. We
10 just saw defendant Johnson. This is defendant Dent and his
11 partner Tony Carnaggio doing the exact same thing. They used a
12 pro forma to sell a doctor on HDL's tests and to induce
13 referrals. Ladies and gentlemen, this is using the P&H
14 kickback to induce referrals.

15 Before we move on, though, I want to make one
16 quick point. Yesterday Mr. Johnson testified that HDL paid its
17 phlebotomists \$52,000 a year and that a temporary phlebotomist
18 could makes upwards of \$38 per hour. Well, that's not what we
19 see here.

20 In this pro forma, Mr. Dent notes that a
21 phlebotomist makes \$12 per hour and roughly \$24,000 per year.
22 Mr. Johnson was only off by a factor of 2 to 3, depending on
23 how you look at this. Now, I want you to remember this when
24 defendants come up and give you their presentation.

25 You also heard Boomer Cornwell tell you how he

1 was trained by Brad and Cal to use the P&H payments to sell
2 tests. He described how, in one training sales call,
3 Mr. Johnson took out a piece of paper and put together a
4 pro forma on the spot that showed the doctor that he could make
5 enough money in P&H payments to handle his lease payments.

6 Mr. Cornwell also confirmed that defendant
7 Johnson was, in fact, using the P&H as a selling point. And
8 remember when Mr. Cornwell explained the tremendous and
9 lucrative business partnership he was referring to in his sales
10 pitch? He said he was referring to the money physicians could
11 make from processing and handling fees. All of that is
12 inducement.

13 How about Plaintiffs' Exhibit Number 1192. This
14 is a communication from Shane Marquess to defendant Mallory.
15 Mr. Marquess was a sales rep who initially worked for HDL but
16 then went to work for BlueWave. In Exhibit 1192, you see
17 Mr. Marquess and how he pitched HDL to potential customers.

18 If we turn to page 8, which is the second part
19 of the screen, Mr. Marquess breaks it down for the physician.
20 "The practice will receive \$20 a patient per draw. This \$20 is
21 called our processing and handling arrangement. This is also
22 attached. This is significantly higher than the typical \$2.76
23 reimbursement. With two offices and ten providers, you can see
24 how much revenue this could generate for MHG."

25 Again, this pitch is not about how good our

1 tests are. It's not about case studies. It's "refer to us
2 because you'll make a ton of money."

3 This is using the P&H kickback to induce
4 referrals, and Mr. Marquess forwards it to defendant Mallory.

5 Defendant Mallory did not disapprove of
6 Mr. Marquess's sales tactics. She did not advise him to stop
7 those sales tactics. In fact, she employed them herself.

8 This is Exhibit 1166. This is an email exchange
9 between defendants from May of 2012. And in this exchange,
10 Ms. Mallory writes that she instructs the Bluewave sales reps
11 that are cc'd to show a physician a pro forma, a pro forma like
12 the ones we saw from defendants Dent and Johnson and some of
13 their sales reps, in order to show the physician why it's
14 financially better to draw the blood himself than to hire a
15 phlebotomist.

16 Ladies and gentlemen, this is using the P&H
17 kickback to induce referrals.

18 So that email is from May of 2012. Two years
19 earlier, Ms. Mallory commissioned a study. She paid Anna
20 McKean to go out and interview physician customers to see what
21 they liked most about ordering from HDL.

22 What did Ms. McKean find? Ms. McKean confirmed
23 that one of the primary reasons doctors liked referring to HDL
24 was because they could generate a positive return on
25 investment. Simply put, they could make money.

1 And Ms. McKean recommended doing precisely what
2 we've just seen in the previous exhibits. She recommended that
3 sales reps show doctors how they could make roughly \$295,000
4 for every thousand patients referred to HDL.

5 Do these calculations look familiar? Initial test,
6 7,500; follow-up test, 18,000; P&H, 4,000. They should look
7 familiar. Those same -- the same calculations, albeit some
8 slightly different numbers, appear in defendants' pro formas,
9 the pro formas that are being sent out to doctors all over the
10 country.

11 Before we move on, I want to make one more point
12 about this document. If you look closely at it, in addition to
13 P&H, Ms. McKean -- the revenue that Ms. McKean calculates
14 includes doctors billing for office visits, which already
15 covers the same services that HDL is purportedly paying the
16 process and handling fees for. That's double payment.

17 So don't believe defendants when they tell you that
18 they had no idea that doctors could be double dipping, a
19 practice the defendants themselves acknowledged would be
20 illegal and a practice that is, in fact, illegal.

21 As Dr. Handrigan from CMS and Alison Coleman from
22 TRICARE told you, CMS and TRICARE already compensate physicians
23 for the processing and handling work as part of the office
24 visit. And what we see in Ms. McKean's memo is an
25 acknowledgment that they know -- defendants know that doctors

1 are billing for the office visit and collecting the payments.

2 So that means that, when a lab pays a physician a
3 processing and handling fee, the physician is receiving a
4 double payment, a double payment that would violate the
5 Anti-Kickback Statute.

6 We also heard from a witness named Paul Mincey.
7 Mr. Mincey was a sales rep that worked at HDL. Specifically,
8 Mr. Mincey testified that Mallory told her sales reps you've
9 got to do it like Bluewave, you've got to sell the business
10 side first.

11 She got up on the whiteboard and started drawing
12 numbers. You've got to show them that, if you do this many
13 tests a day, you're going to get \$20 for each one of those.
14 Extrapolate that out. She wanted her reps to sell the business
15 side first.

16 So we know how they sold, but who did they target?
17 They specifically targeted money-hungry physicians. This is
18 Exhibit 1296. We've seen different exhibits with this
19 information on it because it was sent out throughout the time
20 period. We saw them as late as 2013.

21 Look at Criteria Number 6, "Instruct sales reps to
22 seek out money-hungry physicians." why? why would you want to
23 find money-hungry physicians? Because defendants understood
24 that money-hungry doctors would see the revenue potential that
25 they could earn from referring these tests to HDL and Singulex.

1 In other words, defendants not only used the P&H kickbacks to
2 induce the referrals, but they specifically targeted physicians
3 that would be most susceptible to the inductive effect of the
4 kickbacks.

5 How critical was it for HDL to pay -- I mean for
6 defendants to pay doctors in order to get these tests? well,
7 we know it was critical because, when doctors were specifically
8 told by their own attorneys that they could not receive P&H
9 fees because they were blatantly illegal, defendants
10 immediately tried to figure out other ways to get that same
11 amount of money to the doctors.

12 This is BlueWave Exhibit Number 68, and it's our
13 friend Lester Perling and his client Dr. Reddy. We've heard
14 Mr. Perling's name quite a bit these last two weeks.

15 Mr. Perling told Dr. Reddy that the P&H payments were
16 as blatantly illegal as anything he'd ever seen. So what did
17 defendants do? They immediately considered paying Dr. Reddy a
18 clinical research fee of \$20 per patient. Does that sound
19 familiar, "We need to get this guy \$20 per patient"?

20 Now, we know defendants subscribed to the philosophy
21 that one word makes it legal and one word makes it illegal.
22 well, I submit to you that that's not really correct. Simply
23 changing the name of a kickback does not make it any less of a
24 kickback. Just changing a word does not change the illegality
25 of the payment.

1 In addition to this email, you also heard testimony
2 from Mr. Cornwell that when the Bent Tree medical practice in
3 Texas complained that they needed more money and threatened to
4 stop referring tests, defendant Mallory entered into a separate
5 lease agreement to get them thousands more dollars each month.

6 Similarly, Dr. Hollins, defendants' own witness,
7 testified that he received monthly fees of \$2,000 for being on
8 the medical advisory board. And that was in addition to
9 speakers fees where he could rack up upwards of \$18,000 in a
10 weekend, just a single weekend.

11 Defendants took the stand and testified that they
12 would never sell on P&H. Of course they'd tell you that. But
13 you'll have to decide whether they're telling the truth.

14 Think back to those scales of justice. On the one
15 side, you have defendants' self-serving testimony that they
16 didn't sell on P&H. On the other side, you have all the
17 documents I just showed you.

18 You have Mr. Martel refusing to answer questions
19 about how he sold P&H. You have Mr. Blasko telling this doctor
20 about how sweet a deal this is. You have Mr. Cornwell's and
21 Mr. Mincey's testimony about how they were instructed and
22 trained to sell on the business side. And you have documents
23 where defendants themselves were using the P&H kickbacks to
24 induce referrals.

25 Ladies and gentlemen, documents don't lie and videos

1 don't lie. Stack all of that up on the scales of justice, and
2 there can be only one conclusion: Defendants sold on P&H
3 because that was the easiest and best way to line their pockets
4 with millions of dollars of ill-gotten profits.

5 Defendants' claims that they never used P&H to induce
6 referrals runs contrary to just about every piece of evidence
7 in this case. Simply put, defendants knew that they needed the
8 P&H kickbacks from day one to compete in the marketplace to
9 induce referrals.

10 So we know remuneration was paid, and the evidence
11 shows that defendants used that remuneration to induce test
12 referrals.

13 The evidence also shows that defendants acted
14 knowingly and wrongfully. Now, how do we know that? First of
15 all, defendants' own witnesses, Kevin Carrier and Erika Guest,
16 told you it would be wrong to sell the test by touting the
17 revenue. If they knew it was wrong, surely defendants did too.

18 You also heard defendant Johnson yesterday. He went
19 through all of those documents that I just went through. And
20 for each of them, Oh, that would be inappropriate; can't do
21 that. Who trained those sales reps? Mr. Johnson.

22 We also heard Mr. Cornwell tell us that the
23 Bluewave's defendants' approach to the law is it's not what the
24 law says; it's what the law doesn't say.

25 Additionally and perhaps most importantly, this is a

1 case where defendants were told on numerous occasions by no
2 less than 17 different lawyers, including more than a dozen of
3 their own lawyers, to stop paying the P&H kickbacks because
4 they were wrong and because the government would view these
5 payments as blatant kickbacks.

6 when you disregard 17 of your -- 17 lawyers,
7 including 13 of your own lawyers who were telling you to stop
8 doing something and you continue doing it nonetheless, that is
9 acting knowingly and wrongfully.

10 Here is a slide showing 17 instances when lawyers
11 told defendants that they needed to stop paying P&H fees
12 because it was wrong. If it looks cluttered, it's because it's
13 supposed to. That's a lot.

14 Let's go through some of these. The first warning I
15 want to highlight for you came in December of 2010. This is
16 Plaintiffs' Exhibit Number 1266, and it comes from Mr. Perling.

17 Mr. Perling was a board-certified health care
18 attorney from Florida. Defendants received an email chain that
19 includes Mr. Perling's statement that P&H is blatantly illegal,
20 "as blatantly illegal as anything I have ever seen in a long
21 time. It would be a criminal violation of the federal and
22 state kickback laws and could form the basis for liability
23 under the False Claims Act."

24 Ladies and gentlemen, it does not get much more
25 explicit than that. This is an attorney telling the defendants

1 that what they are doing is blatantly illegal. When they get
2 this warning, do defendants stop offering P&H fees? Do they
3 stop paying P&H fees? No, they do not. They completely
4 disregard this warning and continue to pay the blatantly
5 illegal P&H kickback.

6 The next warning comes in April of 2011. This is
7 Plaintiffs' Exhibit Number 1117. This warning comes from
8 another outside attorney representing a physician who was also
9 approached by Mr. Martel.

10 The attorney advises that the P&H fee would be
11 considered a kickback paid to the medical practice to use HDL
12 rather than another lab. The attorney also notes that Medicare
13 already pays the physician for the tasks associated with
14 processing and handling and that HDL's payment would be
15 receiving -- that HDL's payment would constitute a double
16 payment, something defendants have admitted is illegal.

17 Here's another attorney warning defendants that what
18 they're doing is a violation of the Anti-Kickback Statute. So
19 when defendants get the second warning, do they stop offering
20 P&H fees? Do they stop paying P&H fees? No, they do not.

21 The next warning comes in March of 2012. This is
22 Exhibit Number 1122. Now, this warning doesn't come from a
23 physician's attorney. It's drafted by another laboratory. In
24 fact, this letter makes its way from PathLabs, Pathology Labs,
25 all the way up to defendants. And similar to the warnings we

1 just looked at, the compliance officer from Pathology
2 Laboratory warns that paying physicians to collect samples
3 would potentially place the laboratory and the physician in
4 violation of the federal kickback statute and the False Claims
5 Act.

6 when they get this third warning, do the defendants
7 stop offering P&H fees? Do they stop paying P&H fees? No,
8 they do not.

9 Shortly after the PathLabs email or that letter on
10 April 27th, 2012, HDL receives a two-page letter from Michael
11 Ruggio, an attorney at LeClairRyan. In that letter, Mr. Ruggio
12 states that HDL's P&H payments fall into a safe harbor to the
13 Anti-Kickback Statute that alleviates any issue with the
14 payments.

15 The evidence shows us that HDL's other lawyers
16 advised defendants that Mr. Ruggio's analysis is flat-out
17 wrong. Nonetheless, defendants still try to hide behind this
18 letter.

19 For the following reasons, this letter did not
20 provide the shelter they seek. First and foremost, defendants
21 have done nothing to show that Mr. Ruggio was ever told that it
22 was HDL's outside sales force that negotiated for and set the
23 P&H price. Defendants have done nothing to show that
24 Mr. Ruggio was ever told that defendants were selling HDL's
25 tests by touting how much doctors could earn in P&H by

1 referring samples.

2 Mr. Ruggio was never -- defendants have done nothing
3 to show that Mr. Ruggio was ever told that the sales reps were
4 distributing pro formas showing the doctors they could make
5 upwards of half a million dollars a year in profits by
6 referring samples to HDL.

7 And defendants have done nothing to show that
8 Mr. Ruggio was ever told that defendants were aware of
9 physicians who were treating the P&H as revenue.

10 For all of those reasons, defendants cannot hide
11 behind this letter as justification for their action. But even
12 if they could and for all the reasons I just went through, they
13 cannot. Any and all reliance on this opinion becomes
14 completely unreasonable when defendants' own lawyers
15 subsequently tell them that the Ruggio opinion is wrong, that
16 it is fraud, that it cannot be relied on. And we'll get to
17 those warnings in just a moment.

18 Only a few months after the Ruggio letter, Larry
19 Freedman, an established health care attorney with experience
20 directly on point, writes an explicit warning. This is Exhibit
21 Number 1217.

22 In this email, Mr. Freedman describes a matter he
23 worked on previously with a lab that made payments very much
24 like defendants' P&H kickbacks. He outlines that the other lab
25 was paying a \$10 fee to physicians to compensate for the

1 administrative costs of using the lab's requisition form and
2 collection requirements.

3 Does that sound familiar? It should, because the
4 Ameritox scheme, the scheme that Mr. Freedman is talking about,
5 is almost identical to what HDL was doing.

6 In this email, Mr. Freedman notes that the government
7 took a strong view that the cash payments were blatant
8 kickbacks.

9 Just to make sure we're all clear on who this is,
10 this is an HDL lawyer with experience directly on point warning
11 that the government views HDL's P&H payments as kickbacks.
12 There's nothing mysterious, vague, or ambiguous about that.
13 That's stop what you're doing because you're paying a kickback.

14 And this isn't coming from an unknown third party
15 that defendants can dismiss as a quack or a competitor. This
16 is HDL's own lawyer saying you're paying kickbacks.

17 So what did defendants do? Do they terminate
18 kickbacks or -- yeah, do they terminate the kickbacks? No.
19 They ignore Mr. Freedman's warnings just like they did the
20 other warnings because they're making money hand over fist at
21 this time.

22 Let's go on to the next one. This is less than a
23 month later, on August 22nd, 2012. It comes from the National
24 Lipid Association, an association that was funded in part by
25 HDL, an association of which HDL was a member. This is

1 Plaintiffs' Exhibit Number 1126.

2 what does the National Lipid Association say? They
3 warned their members, including HDL, that these P&H
4 arrangements may run afoul of the Stark Law. Again, this isn't
5 some unknown entity that lacks credibility. This is the
6 National Lipid Association saying that P&H may well run afoul
7 of the law.

8 So do defendants stop offering kickbacks? Do they
9 stop paying kickbacks? No, they ignored this warning as well.

10 Next up, we have Derek Kung. He issued a memorandum
11 to the board at HDL on August 30th, 2012. This is Plaintiffs'
12 Exhibit Number 1244. Derek Kung is HDL's general counsel.
13 This is HDL's top lawyer writing out an informed and reasoned
14 analysis about P&H.

15 what did Mr. Kung say in his memo? He tells the
16 board that the Office of Inspector General has already looked
17 into practices like this, like P&H, and the Office of Inspector
18 General believes they are illegal. He tells the board that the
19 processing and handling fee practice is a red flag for the
20 Office of Inspector General and imposes a high level of risk
21 under the Anti-Kickback Statute and Stark Laws.

22 He also tells the board they need to terminate the
23 program to avoid civil and criminal liability. This is huge.
24 This is HDL's top lawyer coming in and saying, we need to stop
25 this program because it's exposing us to civil and criminal

1 liability. But even these dire words from HDL's top lawyer do
2 not stop defendants from offering the P&H kickbacks.

3 Now we have six attorneys including Perling,
4 PathLabs, Larry Freedman, National Lipid Association, and HDL's
5 own top lawyer. They've all warned that the government will
6 pay -- will view the payment as kickbacks and that HDL needs to
7 stop.

8 So what happens next? The United States Department
9 of Justice issues subpoenas to HDL and Bluewave in January of
10 2015 regarding the investigation into defendants' practices of
11 paying processing and handling fees, among other things.

12 Ladies and gentlemen, this is precisely what all of
13 those lawyers were warning about. They're saying, Terminate
14 the program before the government finds out because you'll be
15 in a lot of trouble. So now the warnings have become a
16 reality.

17 what did defendants do? Nothing, and the only
18 possible reason why they do nothing is greed. The money was
19 too enticing.

20 Defendants were pocketing tens of millions of dollars
21 a year, more money than they had ever dreamed of, and they
22 couldn't bring themselves to do the right thing. So they
23 continued with the P&H kickbacks, but now the cat is out of the
24 bag and the warnings are flooding in.

25 A day after the Department of Justice issued their

1 subpoena, Tony Carnaggio and Cal Dent are told by lawyers from
2 MDVIP that P&H payments are illegal. This is Exhibit 7011. In
3 his direct, Mr. Carnaggio conveniently forgot about this. So
4 when my colleague, Mr. Leventis, asked Mr. Carnaggio about it,
5 all he could say is "Yeah, that's what it says."

6 Shortly thereafter, Nick Pace joins HDL. He's hired
7 in part to develop HDL's compliance program and to identify
8 alternatives to P&H.

9 Now, Mr. Pace came in here and testified. He
10 testified to a lot of things. He said that he advised HDL to
11 cease the P&H payments. He said that he talked about stopping
12 the payments ad nauseam with defendant Mallory. He said that
13 they talked about how they believed Bluewave was using the P&H
14 as part of their sales process to induce doctors to order
15 tests.

16 He testified that Ropes & Gray informed HDL to stop
17 paying P&H fees but Mallory pushed back, because the referrals
18 from physicians would drop off dramatically by 50 to
19 70 percent, and that HDL could have stopped immediately but
20 defendants didn't want to lose the business.

21 Did defendants listen Mr. Pace? No. They treated
22 him the way they treated the other lawyers. Actually, they
23 treated him slightly different. Let me refine that. They
24 didn't ignore him like everybody else. You heard him testify
25 about how defendants actively fought against what he was trying

1 to do. They fought against the very reforms he was trying to
2 implement.

3 In May of 2013, Derek Kung again puts his concerns in
4 writing, and again he's explicit about the problems. This is
5 Plaintiffs' Exhibit Number 1510. In this document, Mr. Kung
6 notes that P&H poses a high level of risk with respect to fraud
7 and abuse laws. He states that the LeClairRyan opinion, the
8 Ruggio opinion is highly flawed and open to multiple attacks.

9 And lest there be any doubt about this, Mr. Kung
10 notes that Ropes & Gray, HDL's outside counsel who has joined
11 now to respond to the Department of Justice in the subpoena,
12 they have advised against P&H and against relying on the
13 LeClairRyan opinion.

14 I want to drive that point home because defendants
15 have tried to cloud this issue to make it seem like the
16 Ropes & Gray lawyers did not give clear guidance on this issue.
17 We now have Pace and Kung showing us that Ropes & Gray was
18 clear that HDL needed to stop paying P&H. So now, in addition
19 to HDL's top lawyer speaking out against P&H, HDL's outside
20 counsel was also saying terminate the kickbacks. He's also
21 saying that the LeClairRyan opinion, the Ruggio opinion was
22 flawed and wrong and you can't hide behind it anymore.

23 We have Perling, PathLab, Freedman, National Lipid
24 Association, Kung, Ryan and all the Ropes & Gray attorneys, and
25 an ongoing DOJ investigation. Surely defendants will pull the

1 plug now; right? wrong. They ignored these warnings and
2 continue unabated.

3 Now, we've heard a lot of testimony about the summit
4 meeting. It all seems to come to a head in June of 2015. This
5 is Plaintiffs' Exhibit Number 1034, and it's a summary of the
6 meeting attended by all the important players.

7 Defendants Dent and Johnson are there accompanied by
8 their lawyers Gene Sellers, Mark White, Augusta Dowd, and Linda
9 Flipppo.

10 Defendant Mallory is there accompanied by HDL's
11 lawyers Derek Kung, Nick Pace along with Brien O'Connor, Laura
12 Hoey, David Rhinesmith, and Michael Lampert from Ropes & Gray.

13 You heard Mr. Pace testify that the purpose of the
14 meeting was to discuss alternatives to the P&H kickback. In
15 fact, Mr. Pace had spent the month leading up to that meeting
16 developing a viable business plan that would result in a
17 transition away from P&H fees.

18 This should have been the moment, ladies and
19 gentlemen. Actually, I want to take that back. The moment
20 should have occurred three years earlier. But certainly now,
21 with all these people in a room saying, "Stop. We have a plan
22 to move away. Let's do it. We're telling the government we're
23 going to move away," what do defendants do? They push back.
24 They tell the lawyers they're wrong.

25 Not only that, when Mr. O'Connor starts to explain

1 why it's necessary to terminate the P&H program, defendant Dent
2 gets revved up and starts arguing with Mr. O'Connor. You heard
3 a lot of testimony about that meeting and what was said and
4 done then.

5 But the most important fact about that meeting,
6 besides all the lawyers telling defendants to stop, is the
7 reason behind defendants' stubborn refusal to stop paying.
8 Defendants' primary concern about stopping the P&H program was
9 that they would lose a large portion of their business. P&H
10 payments-induced referrals.

11 That's right, folks. The dirty little truth came out
12 at that meeting. Without the P&H, defendants knew that HDL
13 would lose 30 to 70 percent of its business. And that was
14 unacceptable to them. So they berate Brien O'Connor and refuse
15 to adopt Mr. Pace's suggestions about how to move away from P&H
16 because they know that no P&H means no money for them. Simply
17 put, money is more important than the law to these defendants.

18 The Ropes & Gray attorneys were not the only lawyers
19 in the room, as I said before. BlueWave brought its own
20 lawyers, white Arnold & Dowd. And you heard Ms. Flipppo's
21 testimony. The white Arnold & Dowd attorneys were never asked
22 to opine on the legality of P&H. And that's why there's a
23 different symbol there.

24 why? why didn't defendants ask white Arnold & Dowd,
25 attorneys that they had already retained, attorneys that were

1 knowledgeable about what was going on, whether what they were
2 doing was wrong?

3 You don't have to think very hard. Certainly, a
4 reasonable person who thought they were acting lawfully but
5 were nonetheless staring up at this growing amount of evidence,
6 a stop sign, would reach out to their counsel and ask, "Hey, is
7 what I'm doing problematic? Is what I'm doing illegal?"

8 But defendants don't do that because they don't want
9 to hear the answer. They know that what they're doing is
10 wrong, and they don't want to have one more set of lawyers tell
11 them that.

12 Remember, those lawyers were at the meeting with
13 Ropes & Gray. Those lawyers were tainted. Those lawyers
14 already knew the answer, and defendants knew the answer they
15 would get from them.

16 So while the summit meeting is going on, there's a
17 Bluewave sales representative named Emily Barron. And she too
18 begins raising concerns about the legality of the P&H payments.
19 Ms. Barron retained her own lawyer to look into this. And what
20 did he conclude? Not surprisingly, he joined the chorus of
21 lawyers in saying that the P&H fees violate the Anti-Kickback
22 Statue if the requisite intent is meant. And we've talked
23 about intent to abuse.

24 Mr. Dent testified that he was aware of this memo and
25 the fact that Mr. Entin had concerns about the legality of the

1 P&H fees, but it didn't change what defendants were doing.

2 Ms. Barron did not rely on just one lawyer either.
3 She went and hired Brian Dickerson, one of the United States'
4 witnesses in this case. And Mr. Dickerson warned defendants
5 that the P&H fees violated the Anti-Kickback Statute, that they
6 obtained doctors based on referrals. He even recommended that
7 defendants reach out to Lester Perling to get a second opinion.

8 Did defendants do anything with this warning? Yes,
9 they did. Something changed. Unlike all the other warnings
10 that they ignored, defendants actually took affirmative steps
11 to address the problem. What did they do? They illegally
12 terminated Emily Barron because she was blowing the whistle on
13 the illegality of their scheme. They took action, but they
14 took wrong action.

15 Let's go over here because I can't quite read it.

16 Mr. Dickerson testified she was terminated because,
17 for the previous 45 days at least, or not -- yeah, 45 days,
18 maybe 50, we're reaching out to Linda Flippo saying that the
19 business operations, the business model, violated the
20 Anti-Kickback Statute, and we needed to have a conversation to
21 see whether or not she can continue to work for them under this
22 model or whether the company is going to change their model.
23 And I told her as well, don't go out and solicit any more
24 doctors with regard to this because it's a violation of the
25 Anti-Kickback Statute.

1 Again, doesn't get much more clear than that.

2 Defendants knew what they were doing was wrong, and
3 they took action to silence the whistle-blower.

4 Moving on. Defendant Mallory's attorney, her
5 personal attorney, also opined on the P&H kickbacks. This is
6 Exhibit 1522. In it, Mr. Hall, her attorney, arrives at the
7 same conclusions as the other lawyers, that Ruggio was wrong,
8 that the safe harbor did not apply, and that P&H fees should be
9 terminated since they represent a high level of risk. Was this
10 enough to get defendants to stop the practice? It should come
11 as no surprise to you that it was not. Defendants chose to
12 disregard the advice from their compliance and legal teams, let
13 the kickback fuel business to generate massive ill-gotten
14 gains.

15 Now, try as they might, defendants Dent and Johnson
16 could only avoid getting their own legal opinion for so long.
17 In November of 2013, defendant Johnson, in the hopes of
18 securing a positive opinion, asked his buddy, a lawyer, to
19 review the compliance test BlueWave offered to its sales reps.
20 He didn't even write it down; he knew the answer he would get.

21 He goes to his buddy. His buddy forwards the test on
22 to a trained health care attorney at Maynard Cooper named
23 Lauren DeMoss. This is Exhibit 1002. What does Ms. DeMoss do
24 after reviewing the test? She does two things.

25 First, she sends a legal opinion confirming the

1 criminal conviction of individuals who offer kickbacks to
2 providers in exchange for referrals. Moreover, one of the
3 defendants in that case was an independent contractor who was
4 convicted of violating the Anti-Kickback Statute for receiving
5 kickbacks in the form of commission payments based on the
6 volume and value of the referrals she generated. Does that
7 sound familiar? It should.

8 Ms. DeMoss also instructs, in answering the test, the
9 P&H fees appear to be prohibited. Mrs. DeMoss's analysis is as
10 clear-cut and dry as you will find. There's no legal-speak.
11 It's prohibited. And it corroborates what all of the other
12 attorneys were telling defendants at that time. She states
13 point-blank, "These payments are prohibited." There's nothing
14 vague or confusing about that.

15 So surely now, after being the subjects of federal
16 investigation, after at least 17 attorneys have advised
17 defendants to stop these payments because they are blatantly
18 illegal, a red flag, blatant kickbacks and prohibited, surely
19 defendants would stop the payments; right? They have to now.

20 But they don't. In fact, they don't even stop when
21 the government specifically tells them to. That's right.
22 You've heard defendants tell you several times that all they
23 ever wanted was an opinion from the Department of Justice.

24 Now, by the way, we heard testimony about getting an
25 advisory opinion. At any point during this timeline, from 2010

1 all the way up to 2014, all defendants had to do was ask the
2 question of the Office of Inspector General. And they would
3 have got an answer within 60 days.

4 why didn't they do that? Because they didn't want
5 the answer they would get.

6 But they ended up getting it from the Department of
7 Justice. In March of 2014, and the Department of Justice says
8 stop -- this is slide 66. We also -- so this is the email --
9 or this is the letter that the Department of Justice wrote to
10 defendants in March of 2014. And we heard Doug Sbertoli talk
11 about that.

12 And you remember when he said that the Department of
13 Justice told HDL to stop paying the practice -- paying --
14 sorry.

15 Do you remember when he said the Department of
16 Justice told HDL to stop the practice of paying P&H right then
17 and there? Even Ms. Mallory testified that she remembered
18 learning in early 2014 that the government -- the government's
19 position on P&H.

20 So what did defendants do with this ultimatum from
21 the Department of Justice? Nothing. As Mr. Sbertoli told you,
22 they weighed the risks and opted to accept the exposure under
23 the Anti-Kickback Statute rather than the risks associated with
24 losing business and referrals. And so HDL continued for three
25 more months after getting this ultimatum.

1 I want to pause for a minute, let you look at that
2 slide. Each one of those stop signs represents an incident
3 when defendants were warned to stop what they were doing. Each
4 one of those stop signs demonstrates the defendants acting
5 knowingly, willfully, and wrongfully.

6 You put all of those signs together and you get an
7 overwhelming amount of evidence establishing that the
8 defendants acted knowingly and willfully.

9 But there's one more layer to this because defendants
10 tried to hide this evidence from the Department of Justice. In
11 2013 and 2014, defendants had their army of attorneys march up
12 to Washington, D.C., to try to convince the Department of
13 Justice that there was no case here because there was no way
14 that the Department of Justice could prove that the defendants
15 acted knowingly and willfully.

16 And, at that same time those lawyers were pleading
17 with defendant -- pleading the defendants' case, defendants
18 were hiding this mountain of incriminating evidence. This is
19 the legal advice the defendants presented to the Department of
20 Justice at those meetings.

21 why? why would the defendants withhold all of that
22 other evidence? why wouldn't they tell the Department of
23 Justice about Freedman's advice or Kung's advice or Pace's
24 advice or Ropes & Gray's advice or Chris Hall's advice or
25 Ms. DeMoss's advice? The answer is simple. It's because they

1 knew just how incriminating this evidence was. To borrow a
2 phrase from defendant Johnson, they knew it would be game over
3 if the Department of Justice found out about those other stop
4 signs.

5 Now, at the beginning of this case, Mr. Cooke stood
6 up here and talked to you about a parable. And in that
7 parable, Mr. Cooke described an individual who drove 45 miles
8 per hour to work every day until he got pulled over because the
9 speed limit was 35.

10 That parable doesn't fit here. Here, the road is
11 actually closed. And it's clearly closed by something called
12 the Anti-Kickback Statute, which prohibits providing money to
13 induce referrals, precisely what defendants were doing.

14 And the evidence shows the defendants were well aware
15 of the sign. They'd been through trainings for years. They
16 knew the Anti-Kickback Statute, and they knew what it meant.
17 Even so, they follow a handful of other cars onto this road.
18 Those other cars are the other labs paying P&H.

19 First of all, just because others are breaking the
20 law doesn't mean you get to break the law. In fact, as I was
21 walking to the courthouse this morning, I walked through
22 several crosswalks. And I saw no less than two cars run a red
23 light. Now, my thought was, hey, that means now I get to run a
24 red light. You don't get to do that. You don't get to see
25 other people doing something illegal and say, yeah, I can do it

1 too now.

2 But there's one more point. Not only did defendants
3 know that that road was closed, they were also going twice as
4 fast as some of the other cars on that road. They were going
5 70 miles an hour, and they're flying by everybody else. Now,
6 that in and of itself is evidence that they know what they're
7 doing is wrong. But defendants aren't alone in this car.
8 Riding along with them are 17 lawyers yelling at them to stop
9 because the road is closed.

10 Now just as an aside, just a little life tip. Never
11 get into a car with 17 lawyers. That should be a crime in and
12 of itself. But if you're so unfortunate as to find yourself in
13 such a predicament, I'm guessing you'd be wise enough to listen
14 when those lawyers warned you repeatedly to stop what you're
15 doing because it's blatantly illegal, prohibited, and exposing
16 you to civil and criminal liability.

17 And so those defendants are going twice as fast as
18 everybody else on that road. And there's 17 lawyers screaming
19 at them to stop. And defendants fly by the Department of
20 Justice. Now, the Department of Justice, just as those lawyers
21 had warned, flashes its lights and starts to pursue.

22 But defendants keep going just as fast as they had
23 all along. So when the Department of Justice -- only way they
24 could reach them, they shout through the bullhorn. They say,
25 "Stop." Defendants yell back that everything is okay because

1 they had one lawyer tell them it's okay to go 70 on some roads.

2 And, oh, by the way, those 17 lawyers in the car,
3 first, defendants try to hide them. But when the Department of
4 Justice sees them, defendants say, "There's nothing to look at
5 here. You don't need to talk to these guys." But the truth
6 comes out and the Department of Justice learned that defendants
7 had been told for years to stop what they were doing.

8 That's not a parable anymore; that's what we have
9 here. Defendants knew they were on a road that was closed.
10 Defendants knew they were going faster than everybody else on
11 that road. Defendants had red flags and stop signs flying at
12 them for years, literally years.

13 Defendants even tried hiding their own behavior from
14 the United States because they knew what they were doing was
15 wrong. Now, when that's the situation, it's a good thing to
16 hold defendants liable. They knew what they were doing was
17 wrong the whole time. And people have to face the consequences
18 of knowingly and willfully disobeying the law.

19 And that brings us to the final question. why? why
20 did defendants pay P&H when they knew it was wrong? why did
21 they keep paying P&H after all those lawyers told them to stop?
22 why did they keep paying P&H after the Department of Justice
23 started investigating them? Money. Defendants knew that
24 without the P&H there was no business.

25 I think Ms. Mallory put it best when she wrote,

1 "Compliance and legal cannot drive our business decisions."

2 That was the philosophy that allowed HDL to soar, unimaginable
3 profits from 2010 to 2013. But that was also the philosophy
4 that brought HDL to bankruptcy less than a year after it
5 stopped paying kickbacks.

6 Ladies and gentlemen, that covers the requirements of
7 the Anti-Kickback Statute when it comes to the P&H kickbacks.
8 The evidence shows the defendants paid remuneration, more than
9 \$52.6 million. The evidence shows that one purpose behind that
10 remuneration was to get physicians to order HDL and Singulex
11 tests. The evidence shows the physicians who received P&H
12 referred claims that were reimbursed by Medicare and TRICARE,
13 taxpayer-funded federal health care programs.

14 And the evidence shows the defendants did all this
15 despite knowing that what they were doing was wrong. When the
16 evidence establishes each of those requirements, you have an
17 anti-kickback violation and a False Claims Act violation
18 stemming from the P&H kickbacks.

19 Let's move on to the illegal commissions defendants
20 paid to each other to arrange for or recommend a physician to
21 refer a test to HDL. We've talked already today a little bit
22 about how this commissions kickback scheme was devised at the
23 same time as the P&H kickback scheme. We've also talked about
24 how intertwined it was with the P&H kickback scheme.

25 But the commissions paid under this scheme are just

1 as much kickbacks as the P&H kickbacks. And the United States
2 is entitled to recover damages it suffered from claims tainted
3 by this kickback.

4 Fortunately, the scheme was much simpler, and it
5 shouldn't take quite as long to explain why.

6 Momentarily, the judge will instruct you that no
7 statutory or regulatory safe harbor applies in this case. Now,
8 there is a safe harbor that permits commission-based
9 compensation schemes but only for employees of a company. That
10 particular safe harbor allows employees of a company to be
11 compensated through commission payments without violating the
12 AKS.

13 Again, this does not apply in this case because we
14 have independent contractors here. But the defendants are
15 using this inapplicable safe harbor to try and create confusion
16 on the point.

17 Last Friday, Mr. Griffith read the deposition
18 testimony of Jennifer Williams, who works at the Office of
19 Inspector General. In that transcript, Ms. Williams explains
20 that this exemption does not extend to independent contractors
21 because companies cannot exercise the same kind of control over
22 independent contractors that they can over employees.

23 Testimony from both defendant Brad Johnson and
24 defendant Cal Dent confirmed that view. They didn't want HDL
25 to exercise control over them the way Berkeley had, especially

1 with respect to the conduct at issue here. They didn't want
2 HDL, like Berkeley had done, to change P&H fees. They didn't
3 want HDL, like Berkeley had done, to change billing policies.
4 And they didn't want HDL, like Berkeley had done, to change
5 their commission structure, the exact conduct that we have at
6 issue in this case.

7 Likewise, they didn't want Bluewave to carry
8 liability for people who go out and do something unethical,
9 people like Kyle Martel and Lennie Blasko, Charles Maimone,
10 Boomer Cornwell, Julie Harding, Jeff Steadman, and Shane
11 Marquess, the Bluewave sales reps who appeared on the video and
12 in the emails and so on. Bluewave sales reps, by the way, many
13 of whom defendant Johnson actually trained.

14 Defendants didn't have control over those people.
15 And they even -- sorry -- defendants did have control over
16 those people, and they even trained some of those people. But
17 they would have had more control if they'd been employees.
18 Similarly, HDL would have had control over the Bluewave sales
19 reps if they'd been employees. The problem is you can't enter
20 into a scheme to violate the Anti-Kickback Statute and use
21 corporate forms to deny your culpability by claiming everybody
22 downstream isn't you.

23 So there's no applicable safe harbor. And, two, this
24 scheme falls squarely within the requirements of the
25 Anti-Kickback Statute.

1 Let's start with remuneration. No one disputes the
2 fact that defendants paid the commissions. Here's Exhibit 1047
3 again. This is the contract that defendants ultimately
4 executed between themselves.

5 We can see from Clause 4 of this contract that
6 defendants agreed that HDL would pay commissions based on a
7 percent of the revenue that HDL received from sales in the
8 Bluewave territory.

9 Singulex had an almost identical arrangement. This
10 is Plaintiffs' Exhibit Number 2008. You may recall that
11 Mr. Dickerson and Mr. Pace told you that such volume-based
12 payments are not allowed in health care law.

13 So how much remuneration did HDL and Singulex remit
14 to BlueWave? Circling back to Mr. Hines's testimony, he
15 explained how he reviewed inflow of \$244 million from HDL and
16 Singulex into Bluewave. He also testified about how BlueWave
17 paid commissions to its sales reps, commissions totaling
18 \$61 million.

19 Ladies and gentlemen, all of those commission
20 payments constituted remuneration, and defendants do not deny
21 that.

22 So defendants pay remunerations. Now, one purpose of
23 that remuneration was to get Bluewave and their sales reps to
24 arrange for and recommend that physicians refer samples to HDL
25 and Singulex. The defendants' commission compensation

1 arrangements provided an incentive or an inducement for
2 Bluewave and its subcontractors to sell as many HDL and
3 Singulex tests as they could. The defendants don't dispute
4 that either.

5 Defendant Dent said simply, "If you sell more cars,
6 you make more money." If you sell more tests, you make more
7 money.

8 And Philippe Goix from Singulex -- hard to forget
9 Philippe Goix. He told you that Singulex paid defendant
10 Bluewave a 24 percent commission to incentivize defendants Dent
11 and Johnson to get as many doctors as they could to refer tests
12 to Singulex.

13 The purpose of defendants' commission kickbacks is
14 particularly easy in this case, because it's written directly
15 into the contract. HDL and Singulex will pay commissions for
16 sales services. And you've heard testimony from sales
17 representatives and defendants themselves saying that Bluewave
18 sales reps were the face of the labs. The reps were the ones
19 who handled all the arrangements. And, certainly, part of any
20 sales pitch involves recommending the product being sold over
21 its competitors' products.

22 Just to circle back to the P&H scheme for a moment --
23 and I promise it will only be a moment -- you know that
24 defendants used the fact that HDL and Singulex paid
25 significantly more than their competitors as one means of

1 recommending HDL and Singulex testing over their competitors.
2 So it was one purpose of the commission of remuneration to get
3 BlueWave to arrange for or recommend HDL and Singulex testing?
4 You bet.

5 And that just leaves the final requirement of the
6 Anti-Kickback Statute, that defendants acted knowingly and
7 willfully. There's circumstantial evidence that defendants
8 understood from the start that their business arrangement
9 violated the Anti-Kickback Statute. Defendants Dent and
10 Johnson were familiar with the Anti-Kickback Statute. And they
11 had been trained on it at all of their previous jobs.

12 Defendants Dent and Johnson had never been
13 independent contractors for a company that billed Medicare and
14 TRICARE before. Defendants Dent and Johnson knew that this
15 arrangement was unique in the industry, yet who did they call
16 for advice on a proposed arrangement? Gene Sellers, who made
17 it clear in his testimony that he was not a health care lawyer.

18 You may also recall when defendant Dent explained
19 that Mark White of White Arnold & Dowd, the counsel they
20 retained to help with the DOJ investigation, warned defendant
21 Dent that, quote, Cal, that's the only way they're going to
22 drag you guys into this thing, end quote. And he was referring
23 to the commission structure.

24 In addition to the circumstantial evidence, it's also
25 clear in this case that defendants knew what they were doing

1 was wrong, again because trained health care attorneys told
2 them specifically that.

3 The first lawyer we know about that told them to stop
4 paying commission kickbacks was Derek Kung, HDL's general
5 counsel, its top lawyer. His memo to the board could not have
6 been clearer. "This is a red-flag practice that needs to end."

7 Did defendants follow Mr. Kung's advice? No, they
8 did not. Just like with P&H, they ignored it and kept paying
9 the illegal kickbacks.

10 And, again, it's clear in this case that defendants
11 knew what they were doing was wrong because Derek Kung told
12 them that.

13 But it wasn't just Derek Kung. Nick Pace also
14 advised against the commission payments to BlueWave. He
15 testified that these payments did not fall within an
16 Anti-Kickback Statute safe harbor or a permitted exception.

17 Nick Pace noted that there was a prohibition against
18 these commission payments. Nick Pace advised that these
19 commission payments had to end. But did defendants follow
20 Mr. Pace's advice? No, they did not. Just like with P&H, they
21 ignored Nick Pace and kept paying the illegal kickback.

22 There was also Brian Dickerson. He alerted
23 defendants to the illegal nature of their contracts. He told
24 defendants that their business model violated the Anti-Kickback
25 Statute.

1 we also heard Sellers testify that Dickerson said,
2 quote, that the Bluewave contract violated every law that had
3 ever been written and stuff like this, in particular health
4 care law. Now, Mr. Sellers may have been exaggerating a little
5 bit there, but it's clear that defendants were aware of
6 Mr. Dickerson's concern.

7 So did defendants listen to Mr. Dickerson and change
8 the structure of their contracts? No. But they didn't merely
9 ignore the warning like they did with Kung and Pace. They
10 fired the sales rep who was blowing the whistle.

11 So that covers the requirements of the Anti-Kickback
12 Statute when it comes to the commission kickbacks. The
13 evidence shows that defendant -- that Singulex and HDL -- HDL
14 on behalf of Tonya Mallory -- paid the Bluewave defendants
15 remuneration in excess of \$244 million. The evidence shows the
16 Bluewave defendants paid remuneration to their sales reps
17 totaling more than \$63 million. The evidence shows that one
18 purpose behind the remuneration was to get the Bluewave sales
19 reps to arrange for or recommend that physicians use HDL and
20 Singulex for lab testing and to order large panels of tests on
21 large portions of their patients.

22 The evidence also shows that claims tainted by the
23 commission kickbacks were reimbursed by Medicare and TRICARE,
24 two taxpayer-funded federal health care programs. The evidence
25 shows that defendants did all this despite knowing that what

1 they were doing was wrong.

2 when the evidence establishes each of these
3 requirements, you have anti-kickback violations and False
4 Claims Act violations stemming from the defendants' commission
5 kickback scheme.

6 Now, the government also alleged that defendants
7 caused the submission of false claims by knowingly submitting
8 medically unnecessary claims to Medicare and TRICARE.
9 Momentarily, we'll talk about what you heard from the doctors
10 that testified in this case.

11 But before we do that, let's talk for a moment about
12 HDL's and Singulex's tests and how the commission kickbacks
13 incentivized the Bluewave sales reps to sell as many HDL and
14 Singulex tests as possible.

15 So here is Plaintiffs' Exhibit 1204. In this
16 instance, defendant Johnson encourages Bluewave sales reps to
17 be sure that all of your accounts have CYP2C19 on their HDL
18 panels and also make sure to sell Singulex.

19 Moving on, we see the same thing here in Plaintiffs'
20 Exhibit 3031. In this email chain, Bluewave instructs Erika
21 Guest to make a concerted effort to add certain tests,
22 including HDL's galectin-3 tests, to each of her customers'
23 panels.

24 And if we look here at Plaintiffs' Exhibit 1033, we
25 see how it happened out in the field. This is an email

1 exchange that I asked Mr. Martel about during his testimony.

2 And you may recall again that he asserted his Fifth Amendment
3 rights and did not answer the question.

4 In the bottom email, Mr. Martel is told that one of
5 his clients wants to remove a number of tests from their panel,
6 including a number of tests that Dr. Trost opined were
7 medically unnecessary. That was the United States expert,
8 Dr. Trost.

9 How does Mr. Martel respond? "That's not going to
10 work. Let me call them." Unless you think this is an isolated
11 instance, think back to the undercover surveillance video of
12 Len Blasko.

13 In that video, you may recall that Bluewave sales rep
14 Charles Maimone joined the call and instructed the physician
15 that "We can't cross off -- we can't cross too many off because
16 then you won't get the full 20. But if it's a couple of
17 things, that's fine."

18 In other words, you can't go crossing off tests if
19 you want the P&H kickback.

20 You heard testimony from Boomer Cornwell, a Bluewave
21 sales rep, who recalled an instance when defendant Johnson told
22 doctors who ordered tests -- and I quote -- whoever they draw
23 blood on to look at, you know, like a screening panel, like a
24 physical, or whoever they would draw blood to get a lipid panel
25 on would be an appropriate patient for this, close quote.

1 Mr. Cornwell also testified that defendant Johnson
2 told doctors about how they could order HDL tests every three
3 months on their patients. Similarly, Dr. Mayes told you that
4 BlueWave sales rep Tony Carnaggio told him he could order the
5 HDL and Singulex tests up to every three months.

6 And Dr. Mayes told you about how the P&H fees
7 corrupted the judgment of his partners and how they used the
8 P&H fees to pay bills and then to distribute as profits and
9 bonuses to themselves.

10 BlueWave's aggressive sales tactics resulted in the
11 physicians ordering medically unnecessary tests on large
12 portions of their patient populations. That's a fact confirmed
13 by Dr. Jeffrey Trost, an interventional cardiologist and
14 assistant professor of medicine at Johns Hopkins University,
15 who opined that HDL's and Singulex's tests were medically
16 unnecessary for a routine population of patients.

17 But Dr. Trost had specific critiques as well. And
18 just as my colleague Mr. Leventis promised in his opening
19 statement, there were many tests that Dr. Trost and
20 Dr. Fishberg, defendants' own expert, agreed were medically
21 unnecessary.

22 Take the CYP2C19 test for example. Dr. Trost
23 testified that the CYP2C19 test is only appropriate for
24 patients who are taking the Plavix medication or whose
25 physician is considering prescribing Plavix. Dr. Trost

1 explained for that reason that it is not appropriate to include
2 on a baseline panel for evaluation or for routine patient
3 population.

4 Now, defendants' medical expert, Dr. Fishberg,
5 reached the same conclusion and indicated that the CYP2C19 test
6 is only helpful for a patient who is taking Plavix or whose
7 physician is considering prescribing Plavix. He indicated that
8 it is not appropriate for every patient who comes in the door.

9 Nonetheless, as we see in the email above -- or
10 previously, not above -- email previously, he indicated that it
11 is not appropriate for -- Bluewave wanted this test on every
12 doctors' panel.

13 There was also the Factor V Leiden test. Dr. Trost
14 explained that the Factor V Leiden test is a genetic test to
15 see if patients are predisposed to developing blood clots in
16 their veins. He explained it is to be used only for patients
17 who have blood clots in their veins or lungs and only after
18 ruling out other more common causes of blood clots.

19 Dr. Trost explained that it is not appropriate to
20 include this in a baseline assessment in an evaluation of a
21 routine patient population. Likewise, Dr. Fishberg explained
22 that the Factor V Leiden test is primarily for patients with
23 venous diseases and, even then, only after taking an extensive
24 family history. Like Dr. Trost, he indicated that it is not
25 appropriate for every patient who walks in the door.

1 Nonetheless, this test appeared on HDL's baseline panel.

2 Then there's the prothrombin and mutation test. Hard
3 to say when your mouth is dry. Dr. Trost explained that this
4 is a genetic test that is offered alongside the Factor V Leiden
5 test that we just talked about. He explained that this is to
6 be used only for patients who have blood clots in their veins
7 or lungs and only after ruling out other more common causes of
8 blood clots.

9 Dr. Trost explained that it is not appropriate to
10 include this in a baseline assessment and evaluation of a
11 routine patient population. Dr. Fishberg echoed these points,
12 indicating that he would only order prothrombin mutation when
13 he orders Factor V Leiden tests.

14 How about the galectin-3 test? Dr. Trost explained
15 that this may give some prognostic information for patients who
16 suffer from acute heart failure, acute heart weakening, or
17 chronic heart weakening. He emphasized that this test is
18 designed for a very specific population of patients. It is not
19 designed for a broad population of patients that walk into any
20 doctor's office.

21 Dr. Fishberg, defendants' expert, indicated that he
22 had never ordered galectin-3 and said it appears to have a
23 similar benefit to NT-proBNP, which happens to be another test
24 already included in HDL's baseline panel.

25 Dr. Fishberg also indicated that he does not use the

1 cystatin C and FFA tests and that he had no opinions on those
2 tests, tests that appear on the baseline panel.

3 what about the interleukin-6 and interleukin-17A test
4 from Singulex? Dr. Trost indicated that these two tests have
5 no clinical utility whatsoever. They test inflammation, but
6 the test is not specific and inflammation could be to any
7 organ.

8 So, in his opinion, the tests do not really convey
9 any useful information because there's really nothing that we
10 can do differently than we ordinarily would do with our usual
11 risk factors in terms of treating that patient.

12 During the time period at issue in this case,
13 Dr. Fishberg was not sure about the long-term benefits of this
14 test. And even to this date, he has used the test only
15 sporadically on people at risk for high inflammation, such as
16 those with rheumatoid arthritis.

17 In addition to these instances of agreement, you may
18 recall that Mr. Cooke asked Dr. Fishberg to opine on the
19 medical necessity of the tests offered by HDL and Singulex.
20 How did Dr. Fishberg reply? "That's a very difficult question
21 for me."

22 That's right, ladies and gentlemen. Not even
23 defendants' own expert was willing to state for the record that
24 these tests, all of them, were medically necessary.

25 But you don't have to trust just Dr. Trost and

1 Dr. Fishberg. You may remember defendant Johnson, defendant
2 Dent -- and BlueWave also called as a witness Dr. Joe Hollins,
3 one of defendant Dent's clients.

4 Dr. Hollins testified that after defendant Dent
5 introduced him to the Singulex panels of tests, including
6 Singulex troponin and two interleukin tests, he ordered those
7 tests only to find that they weren't very useful.

8 Now, you also may remember yesterday that defendant
9 Johnson described the Singulex troponin test as the best thing
10 since sliced butter. Well, that certainly wasn't Dr. Hollins'
11 experience.

12 And just in case that testimony is not enough, think
13 back to this slide from Eric Hines's testimony. If these tests
14 really were the best thing since sliced butter, like defendant
15 Johnson said, if these tests really saved lives like defendants
16 claimed in their sales pitches, then why did doctors stop
17 ordering them as soon as the P&H kickbacks went away?

18 I submit to you it's because these tests were not as
19 great as defendants would have you believe and that doctors
20 needed the inducement of the kickback to order them. These
21 tests were medically unnecessary, and defendants nonetheless
22 knowingly submitted these false claims for reimbursement to
23 Medicare and TRICARE. And for that reason, these claims
24 constitute violations of the False Claims Act.

25 That brings us to damages. The United States is

1 seeking damages related to HDL's claims and also to Singulex's
2 claims. Mr. Hines was kind enough to calculate those figures
3 for us.

4 For the HDL damages, there are 289,818 claims that
5 resulted in \$171,864,547 in damages. Each and every one of
6 those claims and the damages associated with those claims is
7 tainted by both of the kickback schemes; that is, they're
8 tainted by both the P&H kickbacks and the commission kickbacks.
9 And this also covers the United States' medical necessity
10 claims for HDL.

11 For the Singulex damages that the United States is
12 seeking, there are 38,138 claims that resulted in \$4,679,353 in
13 damages. Each and every one of those claims is tainted by both
14 of the kickback schemes, again both the P&H kickbacks and the
15 commission kickbacks. Mr. Hines did that math for us. It also
16 covers the United States' medical necessity claims for
17 Singulex.

18 The last thing I'd like to do with you is to go over
19 the verdict form and how to fill it out.

20 For Question 1, you're asked to determine whether
21 defendants violated the False Claims Act as to HDL's claim. A
22 claim could be false because it includes medically unnecessary
23 services. A claim could also be false because it results from
24 a violation of the Anti-Kickback Statute.

25 Remember here we have two separate, distinct

1 violations. So it could be false because of the P&H kickback.

2 It could be false because of the commission kickback. It could
3 be false if all three apply.

4 Just to be clear, you should check -- and actually
5 could we switch to the ELMO, please.

6 If you find that any of those claims are tainted by
7 any of those three different violations -- medical necessity,
8 P&H kickback, or commission kickbacks -- you should check yes
9 to all four of these boxes because all four of the defendants
10 were involved in that scheme -- or those schemes.

11 And then if you turn the page, how many claims for
12 services by HDL violated the False Claims Act? Again,
13 Mr. Hines did that math for you. 289,818 claims.

14 It's easier to read it if it's on the screen.

15 And what was the dollar value associated with those
16 claims? \$171,864,547. Oops. Those are the damages tied to
17 HDL's claims that were submitted, claims that were tainted by
18 medical necessity, P&H kickbacks, and the commission kickbacks.

19 So then there's Question 4. These are claims unique
20 to Singulex. We parsed that out because defendant Mallory
21 really wasn't part of that, and so that's why there's only
22 three names that appear: Bluewave Healthcare Consultants,
23 Floyd Calhoun Dent, and Robert Bradford Johnson.

24 And the same three theories of liability apply. If
25 you find that any one of those theories attach -- whether or

1 not the tests were medically necessary, whether or not the P&H
2 kickbacks tainted these claims, whether or not the commission
3 kickbacks tainted these claims -- then you should check yes.
4 And, again, the evidence shows by a preponderance of the
5 evidence that all three violations occurred in this instance.

6 And then you move on to the next page, and they ask
7 how many claims were associated with the Singulex violations.
8 38,138. And what was the damage figure associated with those
9 claims? \$4,679,353.

10 They chose the wrong guy for this job, because my
11 penmanship is horrible. I apologize for that.

12 I submit to you that the evidence in this case shows
13 by a preponderance of the evidence that these claims -- that
14 the claims I have outlined here on this verdict form are false.
15 They're false for three distinct reasons: 1, they were
16 medically unnecessary; 2, they were tainted by the commission
17 kickbacks; 3, they were tainted by the P&H kickbacks.

18 All three violations apply to each and every one of
19 the claims listed here.

20 And I will end the way I began and thank you on
21 behalf of me and my colleagues for the time and devotion that
22 you've dedicated to this case. Thank you.

23 **THE COURT:** Ladies and gentlemen, we'll break for
24 lunch. Lunch has arrived.

25 And when y'all have finished lunch, let

1 Ms. Ravenel know that and we'll commence with the next part of
2 closing argument. Have a good lunch.

3 (Whereupon the jury was excused from the courtroom.)

4 **THE COURT:** You may be seated. We'll -- if anyone
5 wants to get a bite to eat -- when Ms. Ravenel tells us they've
6 finished, I'm going to summon you back in. Okay?

7 (Recess.)

8 **THE COURT:** Please be seated.

9 Counsel, are there any matters we need to
10 address before we --

11 **MR. LEVENTIS:** Not from the United States, Your
12 Honor.

13 **MR. COOKE:** Nothing, Your Honor.

14 **THE COURT:** You're ready. Let's bring in the jury.
15 (Whereupon the jury entered the courtroom.)

16 **THE COURT:** Please be seated.

17 I want to again thank y'all for the attention
18 y'all are giving this, and I know you will continue to do that.
19 And I know you will give equal attention to all parties and all
20 counsel.

21 Bluewave defendant, closing argument.

22 **MR. COOKE:** Thank you, Your Honor.

23 Good afternoon.

24 **THE JURY:** Good afternoon.

25 **MR. COOKE:** It's been a long couple of weeks. I want

2 : 0 5 P M 1 to -- I'm Dawes Cooke. I want to join Judge Gergel in thanking
2 : 0 5 P M 2 you and commending you. It was, gosh, two weeks ago that I was
2 : 0 5 P M 3 here before, and I asked you to do one thing. I asked you to
2 : 0 5 P M 4 consider the possibility that what we were going to do over the
2 : 0 5 P M 5 next two weeks would be the most important work that we'd ever
2 : 0 5 P M 6 done. And you guys have treated it exactly like that, and I
2 : 0 5 P M 7 appreciate that.

2 : 0 6 P M 8 The government has it exactly backwards. Stop
2 : 0 6 P M 9 means stop. If you want somebody to stop, you can tell them to
2 : 0 6 P M 10 stop. You don't tell them the government might tell you to
2 : 0 6 P M 11 stop. You don't tell them that we're not sure what the speed
2 : 0 6 P M 12 limit is. You tell them to stop. That's what this case is
2 : 0 6 P M 13 about.

2 : 0 6 P M 14 To find for the government, you'll have to not
2 : 0 6 P M 15 only find what the speed limit was, to use the analogy that I
2 : 0 6 P M 16 used two weeks ago, but you also have to find that the
2 : 0 6 P M 17 government told everyone what the speed limit was. Because
2 : 0 6 P M 18 that's the government's job. You also have to find that Brad
2 : 0 6 P M 19 Johnson and Cal Dent knew and understood what the speed limit
2 : 0 6 P M 20 was and that they deliberately decided not to obey it.

2 : 0 6 P M 21 The government can't just paste stop signs all
2 : 0 7 P M 22 over their graphics and say, "These are all stop signs." Thank
2 : 0 7 P M 23 goodness we have a jury of our peers and they see stop signs
2 : 0 7 P M 24 and they know what stop signs are. And more importantly, they
2 : 0 7 P M 25 have expectations of what the government is going to do to show

1 us where the stop signs and the speed limits are and what they
2 are.

3 I'm going to -- Congress was pretty smart when
4 they wrote the Anti-Kickback Statute. They knew that this was
5 a very complicated area. They knew that there would be
6 differences of opinion on one side or the other. They knew
7 that health care lawyers would be squaring off with their
8 counterpart over at the OIG or the Justice Department and
9 they'd be arguing about where these different lines are. And
10 they knew that these guys usually get the final word. And so
11 what they say the speed limit is, that's going to be the speed
12 limit.

13 But they were also very conscious about the
14 possibility that the government might ruin somebody, might
15 destroy somebody's life, might take everything that they could
16 ever hope to earn because they guessed wrong.

17 And so Congress put a provision in the
18 Anti-Kickback Statute that requires that the government do more
19 than say that this was a dangerous and a complicated area in
20 order to take everything that somebody has worked for.
21 Instead, they put a provision that said that you are guilty of
22 violating the Anti-Kickback Statute if you knowingly and
23 willfully pay remuneration to induce referrals.

24 They put a similar thing in the fraudulent
25 claims act that said that one who knowingly files a claim or

2 : 0 8 P M 1 causes a false claim to be filed will be liable. An act is
2 : 0 9 P M 2 done willfully under the Anti-Kickback Statute if it is done
2 : 0 9 P M 3 voluntarily and with the purpose either to disobey or disregard
2 : 0 9 P M 4 the law. In order to act willfully, a defendant must act
2 : 0 9 P M 5 unjustifiably and wrongly while knowing that his or her actions
2 : 0 9 P M 6 are unjustifiable and wrong.

2 : 0 9 P M 7 Don't take my word for it. Judge Gergel is
2 : 0 9 P M 8 going to give you the instructions of the law. But I submit to
2 : 0 9 P M 9 you that, when you hear the instructions and you hear the
2 : 0 9 P M 10 instructions particularly about the requirement that the
2 : 0 9 P M 11 government not only show you what the speed limit was but show
2 : 0 9 P M 12 that they knew what the speed limit was and that they knowingly
2 : 0 9 P M 13 and willfully violated it before they can be required to pay
2 : 0 9 P M 14 these many, many millions of dollars that the government is
2 : 0 9 P M 15 asking for, you'll conclude that the government cannot and has
2 : 0 9 P M 16 not come close to meeting its burden.

2 : 1 0 P M 17 Red flags. That's all what you saw. They
2 : 1 0 P M 18 turned them into -- into stop signs on their graphics and in
2 : 1 0 P M 19 their argument, but what we -- what we know is that there are
2 : 1 0 P M 20 going to be differences of opinion about almost everything in
2 : 1 0 P M 21 the law, particularly in a complicated area in the health care
2 : 1 0 P M 22 field.

2 : 1 0 P M 23 That's why companies go out and get lawyers
2 : 1 0 P M 24 and -- very specialized lawyers to give them opinions if
2 : 1 0 P M 25 there's an area of doubt. It's not because they're trying to

2 : 1 0 P M 1 sneak around the law. It's because they want to know what the
2 : 1 0 P M 2 law is. They want to know how to stay in a safe area, how to
2 : 1 0 P M 3 not get up to the -- to the line.

2 : 1 0 P M 4 So I'm going to look at each of the red flags or
2 : 1 0 P M 5 the stop signs that the government talked about earlier and
2 : 1 0 P M 6 tell you the rest of the story.

2 : 1 0 P M 7 The first was Mr. Perling. You remember he was
2 : 1 0 P M 8 the lawyer. I believe he was down in Florida, and he's the one
2 : 1 1 P M 9 that wrote the memorandum saying that this was blatantly
2 : 1 1 P M 10 illegal, "as illegal as anything I've ever seen" back on
2 : 1 1 P M 11 December 13, 2010.

2 : 1 1 P M 12 But there's an exhibit in the file which you'll
2 : 1 1 P M 13 have, and it's Bluewave Exhibit 68. And I'm going to -- you
2 : 1 1 P M 14 guys have been watching TV screens for two weeks now, so I'm
2 : 1 1 P M 15 going to do it the old-fashioned way because, when you get to
2 : 1 1 P M 16 the jury room, you're not going to have the TV screens. You're
2 : 1 1 P M 17 going to have the paper itself.

2 : 1 1 P M 18 But this is what it is, and the government
2 : 1 1 P M 19 focused on the -- the earlier statement from Mr. Perling where
2 : 1 1 P M 20 he said it's "the most blatantly illegal thing I've ever seen."
2 : 1 1 P M 21 And then they jump right kind of to the end here where Tonya
2 : 1 1 P M 22 Mallory writes, "Would he" -- Dr. Reddy -- "be interested in
2 : 1 1 P M 23 doing clinical research and we pay him to retrieve electronic
2 : 1 1 P M 24 data from his EMR, \$20 per patient for chart data for our
2 : 1 2 P M 25 research in the development of our portals and health score is

2 : 1 2 P M 1 certainly a bargain for us. Such research information
2 : 1 2 P M 2 typically goes for a lot more."

2 : 1 2 P M 3 So you think from that, golly, this guy, he's a
2 : 1 2 P M 4 certified expert, Perling. He tells him it's blatantly
2 : 1 2 P M 5 illegal. And next thing you know, Tonya Mallory is over there
2 : 1 2 P M 6 trying to find a backdoor way to slip him some money. But they
2 : 1 2 P M 7 left out everything that happened in between.

2 : 1 2 P M 8 Right here, this document says December 16.
2 : 1 2 P M 9 That's almost a week after the initial introduction by
2 : 1 2 P M 10 Mr. Perling. She writes to Kyle Martel, who was in Florida and
2 : 1 2 P M 11 had been the one that raised this issue.

2 : 1 2 P M 12 And she says, "Kyle, I wanted to give you an
2 : 1 2 P M 13 update on the discussions that our attorney has had with
2 : 1 2 P M 14 Dr. Reddy's attorney, Lester Perling. Mr. Perling's email was
2 : 1 2 P M 15 strange, and at first we all believed he didn't know what he
2 : 1 2 P M 16 was talking about. However, our attorney quizzed him and has
2 : 1 3 P M 17 determined that his credentials are quite good and he does know
2 : 1 3 P M 18 health care law. Mr. Lester was actually involved in some of
2 : 1 3 P M 19 the changes that are going to occur in the state of Florida and
2 : 1 3 P M 20 the state's interpretation of inducement laws. Mr. Perling has
2 : 1 3 P M 21 said that Quest has been very active in the state and has
2 : 1 3 P M 22 convinced the State of Florida to change their opinion of the
2 : 1 3 P M 23 inducement laws.

2 : 1 3 P M 24 "He told our attorney that in the future,
2 : 1 3 P M 25 Florida will not allow any P&H fees to be paid to doctors, and

2 : 1 3 P M 1 they will also not allow a lab like HDL to put a phlebotomist
2 : 1 3 P M 2 in the physician practice. Florida's interpretation is that
2 : 1 3 P M 3 these will be viewed as inducement.

2 : 1 3 P M 4 "Mr. Perling did back down on his comments that
2 : 1 3 P M 5 it was illegal, et cetera, and said he only wrote that because
2 : 1 3 P M 6 he's been so entwined in these discussions with the State of
2 : 1 3 P M 7 Florida and Quest.

2 : 1 3 P M 8 "I have asked our attorneys to go back and
2 : 1 3 P M 9 research what Mr. Perling has told them and to come up with a
2 : 1 3 P M 10 solution. This has not gone into law now, but Mr. Perling said
2 : 1 4 P M 11 they do expect that it will be next year. Exact date is
2 : 1 4 P M 12 uncertain.

2 : 1 4 P M 13 I've asked our attorneys to get this
2 : 1 4 P M 14 information. I've asked about the punishment for doing this
2 : 1 4 P M 15 and was told that the State of Florida would require a doctor
2 : 1 4 P M 16 to refund the amount to the lab.

2 : 1 4 P M 17 "One thing I can think of now is to start
2 : 1 4 P M 18 thinking about putting a draw site into strategic locations
2 : 1 4 P M 19 where you have the greatest concentration of doctors. I've
2 : 1 4 P M 20 also asked, if the P&H amount reduced to a smaller amount,
2 : 1 4 P M 21 would it make a difference. I've asked them to think about
2 : 1 4 P M 22 every possible way to help us solve this problem, and they're
2 : 1 4 P M 23 working on it.

2 : 1 4 P M 24 "Therefore, Dr. Reddy can send us samples, but
2 : 1 4 P M 25 he may not want to legitimately sign the P&H agreement at this

2 : 1 4 P M 1 time. Would he be interested in doing clinical research and we
2 : 1 4 P M 2 pay him to retrieve electronic data from his EMR? \$20 per
2 : 1 4 P M 3 patient for chart data for our research in the development of
2 : 1 4 P M 4 our portals and health score is certainly a bargain for us.
2 : 1 4 P M 5 Such research information typically goes for a lot more."

2 : 1 5 P M 6 That's a bit of a different story, isn't it,
2 : 1 5 P M 7 than the way it was portrayed? Instead of quite the contrary
2 : 1 5 P M 8 of showing that any -- that Ms. Mallory, let alone anybody at
2 : 1 5 P M 9 BlueWave, was trying find a way to sneak around Mr. Perling,
2 : 1 5 P M 10 she -- BlueWave did exactly what BlueWave did every single time
2 : 1 5 P M 11 the question came up.

2 : 1 5 P M 12 They referred it to the experts, not to Tonya,
2 : 1 5 P M 13 but to the lawyers that Tonya's company, HDL, had retained, the
2 : 1 5 P M 14 specialists in this area of compliance. That is the
2 : 1 5 P M 15 responsible thing to do. That is not deliberate indifference
2 : 1 5 P M 16 or willful blindness or anything else that the government would
2 : 1 5 P M 17 try to characterize it as.

2 : 1 5 P M 18 And she's trying to solve a legitimate problem
2 : 1 5 P M 19 that arose. And who is she relying on? She's relying on their
2 : 1 5 P M 20 attorneys. That's what you're supposed to do when you run into
2 : 1 5 P M 21 a legal question.

2 : 1 5 P M 22 The next one is Kaibigan's attorney. Do you
2 : 1 6 P M 23 remember that? That was April 29, 2011. There's a statement
2 : 1 6 P M 24 made that, if the laboratory pays you for the P&H but those
2 : 1 6 P M 25 functions are already paid for in the office visit payment,

2 : 1 6 P M 1 blah, blah, it could become a double payment.

2 : 1 6 P M 2 well, there's another exhibit -- they didn't
2 : 1 6 P M 3 just forget about that either -- Exhibit 1117. It looks like
2 : 1 6 P M 4 this.

2 : 1 6 P M 5 And right down here, on April 29, 2011, the
2 : 1 6 P M 6 inquiry from Kaibigan's attorney is routed straight up to HDL
2 : 1 6 P M 7 with the request, "Can you help with this?" And it's at -- I'm
2 : 1 6 P M 8 sorry. It's at 10:13 a.m.

2 : 1 7 P M 9 "Hey, Tonya" -- this is from Cal Dent to Tonya
2 : 1 7 P M 10 with a copy to Brad. "Can you help Kyle with this request?
2 : 1 7 P M 11 Timing is of the utmost importance. I'm sure that you can
2 : 1 7 P M 12 easily put this to rest with the many opinions/letters HDL has
2 : 1 7 P M 13 obtained. Thanks, Cal."

2 : 1 7 P M 14 That's exactly what he should have done, and she
2 : 1 7 P M 15 did exactly what she should have done.

2 : 1 7 P M 16 The next one was Pathology Labs, dated March 27,
2 : 1 7 P M 17 2012. This was the other laboratory that was out there that
2 : 1 7 P M 18 you may recall passing around a letter that warned about the
2 : 1 7 P M 19 possibilities of there being a violation of Anti-Kickback
2 : 1 7 P M 20 Statute.

2 : 1 7 P M 21 And there's an Exhibit 1253. You've seen this
2 : 1 7 P M 22 many times. I'm not going to bother reading it again, but this
2 : 1 8 P M 23 was the -- this was the letter that HDL had -- had done by the
2 : 1 8 P M 24 LeClairRyan firm and by Michael Ruggio, who had many, many
2 : 1 8 P M 25 years in the health care field, including having been a

2 : 1 8 P M 1 government attorney.

2 : 1 8 P M 2 And so after -- after all of these requests from
2 : 1 8 P M 3 Kaibigan's attorney and from Pathology Labs and from
2 : 1 8 P M 4 Mr. Perling, Tonya did the wise thing at the urging of Brad and
2 : 1 8 P M 5 Cal. They went out, and she got a formal legal opinion that
2 : 1 8 P M 6 completely endorsed the process and handling fees. It was
2 : 1 8 P M 7 accompanied by a time and motion study that confirmed that
2 : 1 8 P M 8 everything was being paid appropriately and at fair market
2 : 1 8 P M 9 value.

2 : 1 8 P M 10 Then they brought up the Kung memo. That's
2 : 1 8 P M 11 Exhibit 1244, and it looks like this. And it's got various
2 : 1 9 P M 12 attachments to it, but included in it is a memo dated
2 : 1 9 P M 13 August 30, 2012.

2 : 1 9 P M 14 what the government didn't mention to you is
2 : 1 9 P M 15 that never, ever, ever did Brad or Cal or anybody at BlueWave
2 : 1 9 P M 16 ever see this memo or hear about this memo or get this memo.

2 : 1 9 P M 17 You know, one of the things that's wonderful
2 : 1 9 P M 18 about our jury system is that there are 12 of you, and that
2 : 1 9 P M 19 means you remember 12 times as many things as any one of us
2 : 1 9 P M 20 does. So when you go back to the jury room, I would invite you
2 : 1 9 P M 21 to question each other about which witness was it that
2 : 1 9 P M 22 testified that Brad or Cal or anybody at Bluewave ever heard
2 : 1 9 P M 23 Mr. Kung's opinion that he gave. And the answer is going to be
2 : 1 9 P M 24 nobody. Nobody ever testified to that.

2 : 2 0 P M 25 But here's another important part of what he

2 : 2 0 P M 1 said. He said, "The processing and handling fee practice is a
2 : 2 0 P M 2 red flag for the OIG and poses a high level of risk under the
2 : 2 0 P M 3 AKS and the Stark Law."

2 : 2 0 P M 4 It's a red flag for the OIG. That is a
2 : 2 0 P M 5 recurring theme that you're going to see in almost every one of
2 : 2 0 P M 6 these documents where people raise questions about the legality
2 : 2 0 P M 7 of process and handling. Never once does one of these people
2 : 2 0 P M 8 say -- and these are all lawyers or people who are
2 : 2 0 P M 9 knowledgeable. Never once does one of them say, you know, "I
2 : 2 0 P M 10 looked this up, and this is wrong. You can't do this." Never
2 : 2 0 P M 11 once did Mr. Kung say "stop this."

2 : 2 0 P M 12 You know, you can play with words as much as you
2 : 2 0 P M 13 want; but when somebody says to move away from something or to
2 : 2 0 P M 14 phase something out, that's different than saying "stop it,"
2 : 2 0 P M 15 because it's -- it's no secret -- it's not some secret legal
2 : 2 1 P M 16 society that uses code words.

2 : 2 1 P M 17 If a lawyer has a client who is breaking the
2 : 2 1 P M 18 law, the lawyer says "stop." He doesn't say "come up with
2 : 2 1 P M 19 alternatives. Slow down. Phase this out. Let's start moving
2 : 2 1 P M 20 away from this. Let's think about moving away from this." He
2 : 2 1 P M 21 says "stop."

2 : 2 1 P M 22 That's what a red stop sign looks like. It's
2 : 2 1 P M 23 when a lawyer says, "Stop it. You're breaking the law."
2 : 2 1 P M 24 Because without that, people like him and him and her are
2 : 2 1 P M 25 entitled to believe that they're not breaking the law.

2 : 2 1 P M 1 The Department of Justice subpoena, January 7,
2 : 2 1 P M 2 2013, I think that kind of epitomizes the government's approach
2 : 2 1 P M 3 to this case. And that is, we sent you a subpoena. A subpoena
2 : 2 1 P M 4 is a question. A subpoena says send us all the information you
2 : 2 1 P M 5 have on this subject and all the documents you have on this
2 : 2 2 P M 6 subject.

2 : 2 2 P M 7 You can read that subpoena from front to back
2 : 2 2 P M 8 and you will never see anything in there that says even what
2 : 2 2 P M 9 they're investigating, let alone what they think or what they
2 : 2 2 P M 10 think you're doing wrong or what they want you to do. It says
2 : 2 2 P M 11 give us all of your information and let's start a conversation.
2 : 2 2 P M 12 That's essentially what receiving a subpoena says.

2 : 2 2 P M 13 You know, it's probably an exaggeration to
2 : 2 2 P M 14 say -- maybe we're asking too much to say innocent until proven
2 : 2 2 P M 15 guilty, but you're innocent at least until somebody accuses you
2 : 2 2 P M 16 and tells you that you've done something wrong. And that did
2 : 2 2 P M 17 not happen in this subpoena, and this never happened until much
2 : 2 2 P M 18 later.

2 : 2 2 P M 19 what did the -- what did the defendants do? I
2 : 2 2 P M 20 don't want to keep speaking for Ms. Mallory, but she went out
2 : 2 2 P M 21 and hired probably the best law firm in the whole country to
2 : 2 2 P M 22 get advice on health care compliance. And these guys went out
2 : 2 2 P M 23 and got the very best law firm that they knew about in Alabama,
2 : 2 3 P M 24 probably one of the very finest law firms in Alabama with great
2 : 2 3 P M 25 experience in dealing with the federal government.

2 : 2 3 P M 1 The next one that we saw was the MDVIP inquiry
2 : 2 3 P M 2 that came in on January 8th, 2013. And that's Exhibit 7011.
2 : 2 3 P M 3 And this, again, shows exactly the order that any questions are
2 : 2 3 P M 4 supposed to have.

2 : 2 3 P M 5 There was a question -- you'll see the chain of
2 : 2 3 P M 6 the emails. John Lee sends something to MaryNell waldrup.
2 : 2 4 P M 7 MaryNell waldrup sends it to Tony Carnaggio. Tony Carnaggio
2 : 2 4 P M 8 sends it to Cal Dent. Cal Dent sends it to Tonya Mallory, "for
2 : 2 4 P M 9 your information." That's exactly the course that every one of
2 : 2 4 P M 10 these inquiries or questions goes.

2 : 2 4 P M 11 But here's something else that was going on at
2 : 2 4 P M 12 that time that's also very important. You remember hearing
2 : 2 4 P M 13 reference to this Saranac report. And you haven't actually
2 : 2 4 P M 14 seen that, but HDL was concerned about compliance, as they
2 : 2 4 P M 15 always should be. And so they retained this company.

2 : 2 4 P M 16 This is called -- this is Exhibit BW159. This
2 : 2 4 P M 17 is the report from the Saranac Group, which is an expert on
2 : 2 4 P M 18 health care compliance. If you get into the table of contents,
2 : 2 4 P M 19 you'll see that they covered the -- all the federal statutes,
2 : 2 5 P M 20 the False Claims Act, the Anti-Kickback Statute, the civil
2 : 2 5 P M 21 monetary penalties law. They examine all aspects of -- made
2 : 2 5 P M 22 observance and recommendations including -- they looked
2 : 2 5 P M 23 specifically at the relationship with Bluewave, one of the many
2 : 2 5 P M 24 topics.

2 : 2 5 P M 25 And they issued their report on April 30th,

2 : 2 5 P M 1 2013. And they made zero recommendations to change anything
2 : 2 5 P M 2 about what Bluewave was doing. They didn't make any
2 : 2 5 P M 3 recommendation to get rid of process and handling fees or to
2 : 2 5 P M 4 change how process and handling fees were being done. They
2 : 2 5 P M 5 made no recommendations about waivers of copay or deductible,
2 : 2 5 P M 6 which you've heard a lot about but not much today. And they
2 : 2 5 P M 7 made no recommendations whatsoever about using independent
2 : 2 5 P M 8 contractors or paying salespeople on commission.

2 : 2 5 P M 9 why? Because nobody ever heard that that could
2 : 2 5 P M 10 even possibly be a problem or a violation of the Anti-Kickback
2 : 2 6 P M 11 Statute or False Claims Act.

2 : 2 6 P M 12 The next thing that the government talked about
2 : 2 6 P M 13 was Nick Pace, and he was one of the witnesses who testified.
2 : 2 6 P M 14 And he came up with something called Project Twilight.

2 : 2 6 P M 15 Project Twilight was intended to be a way of
2 : 2 6 P M 16 finding alternative ways of getting the blood specimens
2 : 2 6 P M 17 delivered. The government says that's not a problem, but it's
2 : 2 6 P M 18 a problem. If you have a laboratory, you have to have blood to
2 : 2 6 P M 19 test. And so he started looking for alternatives.

2 : 2 6 P M 20 Now, the problem with that was nobody shared
2 : 2 6 P M 21 that with Brad or Cal until -- until they got to that summit
2 : 2 6 P M 22 conference meeting in June of 2013. We'll talk about that in a
2 : 2 6 P M 23 few minutes.

2 : 2 6 P M 24 But you remember when Mr. Pace was testifying
2 : 2 6 P M 25 and he got so frustrated that he thought that Bluewave wasn't

2 : 2 6 P M 1 going to go along, that they were going to push to keep
2 : 2 6 P M 2 processing and handling fees. And so I asked him a couple
2 : 2 6 P M 3 simple questions.

2 : 2 7 P M 4 I said, "Mr. Pace, did you ever ask them about
2 : 2 7 P M 5 that?"

2 : 2 7 P M 6 "No, I didn't do that."

2 : 2 7 P M 7 "Well, did you shoot them an email to explain
2 : 2 7 P M 8 Project Twilight, how you were going to have all these service
2 : 2 7 P M 9 centers and all these great alternatives?"

2 : 2 7 P M 10 He said, "No, I didn't bother doing that
2 : 2 7 P M 11 either."

2 : 2 7 P M 12 "Did you ever pick up the phone and talk to
2 : 2 7 P M 13 them?"

2 : 2 7 P M 14 "No, I didn't do that either."

2 : 2 7 P M 15 So the idea of moving away from process and
2 : 2 7 P M 16 handling fees was not something that was shared with Brad or
2 : 2 7 P M 17 Cal until that day in June.

2 : 2 7 P M 18 But what's more important, Mr. Pace, who was a
2 : 2 7 P M 19 lawyer and was very conscious about compliance, did not say
2 : 2 7 P M 20 "stop" either. He said we need to move away from processing
2 : 2 7 P M 21 and handling fees. And there's nothing wrong, by the way, with
2 : 2 7 P M 22 that advice whatsoever. BlueWave would have been perfectly
2 : 2 7 P M 23 willing to do that if they'd been given an alternative.

2 : 2 7 P M 24 Kung, I think, was the next red flag. That one
2 : 2 7 P M 25 doesn't apply to Brad or Cal or BlueWave because Kung never had

2 : 2 8 P M 1 a conversation with them, never told them what his opinions
2 : 2 8 P M 2 were about process and handling fees.

2 : 2 8 P M 3 So let's look at the big meeting, June 23rd,
2 : 2 8 P M 4 2013. Now, I told you on -- two weeks ago that things would
2 : 2 8 P M 5 change then, that there would be a new level of -- of
2 : 2 8 P M 6 understanding and concern at that time because, up until then,
2 : 2 8 P M 7 everybody had had, you know, access to the LeClairRyan opinion
2 : 2 8 P M 8 and the time and motion studies and everything that was being
2 : 2 8 P M 9 done.

2 : 2 8 P M 10 But now they were being challenged. The
2 : 2 8 P M 11 government had served the subpoena. The lawyers were talking
2 : 2 8 P M 12 to the government lawyers. It was clear that something was
2 : 2 8 P M 13 going on. There was going to be some tension there. There was
2 : 2 8 P M 14 going to be ongoing discussion, and we were going to find out
2 : 2 8 P M 15 eventually what the future of process and handling fees was
2 : 2 8 P M 16 going to be.

2 : 2 8 P M 17 Are we going to get to keep them? Are we not
2 : 2 9 P M 18 going to get to keep them? Are we going to have to keep them
2 : 2 9 P M 19 but limit them to a certain amount? What are the rules going
2 : 2 9 P M 20 to be? That's all anybody wanted to know was what are the
2 : 2 9 P M 21 rules going to be.

2 : 2 9 P M 22 So at that meeting, the government brings out
2 : 2 9 P M 23 Cal was challenging whether Brien personally believed that
2 : 2 9 P M 24 paying P&H was improper. Let me repeat that. That came out of
2 : 2 9 P M 25 the notes of Linda Flipppo, who was the attorney who testified.

2 : 2 9 P M 1 Cal was challenging whether Brien personally believed that
2 : 2 9 P M 2 paying P&H was improper.

2 : 2 9 P M 3 The government brings that information to you as
2 : 2 9 P M 4 though that's somehow damning information, as if that shows
2 : 2 9 P M 5 that Cal must have known they were doing something wrong
2 : 2 9 P M 6 because he was challenging whether the lawyer personally
2 : 2 9 P M 7 believed that P&H was improper.

2 : 2 9 P M 8 I submit to you, ladies and gentlemen of the
2 : 2 9 P M 9 jury, that that's exactly, exactly the question that should
2 : 2 9 P M 10 have been asked and that needed to be asked but was not
2 : 3 0 P M 11 answered. Not one person who was at that meeting has testified
2 : 3 0 P M 12 that anybody said "stop paying P&H fees."

2 : 3 0 P M 13 And you remember I -- I was kind of talking to
2 : 3 0 P M 14 Mr. Pace -- I think it was Mr. Pace -- about suppose they told
2 : 3 0 P M 15 you that they were selling stolen cars out of the back of the
2 : 3 0 P M 16 building. Would anybody be talking about moving away from
2 : 3 0 P M 17 selling stolen cars out of the back of the building?

2 : 3 0 P M 18 He said, "No. I don't think we'd be saying
2 : 3 0 P M 19 that." Well, no, because a lawyer's job is to tell his client
2 : 3 0 P M 20 to stop if he's breaking the law, and nobody at that meeting
2 : 3 0 P M 21 said "stop. You're breaking the law."

2 : 3 0 P M 22 Mr. Sellers, that was the elderly gentleman who
2 : 3 0 P M 23 testified. He was the lawyer that these guys had relied on.
2 : 3 0 P M 24 He's not a health care attorney, but he's a smart guy. And he
2 : 3 0 P M 25 was up there in the meeting listening.

2 : 3 0 P M 1 And I wrote this quote down verbatim. He was
2 : 3 0 P M 2 asked:

2 : 3 0 P M 3 "QUESTION: "Okay. well, do you recall any attorneys
2 : 3 0 P M 4 at the meeting saying -- directing HDL to stop paying P&H
2 : 3 1 P M 5 fees?

2 : 3 1 P M 6 "ANSWER: No, sir. And I'll guarantee you I would
2 : 3 1 P M 7 have remembered that had it been said."

2 : 3 1 P M 8 "No, sir. And I guarantee you I'd have
2 : 3 1 P M 9 remembered that if it had been said."

2 : 3 1 P M 10 And then Linda Flipppo was there as well. This is
2 : 3 1 P M 11 very important. Brad and Cal testified that what happened was,
2 : 3 1 P M 12 when Cal spoke up and said, "No, I don't think we're all on the
2 : 3 1 P M 13 same page here," then what happened?

2 : 3 1 P M 14 The lawyers began asking questions. "Tell us about
2 : 3 1 P M 15 process and handling fees. You're saying that other companies
2 : 3 1 P M 16 are doing it as well?"

2 : 3 1 P M 17 "Yes, sir, other companies are doing it as well. Not
2 : 3 1 P M 18 only is it other companies, all the other companies like us are
2 : 3 1 P M 19 paying process and handling fees."

2 : 3 1 P M 20 "Oh, well, that's interesting information. Can you
2 : 3 1 P M 21 do some homework? Can you get us some legal opinions? Can you
2 : 3 1 P M 22 get us process and handling fee agreements?"

2 : 3 1 P M 23 So all of a sudden it went from a report of what the
2 : 3 1 P M 24 conversations were with the government to what more information
2 : 3 2 P M 25 do we need to get in order to have a -- a full and fair

2 : 3 2 P M 1 discussion about process and handling fees.

2 : 3 2 P M 2 And Linda Flipppo, who you remember they sat up there
2 : 3 2 P M 3 with a whole notebook full of her notes, and she was very
2 : 3 2 P M 4 prolific in keeping notes of everything that happened. And
2 : 3 2 P M 5 here's what she testified.

2 : 3 2 P M 6 The question was asked:

2 : 3 2 P M 7 "QUESTION: Okay. Did anybody talk at the meeting
2 : 3 2 P M 8 about what the alternatives were? How were they going to
2 : 3 2 P M 9 get the blood to the laboratory if we don't pay P&H fees?"

2 : 3 2 P M 10 She says:

2 : 3 2 P M 11 "ANSWER: I think there were some -- there was some
2 : 3 2 P M 12 discussion, yeah. There was -- I know there was some
2 : 3 2 P M 13 discussion about alternatives to P&H fees, but I don't
2 : 3 2 P M 14 specifically recall what they were.

2 : 3 2 P M 15 "QUESTION: Did you understand discussions that were
2 : 3 2 P M 16 going on about safe harbor?

2 : 3 2 P M 17 "ANSWER: Very little.

2 : 3 2 P M 18 "QUESTION: Did you ever have an occasion to sit down
2 : 3 2 P M 19 afterwards with Brad and Cal and walk them through and
2 : 3 2 P M 20 say, 'Now, this is what we heard from Ropes & Gray. This
2 : 3 2 P M 21 is how the Anti-Kickback Statute works, and this is what a
2 : 3 3 P M 22 safe harbor is'? Did you ever have occasion to have that
2 : 3 3 P M 23 discussion?

2 : 3 3 P M 24 "ANSWER: we did not have that discussion after
2 : 3 3 P M 25 Ropes & Gray lawyers had described it at the meeting.

2 : 3 3 P M 1 "QUESTION: As a lawyer, did you find the discussion
2 : 3 3 P M 2 to be confusing about what is allowed and what's not
2 : 3 3 P M 3 allowed?

2 : 3 3 P M 4 "ANSWER: Yes, sir.

2 : 3 3 P M 5 "QUESTION: Even after that meeting, did Brad and Cal
2 : 3 3 P M 6 ever do or say anything that suggested that they believed
2 : 3 3 P M 7 or understood that it was wrong or illegal to pay
2 : 3 3 P M 8 processing and handling fees?

2 : 3 3 P M 9 "ANSWER: They never understood that there -- that
2 : 3 3 P M 10 there was a problem. They understood that people were
2 : 3 3 P M 11 looking at it. But, in their minds, they didn't see that
2 : 3 3 P M 12 there was -- they didn't understand if there was a
2 : 3 3 P M 13 problem.

2 : 3 3 P M 14 "QUESTION: well, did you believe that what was going
2 : 3 3 P M 15 to happen was that Ropes & Gray and HDL were going to come
2 : 3 3 P M 16 to some agreement with the government on what they could
2 : 3 3 P M 17 and couldn't do?

2 : 3 3 P M 18 "ANSWER: Yes.

2 : 3 3 P M 19 "QUESTION: And did they communicate to you from time
2 : 3 4 P M 20 to time what they were doing with the government?

2 : 3 4 P M 21 "ANSWER: Yes.

2 : 3 4 P M 22 "QUESTION: Did Brad and Cal or either or both of
2 : 3 4 P M 23 them tell you that they would abide by whatever was
2 : 3 4 P M 24 decided with regard to P&H fees?

2 : 3 4 P M 25 "ANSWER: Yes. All they wanted to know was what are

2 : 3 4 P M 1 the rules."

2 : 3 4 P M 2 The next red flag from the government is the lawyers
2 : 3 4 P M 3 for Emily Barron. She was the independent contractor sales
2 : 3 4 P M 4 rep, one of three partners who were down in Florida.

2 : 3 4 P M 5 Testimony you remember hearing was that she had
2 : 3 4 P M 6 stopped working. She didn't want to leave her house and so
2 : 3 4 P M 7 forth and so on. And so she got into a contract dispute.

2 : 3 4 P M 8 But her contract -- her dispute with BlueWave was not
2 : 3 4 P M 9 that my contract is illegal. Her dispute was I want to renew
2 : 3 4 P M 10 my contract and keep the same deal that I've got where I get to
2 : 3 4 P M 11 split all the commissions.

2 : 3 4 P M 12 And so she hires a lawyer. And the testimony was,
2 : 3 4 P M 13 "My understanding" -- from her lawyer -- "my understanding was
2 : 3 5 P M 14 that they had some concerns about whether or not they were
2 : 3 5 P M 15 proper" -- meaning process and handling fees -- "yes."

2 : 3 5 P M 16 Mr. Dickerson testified -- he was the gentleman who
2 : 3 5 P M 17 came who was Ms. Barron's attorney. And what happened to him
2 : 3 5 P M 18 was what happened to everybody else who raised a legal
2 : 3 5 P M 19 question. They were referred to the attorneys up at -- up at
2 : 3 5 P M 20 HDL. And there's an exhibit. It's BW64. And you'll see it's
2 : 3 5 P M 21 dated September 17, 2013. It's from Tonya Mallory to Brad
2 : 3 5 P M 22 Johnson. And if you have time when you get back there, you can
2 : 3 5 P M 23 read it all for yourself.

2 : 3 5 P M 24 But she says, "See note from Emily's attorney below.
2 : 3 5 P M 25 we have confirmed that they are not waiting for anything from

2 : 3 5 P M 1 HDL. Her attorney communicated to Derek" -- Derek Kung,
2 : 3 5 P M 2 general counsel for HDL -- "yesterday and again today that he
2 : 3 6 P M 3 has issues with the BW contract and needs to speak to Gene. He
2 : 3 6 P M 4 told Derek that there is nothing more they need from us."

2 : 3 6 P M 5 Now, the issues that he had with the BlueWave
2 : 3 6 P M 6 contract were not that it was illegal but that his client
2 : 3 6 P M 7 wanted to be paid under that contract. And, in fact, that's
2 : 3 6 P M 8 exactly what happened. There's an Exhibit, BW386, and you've
2 : 3 6 P M 9 seen this before. This is the letter from John Galese to
2 : 3 6 P M 10 Mr. Dickerson in which he says, "We believe that everything
2 : 3 6 P M 11 we're doing is legal, but the enclosed check is tendered in
2 : 3 6 P M 12 full satisfaction of obligation from my client to Ocean
2 : 3 6 P M 13 Diagnostics and Consulting except for October 2013 commissions
2 : 3 6 P M 14 to be paid in January 2014."

2 : 3 6 P M 15 In other words, they paid her the commissions that
2 : 3 7 P M 16 she was asking for, and she, with the advice of her lawyer,
2 : 3 7 P M 17 accepted those conditions. How could she have done that if the
2 : 3 7 P M 18 very contract that she was suing under was illegal?

2 : 3 7 P M 19 well, her lawyer was a smart lawyer, does what any
2 : 3 7 P M 20 good employment lawyer would do. And he says, "We're
2 : 3 7 P M 21 complaining about potential legal problems, so you can't fire
2 : 3 7 P M 22 us. Because if you fire us, then that's retaliation against a
2 : 3 7 P M 23 whistle-blower." And that's exactly what his letter said, and
2 : 3 7 P M 24 that's in evidence too. You'll have an opportunity to see
2 : 3 7 P M 25 that.

2 : 3 7 P M 1 The next red flag was Mr. Hall. That's got no
2 : 3 7 P M 2 objection to BlueWave whatsoever. He was not their attorney.
2 : 3 7 P M 3 His opinions or cautions or whatever he said were in no way
2 : 3 7 P M 4 communicated.

2 : 3 7 P M 5 The next one was Rebecca [verbatim] DeMoss. And I
2 : 3 7 P M 6 guess this comes under the category of no good deed goes
2 : 3 7 P M 7 unpunished, because Brad testified that amidst all of this
2 : 3 7 P M 8 discussion that was going on, he wanted to have somebody who
2 : 3 8 P M 9 was apart from the fray, who could give an opinion about the --
2 : 3 8 P M 10 about the legal tests.

2 : 3 8 P M 11 And so he called a friend of his, who -- and I beg to
2 : 3 8 P M 12 differ with my colleague over here. I don't recall anybody
2 : 3 8 P M 13 saying that he called them to try to get a right opinion or a
2 : 3 8 P M 14 favorable opinion. He said he wanted one that was objective
2 : 3 8 P M 15 and not connected with all the conversation that was going on
2 : 3 8 P M 16 between Ropes & Gray and the Justice Department. And so he
2 : 3 8 P M 17 calls his friend, and then he sends it to Ms. DeMoss, who is a
2 : 3 8 P M 18 very knowledgeable health care lawyer.

2 : 3 8 P M 19 And take a look at Exhibit 1144. This is the HDL
2 : 3 8 P M 20 process and handling fee agreement. You remember the concern
2 : 3 9 P M 21 that Ms. DeMoss expressed, and her enunciation of the answers
2 : 3 9 P M 22 was that Medicare may consider this it be a double payment.
2 : 3 9 P M 23 May consider this to be a double payment because it's already
2 : 3 9 P M 24 being paid for.

2 : 3 9 P M 25 The answer to that is right here in the process and

2 : 3 9 P M 1 handling fee agreements, where there's a specific provision in
2 : 3 9 P M 2 the agreement that says it's up to the doctor, that the doctor
2 : 3 9 P M 3 may not obtain these fees if he is being paid elsewhere. It's
2 : 3 9 P M 4 right here in paragraph -- let's see -- paragraph 5, "Physician
2 : 3 9 P M 5 will not bill, receive, nor collect any reimbursement from any
2 : 3 9 P M 6 third-party payer, including commercial insurers and
2 : 3 9 P M 7 governmental programs such as Medicare and Medicaid, for any
2 : 3 9 P M 8 processing and handling services or collection services for
2 : 3 9 P M 9 which physician receives any fees from HDL."

2 : 4 0 P M 10 But, that said, it would not be wise to ignore the
2 : 4 0 P M 11 advice of someone like Ms. DeMoss. And BlueWave did not ignore
2 : 4 0 P M 12 her advice. What the government didn't mention to you was,
2 : 4 0 P M 13 what was going on at that very moment? What was going on at
2 : 4 0 P M 14 the exact same time? You remember, it was November 14, 2013,
2 : 4 0 P M 15 that the -- that the information came back from Ms. DeMoss
2 : 4 0 P M 16 about her comments on the test.

2 : 4 0 P M 17 Well, it just so happens that, at that very moment,
2 : 4 0 P M 18 Ropes & Gray and the attorneys at HDL were completely rewriting
2 : 4 0 P M 19 the processing and handling fee agreement and the -- and their
2 : 4 0 P M 20 process. They were not eliminating it, but they were rewriting
2 : 4 0 P M 21 it.

2 : 4 0 P M 22 And there's an exhibit. It's BW106. And it's quite
2 : 4 1 P M 23 thick, and I'm not going to take your time to read it all now,
2 : 4 1 P M 24 but you'll see what it includes is that there was a lengthy
2 : 4 1 P M 25 discussion back and forth between Tonya and Mr. Kung and the

2 : 4 1 P M 1 lawyers at Ropes & Gray about the agreement, "How can we tweak
2 : 4 1 P M 2 this treatment or change it to make it stronger?"

2 : 4 1 P M 3 And so that culminated in this email dated October
2 : 4 1 P M 4 25th, 2013, right before this information came from Ms. DeMoss.
2 : 4 1 P M 5 It says, "Cal and Brad, we have modified the P&H agreement to
2 : 4 1 P M 6 strengthen your compliance documentation. Some of the changes
2 : 4 1 P M 7 are simply rewording what we have already written, and others
2 : 4 1 P M 8 are truly adding to our compliance efforts. Since we need to
2 : 4 1 P M 9 add to the documents for our compliance efforts, I have let the
2 : 4 1 P M 10 insignificant changes go."

2 : 4 1 P M 11 I'm not going to read the rest of it to you here, but
2 : 4 1 P M 12 she makes it perfectly clear to BlueWave and Brad and Cal that
2 : 4 2 P M 13 this has the blessing of their attorneys, they have modified
2 : 4 2 P M 14 and changed what they needed to change on this agreement.

2 : 4 2 P M 15 And then there's another exhibit. It's BW480. And
2 : 4 2 P M 16 it's interesting that this perfectly brackets the comments that
2 : 4 2 P M 17 Ms. DeMoss made because this is -- you've seen this email
2 : 4 2 P M 18 before. This is dated November 26th, 2013. It's from Kathy
2 : 4 2 P M 19 Johnson, the compliance office at HDL, to Brad Johnson, Cal
2 : 4 2 P M 20 Dent, Stafford, Mallory, and others. You can read it for
2 : 4 2 P M 21 yourself.

2 : 4 2 P M 22 All, we are going forward tomorrow with a BW sales
2 : 4 2 P M 23 call at 4 p.m. EST to roll out HDL's new P&H agreement, which
2 : 4 2 P M 24 is attached. Cal would like me to review the new P&H agreement
2 : 4 2 P M 25 with the sales rep line by line and then open up the call for

2 : 4 2 P M 1 questions."

2 : 4 2 P M 2 And you'll remember we went through that before, and
2 : 4 3 P M 3 here it all is. It will be there for your inspection.

2 : 4 3 P M 4 So at the very time that Ms. DeMoss was expressing
2 : 4 3 P M 5 her concerns about the P&H agreement, it was being revised and
2 : 4 3 P M 6 reissued by the legal team for HDL.

2 : 4 3 P M 7 I want to talk now about the end game, as things came
2 : 4 3 P M 8 down toward the end of 2013 and the beginning of 2014. We're
2 : 4 3 P M 9 now half a year out from the meeting. Information has been
2 : 4 3 P M 10 gathered about process and handling fees. They learned what
2 : 4 3 P M 11 the rest of the industry is doing. Ropes & Gray is continuing
2 : 4 3 P M 12 to have conversations with the Justice Department in terms --
2 : 4 3 P M 13 and as the year rolls around, these folks all become very
2 : 4 4 P M 14 anxious about, where is this leading?

2 : 4 4 P M 15 You remember Brad testified that, "what did you think
2 : 4 4 P M 16 was going to happen?"

2 : 4 4 P M 17 "Well, I thought that the Justice Department, the
2 : 4 4 P M 18 government, was going to tell us what we could do, that they
2 : 4 4 P M 19 would put a limit on the fees or do something."

2 : 4 4 P M 20 But everybody wanted to know. And so the lawyers
2 : 4 4 P M 21 started pressing the Justice Department attorneys for a
2 : 4 4 P M 22 commitment. What are you guys saying? Are you saying that
2 : 4 4 P M 23 we're breaking the law, or are you not taking a position on
2 : 4 4 P M 24 that?

2 : 4 4 P M 25 And there's an exhibit. It's Mallory 10. And you've

2 : 4 4 P M 1 seen this before, but on the second page, there's a
2 : 4 4 P M 2 communication between Mr. Sbertoli, who was the corporate
2 : 4 4 P M 3 counsel for HDL, and Laura Hoey with Ropes & Gray, who was the
2 : 4 4 P M 4 person talking to the Justice Department. And she says --
2 : 4 5 P M 5 right in the middle, it says "waiver." There's a conversation
2 : 4 5 P M 6 going on about whether they were going to waive attorney-client
2 : 4 5 P M 7 privilege as part of the investigation.

2 : 4 5 P M 8 It says, "Ropes & Gray made clear that HDL was
2 : 4 5 P M 9 putting further waiver discussions on hold in light of DOJ's
2 : 4 5 P M 10 present refusal to take a position on the straight payment of
2 : 4 5 P M 11 P&H fees."

2 : 4 5 P M 12 That's an important sentence.

2 : 4 5 P M 13 "And put a hold on -- further waiver discussions on
2 : 4 5 P M 14 hold in light of DOJ's present refusal to take a position on
2 : 4 5 P M 15 the straight payment of P&H fees. Leventis said he needed to
2 : 4 5 P M 16 connect with Elizabeth on this issue but agreed that for now it
2 : 4 5 P M 17 makes sense to put this on hold."

2 : 4 5 P M 18 And there's another one, Exhibit 114, Mallory put
2 : 4 5 P M 19 into evidence. And Laura Hoey writes to Mr. Leventis with a
2 : 4 6 P M 20 copy to Brien O'Connor and Ms. Short and Ms. Strawn; the
2 : 4 6 P M 21 investigator, Mr. Su Kim; David Rhinesmith regarding HDL recap.

2 : 4 6 P M 22 Right there in the middle, he says that they
2 : 4 6 P M 23 wanted -- did they want to consider -- continue their dialogue
2 : 4 6 P M 24 recording the draft waiver. "You are right that our client has
2 : 4 6 P M 25 elected to hold on executing a waiver until we better

2 : 4 6 P M 1 understand the government's position on the industry practice
2 : 4 6 P M 2 on the straight payment of P&H fees. We understood from our
2 : 4 6 P M 3 conversation on December 12th that, as of now, the government
2 : 4 6 P M 4 is not taking a position on the straight payment of P&H fees,
2 : 4 6 P M 5 so we felt our time and resources better spent addressing the
2 : 4 6 P M 6 issues that you and Elizabeth outlined on the government's
2 : 4 6 P M 7 current areas of concern."

2 : 4 6 P M 8 And there's an answer to that from Mr. Leventis with
2 : 4 6 P M 9 copies to all the same people. "Thanks, Laura. The due date
2 : 4 6 P M 10 for the completion of the subpoena response would be
2 : 4 7 P M 11 February 14, and that is really the longest extension we can
2 : 4 7 P M 12 agree to," not a blatant "You guys have got it wrong; P&H fees
2 : 4 7 P M 13 are illegal. Stop paying them." Nothing like that. It's "our
2 : 4 7 P M 14 investigation is continuing," and they agree that they have not
2 : 4 7 P M 15 taken a position.

2 : 4 7 P M 16 So time goes on. We get to March, and Bluewave's
2 : 4 7 P M 17 attorneys want to know what position the government is taking,
2 : 4 7 P M 18 and there's -- and that's set out in Exhibit 1497. And you've
2 : 4 7 P M 19 seen this before. This is an email from Linda Flipppo, who is
2 : 4 7 P M 20 the attorney from white Arnold & Dowd that you heard testify,
2 : 4 7 P M 21 to Brad Johnson and Gene Sellers and John Galese.

2 : 4 7 P M 22 And she attaches, "Gentlemen, attached is a letter we
2 : 4 7 P M 23 received from Elizabeth Strawn." What Elizabeth Strawn says in
2 : 4 7 P M 24 her letter is that "the purpose of this letter is to give you a
2 : 4 8 P M 25 sense of the direction of the investigation. This is not an

2 : 4 8 P M 1 attempt to provide a full discussion of the issue -- of the
2 : 4 8 P M 2 allegations of the investigation to date."

2 : 4 8 P M 3 Not "your clients are breaking the law, they need to
2 : 4 8 P M 4 stop." Not "process and handling fees are illegal."

2 : 4 8 P M 5 She says, "Based on the investigation to date, it
2 : 4 8 P M 6 appears to us that the laboratory's payments to the referring
2 : 4 8 P M 7 providers raised an inference" -- raised an inference -- "that
2 : 4 8 P M 8 one purpose of these payments was to induce referrals. Those
2 : 4 8 P M 9 payments exceed the amount Medicare pays for blood specimen
2 : 4 8 P M 10 collection and processing services, providing an obvious
2 : 4 8 P M 11 financial benefit to the referring providers," et cetera, et
2 : 4 8 P M 12 cetera.

2 : 4 8 P M 13 Then she says, "We are continuing to investigate the
2 : 4 8 P M 14 facts surrounding the payment of these fees, including
2 : 4 8 P M 15 Bluewave's conduct and representations to providers regarding
2 : 4 9 P M 16 these fees."

2 : 4 9 P M 17 They had not even interviewed Brad or Cal yet. They
2 : 4 9 P M 18 would later do that. They would learn information about what
2 : 4 9 P M 19 the industry is doing with the process and handling fees, all
2 : 4 9 P M 20 sorts of -- all sorts of interesting information.

2 : 4 9 P M 21 But she concludes with saying "we're continuing to
2 : 4 9 P M 22 investigate the facts," not that "your clients need to stop."

2 : 4 9 P M 23 I believe Mr. Sbertoli was quoted a little bit out of
2 : 4 9 P M 24 context, because the question was asked of him on the witness
2 : 4 9 P M 25 stand, when did the Justice Department first tell you to stop?"

2 : 4 9 P M 1 And he said, "well, it was sometime between January
2 : 4 9 P M 2 and when the special fraud alert came out in June."

2 : 4 9 P M 3 He didn't say it was March, April, May, June. He
2 : 4 9 P M 4 didn't give a date when that happened. He said sometime
2 : 4 9 P M 5 between those two dates. But this letter represents the only
2 : 4 9 P M 6 communication that you have heard about from the Justice
2 : 5 0 P M 7 Department that made its way to BlueWave, to Cal and Brad.
2 : 5 0 P M 8 This was the last word that they had gotten from the Justice
2 : 5 0 P M 9 Department.

2 : 5 0 P M 10 By the way, no mention whatsoever in that letter of
2 : 5 0 P M 11 "we also think that the mere act of selling these tests on
2 : 5 0 P M 12 commission is also illegal, and you need to stop that." Or
2 : 5 0 P M 13 that "waiving copays and deductibles is illegal, you need to
2 : 5 0 P M 14 stop that." Those aren't even mentioned in there. The only
2 : 5 0 P M 15 thing that's mentioned is we're investigating process and
2 : 5 0 P M 16 handling fees.

2 : 5 0 P M 17 So on June 25th, 2014, the special fraud alert came
2 : 5 0 P M 18 out. You're going to have that. That's Exhibit 508. I don't
2 : 5 0 P M 19 want to take the time to read it to you now, but even if you
2 : 5 0 P M 20 read that, you have to piece different pieces of it together
2 : 5 0 P M 21 because they never say that processing and handling fees are
2 : 5 0 P M 22 illegal.

2 : 5 0 P M 23 They say, well, there could be an inference that a --
2 : 5 0 P M 24 one purpose of it could be to influence referrals, and it could
2 : 5 0 P M 25 be a double payment, and it goes on for pages talking about

2 : 5 1 P M 1 that as well as something else that doesn't even apply to
2 : 5 1 P M 2 this -- for this case.

2 : 5 1 P M 3 You heard testimony about, you know, that there was
2 : 5 1 P M 4 some celebration among some of the lawyers because, for the
2 : 5 1 P M 5 first time, there was an official recognition that there was a
2 : 5 1 P M 6 difference between the draw fee, the \$3 draw fee, and the
2 : 5 1 P M 7 processing and handling. So now that that's been established,
2 : 5 1 P M 8 we can talk about how much. How much can you pay in processing
2 : 5 1 P M 9 and handling fees, since the government's now acknowledging for
2 : 5 1 P M 10 the first time officially that they're separate.

2 : 5 1 P M 11 But that's too close for comfort for these guys. And
2 : 5 1 P M 12 I ask you to take this -- what happens next? I want you to --
2 : 5 1 P M 13 I would ask you to talk about what happens next when you get
2 : 5 1 P M 14 back in the jury room, because when you start trying to decide,
2 : 5 1 P M 15 did these guys knowingly and willfully violate the
2 : 5 1 P M 16 Anti-Kickback Statute? Were they trying to break the law? Did
2 : 5 2 P M 17 they know they were breaking the law? I want you to think
2 : 5 2 P M 18 about what they did next.

2 : 5 2 P M 19 They said, "We want you to call and get
2 : 5 2 P M 20 clarification. We don't think this is good news." I mean, for
2 : 5 2 P M 21 the first time, the Justice Department -- or the OIG is telling
2 : 5 2 P M 22 us that there's a problem with processing and handling fees and
2 : 5 2 P M 23 we are not going to ignore this.

2 : 5 2 P M 24 And so take a look at Exhibit 123. And this is very
2 : 5 2 P M 25 important. This is -- at the bottom of this, the punchline is

2 : 5 2 P M 1 at the top, so I'm going to skip that for now. But down here
2 : 5 2 P M 2 is an email from Tonya Mallory, reporting to Brad and Cal what
2 : 5 2 P M 3 the Ropes & Gray lawyers learned when they called and talked to
2 : 5 2 P M 4 Ms. Strawn.

2 : 5 2 P M 5 "Cal and Brad, Laura and Brien from R&G" -- that's
2 : 5 2 P M 6 Ropes & Gray -- "had a chance to speak with Elizabeth Strawn.
2 : 5 3 P M 7 Elizabeth confirmed that this advisory was written by the OIG
2 : 5 3 P M 8 person working on our case and has been present in the room
2 : 5 3 P M 9 when our attorneys met with them. The OIG person is a female,
2 : 5 3 P M 10 but I forgot her name. Laura and Brien said they spoke to
2 : 5 3 P M 11 Elizabeth for about 20 minutes. Elizabeth told R&G that they
2 : 5 3 P M 12 have never had a situation like this in the past, where an
2 : 5 3 P M 13 advisory was written in the middle of the investigation, and
2 : 5 3 P M 14 admitted that had these are typically written when there are
2 : 5 3 P M 15 areas that are vague or not spoken that need to be clarified."

2 : 5 3 P M 16 There are areas that are vague or not spoken that
2 : 5 3 P M 17 need to be clarified.

2 : 5 3 P M 18 "Elizabeth clarified that the intention of this
2 : 5 3 P M 19 advisory was to state that there is no possible scenario in
2 : 5 3 P M 20 which P&H payments were okay and to stop the practice in the
2 : 5 3 P M 21 market. R&G explained that there are many in the market that
2 : 5 4 P M 22 believes that it blesses the use of P&H and will continue to
2 : 5 4 P M 23 use them. Elizabeth repeated several times that the intention
2 : 5 4 P M 24 was to make it clear there was no possible scenario in which
2 : 5 4 P M 25 P&H was okay. She was interested to hear more about those

2 : 5 4 P M 1 companies that will continue the practice.

2 : 5 4 P M 2 "This concludes that we have to move forward with
2 : 5 4 P M 3 discontinuing. We would like to get the letters out tomorrow
2 : 5 4 P M 4 to get ahead of LabCorp talking to our practices. Attached is
2 : 5 4 P M 5 the final version that has been blessed by yours and our
2 : 5 4 P M 6 attorneys. I think it is the most expensive letter I have ever
2 : 5 4 P M 7 written," which was, of course, reflecting the amount of legal
2 : 5 4 P M 8 fees that went into it.

2 : 5 4 P M 9 And here's the punchline: Cal responds, "That's what
2 : 5 4 P M 10 we needed to know. Thanks, Cal."

2 : 5 4 P M 11 "That's what we needed to know. Thanks, Cal."

2 : 5 4 P M 12 So does that sound like somebody who knew he was
2 : 5 5 P M 13 breaking the law? I ask you to consider that very strongly
2 : 5 5 P M 14 when you get back and start deliberating, who knew what when.

2 : 5 5 P M 15 How hard was it? That's a stop sign. When somebody
2 : 5 5 P M 16 says, "I want to make it clear there's no scenario under which
2 : 5 5 P M 17 you can justify process and handling fees," now that's a stop
2 : 5 5 P M 18 sign. But saying "We have no official position," saying "we're
2 : 5 5 P M 19 investigating," saying "we think that there may be an issue
2 : 5 5 P M 20 here," that's not a stop sign.

2 : 5 5 P M 21 When your lawyers are in active negotiation and
2 : 5 5 P M 22 discussing the future processing and handling fees, that's not
2 : 5 5 P M 23 knowingly and intentionally, willfully breaking the law.

2 : 5 5 P M 24 So what guidance did they have? I've spent way too
2 : 5 5 P M 25 much of your time already on previous days reading attorney

2 : 5 5 P M 1 letters, but let's just summarize it. And I want you to be
2 : 5 5 P M 2 able to take a look at them for yourself.

2 : 5 6 P M 3 This is ironic. The very first advice that we've
2 : 5 6 P M 4 seen. This is BW Exhibit 493, and this is the letter dated
2 : 5 6 P M 5 June -- July 28th, 2005, that was written to Berkeley
2 : 5 6 P M 6 HeartLabs, where Brad and Cal used to work. And it's from
2 : 5 6 P M 7 Ropes & Gray, the very same firm that now are the protagonists
2 : 5 6 P M 8 of our story who are negotiating and giving advice to -- to
2 : 5 6 P M 9 HDL. And you'll see in there that it very clearly says that a
2 : 5 6 P M 10 process and handling fee paid at fair market value is legal.

2 : 5 6 P M 11 The next one is Exhibit 42, Mallory Exhibit 42. This
2 : 5 6 P M 12 is a letter from Greg Root dated December 27, 2007. I'll
2 : 5 7 P M 13 encourage you, when you get in there, to spend some time
2 : 5 7 P M 14 looking at the advice he gives. It's very well thought out,
2 : 5 7 P M 15 very concise. But what's very important about this is that
2 : 5 7 P M 16 when Tonya started HDL and when Brad and Cal started
2 : 5 7 P M 17 Bluewave -- well, I can speak only for them, but this was their
2 : 5 7 P M 18 template. This was what they knew the law to be. This was
2 : 5 7 P M 19 what they knew the legal advice to be. And they followed that
2 : 5 7 P M 20 to a tee in setting up the way that HDL and Bluewave were going
2 : 5 7 P M 21 to do business.

2 : 5 7 P M 22 You've seen Exhibit 1136. This is the May 1st, 2010,
2 : 5 7 P M 23 position statement. This was before HDL had been able to get a
2 : 5 7 P M 24 formal legal opinion, but Tonya's testimony was that
2 : 5 7 P M 25 LeClairRyan had very detailed and intimate involvement in

2 : 5 8 P M 1 preparing this, which explain the purpose of process and
2 : 5 8 P M 2 handling fees and explain why they had a -- and, again, Tonya
2 : 5 8 P M 3 probably would have done it herself eventually; but, at the
2 : 5 8 P M 4 urging of Brad and Cal, taking note of what Berkeley HeartLab
2 : 5 8 P M 5 had done previously, they said, "You need to get a time and
2 : 5 8 P M 6 motion study and a formal opinion."

2 : 5 8 P M 7 And here it is. It's Exhibit 157. And I'm not going
2 : 5 8 P M 8 to read the whole thing to you. And I don't even think you
2 : 5 8 P M 9 need to read the whole thing. But for purposes of something
2 : 5 8 P M 10 that we're going to talk about in a few minutes, in terms of
2 : 5 8 P M 11 whether doctors make money with process and handling fees, turn
2 : 5 8 P M 12 to page 6. And you will see a discussion of what the cost
2 : 5 9 P M 13 estimates are and what they assume in terms of staff training
2 : 5 9 P M 14 and hourly salary. And they talk about the different types of
2 : 5 9 P M 15 people who can draw blood and processing and handling
2 : 5 9 P M 16 specimens.

2 : 5 9 P M 17 It can be done by medical assistants or nurses or
2 : 5 9 P M 18 more highly trained professionals. But he says, "The remaining
2 : 5 9 P M 19 collection is performed by health care providers with various
2 : 5 9 P M 20 credentials, technologists, phlebotomists, based on a
2 : 5 9 P M 21 systematic review of staff conducted by HDL and national wage
2 : 5 9 P M 22 information from the Bureau of Labor statistics. A weighted
2 : 5 9 P M 23 average hourly rate of \$37.30 was calculated."

2 : 5 9 P M 24 Now, that's a far cry from the \$12 that we heard a
2 : 5 9 P M 25 little while ago. And I would submit to you that common sense

2 : 5 9 P M 1 tells you you're not going to get somebody who's trained as a
2 : 5 9 P M 2 medical professional for \$12 an hour.

2 : 5 9 P M 3 But the number that Exponent came up with -- and this
3 : 0 0 P M 4 is -- their business is to do this -- was \$37.30. And they
3 : 0 0 P M 5 determined, based on that and their other examinations of
3 : 0 0 P M 6 circumstances, that the cost for processing and handling the
3 : 0 0 P M 7 four tubes that are required for HDL was \$36.03, which is about
3 : 0 0 P M 8 twice what they were actually paying.

3 : 0 0 P M 9 why? well, it's to leave yourself margin for error,
3 : 0 0 P M 10 because you're not trying to rub up against the guardrail;
3 : 0 0 P M 11 you're trying to stay in the middle of the road.

3 : 0 0 P M 12 I'm not going to show it to you again, but Exhibit
3 : 0 0 P M 13 1253 is the LeClairRyan letter from Mr. Ruggio which references
3 : 0 0 P M 14 the Exponent report and says based on that, process and
3 : 0 0 P M 15 handling fees are legal and they fall within the safe harbor.

3 : 0 0 P M 16 All of the contracts that were involved in this case
3 : 0 0 P M 17 were reviewed by numerous attorneys. I'm not going to repeat
3 : 0 1 P M 18 them all, but you heard it. Not only was HDL having their
3 : 0 1 P M 19 teams of lawyers review these contracts; Singulex was doing the
3 : 0 1 P M 20 same thing with their teams out in California while these
3 : 0 1 P M 21 contracts were being negotiated.

3 : 0 1 P M 22 The P&H agreements were drafted and approved by those
3 : 0 1 P M 23 same teams of lawyers. Not one of them, not a single one of
3 : 0 1 P M 24 them, ever said, "Stop, you can't pay processing and handling
3 : 0 1 P M 25 fees." Not one of them of said, "Oh, by the way, you can't

3 : 0 1 P M 1 waive copays and deductibles of TRICARE." That subject never
3 : 0 1 P M 2 came up. And not one of them ever said, "Oh, by the way, you
3 : 0 1 P M 3 might be violating the Anti-Kickback Statute if you have an
3 : 0 1 P M 4 independent contractor and you're paying commissions."

3 : 0 1 P M 5 who would have ever thought that the Anti-Kickback
3 : 0 1 P M 6 Statute is intended to prevent you from selling your property,
3 : 0 1 P M 7 and no lawyer certainly ever said that.

3 : 0 1 P M 8 Audits. As it turns out, they think they were being
3 : 0 2 P M 9 audited by everybody they did business with. The -- Exhibit
3 : 0 2 P M 10 142 is the Navigant Consulting audit that was done September
3 : 0 2 P M 11 2012 for Singulex pursuant to their contract. Remember the
3 : 0 2 P M 12 testimony being that their goal was to go public, and so they
3 : 0 2 P M 13 needed extra transparency and they wanted to make sure
3 : 0 2 P M 14 everything was squeaky clean. So they put in their contract,
3 : 0 2 P M 15 with their lawyers' advice, a provision that required them to
3 : 0 2 P M 16 have a compliance audit done every year. It was done by a huge
3 : 0 2 P M 17 company called Navigant in 2012. And then it was done by
3 : 0 2 P M 18 another huge company called Collaborate in 2013.

3 : 0 2 P M 19 Meanwhile -- I showed you this document, the Saranac
3 : 0 2 P M 20 Group report that was being done on behalf of HDL at the same
3 : 0 2 P M 21 time. This was done in April of 2013. The report came out
3 : 0 3 P M 22 even after the Justice Department subpoena had come.

3 : 0 3 P M 23 So, again, putting yourself in these gentlemen's
3 : 0 3 P M 24 position, did they know that they were breaking the law?
3 : 0 3 P M 25 Everybody -- every professional that was being paid to

3 : 0 3 P M 1 scrutinize their work said no, that everything you're doing is
3 : 0 3 P M 2 perfectly right, perfectly supported, perfectly legal.

3 : 0 3 P M 3 what help is the government in this process? The
3 : 0 3 P M 4 comment was made during government's closing that all you had
3 : 0 3 P M 5 to do was ask. Just ask the OIG, and we'll give you an
3 : 0 3 P M 6 opinion.

3 : 0 3 P M 7 Not so fast. One of the drearier parts of this trial
3 : 0 3 P M 8 was your having to sit there -- well, the second dreariest
3 : 0 3 P M 9 after listening to me -- but the other dreariest was listening
3 : 0 3 P M 10 to that deposition that was being read of Jennifer Williams.
3 : 0 4 P M 11 She was the designee of the government to speak on behalf of
3 : 0 4 P M 12 the OIG. And I want to give you a few of the excerpts of her
3 : 0 4 P M 13 testimony.

3 : 0 4 P M 14 And to your credit, I noticed that you were taking
3 : 0 4 P M 15 notes as it was being given. But she says, "If the statute is
3 : 0 4 P M 16 implicated" -- meaning the Anti-Kickback Statute -- "then we'll
3 : 0 4 P M 17 look to see if it satisfies the requirement of the safe harbor.
3 : 0 4 P M 18 If it does not, then we move on to a case-by-case analysis."

3 : 0 4 P M 19 All right. So if you're outside the safe harbor,
3 : 0 4 P M 20 it's not illegal. We then go to a case-by-case analysis.

3 : 0 4 P M 21 "Does the Anti-Kickback Statute have a definition of
3 : 0 4 P M 22 the term 'arranging?'" because it makes it illegal to pay
3 : 0 4 P M 23 somebody remunerations to induce them to arrange for a product
3 : 0 4 P M 24 or a referral.

3 : 0 4 P M 25 "ANSWER: The statute does not.

3 : 0 5 P M 1 "QUESTION: Do any AKS-related regulations have a
3 : 0 5 P M 2 definition of "arranging"?

3 : 0 5 P M 3 "ANSWER: Not to my knowledge.

3 : 0 5 P M 4 "QUESTION: I'm asking specifically in OIG guidance.
3 : 0 5 P M 5 Has OIG provided any definition of "arranging" in any of
3 : 0 5 P M 6 its guidance?

3 : 0 5 P M 7 "ANSWER: There is not a per se definition.

3 : 0 5 P M 8 "QUESTION: Does the AKS statute have a definition of
3 : 0 5 P M 9 "recommending"?

3 : 0 5 P M 10 "ANSWER: It does not." Because, again, it makes it
3 : 0 5 P M 11 illegal to pay remuneration to induce someone to recommend
3 : 0 5 P M 12 or arrange for a product or a test, and in this case, it
3 : 0 5 P M 13 would be the test.

3 : 0 5 P M 14 "QUESTION: Does the AKS Statute have a definition of
3 : 0 5 P M 15 recommending?

3 : 0 5 P M 16 "ANSWER: It does not.

3 : 0 5 P M 17 "QUESTION: Do any AKS-related regulations have a
3 : 0 5 P M 18 definition of recommending?

3 : 0 5 P M 19 "ANSWER: There is no per se definition."

3 : 0 5 P M 20 Now, that's pretty important.

3 : 0 5 P M 21 "QUESTION: Does the OIG have any guidance on the
3 : 0 5 P M 22 definition of "recommending"? So, again, it's very
3 : 0 5 P M 23 contextual, meaning it depends on the context. So there
3 : 0 6 P M 24 is no per se definition of the term.

3 : 0 6 P M 25 That's important because the government's -- they

3 : 0 6 P M 1 call it a scheme, but the idea of paying an independent
3 : 0 6 P M 2 contractor based on commission, they're saying, quote, we're
3 : 0 6 P M 3 basically bribing the salesmen to go sell. And I'm not
3 : 0 6 P M 4 kidding. That's exactly what their claim is. They're saying
3 : 0 6 P M 5 you are bribing the salesmen to go sell his product because
3 : 0 6 P M 6 you're remunerating him to recommend or arrange for the test.

3 : 0 6 P M 7 And Brad and Cal contend, we're not allowed to
3 : 0 6 P M 8 recommend or arrange as that term is being used there. That's
3 : 0 6 P M 9 referring to what doctors do. Doctors are licensed to
3 : 0 6 P M 10 recommend and arrange treatment for their patients. We can't
3 : 0 6 P M 11 do that. All we can do is talk about the benefits of the test
3 : 0 6 P M 12 and encourage them to do it and tell them what other people are
3 : 0 6 P M 13 doing. So it's not a recommendation.

3 : 0 6 P M 14 well, I don't know what that means. I don't think
3 : 0 6 P M 15 you know what that means. I don't think anybody knows what
3 : 0 7 P M 16 that means. And Ms. Williams, the government designee,
3 : 0 7 P M 17 admitted that "we don't define those terms. we don't define
3 : 0 7 P M 18 those terms."

3 : 0 7 P M 19 well, if they don't define those terms, how can these
3 : 0 7 P M 20 guys be accused of having willfully broken that law?

3 : 0 7 P M 21 Talking about process and handling:

3 : 0 7 P M 22 "QUESTION: In February of 2011, OIG received a
3 : 0 7 P M 23 request for a special fraud alert?

3 : 0 7 P M 24 "ANSWER: That's correct.

3 : 0 7 P M 25 "QUESTION: Regarding process and handling?

3 : 0 7 P M 1 "ANSWER: Yes."

3 : 0 7 P M 2 Now, that's interesting. In February 2011, OIG
3 : 0 7 P M 3 received a request for a special fraud alert. Well, it so
3 : 0 7 P M 4 happens that that's when Dr. Mayes testified that he filed his
3 : 0 7 P M 5 lawsuit that was under seal under the provisions of the key
3 : 0 7 P M 6 statutes. It's when the government investigation began.

3 : 0 7 P M 7 "QUESTION: When did the special fraud alert finally
3 : 0 7 P M 8 come out?

3 : 0 7 P M 9 "ANSWER: June 25th, 2014, three and a half years
3 : 0 8 P M 10 later.

3 : 0 8 P M 11 "QUESTION: Does OIG take the position that, if a
3 : 0 8 P M 12 doctor chooses not to bill Medicare for a specimen
3 : 0 8 P M 13 collection fee, that the doctor can receive a payment from
3 : 0 8 P M 14 the lab for the same?

3 : 0 8 P M 15 "ANSWER: Right. That's correct."

3 : 0 8 P M 16 That's really important.

3 : 0 8 P M 17 "QUESTION: Does the OIG take the position that, if a
3 : 0 8 P M 18 doctor chooses not to bill Medicare for a specimen
3 : 0 8 P M 19 collection fee, that the doctor can receive a payment from
3 : 0 8 P M 20 the lab for the same?

3 : 0 8 P M 21 "ANSWER: Right. That's correct.

3 : 0 8 P M 22 well, guess what? Every single doctor that
3 : 0 8 P M 23 receives processing and handling fees from Singulex or from HDL
3 : 0 8 P M 24 agrees in writing that they will not bill Medicare for specimen
3 : 0 8 P M 25 collection if they're being paid for specimen collection and

3 : 0 8 P M 1 process and handling by HDL or Singulex. That's part of their
3 : 0 8 P M 2 agreement.

3 : 0 8 P M 3 "QUESTION: Has OIG taken the position that a lab's
3 : 0 8 P M 4 fair market value payment to a physician who refers to the
3 : 0 9 P M 5 lab can ever not be considered an inducement for
3 : 0 9 P M 6 referrals?

3 : 0 9 P M 7 "ANSWER: Okay. So we haven't analyzed that in a
3 : 0 9 P M 8 vacuum. We analyzed the arrangement in its entirety. So
3 : 0 9 P M 9 I can't say that we've taken a specific position on that.

3 : 0 9 P M 10 "QUESTION: Okay. Okay. And so do you agree that in
3 : 0 9 P M 11 this particular instance" -- we're skipping ahead here --
3 : 0 9 P M 12 "in Advisory Opinion 99-3" -- which is a different
3 : 0 9 P M 13 advisory opinion than we looked at -- "the OIG issued a
3 : 0 9 P M 14 favorable opinion on the sales commission arrangement even
3 : 0 9 P M 15 though the aggregate compensation took into account the
3 : 0 9 P M 16 value or volume of referrals?

3 : 0 9 P M 17 "ANSWER: We apparently felt that there were enough
3 : 0 9 P M 18 safeguards under the facts as presented to let us issue a
3 : 0 9 P M 19 favorable, yes.

3 : 0 9 P M 20 "QUESTION: Okay. And the OIG found favorably on
3 : 0 9 P M 21 this sales commission arrangement even though the salesmen
3 : 0 9 P M 22 may have had direct contact with those ordering the
3 : 0 9 P M 23 services; is that correct?

3 : 0 9 P M 24 "ANSWER: That is correct."

3 : 0 9 P M 25 Then -- and then referring to OIG opinions, the

3 : 0 9 P M 1 question is quoted here:

3 : 0 9 P M 2 "QUESTION: Then it goes on to say, however, the
3 : 1 0 P M 3 absence of safe harbor protection is not fatal.

3 : 1 0 P M 4 Do you see that?

3 : 1 0 P M 5 "ANSWER: Yes, it's very dramatic.

3 : 1 0 P M 6 "QUESTION: Huh?

3 : 1 0 P M 7 "ANSWER: It's very dramatic when you change that
3 : 1 0 P M 8 language.

3 : 1 0 P M 9 "QUESTION: well, you consider that dramatic
3 : 1 0 P M 10 language?

3 : 1 0 P M 11 "ANSWER: It means the arrangement does not
3 : 1 0 P M 12 necessarily violate the kickback statute.

3 : 1 0 P M 13 "QUESTION: Okay. And is this considered a favorable
3 : 1 0 P M 14 opinion?

3 : 1 0 P M 15 "ANSWER: Yes, this is what we would characterize as
3 : 1 0 P M 16 a favorable.

3 : 1 0 P M 17 "QUESTION: And so just to try to summarize, the
3 : 1 0 P M 18 arrangement in question in this Advisory Opinion 98-10
3 : 1 0 P M 19 appears to be the payment of a sales commission to an
3 : 1 0 P M 20 independent manufacturer represent?

3 : 1 0 P M 21 "ANSWER: Yes.

3 : 1 0 P M 22 "QUESTION: And if you look at page 2, it says that
3 : 1 0 P M 23 the sales agent, A, would receive a monthly commission of
3 : 1 0 P M 24 between 1 and 1.25 percent of invoiced amounts, the
3 : 1 0 P M 25 specific percentage being set in advance for each

3 : 1 0 P M 1 purchaser.

3 : 1 0 P M 2 "Do you see that?

3 : 1 0 P M 3 "ANSWER: Yes.

3 : 1 0 P M 4 "QUESTION: As a lawyer, did you find the discussion
3 : 1 0 P M 5 to be confusing about what is allowed" --

3 : 1 0 P M 6 I'm sorry. I'm reading Linda Flipppo again.

3 : 1 1 P M 7 So those are the guidances that the OIG was able
3 : 1 1 P M 8 to offer in response to anybody who had any questions
3 : 1 1 P M 9 whatsoever about the legality of processing and handling fees
3 : 1 1 P M 10 or the legality of independent contractor agreements. And that
3 : 1 1 P M 11 is exactly no guidance.

3 : 1 1 P M 12 Somebody had asked in February of 2011 for a
3 : 1 1 P M 13 special fraud alert on process and handling fees, and it wasn't
3 : 1 1 P M 14 until June 25th of 2014 that that was made available to the
3 : 1 1 P M 15 public.

3 : 1 1 P M 16 Very much -- very much like the example I gave
3 : 1 1 P M 17 two weeks ago where the police officer pulls up and he taps on
3 : 1 1 P M 18 the window and you roll it down and say, "Yes, officer. How
3 : 1 1 P M 19 can I help you?"

3 : 1 1 P M 20 And he says, "Well, you've been driving too
3 : 1 1 P M 21 fast, we think, but we haven't actually set the speed limit
3 : 1 1 P M 22 yet. But I want to think about it some more. I want to ask
3 : 1 2 P M 23 some questions, and we'll get back to you about that."

3 : 1 2 P M 24 That would be an interesting conversation
3 : 1 2 P M 25 because you could go back and forth all day long about what the

3 : 1 2 P M 1 speed limit should be. But that's not what the government
3 : 1 2 P M 2 chose to do here. What the government chose to do is to say
3 : 1 2 P M 3 once we decide what the speed limit was, if you were going too
3 : 1 2 P M 4 fast, we want everything you own. We want millions of dollars
3 : 1 2 P M 5 because you've broken the invisible speed limit. And that's
3 : 1 2 P M 6 the guidance that would have been made available.

3 : 1 2 P M 7 Fair market value, that was the key. If you
3 : 1 2 P M 8 read all these opinions, every single one of them says stick
3 : 1 2 P M 9 with fair market value. Everything was fair market value.

3 : 1 2 P M 10 There's -- on Exhibit 59, just so you'll know
3 : 1 2 P M 11 what it looks like, this was the -- this was the time and
3 : 1 2 P M 12 motion study that Tonya did when she first started HDL.

3 : 1 3 P M 13 You've seen Exhibit 55, which is the Singulex
3 : 1 3 P M 14 time and motion study that they had done. All of these people
3 : 1 3 P M 15 did what they could do to try to comply with the law.

3 : 1 3 P M 16 And another indicia of following the law is doing
3 : 1 3 P M 17 what the industry standard is doing. And we put up a little
3 : 1 3 P M 18 slide here to show what Brad and Cal and Bluewave knew the
3 : 1 3 P M 19 other people out in the industry were doing.

3 : 1 3 P M 20 Do you have that that's got the different labs on it?

3 : 1 3 P M 21 These are all the little labs. Remember we talked
3 : 1 3 P M 22 about those two weeks ago. And these are the ones that they
3 : 1 3 P M 23 found had -- had paid process and handling fees, virtually
3 : 1 3 P M 24 every single one of them, even Quest for a while. After they
3 : 1 4 P M 25 purchased Berkeley HeartLab, they eventually phased out and

3 : 1 4 P M 1 started using their own processing and handling centers, but
3 : 1 4 P M 2 even they did it. All of these smaller labs were paying
3 : 1 4 P M 3 processing and handling fees, and you heard that from the
3 : 1 4 P M 4 physicians.

3 : 1 4 P M 5 Intent. So let's look at more -- at what
3 : 1 4 P M 6 evidence you're going to have before you. They started out
3 : 1 4 P M 7 their company by saying we're not going to just hire people off
3 : 1 4 P M 8 the street; we're going to hire experienced sales
3 : 1 4 P M 9 representatives, not experienced car salesmen or -- one
3 : 1 4 P M 10 exception, they hired somebody with real estate sales
3 : 1 4 P M 11 experience.

3 : 1 4 P M 12 But almost every one of them had extensive
3 : 1 4 P M 13 experience in the health care field. That meant that they were
3 : 1 4 P M 14 going to have had extensive compliance training. They had
3 : 1 4 P M 15 their own compliance training. HDL had their own compliance
3 : 1 5 P M 16 training. I'm going to spare you showing y'all the PowerPoints
3 : 1 5 P M 17 here, but they'll be available to you in evidence.

3 : 1 5 P M 18 Singulex had its own compliance training. They
3 : 1 5 P M 19 provided regular testing of -- you've seen way too many of the
3 : 1 5 P M 20 tests where they're inquiring what the rules are.

3 : 1 5 P M 21 And not a single one of the sales
3 : 1 5 P M 22 representatives testified that they were ever instructed by
3 : 1 5 P M 23 Brad Johnson or Cal Dent to push process and handling fees as a
3 : 1 5 P M 24 reason to order these tests, not a single one, even the
3 : 1 5 P M 25 gentleman who testified that he was at a meeting with Tonya and

3 : 1 5 P M 1 Tonya supposedly told him go out and do like Bluewave does, you
3 : 1 5 P M 2 know, that they push the economic benefits of testing.

3 : 1 5 P M 3 She didn't know what they did. She was a
3 : 1 5 P M 4 laboratory person. She was not a salesperson.

3 : 1 6 P M 5 And then he testified, well, when he actually
3 : 1 6 P M 6 did ride along, they did not push process and handling fees.
3 : 1 6 P M 7 They talked exhaustively about the clinical benefits of these
3 : 1 6 P M 8 tests. That's how these tests were sold.

3 : 1 6 P M 9 Not a single sales rep ever said -- even Boomer
3 : 1 6 P M 10 Cornwell testified that he was never told to press process and
3 : 1 6 P M 11 handling fees. And you remember the one incident he said where
3 : 1 6 P M 12 Cal ever talked about processing and handling fees was in
3 : 1 6 P M 13 response to a specific question by a doctor who asked him about
3 : 1 6 P M 14 process and handling fees.

3 : 1 6 P M 15 They were very candid with you. It would have
3 : 1 6 P M 16 been easy for them to stand up there on the witness stand and
3 : 1 6 P M 17 look at all these emails from people like Kyle Martel, who came
3 : 1 6 P M 18 in here and pleaded the Fifth amendment, or Boomer Cornwell or
3 : 1 6 P M 19 any of the other ones that were sort of renegades. He could
3 : 1 7 P M 20 have made excuses for them. He could have said, "well, they're
3 : 1 7 P M 21 not really crossing the line. No, they didn't do that at all."

3 : 1 7 P M 22 They said, "This is wrong. That is not the
3 : 1 7 P M 23 Bluewave way. I would not accept this." And coincidentally or
24 not, not a single one of them copied either Brad or Cal on any
25 of those communications where they were promoting the economic

1 benefits.

2 And I need to make an important distinction for
3 you. It is not against the law to talk about the financial
4 benefits of testing. The claim that the government is making
5 in this case is that it's the process and handling fees that
6 are the kickbacks.

7 So it's one thing to go out to a doctor and say,
8 you know, "You can have a more vibrant practice if you give
9 these tests because you're going to find out about more
10 diseases than you would have known about. And then you're
11 going to provide more treatment, and you're going to make
12 money." That's okay. That's not a kickback. That's promoting
13 the value of the test.

14 The kickback would be if you said, "Hey, Doc, there's
15 an economic opportunity here for you. You're going to make a
16 bunch of money off processing and handling fees. It's our
17 little way of getting money to you." That would be the knowing
18 payment or arranging for payment of remuneration to induce
19 referrals.

20 And not a single witness, not a single witness ever
21 testified that these two gentlemen encouraged them or ever even
22 allowed them to do that. In fact, you heard a couple of them
23 say just the opposite. A couple of them said, you know, "I
24 slipped up once and I said something kind of aggressive about
25 the finances. And we went outside. Brad told me don't ever do

3 : 1 8 P M 1 that again. That's not what we do."

3 : 1 8 P M 2 I'm going to pause for just a moment to talk about
3 : 1 8 P M 3 independent contractors. We were very candid, Brad and Cal
3 : 1 8 P M 4 were very candid in saying some of the things that people were
3 : 1 9 P M 5 doing in the name of Bluewave were wrong. It's going to be up
3 : 1 9 P M 6 to you to decide whether they were against the law or not, but
3 : 1 9 P M 7 they were certainly against the policies of Bluewave and
3 : 1 9 P M 8 certainly against what they were told.

3 : 1 9 P M 9 Some of these emails from Kyle Martel, some of these
3 : 1 9 P M 10 pro formas that talked about lost revenue opportunities, those
3 : 1 9 P M 11 were not what they were taught to do.

3 : 1 9 P M 12 The law is that, if it's an employee and the employee
3 : 1 9 P M 13 does something wrong, whether it be violating the Anti-Kickback
3 : 1 9 P M 14 Statute or run somebody over in their car by accident, that
3 : 1 9 P M 15 goes back to the employer. It wouldn't necessarily go to Brad
3 : 1 9 P M 16 and Cal because they're not the employer. BlueWave was the
3 : 1 9 P M 17 employer. But if they were an employee, what they do, the
3 : 1 9 P M 18 company does. It's different for independent contractors.

3 : 1 9 P M 19 And Judge Gergel is going to give you the law, and
3 : 1 9 P M 20 you should follow him and not me. But our interpretation of
3 : 2 0 P M 21 the law is that unless -- unless it turns out that they were
3 : 2 0 P M 22 endorsing that or contributing to that or approving that
3 : 2 0 P M 23 conduct, then they're not responsible for it. If they did --
3 : 2 0 P M 24 if you find that they conspired with Boomer or Blasko or Martel
3 : 2 0 P M 25 or any of his people, if you find that they conspired and that

3 : 2 0 P M 1 they were really telling them to go out and sell on processing
3 : 2 0 P M 2 and handling fees, then they'd be responsible for that. But
3 : 2 0 P M 3 not a single person, not a single document suggested that that
3 : 2 0 P M 4 ever happened.

3 : 2 0 P M 5 I'm going to talk about one example. This is
3 : 2 0 P M 6 Exhibit 1099. This is -- Burt Lively testified about this, and
3 : 2 0 P M 7 Brad Johnson testified about this. But this is a pro forma
3 : 2 0 P M 8 that was sent to a Lori Mallory -- no relation to Tonya, that
3 : 2 1 P M 9 we're aware of -- out at Kansas City Internal Medicine.

3 : 2 1 P M 10 "Ms. Mallory, my name is Burt Lively. I'm a
3 : 2 1 P M 11 colleague of Brad Johnson. He asked me to provide you with a
3 : 2 1 P M 12 lipid clinic pro forma based on your discussion."

3 : 2 1 P M 13 And he goes down there and he calculates that, based
3 : 2 1 P M 14 on 200 specimens per week, you get \$4,000 in processing and
3 : 2 1 P M 15 handling fees. And Brad testified that he laughed about that;
3 : 2 1 P M 16 that if they actually did 200 tests a week, they'd be the most
3 : 2 1 P M 17 prolific orderer of tests in the whole country.

3 : 2 1 P M 18 But is he saying here that you're going to make a
3 : 2 1 P M 19 profit from processing and handling fees? And I suggest to you
3 : 2 1 P M 20 that they're telling them just the opposite. Remember the
3 : 2 1 P M 21 testimony was that a phlebotomist can do 30 to 35 specimens a
3 : 2 1 P M 22 week. And so if you're going to add 200 tests a week -- which
3 : 2 2 P M 23 nobody has done, but if you did -- to their workload, you'd
3 : 2 2 P M 24 have to hire 5.7 additional phlebotomists to do that work.

3 : 2 2 P M 25 Now, let's assume that they could make -- that they

3 : 2 2 P M 1 made \$21 an hour. That's more than 12, but it's considerably
3 : 2 2 P M 2 less than the \$37 that the Exponent study that they said they
3 : 2 2 P M 3 would make. But let's just say \$21 an hour. That means that
3 : 2 2 P M 4 it would cost \$4,788 per week just for the phlebotomist.
3 : 2 2 P M 5 Figure that math out. Do the math.

3 : 2 2 P M 6 That would be a loss to the practice of \$788 before
3 : 2 2 P M 7 they even considered overhead or space or equipment or any of
3 : 2 2 P M 8 the other costs associated with that.

3 : 2 2 P M 9 And so if you read this particular pro forma -- and
3 : 2 2 P M 10 you notice, this one doesn't have big capital letters that say
3 : 2 3 P M 11 "missed opportunity" or "missed process and handling
3 : 2 3 P M 12 opportunity." Instead what he's telling them is that you can
3 : 2 3 P M 13 make money by the follow-up work that you're going to do
3 : 2 3 P M 14 because you're going to find out more about your patients than
3 : 2 3 P M 15 you ever would have known, you're going to find some of them
3 : 2 3 P M 16 are sick that didn't know that they were sick, and you're going
3 : 2 3 P M 17 to be able to treat them, and you're going to make money.

3 : 2 3 P M 18 That's where the profitability would be. That's not
3 : 2 3 P M 19 a violation of the Anti-Kickback Statute. That's not a
3 : 2 3 P M 20 violation of the False Claims Act. And telling this guy that
3 : 2 3 P M 21 he can get \$4,000 of revenue and it's going to cost him at
3 : 2 3 P M 22 least \$4,800 in extra phlebotomist time is not promoting
3 : 2 3 P M 23 process and handling fee as an incentive to do this.

3 : 2 3 P M 24 And I want to talk about Dr. Alam at the Keowee
3 : 2 3 P M 25 Primary Care Center because he gave you some numbers. And

3 : 2 3 P M 1 these are in the record. But we did a little calculation for
3 : 2 3 P M 2 his practice as well.

3 : 2 4 P M 3 You see he was listed here as one of the very top
3 : 2 4 P M 4 practices. He was in the top 20. They earned \$409,473 over
3 : 2 4 P M 5 the entire time that they did business with HDL. And so they
3 : 2 4 P M 6 earned a total of --

3 : 2 4 P M 7 Let's show the annual. All right. There they are.
3 : 2 4 P M 8 Go to the next one.

3 : 2 5 P M 9 The total in a single year of \$158,973. That's
3 : 2 5 P M 10 the total that they received, HDL and Singulex. So if they had
3 : 2 5 P M 11 to pay a phlebotomist \$21 an hour, that would average out to
3 : 2 5 P M 12 \$42,160 a year. It would take four phlebotomists to do the
3 : 2 5 P M 13 number of tests that they did. That would cost them \$168,640.
3 : 2 5 P M 14 So they're already operating at a loss. You add in a figure
3 : 2 5 P M 15 for office space, and that doesn't include additional overhead.

3 : 2 5 P M 16 So the government says that they don't need to
3 : 2 5 P M 17 show that any doctors were actually influenced by the process
3 : 2 5 P M 18 and handling or by the scheme to pay kickbacks. We don't agree
3 : 2 5 P M 19 with that because the Anti-Kickback Statute -- the False Claims
3 : 2 5 P M 20 Act provides that claims that result from a violation of the
3 : 2 6 P M 21 Anti-Kickback Statute are False Claims Act.

3 : 2 6 P M 22 So in order for you to find that a violation of
3 : 2 6 P M 23 the -- that there's a violation of the False Claims Act, which
3 : 2 6 P M 24 allows for recovery of damages, the government must have
3 : 2 6 P M 25 convinced you that the claims arose from a violation of the

3 : 2 6 P M 1 Anti-Kickback Statute.

3 : 2 6 P M 2 So, interestingly, every single one of those
3 : 2 6 P M 3 rogue pro formas that you saw or those emails from Kyle Martel
3 : 2 6 P M 4 or Jeff Steadman or any of those, notice that the government
3 : 2 6 P M 5 didn't prove that a single one of those potential customers
3 : 2 6 P M 6 ever ordered a single test or did Medicare or Medicaid or
3 : 2 6 P M 7 TRICARE or every for a single test ordered by any of these
3 : 2 7 P M 8 people.

3 : 2 7 P M 9 So how are you going find that -- even if you
3 : 2 7 P M 10 find that that was bad conduct and that they shouldn't have
3 : 2 7 P M 11 done that, how are you going to find that any claims arose from
3 : 2 7 P M 12 the violations of the Anti-Kickback Statute? The answer is you
3 : 2 7 P M 13 can't.

3 : 2 7 P M 14 what the government chose instead was to say all
3 : 2 7 P M 15 claims are tainted because all process and handling fees are
3 : 2 7 P M 16 bad and, therefore, every single one is a violation of the
3 : 2 7 P M 17 Anti-Kickback Statue. So all we have to do is show you how
3 : 2 7 P M 18 much we paid in Medicare and TRICARE, and that's how much money
3 : 2 7 P M 19 we get. It doesn't work that way.

3 : 2 7 P M 20 They've got to show you that the claims arose --
3 : 2 7 P M 21 resulted from a violation of the Anti-Kickback Statute. And
3 : 2 7 P M 22 they misled you, quite frankly, in the evidence that they've
3 : 2 7 P M 23 got.

3 : 2 7 P M 24 Could we see the government's chart on the
3 : 2 7 P M 25 reimbursement --

3 : 2 7 P M 1 THE COURT: How much longer are you going to be? My
3 : 2 7 P M 2 jurors may need a break.

3 : 2 7 P M 3 MR. COOKE: They look like they could use a break.

3 : 2 8 P M 4 THE COURT: I don't hear an objection. Let's take a
3 : 2 8 P M 5 break.

3 : 2 8 P M 6 MR. COOKE: Okay. Thank you.

3 : 2 8 P M 7 (Whereupon the jury was excused from the courtroom.)

3 : 2 8 P M 8 THE COURT: For the record, I -- y'all may be seated.
3 : 2 8 P M 9 I had a note from a juror, "I'm about to be
3 : 2 8 P M 10 sick."

3 : 2 8 P M 11 I don't know if that was a comment on your
3 : 2 8 P M 12 argument or not, Mr. Cooke, but that's why I immediately
3 : 2 8 P M 13 accommodated the juror. Sorry to interrupt you. I would not
3 : 2 8 P M 14 have otherwise.

3 : 2 8 P M 15 MR. COOKE: I appreciate you doing that. I probably
3 : 2 8 P M 16 needed a break myself.

3 : 2 8 P M 17 THE COURT: I probably wouldn't have done that to
3 : 2 9 P M 18 give you a break, but -- might want you to go longer, but we'll
3 : 2 9 P M 19 take about a 10-minute break.

3 : 2 9 P M 20 Miss Eunice, would you make this part of the
3 : 2 9 P M 21 record, please, for the Court.

3 : 2 9 P M 22 THE DEPUTY CLERK: Okay.

3 : 3 0 P M 23 (Recess.)

3 : 4 6 P M 24 THE COURT: Please be seated.

3 : 4 6 P M 25 Folks, Miss Eunice says that, notwithstanding

3 : 4 6 P M 1 Mr. Cooke's argument, she has recovered. It's amazing recovery
3 : 4 7 P M 2 of even the sickest people.

3 : 4 7 P M 3 So let's bring back the jury.

3 : 4 8 P M 4 (Whereupon the jury entered the courtroom.)

3 : 4 8 P M 5 **THE COURT:** Please be seated.

3 : 4 8 P M 6 Mr. Cooke, please continue closing argument.

3 : 4 8 P M 7 **MR. COOKE:** Thank you. Thanks very much for bearing
3 : 4 8 P M 8 with me. This has already gone on a lot longer than I had
3 : 4 9 P M 9 hoped it would, but we always have a dilemma.

3 : 4 9 P M 10 We can't read your minds. We don't know what
3 : 4 9 P M 11 you're thinking. It would be great if I just had a chance to
3 : 4 9 P M 12 say what worries you about this case and we can focus on those
3 : 4 9 P M 13 things. There's just so much to cover, and we're scared to
3 : 4 9 P M 14 death that I'll sit down without having covered everything that
3 : 4 9 P M 15 we need to cover. So I apologize that it's taking this long.

3 : 4 9 P M 16 I did want to pause and talk before I get this
3 : 4 9 P M 17 next section in -- and, actually, if you'll notice my notebook
3 : 4 9 P M 18 you'll notice a lot more I've already been through than I've
3 : 4 9 P M 19 got to go. So we're actually doing pretty well.

3 : 4 9 P M 20 We talked about the pro formas and the
3 : 4 9 P M 21 incidences where either Brad or Cal agreed to a doctor or an
3 : 4 9 P M 22 administrator's request for the pro forma or in some cases
3 : 4 9 P M 23 where we've seen really pro formas that did not meet the
3 : 5 0 P M 24 Bluewave standards, the ones that talked about, you know,
3 : 5 0 P M 25 specifically your revenue opportunities for process and

3 : 5 0 P M 1 handling fees.

3 : 5 0 P M 2 A couple of points I want to make about that.
3 : 5 0 P M 3 One is you've heard the testimony that Bluewave didn't hide
3 : 5 0 P M 4 anything from the government; that when they received that
3 : 5 0 P M 5 subpoena, I think they testified -- Brad probably mentioned it
3 : 5 0 P M 6 twice, maybe more than that, they spent \$400,000-plus on legal
3 : 5 0 P M 7 fees to make sure that the government had every single
3 : 5 0 P M 8 document, every scrap of paper, literally millions of
3 : 5 0 P M 9 documents, including every single email, their servers, their
3 : 5 0 P M 10 iPhones. Everything was produced and made available.

3 : 5 0 P M 11 And so what you've seen is the very best -- or
3 : 5 0 P M 12 worst in our case, but the best for the government to try to
3 : 5 0 P M 13 make their case. You've seen -- you've seen the outliers.
3 : 5 0 P M 14 You've seen everything that they thought that they could
3 : 5 1 P M 15 make -- make BlueWave look bad. You've seen it.

3 : 5 1 P M 16 But I urge you to do this. Whenever you see a
3 : 5 1 P M 17 document and you go back there and it talks about revenue
3 : 5 1 P M 18 opportunities, just do that simple math that I did a few
3 : 5 1 P M 19 minutes ago. Let's assume that the average phlebotomist is
3 : 5 1 P M 20 going to cost about, let's just say, \$21 an hour -- that's
3 : 5 1 P M 21 lower than average, but \$21 an hour -- and that a phlebotomist
3 : 5 1 P M 22 can do 30 to 35 special -- specialty tests a week.

3 : 5 1 P M 23 And from that, it's very easy to figure that
3 : 5 1 P M 24 nobody -- no practice is going to make more money on processing
3 : 5 1 P M 25 and handling fees by doing more tests. They're going to lose

3 : 5 1 P M 1 more money the more they do.

3 : 5 1 P M 2 It reminds me of an old episode of "I Love Lucy"
3 : 5 1 P M 3 where she and Ethel decide to get into, I think, the
3 : 5 1 P M 4 bread-making business or cake-making business. And they had
3 : 5 1 P M 5 this assembly line and they're just going and they're going and
3 : 5 2 P M 6 they're going. And Ricky comes in and he says, you know, "I've
3 : 5 2 P M 7 been doing the numbers and you're losing 25 cents on every cake
3 : 5 2 P M 8 that you make."

3 : 5 2 P M 9 And Lucy says, "Oh, that's all right. I'll make
3 : 5 2 P M 10 it up on the volume."

3 : 5 2 P M 11 well, you don't do that. If you're losing money
3 : 5 2 P M 12 on each one, you're going to lose more the more you do. And so
3 : 5 2 P M 13 the government's basic premise, which is that process and
3 : 5 2 P M 14 handling fees are an inherent inducement to do more tests, is
3 : 5 2 P M 15 just the opposite because they -- the doctors -- according to
3 : 5 2 P M 16 these numbers and the Exponent study and all the time and
3 : 5 2 P M 17 motion studies, the doctors are actually going to lose money
3 : 5 2 P M 18 the more tests that they do.

3 : 5 2 P M 19 So that's the -- those are the points I'd like
3 : 5 2 P M 20 to make on that.

3 : 5 2 P M 21 So how did the government prove that process and
3 : 5 2 P M 22 handling fees were, in fact, an inducement and had the effect
3 : 5 2 P M 23 of being an inducement? well, what they said -- you heard this
3 : 5 2 P M 24 several times. You heard Dr. Mayes, who is an interested party
3 : 5 3 P M 25 because he is the relator, meaning that he is actually a

1 plaintiff in this case and stands to gain if the government
2 wins.

3 He testified, "well, all my partners just quit
4 ordering when the process and handling fees stopped."

5 And then we pressed him a little bit and said
6 Mr. Mayes -- "Dr. Mayes, would it surprise you to find out
7 that, in fact, they really slowed down their ordering way back
8 in 2013 and not when the process and handling fees were stopped
9 in July of -- or June of 2014?"

10 And he very quickly changed fields and said,
11 "Oh, well, that was because of all the controversy surrounding
12 this investigation and the publicity and so forth."

13 well, that's a very different thing. That's a
14 very different thing. It's not at all surprising. And you
15 heard during the closing argument about, well, the proof is in
16 the pudding that HDL went into bankruptcy shortly after that.

17 well, with all due respect, this investigation
18 and the lawsuits arising out of this and the publicity
19 surrounding the lawsuits and the opportunistic predatory
20 activity of their competitors who are using that whole special
21 fraud alert and this whole investigation against them to scare
22 these doctors, that -- that's what's had the effect on their --
23 on their ordering.

24 And -- but what you've heard from each
25 individual salesperson is "I didn't really experience that.

3 : 5 4 P M 1 I'm still working for the successor company, and I've got 80,
3 : 5 4 P M 2 90 percent of the same customers I had before."

3 : 5 4 P M 3 The doctors who believe in these tests believe
3 : 5 4 P M 4 in these tests. But even the data that they're making
3 : 5 4 P M 5 available to you is misleading. And I want to show you -- this
3 : 5 4 P M 6 was a chart that Mr. Hines put up.

3 : 5 5 P M 7 Can you find that, John? That's the
3 : 5 5 P M 8 reimbursement to HDL chart, the bell curve. And then after I
3 : 5 5 P M 9 talk about that, can you put up the ones with the lines on it.

3 : 5 5 P M 10 Okay. So you remember this chart. And this is
3 : 5 5 P M 11 the one --

3 : 5 5 P M 12 And go ahead and put that extra line up there.

3 : 5 5 P M 13 There is where P&H stops. And you remember the
3 : 5 5 P M 14 testimony was the -- this is claims paid by Medicare. And
3 : 5 5 P M 15 TRICARE is down there at the bottom. What they said was the
3 : 5 5 P M 16 claims dropped off by 40 percent after process and handling
3 : 5 5 P M 17 fees stopped. The claims dropped off by 40 percent after
3 : 5 6 P M 18 process and handling fees were no longer offered.

3 : 5 6 P M 19 And that's the proof you're supposed to infer
3 : 5 6 P M 20 from that, that because process -- they dropped off because
3 : 5 6 P M 21 process and handling fees stopped. But their data actually
3 : 5 6 P M 22 disproves that. This red line shows you June of 2014 when
3 : 5 6 P M 23 process and handling fees stopped. But this line that I had
3 : 5 6 P M 24 drawn up here shows you that the peak -- the peak was actually
3 : 5 6 P M 25 way back in about August of 2013.

3 : 5 6 P M 1 So the doctors are all still receiving their
3 : 5 6 P M 2 process and handling fees all along. And, in fact, if
3 : 5 6 P M 3 anything, there's a little jump up immediately after process
3 : 5 6 P M 4 and handling fees stop. But, again, these are when the claims
3 : 5 6 P M 5 are being paid. These are not the claims that are actually
3 : 5 6 P M 6 being filed.

3 : 5 6 P M 7 So one of the very first things you heard --
3 : 5 6 P M 8 Mr. Hines was one of our first witnesses, and we would hope
3 : 5 6 P M 9 that the government wants to just give you the raw facts and
3 : 5 6 P M 10 let you reach a conclusion. But he said right to you, he said,
3 : 5 6 P M 11 the reason we know that P&H was an inducement was because
3 : 5 6 P M 12 claims dropped off about 40 percent after this.

3 : 5 6 P M 13 But look at this. Can anybody in their right
3 : 5 6 P M 14 mind look at this trend and say that trend is because P&H fees
3 : 5 6 P M 15 were discontinued? In fact, the peak was much earlier than
3 : 5 6 P M 16 process and handling fees stopped.

3 : 5 6 P M 17 Cal Dent testified as to why that was. The
3 : 5 6 P M 18 investigation was going on around this time. They had a hiring
3 : 5 6 P M 19 freeze. Many of the tests, because of the fact that you don't
3 : 5 6 P M 20 do all the tests in follow-up, it's a declining revenue model;
3 : 5 6 P M 21 and, therefore, all things being equal, you're going to have a
3 : 5 6 P M 22 decrease in the amount of revenue. And some of the more
3 : 5 6 P M 23 expensive tests are designed not to be repeated.

3 : 5 8 P M 24 So that's a misleading piece of information.

3 : 5 8 P M 25 We did another chart to show, based on the -- on

3 : 5 8 P M 1 the claims data that the government gave us, the number of
3 : 5 8 P M 2 claims actually made. This came right out of the same data
3 : 5 8 P M 3 that -- that Mr. Hines gave you. And you can see, going
3 : 5 8 P M 4 quarter by quarter, the peak is in actually the fourth quarter
3 : 5 8 P M 5 of 2012. And then it drops off, and it goes down, and it goes
3 : 5 8 P M 6 down, and it goes down.

3 : 5 8 P M 7 And I put a big question mark there because the
3 : 5 8 P M 8 government, when they put in their evidence and Mr. Hines put
3 : 5 8 P M 9 in this evidence, he stopped. He stopped at the second quarter
3 : 5 8 P M 10 of 2014.

3 : 5 8 P M 11 In other words, coincidentally, he stopped his
3 : 5 8 P M 12 data right when process and handling fees were turned off. And
3 : 5 9 P M 13 they said, well, we're not claiming any damages after that, so
3 : 5 9 P M 14 I'm not giving you the data on the claims after that.

3 : 5 9 P M 15 So what we have instead -- I put a question mark
3 : 5 9 P M 16 there because, based on the actual claims being made, the
3 : 5 9 P M 17 number of tests that were being done, the government has chosen
3 : 5 9 P M 18 not to give you that information of -- of how that happened
3 : 5 9 P M 19 afterwards.

3 : 5 9 P M 20 And, in fact, the evidence that we do have
3 : 5 9 P M 21 shows -- let me show the next chart of a couple of the
3 : 5 9 P M 22 practices that we did bring to you, and these are both in
3 : 5 9 P M 23 the -- in the top 20 of ordering -- I mean of ordering tests.

3 : 5 9 P M 24 This was for the Keowee Primary Care Internal
3 : 5 9 P M 25 Medicine. Do you recall this? And this is an exhibit which

3 : 5 9 P M 1 you'll have. This is their ordering data. This was Dr. Alam,
3 : 5 9 P M 2 and it shows when process and handling fees stopped.

3 : 5 9 P M 3 Just as he testified, he said process and
4 : 0 0 P M 4 handling fees had no influence on my ordering practice. And
4 : 0 0 P M 5 his orders reflect that as well.

4 : 0 0 P M 6 Can you show the Columbia Heart Clinic.

4 : 0 0 P M 7 This was -- this was Dr. Hollins. And, again,
4 : 0 0 P M 8 you can see virtually no discernable change in their orders,
4 : 0 0 P M 9 and he said, "I'm completely oblivious to the process and
4 : 0 0 P M 10 handling fees."

4 : 0 0 P M 11 Dr. Mayes also testified to something
4 : 0 0 P M 12 interesting. He said that he and his partners stopped -- or
4 : 0 0 P M 13 his partners stopped ordering from HDL after P&H fees stopped.
4 : 0 0 P M 14 He then admitted that that was actually not true, that they had
4 : 0 0 P M 15 stopped -- slowed down ordering sooner. But he also said that
4 : 0 0 P M 16 his partners, the ones that participated, were taking home
4 : 0 0 P M 17 \$3,000 to \$5,000 a month in process and handling fees. \$3,000
4 : 0 0 P M 18 to \$5,000 a month.

4 : 0 1 P M 19 Now, hearing that early in this case, that might
4 : 0 1 P M 20 have been surprising to some of you. Some of you may have
4 : 0 1 P M 21 said, "That's a lot of money. I think that would be an
4 : 0 1 P M 22 inducement. That kind of money, taking home, would -- would
4 : 0 1 P M 23 probably induce a lot of doctors to order more tests."

4 : 0 1 P M 24 But, actually, what he said is impossible. We
4 : 0 1 P M 25 got a chart that shows their actual orders. In the year 2013

4 : 0 1 P M 1 to 2014, their total -- and this is an exhibit that you'll
4 : 0 1 P M 2 have -- is 366 total tests, 366 total tests. That would yield,
4 : 0 1 P M 3 assuming that they got process and handling fees on every one
4 : 0 1 P M 4 of them, \$7,320 for the entire practice for the entire year to
4 : 0 1 P M 5 be divided among all the doctors and divided by months.

4 : 0 2 P M 6 So I submit to you that it's impossible. It's
4 : 0 2 P M 7 impossible for those doctors to each -- each one having been
4 : 0 2 P M 8 taking home 3,000 to \$5,000 a month. But that's what you
4 : 0 2 P M 9 heard. And you guys have been sitting here for almost two
4 : 0 2 P M 10 weeks now under the impression that these doctors were just a
4 : 0 2 P M 11 bunch of bandits taking home the wild riches of process and
4 : 0 2 P M 12 handling fees.

4 : 0 2 P M 13 And, instead, what you've learned is that -- is
4 : 0 2 P M 14 that they don't. And what you've learned, and if you look at
4 : 0 2 P M 15 any pro forma that is in the exhibit stack there, and do that
4 : 0 2 P M 16 simple math of 30 to 35 a week per -- per phlebotomist and \$21
4 : 0 2 P M 17 an hour, you're going to find that every single practice who
4 : 0 2 P M 18 accepted process and handling fees would have lost money on
4 : 0 2 P M 19 that.

4 : 0 2 P M 20 The testimony was that there are about 3500 -- a
4 : 0 2 P M 21 little bit more than that -- practices across the country that
4 : 0 2 P M 22 are using tests from HDL. And out of those, not a single
4 : 0 3 P M 23 one -- you would think that, with all the resources the federal
4 : 0 3 P M 24 government has, that they could have found just one, just one
4 : 0 3 P M 25 to say that, when those Bluewave sales reps came, they -- they

4 : 0 3 P M 1 pushed the process and handling fees. They encouraged them to
4 : 0 3 P M 2 order tests and process and handling fees.

4 : 0 3 P M 3 Do you remember Dr. Mayes? He said, "well, that
4 : 0 3 P M 4 Tony Carnaggio, I recorded a conversation with him, and he was
4 : 0 3 P M 5 kind of pushing process and handling fees." But did you ever
4 : 0 3 P M 6 hear the tape? I didn't hear the tape here.

4 : 0 3 P M 7 And so one would think that if, in fact, that
4 : 0 3 P M 8 was right, that he had recorded Mr. Carnaggio trying to
4 : 0 3 P M 9 encourage him about process and handling fees, that we would
4 : 0 3 P M 10 have heard that tape. But we didn't.

4 : 0 3 P M 11 And so absent that testimony from Mr. Mayes,
4 : 0 3 P M 12 there's not a single doctor in the entire United States who
4 : 0 3 P M 13 came in here to testify that they ordered tests because of
4 : 0 4 P M 14 process and handling fees or that anybody at Bluewave
4 : 0 4 P M 15 encouraged them to do that.

4 : 0 4 P M 16 Therefore, I submit to you that, even if you
4 : 0 4 P M 17 found -- even if you found that somehow Bluewave violated the
4 : 0 4 P M 18 Anti-Kickback Statute, you will not be able to find, by a
4 : 0 4 P M 19 preponderance of the evidence, that even a single test or a
4 : 0 4 P M 20 single claim arose out of a violation of the Anti-Kickback
4 : 0 4 P M 21 Statute.

4 : 0 4 P M 22 Medical necessity. I didn't understand any of
4 : 0 4 P M 23 the medical testimony. I mean, you could follow it and you got
4 : 0 4 P M 24 the general idea. What I hope you took away from it is that
4 : 0 4 P M 25 not all doctors are believers but the ones that are really are

4 : 0 4 P M 1 believers. They really do believe that they can save their
4 : 0 4 P M 2 patients' lives and make them healthier longer by giving them
4 : 0 5 P M 3 these tests.

4 : 0 5 P M 4 Now, let me show you Exhibit 496. My copy of it
4 : 0 5 P M 5 is not in color, but it's really beautiful when you see it in
4 : 0 5 P M 6 color. This was the test case study number 2, the one where
4 : 0 5 P M 7 you had each of the sales reps. Cal Dent, I thought, did a
4 : 0 5 P M 8 particularly impressive job of explaining how he can show that.

4 : 0 5 P M 9 The tests up at the top are what most of us get
4 : 0 5 P M 10 from our doctors when they do a standard lipid panel. And that
4 : 0 5 P M 11 patient, that particular patient would have come across as
4 : 0 5 P M 12 doing great. And, probably, the doctor wouldn't have seen any
4 : 0 5 P M 13 reason for follow-up or any special treatment for the patient.

4 : 0 5 P M 14 But as you scroll down, you see that patient was
4 : 0 5 P M 15 in bad trouble. And it was the kind of bad trouble that only
4 : 0 6 P M 16 modern technology could help you find. And there are other
4 : 0 6 P M 17 examples of that. Maybe you looked at that and said, "well,
4 : 0 6 P M 18 that's when they go on with sales."

4 : 0 6 P M 19 But that's what people probably said about MRIs
4 : 0 6 P M 20 or nuclear resonance or advanced testing before they were
4 : 0 6 P M 21 widely accepted. You have to start somewhere, and you have to
4 : 0 6 P M 22 start with a few doctors who are believers. And you heard from
4 : 0 6 P M 23 some of them, not all of them. But there are about 3500
4 : 0 6 P M 24 practices out there that -- that swear by these and use them in
4 : 0 6 P M 25 various degrees.

4 : 0 6 P M 1 Dr. Trost, there's a phrase that we use. It's
4 : 0 6 P M 2 not just a legal term, but a lot of people use it. We call it
4 : 0 6 P M 3 a straw man argument. And that is when you're trying to argue
4 : 0 6 P M 4 against somebody, sometimes you'll attribute to them an
4 : 0 6 P M 5 argument that they're not really making. And then you knock it
4 : 0 6 P M 6 down -- that's why it's called a straw man -- a straw man is
4 : 0 6 P M 7 easy to knock down -- and then it makes it look like you won
4 : 0 7 P M 8 the argument.

4 : 0 7 P M 9 Well, that's what Dr. Trost did. Dr. Trost said
4 : 0 7 P M 10 these tests are not medically necessary as routine screening
4 : 0 7 P M 11 procedure. Well, nobody said they were. Not a single
4 : 0 7 P M 12 salesperson, not a single doctor who came here to testify for
4 : 0 7 P M 13 the defense said that they used these as a routine screening
4 : 0 7 P M 14 procedure on every patient. Every single doctor testified
4 : 0 7 P M 15 that -- that they hand select which tests they want to give to
4 : 0 7 P M 16 which patients. Not a single one said that I am a
4 : 0 7 P M 17 straight-ticket voter or that I am a straight-ticket test
4 : 0 7 P M 18 orderer and that I blindly order all the panels that are
4 : 0 7 P M 19 offered.

4 : 0 7 P M 20 In fact, the testimony was that there are over
4 : 0 7 P M 21 5,000 different panels on register at HDL for their -- or they
4 : 0 7 P M 22 were -- for the different doctors that use those tests. So you
4 : 0 7 P M 23 heard from a Dr. Fishberg. He's not a professional expert
4 : 0 7 P M 24 witness, but he was very sincere about -- about why he thinks
4 : 0 8 P M 25 doctors should use these tests when appropriate. Dr. Alam uses

4 : 0 8 P M 1 these tests. Dr. Hollins uses these tests.

4 : 0 8 P M 2 Couple of things I want to mention to you. Dr.
4 : 0 8 P M 3 Fishberg is not an HDL customer. That's kind of why we brought
4 : 0 8 P M 4 him. We wanted somebody who, you know, has no allegiance to
4 : 0 8 P M 5 HDL. Dr. Alam and Dr. Hollins were both on the medical
4 : 0 8 P M 6 advisory board, but I was careful to ask each of them, I said,
4 : 0 8 P M 7 "Did you get on the medical advisory board and then start
4 : 0 8 P M 8 ordering tests, or did you get on the medical board because you
4 : 0 8 P M 9 were ordering tests?"

4 : 0 8 P M 10 And they both said, "No, no, we were -- we were
4 : 0 8 P M 11 ardent supporters before we were invited to be on the medical
4 : 0 8 P M 12 advisory board." And so they became that so that they could
4 : 0 8 P M 13 share their knowledge and their belief with other doctors.

4 : 0 8 P M 14 One would like to think that, but for the
4 : 0 8 P M 15 publicity around this case and the investigation and the, you
4 : 0 8 P M 16 know, the financial hardships and so forth, that maybe we'd be
4 : 0 8 P M 17 farther along now, that these tests would be available to more
4 : 0 9 P M 18 people and more doctors would be unabashed about ordering them
4 : 0 9 P M 19 when they thought they would be useful.

4 : 0 9 P M 20 So there is a -- a genuine dispute between the
4 : 0 9 P M 21 likes of Dr. Fishberg and Alam and Hollins on one side and the
4 : 0 9 P M 22 federal government on the other side about who needs these
4 : 0 9 P M 23 tests and how beneficial they are.

4 : 0 9 P M 24 But here's why it's a straw man argument. It's
4 : 0 9 P M 25 not up to Bluewave, it's not up to HDL, to decide which tests

4 : 0 9 P M 1 are medically necessary. That is to be decided on a
4 : 0 9 P M 2 case-by-case basis by the doctor. Each doctor sees the
4 : 0 9 P M 3 patient. Only the doctor can decide what's medically necessary
4 : 0 9 P M 4 or appropriate. You've heard the testimony that, if they
4 : 0 9 P M 5 submit a claim to Medicare or to an insurance company, they
4 : 0 9 P M 6 won't pay it if it's not medically necessary by their
4 : 0 9 P M 7 standards. You've heard testimony about HDL having to go make
4 : 0 9 P M 8 their case to insurance companies so that they would recognize
4 : 1 0 P M 9 the validity, and then they started paying those tests.

4 : 1 0 P M 10 The three-month follow-up. You've heard -- you
4 : 1 0 P M 11 didn't hear a single bit of medical testimony from any of the
4 : 1 0 P M 12 doctors that actually believe in those tests that said that
4 : 1 0 P M 13 that was overaggressive. The testimony is that, on the
4 : 1 0 P M 14 average, doctors don't do it that frequently. But a
4 : 1 0 P M 15 three-month follow-up is very much supported by the literature.

4 : 1 0 P M 16 And here's another important thing that I don't
4 : 1 0 P M 17 want to get lost. It's not against the law to try to sell
4 : 1 0 P M 18 medical tests. It's -- let me repeat that. It is not against
4 : 1 0 P M 19 the law to make a living as a salesman, even if you're in the
4 : 1 0 P M 20 medical field.

4 : 1 0 P M 21 That's why they've got rules, that's why they
4 : 1 0 P M 22 have so much compliance training, so that you can do that, so
4 : 1 0 P M 23 that you can go out and you can stand there in front of a
4 : 1 0 P M 24 doctor and tell him about how your mother's life was saved or
4 : 1 0 P M 25 how somebody else's life was saved because of these tests.

4 : 1 0 P M 1 You're allowed to do that. You're allowed to be a good
4 : 1 0 P M 2 salesman, a great salesman. There are just certain things that
4 : 1 1 P M 3 you're not allowed to do.

4 : 1 1 P M 4 No doctor, not a single doctor out of these 3500
4 : 1 1 P M 5 practices came in here to tell you that he was pressured into
4 : 1 1 P M 6 ordering tests that he didn't think were medically necessary.

4 : 1 1 P M 7 You know, Dr. Trost had a stack of reports. And
4 : 1 1 P M 8 he said, "I looked at these, and I felt like there are a lot of
4 : 1 1 P M 9 unnecessary tests ordered here and they were ordered regular
4 : 1 1 P M 10 screening panels."

4 : 1 1 P M 11 well, you've got that to look at. You're not
4 : 1 1 P M 12 going to have the patients' charts in there, so you're not
4 : 1 1 P M 13 going to know what all their diagnoses were or what other
4 : 1 1 P M 14 things the doctor had done before he got to the point of
4 : 1 1 P M 15 ordering those tests, but you're going to find one thing in
4 : 1 1 P M 16 common if you take the time to look through them.

4 : 1 1 P M 17 They all came from Dr. Mayes's practice. So
4 : 1 1 P M 18 contrary to maybe what was suggested, that this was a random
4 : 1 1 P M 19 cross-section of tests that Dr. Trost or that the government
4 : 1 1 P M 20 had selected from the millions and millions that have been
4 : 1 2 P M 21 ordered around the country, these were the ones that Dr. Mayes,
4 : 1 2 P M 22 the plaintiff in this lawsuit, hand-picked and gave to the
4 : 1 2 P M 23 government, who then gave them to Dr. Trost without any
4 : 1 2 P M 24 supporting medical records, without any information from which
4 : 1 2 P M 25 he could inform himself as to whether these were medically

4 : 1 2 P M 1 necessary.

4 : 1 2 P M 2 So Brad Johnson and Cal Dent never hid anything
4 : 1 2 P M 3 from anybody. They produced everything that the government
4 : 1 2 P M 4 asked for. They produced everything that the lawyers asked
4 : 1 2 P M 5 for. They told you the good and the bad as they stood up here.
4 : 1 2 P M 6 They agreed with the government that some of the things that
4 : 1 2 P M 7 sales reps did were not in keeping with their standards.

4 : 1 2 P M 8 But everything they've said was the truth. And
4 : 1 2 P M 9 that's not what happens when somebody is -- believes that
4 : 1 3 P M 10 they're obeying the law. It's very unusual to have lawyers
4 : 1 3 P M 11 disclose all of their most intimate communications with their
4 : 1 3 P M 12 clients, but that's what happened in this case. You got to see
4 : 1 3 P M 13 internal memoranda from lawyers. You got to hear testimony
4 : 1 3 P M 14 asking them direct questions that ordinarily would be
4 : 1 3 P M 15 privileged.

4 : 1 3 P M 16 And the answer to every single one of those
4 : 1 3 P M 17 questions, Mr. Sellers testified -- excuse me -- testified very
4 : 1 3 P M 18 openly and candidly. Linda Flippo testified very openly and
4 : 1 3 P M 19 candidly. Without any exception whatsoever, they testified
4 : 1 3 P M 20 that these guys believed that they were following the law and
4 : 1 3 P M 21 they just wanted to know what the rules of the road were.

4 : 1 3 P M 22 The government is asking for many millions of
4 : 1 3 P M 23 dollars. They want all of their money back. And when counsel
4 : 1 4 P M 24 showed you how to fill out the verdict form, he didn't give you
4 : 1 4 P M 25 a range, he didn't give you a choice; he wrote in the maximum

4 : 1 4 P M 1 amount. The government wants you to conclude not just that
4 : 1 4 P M 2 Mr. Martel or Boomer or Mr. Blasko crossed the line; they want
4 : 1 4 P M 3 to tar the entire company.

4 : 1 4 P M 4 They want to tar Brad and Cal. Regardless of
4 : 1 4 P M 5 how zealously they believed in these tests, how good their
4 : 1 4 P M 6 hearts were, they want you to tar them with the very few
4 : 1 4 P M 7 examples that they could find of -- of salespeople trying to
4 : 1 4 P M 8 appeal to doctors' financial interests. They've clouded the
4 : 1 4 P M 9 issues for you. They've mixed together the idea of selling
4 : 1 4 P M 10 based on process and handling fees with the idea of doing a pro
4 : 1 4 P M 11 forma or selling -- or responding to a doctor's questions about
4 : 1 5 P M 12 the financial aspects.

4 : 1 5 P M 13 They haven't given you any information from
4 : 1 5 P M 14 which you can determine whether even a single test was ever
4 : 1 5 P M 15 ordered that was not medically necessary. Even Dr. Trost, when
4 : 1 5 P M 16 he was going through those, nobody has told you whether those
4 : 1 5 P M 17 were Medicare claims or how much Medicare paid for any of them
4 : 1 5 P M 18 or TRICARE. All -- you're just supposed to take what he said
4 : 1 5 P M 19 and extrapolate it to every single test that was ever done.

4 : 1 5 P M 20 The government -- for the government, it's all
4 : 1 5 P M 21 or nothing in this lawsuit. They are putting you in an
4 : 1 5 P M 22 absolutely impossible position. They gave you no information
4 : 1 5 P M 23 whatsoever from which -- if you were inclined to rule with the
4 : 1 5 P M 24 government, and if you were inclined to find that my clients
4 : 1 5 P M 25 violated the Anti-Kickback Statute knowingly and willfully,

4 : 1 5 P M 1 they gave you no tools from which you could do anything other
4 : 1 5 P M 2 than return the maximum verdict. wipe them out. wipe them
4 : 1 6 P M 3 out. Enter a verdict that nobody could pay.

4 : 1 6 P M 4 That's the choice that they gave you.

4 : 1 6 P M 5 The government has tremendous power. They've
4 : 1 6 P M 6 been able to bring their full resources to bear to develop the
4 : 1 6 P M 7 facts of this case. Anything that would be favorable to them,
4 : 1 6 P M 8 you've seen it.

4 : 1 6 P M 9 And we went through every single document and
4 : 1 6 P M 10 gave you Brad and Cal's honest explanation. And when they felt
4 : 1 6 P M 11 that somebody had done something wrong, they told you candidly
4 : 1 6 P M 12 that they thought something had been done wrong.

4 : 1 6 P M 13 It's not supposed to be easy for the government
4 : 1 6 P M 14 to take everything that somebody owns. And so the law does put
4 : 1 6 P M 15 a high barrier there. And the most important thing it does is
4 : 1 6 P M 16 it puts 12 honest and true citizens in the box here. And it
4 : 1 6 P M 17 puts the judge on the bench. And it tells the federal
4 : 1 7 P M 18 government that "You're not always right. You've got to come
4 : 1 7 P M 19 make your case. You have to prove every single element of your
4 : 1 7 P M 20 case before you can take one thin dime from a citizen. If you
4 : 1 7 P M 21 want to come in here and take the position that it's against
4 : 1 7 P M 22 the law to pay process and handling fees when you never said
4 : 1 7 P M 23 before that it was against the law to pay process and handling
4 : 1 7 P M 24 fees, if you want to come in and take everything they own
4 : 1 7 P M 25 because it's against the law to sell on commission, if you want

4 : 1 7 P M 1 to take everything they own because it's against the law to
4 : 1 7 P M 2 waive copays and deductibles and have a no-balance billing
4 : 1 7 P M 3 policy, then you've got to prove every single element of your
4 : 1 7 P M 4 claim.

4 : 1 7 P M 5 "You've got to prove that there was a knowing
4 : 1 7 P M 6 filing of false claims. You've got to show that there was a
4 : 1 7 P M 7 knowing and willful violation of the Anti-Kickback Statute.
4 : 1 8 P M 8 You've got to show that the claims resulted from the knowing
4 : 1 8 P M 9 and willful violation of the Anti-Kickback Statute."

4 : 1 8 P M 10 There's nothing wrong, I submit to you, with
4 : 1 8 P M 11 making an honest living as a salesman. And in the medical
4 : 1 8 P M 12 supply business, there's nothing wrong or illegal about doing
4 : 1 8 P M 13 that either.

4 : 1 8 P M 14 These guys made a lot of money. They made a lot
4 : 1 8 P M 15 of money. But as I said two weeks ago, if they played guitars
4 : 1 8 P M 16 or played basketball or coached football as well as they sold
4 : 1 8 P M 17 these tests and as much as they believe in these tests, they'd
4 : 1 8 P M 18 be household names. And nobody would think twice about them
4 : 1 8 P M 19 making many times as much money as they made.

4 : 1 8 P M 20 If the government wants to take it away from
4 : 1 8 P M 21 them, they've got to convince you, ladies and gentlemen of the
4 : 1 8 P M 22 jury, every single one of you, that the -- that an act was done
4 : 1 8 P M 23 willfully under the Anti-Kickback Statute because it was done
4 : 1 8 P M 24 voluntarily and with the purpose either to disobey or disregard
4 : 1 9 P M 25 the law. In order to act willfully, a defendant must act

4 : 1 9 P M 1 unjustifiably and wrongly while knowing -- while knowing that
4 : 1 9 P M 2 his or her actions are unjustifiable and wrong.

4 : 1 9 P M 3 And I submit to you that the government has
4 : 1 9 P M 4 fallen far short of that. And they've got to do a lot more
4 : 1 9 P M 5 than putting stop signs on things that aren't stop signs.

4 : 1 9 P M 6 Let's go back to the analogy that I began with
4 : 1 9 P M 7 two weeks ago. You're probably tired of hearing it by now.
4 : 1 9 P M 8 But that same constable who's been watching the gentleman or
4 : 1 9 P M 9 the lady drive back and forth every single day for year after
4 : 1 9 P M 10 year, pulls up behind them, rolls -- and puts on the blue
4 : 1 9 P M 11 light, rolls down the window.

4 : 1 9 P M 12 "Officer, may I help you?"

4 : 1 9 P M 13 He says, "Yes, sir. I've decided -- I can't
4 : 1 9 P M 14 show you -- I can't show you where it's written anywhere, but
4 : 1 9 P M 15 I've decided that the law says you've been speeding for all
4 : 1 9 P M 16 this time. And so the penalty is \$170 million."

4 : 2 0 P M 17 I'm not kidding. You probably thought I was
4 : 2 0 P M 18 exaggerating two weeks ago when I gave you that little story.
4 : 2 0 P M 19 But that's a horrible thing to happen. It's not supposed to
4 : 2 0 P M 20 happen in the United States of America. There's only one
4 : 2 0 P M 21 force, one body in the entire world that has the power to tell
4 : 2 0 P M 22 the federal government that you've gone too far, you need to
4 : 2 0 P M 23 back off. And it's you, ladies and gentlemen.

4 : 2 0 P M 24 So I'm going to show you the verdict form.

4 : 2 0 P M 25 Do we have that?

4 : 2 0 P M 1 After Judge Gergel gives you your -- your
4 : 2 0 P M 2 instructions and you retire to the jury room, you're going to
4 : 2 0 P M 3 have with you a two-sheet piece of paper here. And we're going
4 : 2 0 P M 4 to ask you to check "no" in each of these boxes.

4 : 2 0 P M 5 And then go to the next page, and you come down
4 : 2 0 P M 6 here to the bottom. If you check "no," you don't have to fill
4 : 2 0 P M 7 in the values because there will be no claims for services
4 : 2 1 P M 8 by -- that HDL violated. There will be no value to those
4 : 2 1 P M 9 claims.

4 : 2 1 P M 10 And then you'll come down to the second part.
4 : 2 1 P M 11 And Box 4, check "no" to each of those.

4 : 2 1 P M 12 Because the government has failed to prove by a
4 : 2 1 P M 13 preponderance of the evidence that Cal Dent and Brad Johnson
4 : 2 1 P M 14 intended to break the law. All they wanted to know was what
4 : 2 1 P M 15 the rules were. And I come back to that last word that Cal
4 : 2 1 P M 16 Dent said on the email when he got the news from Tonya that
4 : 2 1 P M 17 Elizabeth Strawn had finally told them that process and
4 : 2 1 P M 18 handling fees are illegal for everybody.

4 : 2 1 P M 19 He said, "That's all I need to know. Thanks,
4 : 2 1 P M 20 Cal."

4 : 2 1 P M 21 **THE COURT:** Closing argument, Mallory?

4 : 2 1 P M 22 **MR. ASHMORE:** Thank you, Your Honor. May it please
4 : 2 1 P M 23 the Court.

4 : 2 2 P M 24 This is not as bad as it looks. Mr. Cooke has
4 : 2 2 P M 25 very artfully covered a lot of ground that I had planned to

4 : 2 2 P M 1 cover, so we'll get you out of here in a -- at a reasonable
4 : 2 2 P M 2 hour.

4 : 2 2 P M 3 Ladies and gentlemen, thank you, thank you,
4 : 2 2 P M 4 thank you for your service. It's an incredible thing what
4 : 2 2 P M 5 you've done. You've worked so hard with taking notes. Let me
4 : 2 2 P M 6 just echo the comments of Judge Gergel and Mr. Shaheen and
4 : 2 2 P M 7 Mr. Cooke. It's just a wonderful job that you've done.

4 : 2 2 P M 8 Today is a great day for Tonya Mallory and her
4 : 2 2 P M 9 family because finally, after all this time, this nightmare
4 : 2 2 P M 10 will come to an end. She stood up against the United States of
4 : 2 2 P M 11 America and finally, ladies and gentlemen, is about to be in
4 : 2 2 P M 12 your hands.

4 : 2 2 P M 13 And think about that. Think about how awesome
4 : 2 2 P M 14 that is. 12 people she's never met, and you hold her entire
4 : 2 3 P M 15 fate in your hands, her entire economic fate. And, again, we
4 : 2 3 P M 16 thank you for your service.

4 : 2 3 P M 17 Let me just say this, ladies and gentlemen --
4 : 2 3 P M 18 let me start with this: If you're going to bribe somebody,
4 : 2 3 P M 19 bribe somebody. Okay? Where are the flat-screen TVs? Where's
4 : 2 3 P M 20 the cash? Where's the Rolex watches? \$17? 3500 doctors have
4 : 2 3 P M 21 decided that they would be induced for \$17 per test?

4 : 2 3 P M 22 Picture two men wearing long trench coats in an
4 : 2 3 P M 23 alleyway late at night. One reaches in his pocket and pulls
4 : 2 3 P M 24 out a white unmarked envelope full of cash and gives it to the
4 : 2 3 P M 25 other one. That's a bribe. That's a bribe.

4 : 2 3 P M 1 we don't have that in this case. We've got \$17.
4 : 2 3 P M 2 That doesn't sound like a bribe. It doesn't sound like a
4 : 2 3 P M 3 kickback. That doesn't sound like an inducement, does it,
4 : 2 4 P M 4 ladies and gentlemen?

4 : 2 4 P M 5 This has been two weeks, ladies and gentlemen,
4 : 2 4 P M 6 of all smoke and no fire. It has been the government's burden
4 : 2 4 P M 7 to establish and prove beyond a preponderance of the evidence
4 : 2 4 P M 8 the fire. There's just no fire in this case.

4 : 2 4 P M 9 Now, forgive me if I'm a little disjointed in my
4 : 2 4 P M 10 presentation. I like my closing arguments to be seamless and
4 : 2 4 P M 11 perfect in each and every way. I just can't do that in this
4 : 2 4 P M 12 case. I'm going to be tied to my notes some because there's
4 : 2 4 P M 13 too much to be covered, too much has gone on. And, frankly,
4 : 2 4 P M 14 I'm having to tailor my arguments on the fly because Mr. Cooke,
4 : 2 4 P M 15 again, has done such a wonderful job covering many of the very
4 : 2 4 P M 16 same defenses that Tonya Mallory has. And so, again, I want to
4 : 2 4 P M 17 get us out of here at a reasonable hour. Remember, I'm the guy
4 : 2 5 P M 18 that doesn't object or ask questions past 5:00. So I might get
4 : 2 5 P M 19 a few of those minutes back from you today, but not many.
4 : 2 5 P M 20 Okay? So thanks for bearing with me.

4 : 2 5 P M 21 Let me -- let me talk briefly about Tonya
4 : 2 5 P M 22 Mallory. And let me say this about her right off the bat. She
4 : 2 5 P M 23 always acted in good faith. Tonya Mallory always acted in good
4 : 2 5 P M 24 faith. She always did the right thing, the reasonable thing.
4 : 2 5 P M 25 If something was broke, she wanted it fixed. If there was a

4 : 2 5 P M 1 question, she wanted an answer.

4 : 2 5 P M 2 She wanted to do things the right way, and she
4 : 2 5 P M 3 did things the right way. All of her adult life, all of her --
4 : 2 5 P M 4 all of her life at HDL, she did things the right way. She
4 : 2 5 P M 5 surrounded herself with good people, including Mr. Dent and
4 : 2 6 P M 6 Mr. Johnson. Russ Warnick, Joe McConnell, those guys were
4 : 2 6 P M 7 titans of the industry in the lab testing business. We've
4 : 2 6 P M 8 established that. You've heard that time and time again.
4 : 2 6 P M 9 Those are the kind of people that she engaged with. She hired
4 : 2 6 P M 10 the best of the best because she wanted HDL to be its best.

4 : 2 6 P M 11 She relied constantly, ladies and gentlemen, on
4 : 2 6 P M 12 the best lawyers in America. Okay? She didn't hire the
4 : 2 6 P M 13 lawyers that screech and scream at you every morning on your
4 : 2 6 P M 14 television. Those guys certainly do well in wreck cases, et
4 : 2 6 P M 15 cetera. She didn't get a number off of a large pink bus in
4 : 2 6 P M 16 downtown Charleston.

4 : 2 6 P M 17 She got Ropes & Gray, which even Brian
4 : 2 6 P M 18 Dickerson, one of the government witnesses, told us is
4 : 2 6 P M 19 essentially the best law firm in the United States in terms of
4 : 2 6 P M 20 health care. Laura Hoey and those lawyers that we've talked
4 : 2 6 P M 21 about for the last two weeks, they're the best of the best.
4 : 2 7 P M 22 Okay? That's what she wanted. She didn't want some lawyer
4 : 2 7 P M 23 that was just going to go along and tell her what she wanted to
4 : 2 7 P M 24 hear. She wanted answers, and she hired the best of the best.

4 : 2 7 P M 25 Ladies and gentlemen, every business has a risk.

4 : 2 7 P M 1 Every single business has a risk. And you have to manage those
4 : 2 7 P M 2 risks. Tonya Mallory knew well that the payment of P&H fees
4 : 2 7 P M 3 was a risky business. She knows that. She knew that all
4 : 2 7 P M 4 along. She never ran and hid from that. But it was a risk.
4 : 2 7 P M 5 Okay?

4 : 2 7 P M 6 I told you in opening, Tonya Mallory, she went
4 : 2 7 P M 7 through some yellow lights. That's a -- that's a risk. Use
4 : 2 7 P M 8 caution. Okay? She never went through a red light.
4 : 2 7 P M 9 Mr. Shaheen saw two people this morning run a red light. He
4 : 2 7 P M 10 didn't see Tonya Mallory run a red light.

4 : 2 7 P M 11 She never ran a red light in this case because
4 : 2 8 P M 12 the lawyers never told her to stop, never told her it was
4 : 2 8 P M 13 illegal. Her lawyers never, ever told her that. And when
4 : 2 8 P M 14 others would raise those points, we know the process. She
4 : 2 8 P M 15 would get her lawyers involved and a resolution will be had.

4 : 2 8 P M 16 So what else is she supposed to think? What was
4 : 2 8 P M 17 her state of mind? I'll get to that in some detail. You have
4 : 2 8 P M 18 got to judge her state of mind. What does she know? What was
4 : 2 8 P M 19 she thinking at all relevant periods of time?

4 : 2 8 P M 20 As promised in opening, ladies and gentlemen, no
4 : 2 8 P M 21 lawyer for HDL and Tonya Mallory took the stand and said that
4 : 2 8 P M 22 the payment of P&H fees was illegal nor that they told her to
4 : 2 8 P M 23 stop. And when we say stop, let me reiterate the same point
4 : 2 8 P M 24 that Mr. Cooke has made.

4 : 2 9 P M 25 There's a difference between stop and move away.

4 : 2 9 P M 1 The testimony was that no lawyer had ever said stop right now.
4 : 2 9 P M 2 The testimony was you need to stop P&H. Okay? You need to
4 : 2 9 P M 3 eliminate that risk, and what we needed to do is move away.
4 : 2 9 P M 4 You heard that time and time again, "move away."

4 : 2 9 P M 5 So they were stopping, but no lawyer ever told
4 : 2 9 P M 6 Tonya Mallory to stop immediately. Just didn't happen. No
4 : 2 9 P M 7 evidence of that whatsoever.

4 : 2 9 P M 8 Now, this has been Tonya Mallory, ladies and
4 : 2 9 P M 9 gentlemen, against the states. And let me make a point. These
4 : 2 9 P M 10 are great lawyers from the Department of Justice. They're not
4 : 2 9 P M 11 going to send the B team down from Washington, D.C., in a case
4 : 2 9 P M 12 where they're asking for \$170 million. These are the best of
4 : 2 9 P M 13 the best at the Department of Justice. I think there's six,
14 perhaps seven. There's a -- one of the lawyers on the video
15 deposition that we heard apparently hasn't been in the
16 courtroom. Anyway, a number of really good, really talented
17 lawyers from the Department of Justice.

4 : 3 0 P M 18 And stand up, Tonya Mallory, please. Stand up,
4 : 3 0 P M 19 Tonya.

4 : 3 0 P M 20 And this is Tonya Mallory, ladies and gentlemen.
4 : 3 0 P M 21 And she is still standing.

4 : 3 0 P M 22 Have a seat.

4 : 3 0 P M 23 She took their best shot, and she is still
4 : 3 0 P M 24 standing. The United States of America, with all their
4 : 3 0 P M 25 resources, all their power, all their might, she's still

4 : 3 0 P M 1 standing.

4 : 3 0 P M 2 You know the evidence. You've heard the
4 : 3 0 P M 3 evidence. And the government cannot establish liability on
4 : 3 0 P M 4 behalf of Tonya Mallory because of the facts. It's simply
4 : 3 0 P M 5 because of the facts. They don't have the facts. As talented
4 : 3 0 P M 6 as this legal team is, they don't have the facts to establish
4 : 3 0 P M 7 liability on behalf of Tonya Mallory.

4 : 3 0 P M 8 Now, think about it too. I mean, that
4 : 3 0 P M 9 evidence -- the evidence is over. What's in the record, it's
4 : 3 0 P M 10 over. This case is now in your hands. But think about it.
4 : 3 1 P M 11 The mountains of evidence, billions of pages, all the emails,
4 : 3 1 P M 12 and they're running an undercover operation at the same time?
4 : 3 1 P M 13 They're putting cameras in doctors' offices? And the best they
4 : 3 1 P M 14 come at us with is Leonard Blasko.

4 : 3 1 P M 15 Remember Mr. Blasko? He didn't even know Tonya
4 : 3 1 P M 16 Mallory. He introduced himself to Ms. Mallory from the stand,
4 : 3 1 P M 17 Mr. Blasko. He was -- no one knew who Mr. Blasko was. We
4 : 3 1 P M 18 learned through testimony that -- that he was a helper for one
4 : 3 1 P M 19 of the BlueWave independent reps. Certainly, Tonya Mallory
4 : 3 1 P M 20 didn't know him. But that's their best evidence?

4 : 3 1 P M 21 Tonya Mallory, ladies and gentlemen, it's been
4 : 3 2 P M 22 established, was never in the field. She never went out and
4 : 3 2 P M 23 met with the doctors. It certainly can't be argued that she
4 : 3 2 P M 24 went to a doctor and induced -- personally and tried to induce
4 : 3 2 P M 25 a doctor for \$17 to use these HDL tests. That just didn't

4 : 3 2 P M 1 happen. She just didn't meet with these doctors. She never
4 : 3 2 P M 2 was in the field.

4 : 3 2 P M 3 Let's talk about Tonya's state of mind. And
4 : 3 2 P M 4 you -- you need to determine, ladies and gentlemen, just that,
4 : 3 2 P M 5 her state of mind. And here's what you look at. This is why
4 : 3 2 P M 6 she thought P&H fees were perfectly legal at all relevant
4 : 3 2 P M 7 times.

4 : 3 2 P M 8 Number one, because all competitors were paying
4 : 3 2 P M 9 P&H fees. And Mr. Cooke put up a nice graphic showing all the
4 : 3 2 P M 10 many blood labs that were out there that were actually paying
4 : 3 2 P M 11 P&H fees. So that's what Tonya knew. She knew that all the
4 : 3 2 P M 12 competitors were paying P&H fees. So if all of those
4 : 3 3 P M 13 competitors were paying P&H fees, why is it wrong for HDL to
4 : 3 3 P M 14 pay P&H fees?

4 : 3 3 P M 15 That was her state of mind. The whole industry
4 : 3 3 P M 16 is doing it. She knew it back from her days at Berkeley when
4 : 3 3 P M 17 she first started. It's just what you did. They paid P&H
4 : 3 3 P M 18 fees.

4 : 3 3 P M 19 Whenever a question was raised in the field that
4 : 3 3 P M 20 was resolved by the lawyers -- okay? -- again, what was she
4 : 3 3 P M 21 supposed to think when Lester Perling -- we've heard about him
4 : 3 3 P M 22 time and time again, blatantly illegal. By the time -- as
4 : 3 3 P M 23 Mr. Cooke explains it to you, by the time all of that ends,
4 : 3 3 P M 24 well, Lester Perling has talked to the HDL lawyers and he's
4 : 3 3 P M 25 backed off completely. As a matter of fact, as the testimony

1 established, his doctors began to order HDL tests. So what was
2 Tonya supposed to think but that it's perfectly fine for us to
3 pay P&H fees?

4 And it gets back to the bribe and the kickback.
5 The doctors signed a P&H fee agreement. I mean, you don't put
6 a bribe inducement kickback in writing. All of that was
7 documented, completely documented.

8 Tonya thought that all times HDL was paying fair
9 market value. I'm not going to go through all of the exercise,
10 but \$17, ladies and gentlemen, was the fair market value. It's
11 not a bribe. It's not an inducement. It is a reimbursement.

12 "Doctor, you got to use your staff, your office,
13 your materials, your supplies, your equipment, your overhead,
14 and we're going to give you \$17 to make up for that." It's
15 that simple. It's a reimbursement. It's not a bribe. It's
16 not an inducement. It's \$17. Okay? This is what the industry
17 does. You get a P&H fee. All right? Process and handling.
18 That's why that money was paid to the doctors. It was
19 reimbursement. Okay?

20 Now, if you exceed fair market value, that's an
21 issue. That's a problem. There's no testimony whatsoever that
22 we exceeded fair market value. \$17, we know from the time and
23 motion studies done by Exponent and others, that \$17 was
24 certainly a reasonable figure, fair market value.

25 Let's also talk about the government's

4 : 3 5 P M 1 insinuation about how all the lawyers were saying stop. Okay?
4 : 3 5 P M 2 Stop. I want to show you in a little bit Exhibit 29. Okay?
4 : 3 5 P M 3 Mallory 29, and I hope you'll take a look at that one during
4 : 3 5 P M 4 your deliberations, first and foremost.

4 : 3 5 P M 5 That's the one where Ropes & Gray modifies the
4 : 3 5 P M 6 P&H agreement. They don't say "Stop immediately." On the
4 : 3 6 P M 7 contrary, they rework the very P&H agreement that's at issue.
4 : 3 6 P M 8 They make it better. They're not telling Tonya to stop. They
4 : 3 6 P M 9 reworked and modified the P&H agreement. That's our
4 : 3 6 P M 10 Exhibit 29, and I'm going to show that to you in just a minute.

4 : 3 6 P M 11 Tonya had her own personal lawyer. He never
4 : 3 6 P M 12 told her to stop. Russ and Joe. Okay? Russ Warnick, Joe
4 : 3 6 P M 13 McConnell, they could have stopped paying P&H at any time.
4 : 3 6 P M 14 They were on the board of directors. They founded HDL with
4 : 3 6 P M 15 Tonya Mallory, Russ and Joe. Those are the two that ran HDL
16 after Tonya got fired. It's just Tonya left. It's just Tonya
17 left.

4 : 3 7 P M 18 Some of the witnesses in the case, I want to
4 : 3 7 P M 19 address briefly.

4 : 3 7 P M 20 Boomer Cornwell, here's what I remember about
4 : 3 7 P M 21 him. He said he was threatened by HDL after Tonya left. She
4 : 3 7 P M 22 left in September of '14, and he testified that in October of
4 : 3 7 P M 23 '14 he was threatened by those at HDL.

4 : 3 7 P M 24 Dr. Hines, he was the first and last witness for
4 : 3 7 P M 25 the government. I think the government paid him a substantial

1 amount of money for his efforts. And he gave us an expert
2 opinion. But he admitted on the stand that he attributed the
3 Singulex damages to my client, Tonya Mallory, when we all know
4 she had nothing to do with Singulex. The government had you
5 assume that there had been a violation of the Anti-Kickback
6 Statute for purposes of his calculations.

7 Carnaggio, you know, again, he testified, as I
8 think all the Bluewave reps, that these tests save lives.
9 That's what they get from the field, these guys in the field.
10 These doctors are telling them, these tests, these are great
11 tests, they work. Right? After HDL went into bankruptcy, True
12 Health bought them. And, again, those guys are almost all
13 working for True Health selling that same good test. They help
14 patients. No evidence at all even insinuated that any patient
15 was ever harmed. On the contrary, these are highly specialized
16 tests that make people better. They make people better.

17 Nick Pace. I lost count at how many times he
18 said "move away." Nick Pace, who came in here with an axe to
19 grind against Tonya Mallory for whatever reason. He worked
20 there six months. They didn't get along apparently. But even
21 he admitted the advice, the game plan, what HDL was doing until
22 they got any clear direction from the Department of Justice was
23 to move away from P&H fees. That's what they were doing.

24 Project Twilight, the government didn't tell you
25 about Project Twilight in their closing because that's not what

4 : 3 9 P M 1 they want to talk about. Project Twilight, we well know, was
4 : 3 9 P M 2 the HDL plan. It was the business plan. And, again, it was
4 : 3 9 P M 3 Nick Pace and Tonya Mallory, they disagreed over Project
4 : 3 9 P M 4 Twilight because he wanted just the bare bones, you know, the
4 : 3 9 P M 5 walk-in and walk-out get your blood test.

4 : 3 9 P M 6 Tonya Mallory wanted something better for the
4 : 3 9 P M 7 patients. She wanted a nutritionist. She wanted yoga. All
4 : 4 0 P M 8 right? Nick Pace thought it was just too expensive to do that.
4 : 4 0 P M 9 It just cost too much money. But Tonya wanted the best for the
4 : 4 0 P M 10 patients. And patients would use those blood labs. That
4 : 4 0 P M 11 was -- that was her position. She was -- she worked with Nick
4 : 4 0 P M 12 Pace to help effectuate Project Twilight. That's what they
4 : 4 0 P M 13 were doing.

4 : 4 0 P M 14 Brian Dickerson, he acknowledged if he was
4 : 4 0 P M 15 representing doctors in an illegal scheme, then he would
4 : 4 0 P M 16 withdraw. That's -- as Mr. Cooke pointed out, that's the duty
4 : 4 0 P M 17 of a lawyer. You can't -- you can't facilitate illegal acts.
4 : 4 0 P M 18 You have to withdraw. And even Brian Dickerson said that, the
4 : 4 0 P M 19 government witness.

4 : 4 0 P M 20 Dr. Alam, he ordered tests because they worked.
4 : 4 0 P M 21 Dr. Trost -- you know, one thing he pointed out is that this is
4 : 4 0 P M 22 a \$3.2 trillion industry. That's a lot to keep up with, ladies
4 : 4 1 P M 23 and gentlemen. There are a lot of rules and a lot of
4 : 4 1 P M 24 regulations out there in a \$3.2 trillion industry.

4 : 4 1 P M 25 Tonya's not a lawyer. She's just hardworking and

4 : 4 1 P M 1 she's tough. She's not a lawyer, and so she got the best
4 : 4 1 P M 2 lawyers she possibly could find to help her wade through these
4 : 4 1 P M 3 difficult issues.

4 : 4 1 P M 4 He also casually commented that -- you know, that
4 : 4 1 P M 5 there are widely varying costs of stents. And let's think
4 : 4 1 P M 6 about that. Here's Dr. Trost, their expert, and he volunteers
4 : 4 1 P M 7 that even putting in stents in people, there's just widely
4 : 4 1 P M 8 varying costs across the nation. And, you know, why is that?
4 : 4 1 P M 9 who knows? who knows? It's the nature of our health care
4 : 4 1 P M 10 business, I guess, for better or for worse. It's just so
11 complicated.

4 : 4 1 P M 12 Burt Lively had a good point. Most of the doctors
4 : 4 1 P M 13 that order from HDL order for about 10 percent of their patient
4 : 4 2 P M 14 population. Okay? 10 percent of their patient population is
4 : 4 2 P M 15 what most doctors use for HDL. If you're in it to make money,
4 : 4 2 P M 16 you send all your patients' blood tests to HDL, 100 percent of
4 : 4 2 P M 17 your patients. That's how -- if you're in it to make money,
4 : 4 2 P M 18 you use it across the board. Okay? 10 percent of the patient
4 : 4 2 P M 19 population. And, again, out of the 10,000 doctors that have
4 : 4 2 P M 20 used HDL, 3500 got paid P&H. Okay?

4 : 4 2 P M 21 Doug Sbertoli, Ropes & Gray, never told the board to
4 : 4 2 P M 22 stop paying P&H. Okay? Never told -- never -- Ropes & Gray
4 : 4 2 P M 23 never told the board to stop paying P&H.

4 : 4 2 P M 24 Brad Johnson, Cal Dent, these are the -- these are
4 : 4 2 P M 25 the kind of people that Tonya Mallory wants to do business

4 : 4 2 P M 1 with. Cal Dent had his finger on the button for Tomahawk
4 : 4 3 P M 2 Missiles on a Navy cruise ship. Brad Johnson adopted five
4 : 4 3 P M 3 girls. Two rock-solid guys. They're the kind of people that
4 : 4 3 P M 4 Tonya Mallory wants to do business with. She wants to work
4 : 4 3 P M 5 with the best of the best -- okay? -- for very obvious reasons.
4 : 4 3 P M 6 She wants to make the best product. She wants to bring the
4 : 4 3 P M 7 best she can to patients, and that's what she tried very, very
4 : 4 3 P M 8 hard to do until she got fired and HDL continued with their
4 : 4 3 P M 9 business.

4 : 4 3 P M 10 Let me get to some of these documents, ladies and
4 : 4 3 P M 11 gentlemen.

4 : 4 3 P M 12 May I get the ELMO, please.

4 : 4 3 P M 13 And I neglected to acknowledge the fine work of
4 : 4 4 P M 14 Ms. Ravenel and Madam Court Reporter. Couldn't do this without
4 : 4 4 P M 15 them. As we say down here in the south, bless your little
4 : 4 4 P M 16 heart, Madam Court Reporter. She's put up with a lot.

4 : 4 4 P M 17 Let me start -- and I've tried to do this in a
4 : 4 4 P M 18 chronological order. This is Tonya Mallory in 2009, October
4 : 4 4 P M 19 2009. And it's the beginning of the discussion of a processing
4 : 4 4 P M 20 and handling fee, \$15 at the time, of course, it went to \$17.

4 : 4 4 P M 21 So here's Tonya Mallory to Dennis Ryan who is quite
4 : 4 4 P M 22 the attorney from Richmond, Virginia, LeClairRyan, a 2,
4 : 4 4 P M 23 300-person firm.

4 : 4 5 P M 24 "I've attached a document" -- the P&H document
4 : 4 5 P M 25 she's referring to. "Could you review it to make any changes

4 : 4 5 P M 1 you think we need to make sure that it is not misconstrued as
4 : 4 5 P M 2 inducement?"

4 : 4 5 P M 3 So she's well aware of the issue in 2009. It
4 : 4 5 P M 4 can't be an inducement. We cannot have that. We don't want
4 : 4 5 P M 5 that. So she's asking her lawyer, Mr. Ryan, to make sure that
4 : 4 5 P M 6 it's in compliance, to which he replies -- he sends it out
4 : 4 5 P M 7 to -- to Pat Hurd, who was a health care lawyer who used to
4 : 4 5 P M 8 work for the hospital.

4 : 4 5 P M 9 And Pat Hurd replies to Dennis Ryan, "Dennis, my
4 : 4 5 P M 10 recollection is that such a fee for prep services and applied
4 : 4 5 P M 11 at the same amount to fed and nonfed beneficiaries does not run
4 : 4 5 P M 12 afoul of anti-kickback. I want to confirm that no recent OIG
4 : 4 5 P M 13 opinions have slipped past me and may have a suggested revision
4 : 4 5 P M 14 to the attachment."

4 : 4 6 P M 15 So, again, she's running it by her lawyers as
4 : 4 6 P M 16 early as 2009, and her lawyers are confirming that it does not
4 : 4 6 P M 17 run afoul of the Anti-Kickback Statute.

4 : 4 6 P M 18 Next is the email from Tonya Mallory to Dennis
4 : 4 6 P M 19 Ryan about P&H and the OIG opinion letter. "I found the
4 : 4 6 P M 20 attached letter in my files. This was the letter we had done
4 : 4 6 P M 21 at BHL" -- that's Berkeley HeartLab -- "to justify the P&H
4 : 4 6 P M 22 fees. I did a lot of the time and motion studies but cannot
4 : 4 6 P M 23 find those documents now. Is this any help?"

4 : 4 6 P M 24 And attached to this, ladies and gentlemen, is
4 : 4 6 P M 25 the code map. We've talked plenty about that. But, again,

4 : 4 6 P M 1 that is the original legal opinion back in 2007. So -- she was
4 : 4 6 P M 2 at Berkeley. So she was, again, familiar with the issues and
4 : 4 6 P M 3 confronted it with her lawyers.

4 : 4 7 P M 4 Here we go to 2010, and this is from Pat Hurd,
4 : 4 7 P M 5 the lawyer to Tonya Mallory. And look at that subject line.
4 : 4 7 P M 6 "Slight revision to process and handling fees position paper."
4 : 4 7 P M 7 So, again, she is getting her lawyers involved to make sure
4 : 4 7 P M 8 that it is permissible.

4 : 4 7 P M 9 Again 2010, Dennis Ryan to Tonya Mallory,
4 : 4 7 P M 10 "Tonya, please see a marked-up clean copy of my suggested
4 : 4 7 P M 11 changes regarding the billing process. After your review, call
4 : 4 7 P M 12 me with any questions." Including her lawyers at every step of
4 : 4 8 P M 13 the way.

4 : 4 8 P M 14 And here's one. This is -- this relates back
4 : 4 8 P M 15 to -- somebody says something bad about P&H, and it goes to
4 : 4 8 P M 16 Tonya who involves her lawyers, which, again, this is
4 : 4 8 P M 17 Defendants' Exhibit 31. And you will have all of these
4 : 4 8 P M 18 exhibits. I don't mean to rush through them, because you can
4 : 4 8 P M 19 flip through them, but this is the point I need to make.

4 : 4 8 P M 20 This is Dennis Ryan in 2010 telling Tonya
4 : 4 8 P M 21 Mallory, "We are on solid ground with the OIG advisory opinion
4 : 4 8 P M 22 that Pat is sending." We're on solid ground. That's what she
4 : 4 8 P M 23 knows. That was her state of mind. We're on solid ground.
4 : 4 8 P M 24 That's from her own lawyer.

4 : 4 8 P M 25 Tonya Mallory in 2011. Tonya to Dennis Hurd --

4 : 4 9 P M 1 I mean, Patrick Hurd and Dennis Ryan. "You guys have reviewed
4 : 4 9 P M 2 this document" -- that's the P&H document again. That's
4 : 4 9 P M 3 attached to this exhibit that you can review -- "in the past
4 : 4 9 P M 4 and did not have an issue with it then; however, in light of
4 : 4 9 P M 5 this new possible interpretation, I'd like you to take a look
4 : 4 9 P M 6 at it again. Could you please review this document and please
4 : 4 9 P M 7 tell me what should be changed?"

4 : 4 9 P M 8 Again, this is in response to somebody saying
4 : 4 9 P M 9 something bad about the P&H agreement. So she wants to confirm
4 : 4 9 P M 10 with her lawyers it's perfectly legal and that -- and
4 : 4 9 P M 11 permissible and that there's nothing wrong with it.

4 : 4 9 P M 12 Here's Defendants' 32, Tonya Mallory. This is
4 : 4 9 P M 13 Ruggio, Dennis Ryan, Sims. These are all lawyers. This is
4 : 4 9 P M 14 legal training, and this is Tonya saying, "Michael, I've
4 : 4 9 P M 15 committed to BlueWave and our sales team that we will create a
4 : 5 0 P M 16 sales training program for all the guys that contact docs
4 : 5 0 P M 17 directly on a daily basis."

4 : 5 0 P M 18 These are the things that she wants to cover.
4 : 5 0 P M 19 She wants to make sure that everybody is in compliance, that
4 : 5 0 P M 20 she's doing it the right way.

4 : 5 0 P M 21 The Exponent time and motion study, you've heard
4 : 5 0 P M 22 plenty about that. And this is from Exponent to Mike Ruggio.
4 : 5 0 P M 23 Again, he's the health care lawyer at LeClairRyan. "Based on
4 : 5 0 P M 24 our analysis, the estimate of the fair market value of
4 : 5 0 P M 25 processing and handling tasks was 36.03 per specimen."

4 : 5 0 P M 1 \$36 a specimen, and we were paying \$17.

4 : 5 0 P M 2 Mike Ruggio to Tonya Mallory. This is our
4 : 5 0 P M 3 Defendants' Exhibit 7. "Tonya, attached is our time and motion
4 : 5 1 P M 4 study legal analysis letter. Please let me know if you have
4 : 5 1 P M 5 any questions."

4 : 5 1 P M 6 And this is how he concludes, "Based on our
4 : 5 1 P M 7 recent analysis of the report prepared by Exponent of HDL's
4 : 5 1 P M 8 staff and resources involved, and HDL has opined this as a
4 : 5 1 P M 9 typical site, a fair market value up to but not exceeding 36.03
4 : 5 1 P M 10 per specimen is appropriate and justifiable. Based on this
4 : 5 1 P M 11 careful study, this arm's length, fixed-in-advance fair market
4 : 5 1 P M 12 value fee will fall into the safe harbor exceptions under the
4 : 5 1 P M 13 Anti-Kickback Statute and civil False Claims Act to alleviate
4 : 5 1 P M 14 any issue in that regard."

4 : 5 1 P M 15 So that's what her own lawyers were telling her
4 : 5 1 P M 16 in 2012. That's what she believes, that everything has been
4 : 5 1 P M 17 reviewed by the legal team, experts in their field, and that it
4 : 5 1 P M 18 is all appropriate.

4 : 5 2 P M 19 This is a government exhibit, 7010, 7010. And
4 : 5 2 P M 20 I'm looking at this particular page. This is a BlueWave sales
4 : 5 2 P M 21 rep, and she's talking to Brad and Cal. "I'm sure you're aware
4 : 5 2 P M 22 of the smackdown we're getting from LabCorp."

4 : 5 2 P M 23 And, of course, this is the process. This is
4 : 5 2 P M 24 what Mr. Dent told us about. This is how it works. You get a
4 : 5 2 P M 25 bad report out in the field. It goes to Cal and Brad, and then

4 : 5 2 P M 1 Cal sends it to Tonya Mallory. Tonya in turn sends it to her
4 : 5 2 P M 2 lawyers, Dennis Ryan. Derek Kung is on board by that period of
4 : 5 2 P M 3 time.

4 : 5 2 P M 4 Russ Warnick and Joe McConnell. Okay? Her two
4 : 5 2 P M 5 fellow founders and members of the board. All right? FYI.
4 : 5 2 P M 6 And here's Dennis Ryan. "We should discuss. Can I have Cheryl
4 : 5 3 P M 7 schedule a meeting for all?"

4 : 5 3 P M 8 That was the process, ladies and gentlemen, and
4 : 5 3 P M 9 it was a process that worked well. Have an issue in the field,
4 : 5 3 P M 10 legal issue, to Cal and Brad, to Tonya, to the legal
4 : 5 3 P M 11 department. What else was Tonya to think once the lawyers got
4 : 5 3 P M 12 involved? They come back to her and say that the issue is
4 : 5 3 P M 13 resolved. What else is she supposed to think other than it's
4 : 5 3 P M 14 perfectly appropriate and legal to pay P&H fees? She never
4 : 5 3 P M 15 willfully violated a law. She never intended to violate the
4 : 5 3 P M 16 law.

4 : 5 3 P M 17 This is a physician report card. I've been --
4 : 5 3 P M 18 in the interest of time, I'm not going to go into it in any
4 : 5 3 P M 19 detail other than these tests worked. These tests worked.
4 : 5 3 P M 20 They benefited the patients.

4 : 5 3 P M 21 Here's Nick Pace to Joe McConnell, Russ Warnick,
4 : 5 3 P M 22 Tonya Mallory, Dennis Ryan. "I wanted to provide the board an
4 : 5 3 P M 23 update on Project Twilight. We're working on alternatives to
4 : 5 4 P M 24 this: in-office phlebotomists, third-party sites, and leased
4 : 5 4 P M 25 HDL sites."

4 : 5 4 P M 1 That's May 24, 2013. That's Project Twilight.
4 : 5 4 P M 2 It's exactly as we've been representing. They were moving
4 : 5 4 P M 3 away. This is evidence that they were moving away.

4 : 5 4 P M 4 And here is my favorite, Exhibit 29. This is
4 : 5 4 P M 5 from Tonya Mallory to Cal and Brad. "We modified the P&H
4 : 5 4 P M 6 agreement to strengthen compliance documentation."

4 : 5 4 P M 7 So let me flip you back a page. It begins --
4 : 5 4 P M 8 this is Peter Holman with Ropes & Gray. And this is in October
4 : 5 4 P M 9 of 2013, and he sends it to Derek Kung. "I attach a revised
4 : 5 4 P M 10 P&H agreement." October 22nd, 2013, Ropes & Gray is revising
4 : 5 4 P M 11 the P&H agreement. They're not saying stop paying P&H
4 : 5 5 P M 12 immediately. "We're revising the P&H agreement." That's what
4 : 5 5 P M 13 Tonya knew.

4 : 5 5 P M 14 So what does Derek Kung do? He sends it to
4 : 5 5 P M 15 Tonya Mallory and others. And this is the same Derek Kung that
4 : 5 5 P M 16 wrote the Derek Kung memo. Hmm. So bad. What a bad memo. It
4 : 5 5 P M 17 was a memo that said that there were risks. We acknowledge
4 : 5 5 P M 18 that. It was a risky business.

4 : 5 5 P M 19 But look at what Derek Kung says. Okay? This
4 : 5 5 P M 20 was later, after his Kung memo in 2013. "I don't think there's
4 : 5 5 P M 21 anything controversial."

4 : 5 5 P M 22 Wow. Is that telling HDL to stop immediately?
4 : 5 5 P M 23 Is that saying P&H fees are illegal? "I don't think there's
4 : 5 5 P M 24 anything controversial."

4 : 5 5 P M 25 Exhibit 10, Mr. Cooke has addressed. I won't go

4 : 5 6 P M 1 into much detail, but this is where, in 2014, in January, again
4 : 5 6 P M 2 the discussion of DOJ -- he expects DOJ will have to take a
4 : 5 6 P M 3 position on this issue at some point during the course of the
4 : 5 6 P M 4 investigation. It's still very unclear what DOJ's position was
4 : 5 6 P M 5 as late as January of 2014.

4 : 5 6 P M 6 More evidence of the same. This is Laura Hoey,
4 : 5 6 P M 7 I believe, January of 2014. I highlight, "we understood from
4 : 5 6 P M 8 our conversation on December 12 that, as of now, the government
4 : 5 6 P M 9 is not taking a position on the straight payment of P&H fees."

4 : 5 6 P M 10 And this is simply Defendants' 36. This
4 : 5 6 P M 11 demonstrates -- this is Derek Kung to Tonya Mallory and Doug
4 : 5 6 P M 12 Sbertoli, Laura Hoey, Ryan Smith. And it's -- I've covered it
4 : 5 7 P M 13 up. It's proposed slides, privileged and confidential, draft
4 : 5 7 P M 14 P&H to LeClairRyan. So this was the slide presentation that
4 : 5 7 P M 15 they were working on to present to the government, again
4 : 5 7 P M 16 defending the practice of paying P&H fees. And Tonya Mallory
4 : 5 7 P M 17 was involved in helping them prepare some of those slides.

4 : 5 7 P M 18 This is one of the slides. And this is what
4 : 5 7 P M 19 Tonya Mallory knew. Okay? And in fall of 2013. This was --
4 : 5 7 P M 20 this is what their competitors were doing. They're paying P&H.
4 : 5 7 P M 21 They're paying P&H. Berkeley, Cleveland, HDL, Atherotech,
4 : 5 7 P M 22 Boston Heart lab, Singulex, they're all paying P&H.

4 : 5 7 P M 23 And as an aside point, if you look at it, paid
4 : 5 7 P M 24 per container, HDL was actually the cheapest of them all when
4 : 5 7 P M 25 you look at it per container. That was the fair market value,

4 : 5 8 P M 1 ladies and gentlemen. Not more. That was fair market value,
4 : 5 8 P M 2 which is what was paid.

4 : 5 8 P M 3 This is HDL getting it done the right way.
4 : 5 8 P M 4 voluntary self-referral disclosure, Health Diagnostic
4 : 5 8 P M 5 Laboratory. This is to CMS, one of the government agencies.
4 : 5 8 P M 6 But you remember Dr. Mayes admitting that his patients -- I'm
4 : 5 8 P M 7 sorry -- his practice was receiving \$17 P&H, and they had a
4 : 5 8 P M 8 phlebotomist in the office at the same time. Okay? Can't do
4 : 5 8 P M 9 that. Everybody acknowledges that, but that happened
4 : 5 8 P M 10 apparently at Dr. Mayes' office.

4 : 5 8 P M 11 So it was discovered, and then HDL reported that
4 : 5 8 P M 12 to the government. And they reimbursed the government
4 : 5 9 P M 13 \$979,471.70 as a result of what happened at Heritage Medical
4 : 5 9 P M 14 Partners with Michael Mayes, MD.

4 : 5 9 P M 15 This is the processing and handling fees
4 : 5 9 P M 16 presented to the government in 2013. And I want to highlight
4 : 5 9 P M 17 some of the -- some of these pages. This is HDL's leadership:
4 : 5 9 P M 18 Mallory, McConnell, Warnick. They started with 15 employees,
4 : 5 9 P M 19 no income, in a 500-square-foot biotech park.

4 : 5 9 P M 20 These are the ways of obtaining the samples:
4 : 5 9 P M 21 reimburse, in-office phlebotomist, or draw sites. And HDL
5 : 0 0 P M 22 did all of those things.

5 : 0 0 P M 23 HDL sought input from and consulted with counsel
5 : 0 0 P M 24 throughout.

5 : 0 0 P M 25 Legal review of P&H fees. From the company's

5 : 0 0 P M 1 inception, HDL has relied on outside counsel's advice on an
5 : 0 0 P M 2 ongoing basis. Beginning in the fall of 2009, when HDL began
5 : 0 0 P M 3 considering paying P&H, the company consulted with outside
5 : 0 0 P M 4 counsel. HDL paid P&H only after seeking input from outside
5 : 0 0 P M 5 counsel.

5 : 0 0 P M 6 Terms reviewed by outside counsel. Here's
5 : 0 0 P M 7 LeClairRyan. You've seen these names. Ryan, Hurd -- who, by
5 : 0 0 P M 8 the way, director of risk management at the Virginia Hospital.
5 : 0 0 P M 9 And Mike Ruggio was previously a senior trial counsel in the
5 : 0 0 P M 10 United States Department of Justice. That's a DOJ lawyer that
5 : 0 1 P M 11 wrote that opinion.

5 : 0 1 P M 12 When HDL's payment of P&H fees was challenged,
5 : 0 1 P M 13 the company promptly involved outside counsel. And I've walked
5 : 0 1 P M 14 you through that enough, that process.

5 : 0 1 P M 15 In response to challenges, counsel raised OIG
5 : 0 1 P M 16 opinion 05-08 and offered assurances about reimbursing for P&H.
5 : 0 1 P M 17 And there it is again. "We are on solid ground with the OIG
5 : 0 1 P M 18 advisory opinion." So they didn't have much to work with back
5 : 0 1 P M 19 then. I mean, it was -- it was still working with an opinion
5 : 0 1 P M 20 handed down in '05.

5 : 0 1 P M 21 Upon hearing that competitors are calling it an
5 : 0 1 P M 22 inducement, HDL requested counsel take another look. That was
5 : 0 1 P M 23 Tonya Mallory. Look at this again. And their long-term
5 : 0 2 P M 24 outlook was to grow and develop networks using storefront
5 : 0 2 P M 25 locations, discussing partnerships with national retail health

5 : 0 2 P M 1 care. They were moving away.

5 : 0 2 P M 2 You'll have a clean copy of this. Forgive my
5 : 0 2 P M 3 writing on my example. You'll have the original. May 12,
5 : 0 2 P M 4 2014, this is to Ms. Strawn and Mr. Leventis from Brien
5 : 0 2 P M 5 O'Connor with Ropes & Gray. "This letter is to follow up on
5 : 0 2 P M 6 our recent discussion. We understand the government is
5 : 0 2 P M 7 alleging that HDL had violated the FCA as a violation of the
5 : 0 2 P M 8 AKS."

5 : 0 2 P M 9 So that's on May 12, 2014. "I understand the
5 : 0 2 P M 10 government is alleging a violation of FCA." So then they go
5 : 0 2 P M 11 off three days later on May 15th, 2014, and meet with the
5 : 0 3 P M 12 government. HDL's reliance on advice of counsel for the
5 : 0 3 P M 13 payment of processing and handling fees.

5 : 0 3 P M 14 And I'm not going to bore you with this
5 : 0 3 P M 15 document, but please take a look at it, if you would, because
5 : 0 3 P M 16 it outlines again the advice of counsel that was rendered.

5 : 0 3 P M 17 The judge will instruct you on the law. And,
5 : 0 3 P M 18 obviously, anything the lawyers say doesn't really matter when
5 : 0 3 P M 19 it comes to the law. It's up to the judge, and he will
5 : 0 3 P M 20 instruct you on the law.

5 : 0 3 P M 21 And, ladies and gentlemen, in terms of
5 : 0 3 P M 22 remuneration, he will instruct that remuneration includes
5 : 0 3 P M 23 payment for services already paid by another or payment for
5 : 0 3 P M 24 more than fair market value. HDL never paid more than fair
5 : 0 4 P M 25 market value. They paid fair market value. They paid \$17.

5 : 0 4 P M 1 That's what all the other competitors were doing, paying P&H,
5 : 0 4 P M 2 and it was fair market value. I don't think there's any
5 : 0 4 P M 3 evidence that it exceeded fair market value.

5 : 0 4 P M 4 The government takes the position that nothing
5 : 0 4 P M 5 should have been paid. And, as far as Tonya Mallory knew at
5 : 0 4 P M 6 all relevant periods, she was doing the right thing, paying P&H
5 : 0 4 P M 7 like the industry did.

5 : 0 4 P M 8 willfully? Tonya Mallory never intended to
5 : 0 4 P M 9 break the law. She never broke the law. She didn't break the
5 : 0 4 P M 10 law.

5 : 0 4 P M 11 But this is what the judge will instruct you.
5 : 0 4 P M 12 "An act done willfully under the Anti-Kickback Statute if it is
5 : 0 4 P M 13 done voluntarily and with the purpose either to disobey or
5 : 0 4 P M 14 disregard the law."

5 : 0 4 P M 15 The government has got to prove that Tonya
5 : 0 4 P M 16 Mallory had the purpose to disobey or disregard the law. They
5 : 0 5 P M 17 can't do that because it didn't happen. They don't have the
5 : 0 5 P M 18 facts to establish that. It just didn't happen. She acted in
5 : 0 5 P M 19 good faith. She did the right thing at all relevant periods of
5 : 0 5 P M 20 time.

5 : 0 5 P M 21 "In order to act willfully, a defendant must act
5 : 0 5 P M 22 unjustifiably and wrongly while knowing his or her actions are
5 : 0 5 P M 23 unjustifiable and wrong."

5 : 0 5 P M 24 She asked her lawyers time and time again. Can
5 : 0 5 P M 25 we do this? Is this okay? All right? Talk to the Department

5 : 0 5 P M 1 of Justice. Get an answer from them. Get an answer from them.

5 : 0 5 P M 2 Defendant may not be aware of the specific law
5 : 0 5 P M 3 or rule that he or she may be violating. And in this -- and
5 : 0 5 P M 4 I'm getting ready to close, ladies and gentlemen. This might
5 : 0 5 P M 5 be one of the most important things I say.

5 : 0 5 P M 6 This is what the judge is going to tell you. "A
5 : 0 5 P M 7 defendant who acts with a good-faith belief that his or her
5 : 0 5 P M 8 conduct is lawful does not willfully violate the Anti-Kickback
5 : 0 5 P M 9 Statute even if that belief is mistaken."

5 : 0 6 P M 10 A defendant who acts with good faith that his or
5 : 0 6 P M 11 her conduct is lawful does not willfully violate the
5 : 0 6 P M 12 Anti-Kickback Statute.

5 : 0 6 P M 13 If you find that Tonya Mallory acted with a
5 : 0 6 P M 14 good-faith belief that her conduct was lawful, then you can't
5 : 0 6 P M 15 find that she violated the Anti-Kickback Statute. And that's
5 : 0 6 P M 16 where we are. That's what this case is all about. Tonya
5 : 0 6 P M 17 Mallory acted with good faith. She did the right thing. She
5 : 0 6 P M 18 used the right people. She asked the right questions. She
5 : 0 6 P M 19 followed the lawyers' guidance.

5 : 0 6 P M 20 The government can't meet their burden of proof
5 : 0 6 P M 21 because they don't have the facts necessary to do that.
5 : 0 6 P M 22 They've done their best. They've brought all the many things
5 : 0 7 P M 23 that the United States of America can bring to a trial. All
5 : 0 7 P M 24 right? They're asking for what? \$170 million? I told you on
5 : 0 7 P M 25 day one, Tonya Mallory doesn't owe the government a dime.

5 : 0 7 P M 1 Ladies and gentlemen, she didn't do anything
5 : 0 7 P M 2 wrong. She's the last one standing, but she didn't do anything
5 : 0 7 P M 3 wrong. Don't find for the government against Tonya Mallory.
5 : 0 7 P M 4 The evidence does not support it.

5 : 0 7 P M 5 So, as has been pointed out, you'll get the
5 : 0 7 P M 6 verdict form. And the verdict form looks like this. And, as
5 : 0 8 P M 7 Mr. Cooke said, we want you to find that Tonya Mallory did not
5 : 0 8 P M 8 violate the False Claims Act.

5 : 0 8 P M 9 Ladies and gentlemen, it's been a long trial.
5 : 0 8 P M 10 I'm 10 minutes past my 5:00 cutoff, but I tried. But you owed
5 : 0 8 P M 11 me some minutes from earlier in the week.

5 : 0 8 P M 12 Thank you again for your careful consideration.
5 : 0 8 P M 13 Tonya Mallory and her family thank you so much for your careful
5 : 0 8 P M 14 deliberation. You've taken notes. You've taken time out of
5 : 0 8 P M 15 your day -- and out of your weeks, I should say. And we all
5 : 0 8 P M 16 just can't thank you enough.

5 : 0 8 P M 17 Please, ladies and gentlemen, please, the
5 : 0 8 P M 18 evidence is not there to support a finding for the government.
5 : 0 9 P M 19 Find for Tonya Mallory.

5 : 0 9 P M 20 **THE COURT:** Let me just ask, we've been going almost
5 : 0 9 P M 21 an hour and a half. Are we okay to continue for a while?

5 : 0 9 P M 22 Good. Reply by the government.

5 : 0 9 P M 23 **MR. LEVENTIS:** All right. Thank you, Your Honor.

5 : 0 9 P M 24 All right. I've been itching to get back in
5 : 0 9 P M 25 front of you guys. Certainly, we take issue with a number of

5 : 0 9 P M 1 things that defendants have said. I'm not going to go through
5 : 0 9 P M 2 those because it's not what we lawyers say; it's what the
5 : 0 9 P M 3 evidence shows, evidence like the pro formas, the medical
5 : 0 9 P M 4 advisory board, the target list, the money-hungry doctors
5 : 0 9 P M 5 they're targeting, selling doctors on the lucrative business
5 : 0 9 P M 6 deals.

5 : 0 9 P M 7 I could go on. There's a mountain of evidence
5 : 0 9 P M 8 of a conspiracy here to promote the sales of medically
5 : 0 9 P M 9 unnecessary tests. All three defendants admitted that they --
5 : 0 9 P M 10 excuse me -- that they failed to show any of that mountain of
5 : 0 9 P M 11 evidence to their attorneys. So all this talk about the
5 : 0 9 P M 12 attorney letters and the -- this mountain of stuff here, it
5 : 1 0 P M 13 becomes irrelevant. If the attorneys didn't know what was
5 : 1 0 P M 14 going on, then how good are those opinions?

5 : 1 0 P M 15 But you will have the evidence. You'll see them
5 : 1 0 P M 16 there in those binders over there. You'll get a chance to go
5 : 1 0 P M 17 back and look at them yourselves.

5 : 1 0 P M 18 And when the judge -- he's going to instruct you
5 : 1 0 P M 19 on the law. I want you to listen out for actual knowledge,
5 : 1 0 P M 20 deliberate ignorance, and reckless disregard. Those are the
5 : 1 0 P M 21 three standards you should pay close attention to, because, as
5 : 1 0 P M 22 I said, the defendants didn't share all the negative evidence
5 : 1 0 P M 23 with their attorneys. And legal advice is only as good as the
5 : 1 0 P M 24 information it's based on. The defendants hid what was
5 : 1 0 P M 25 actually going on in the field from their attorneys, and

5 : 1 0 P M 1 shopping for cover is not legal advice.

5 : 1 0 P M 2 Common sense will tell you why they hid the
5 : 1 0 P M 3 evidence. They hid the bad evidence so they could keep paying
5 : 1 0 P M 4 these process and handling fees. The defendants Tonya Mallory,
5 : 1 0 P M 5 Cal Dent, and Brad Johnson all admitted that they thought, if
5 : 1 0 P M 6 they quit paying P&H, the doctors would stop ordering the
5 : 1 1 P M 7 tests. Sure enough, 2014, when they stopped paying, you saw
5 : 1 1 P M 8 the chart. Tests went down and HDL quickly went bankrupt.

5 : 1 1 P M 9 Now, I was surprised when I heard Mr. Cooke say
5 : 1 1 P M 10 he now wants you to look at these pro formas. And his position
5 : 1 1 P M 11 is that they're -- somehow the doctors are losing money? Now,
5 : 1 1 P M 12 we went through a bunch of those yesterday, so I'm not going to
5 : 1 1 P M 13 go through them again, but you saw where they're telling these
5 : 1 1 P M 14 doctors they're going to make half a million dollars. It's
5 : 1 1 P M 15 hard to figure out how they're saying they're now going to lose
5 : 1 1 P M 16 some money.

5 : 1 1 P M 17 One think I want you to do is I want you to look
5 : 1 1 P M 18 at -- could we just pull this up real quick? Exhibit 1004.
5 : 1 1 P M 19 Don't just take it from me.

5 : 1 1 P M 20 Look at -- here's a pro forma from defendant Cal
5 : 1 1 P M 21 Dent. Email says, "Cal asked me to forward the attached
5 : 1 1 P M 22 pro forma." Look on the chart that they put together here.
5 : 1 1 P M 23 This is not saying you're going to lose money with P&H.
5 : 1 1 P M 24 They've got 27,000 you're currently making, almost 28,000.
5 : 1 2 P M 25 Proposed is 33,344.

5 : 1 2 P M 1 Now, look at these -- use these phlebotomist
5 : 1 2 P M 2 numbers. I mean, they're going to get up there and testify
5 : 1 2 P M 3 about something about \$30-something an hour. Look what
5 : 1 2 P M 4 Mr. Dent was using in an actual email to a physician in 2012.
5 : 1 2 P M 5 He's saying a phlebotomist is \$12 an hour. See that over on
5 : 1 2 P M 6 the right side? A half day would be \$12,480. For a full day
5 : 1 2 P M 7 of a phlebotomist, 24,960.

5 : 1 2 P M 8 You compare that 24,960 to these others, they're
5 : 1 2 P M 9 not losing money. They weren't pushing this P&H fee to lose
5 : 1 2 P M 10 money.

5 : 1 2 P M 11 Also remember you've heard testimony that
5 : 1 2 P M 12 doctors are already getting paid for the process and handling.
5 : 1 2 P M 13 They get paid through the office visit for this same procedure.
5 : 1 2 P M 14 So it's a double payment.

5 : 1 2 P M 15 Now, I want to address damages. The amount of
5 : 1 2 P M 16 damage we are seeking, it's not the defendants' money. This is
5 : 1 3 P M 17 money they took from Medicare and TRICARE through fraud. And
5 : 1 3 P M 18 as I told you when you I stood up here two weeks ago, this case
5 : 1 3 P M 19 was going to be about the love of money and what the defendants
5 : 1 3 P M 20 are willing to do for that money.

5 : 1 3 P M 21 So you've now seen the evidence. Based on that
5 : 1 3 P M 22 overwhelming evidence in this case, we ask that you hold the
5 : 1 3 P M 23 defendants Cal Dent, Brad Johnson, and Tonya Mallory, and the
5 : 1 3 P M 24 company BlueWave accountable for violating the False Claims Act
5 : 1 3 P M 25 and find that they are liable for the total amount of the

5 : 1 3 P M 1 claims that they fraudulently took from Medicare and TRICARE.

5 : 1 3 P M 2 Thank you.

5 : 1 3 P M 3 Thank you, Your Honor.

5 : 1 3 P M 4 **THE COURT:** Thank you.

5 : 1 3 P M 5 Ladies and gentlemen, I have a little guidance
5 : 1 3 P M 6 you need to give to me. It's 5:15, obviously, later than we
5 : 1 3 P M 7 anticipated. My charge will take about 30 to 45 minutes to
5 : 1 4 P M 8 give you. We need to take a break here, so it will start about
5 : 1 4 P M 9 5:25 or 5:30. And you would have the -- you'd probably
5 : 1 4 P M 10 complete my charge by 6:15.

5 : 1 4 P M 11 We can stay tonight if that's what you prefer to
5 : 1 4 P M 12 do, or we can come back tomorrow morning, and I will charge you
5 : 1 4 P M 13 and you will deliberate tomorrow. I'm going to let you decide
5 : 1 4 P M 14 that. Can you give me some indication what your preference
5 : 1 4 P M 15 would be?

5 : 1 4 P M 16 **UNIDENTIFIED JUROR:** Now.

5 : 1 4 P M 17 **THE COURT:** Let's take a 10-minute break, and then
5 : 1 4 P M 18 we'll be back.

5 : 1 4 P M 19 (Whereupon the jury was excused from the courtroom.)

5 : 1 5 P M 20 **THE COURT:** Okay. Any matters y'all need to address
5 : 1 5 P M 21 with me?

5 : 1 5 P M 22 **MR. LEVENTIS:** Not from the government, Your Honor.

5 : 1 5 P M 23 **THE COURT:** Please be seated.

5 : 1 5 P M 24 Okay. Let's take about 10 minutes, and I will
5 : 1 5 P M 25 charge the jury.

5 : 1 5 P M 1 Miss Eunice, you've got my blue-back form for
5 : 1 5 P M 2 me?

5 : 1 5 P M 3 THE DEPUTY CLERK: Yes.

5 : 1 5 P M 4 THE COURT: I've never had anybody -- y'all can be
5 : 1 5 P M 5 seated. I've never had anybody -- I've never had one party do
5 : 1 5 P M 6 it. All three of you telling people how I'm going to do it.
5 : 1 5 P M 7 So be it. I was going to say come up here and go ahead and
5 : 1 5 P M 8 charge them too. That's fine. We'll take about a 10-minute
5 : 1 5 P M 9 break.

5 : 1 5 P M 10 (Recess.)

5 : 2 7 P M 11 THE COURT: Please be seated.

5 : 2 7 P M 12 Ladies and gentlemen, Miss Eunice tells me that,
5 : 2 7 P M 13 when they realized that charging the jury meant deliberating
5 : 2 7 P M 14 that day, they, on reflection, think the morning would be
5 : 2 7 P M 15 better. I concur on that, frankly. I wasn't going to make
5 : 2 7 P M 16 them stay here; I wasn't going to make them come back tomorrow
5 : 2 7 P M 17 if they wanted to do it this evening. But I think the more
5 : 2 7 P M 18 prudent thing is for them to do exactly what they're now asking
5 : 2 7 P M 19 me.

5 : 2 7 P M 20 So I'm going to bring them in, send them home
5 : 2 7 P M 21 for the day. I'm going to bring them back at 9:00 tomorrow
5 : 2 7 P M 22 morning, and I'm going to charge them. And then I'm going
5 : 2 7 P M 23 to -- and then they'll deliberate.

5 : 2 7 P M 24 Any objections to anything? Any questions or
5 : 2 7 P M 25 concerns?

5 : 2 7 P M 1 MR. LEVENTIS: No, Your Honor. Thank you.

5 : 2 7 P M 2 MR. COOKE: No, none.

5 : 2 7 P M 3 MR. ASHMORE: No, sir.

5 : 2 8 P M 4 THE COURT: Very good. Let's bring them in.

5 : 2 8 P M 5 (Whereupon the jury entered the courtroom.)

5 : 2 9 P M 6 THE COURT: Please be seated.

5 : 2 9 P M 7 Ladies and gentlemen of the jury, I understand
5 : 2 9 P M 8 that, upon understanding, when I said I was going to charge the
5 : 2 9 P M 9 jury, that meant deliberating tonight, I think you've made the
5 : 2 9 P M 10 prudent choice to go home and get a night's sleep. You know,
5 : 2 9 P M 11 these lawyers in the court can give you a lot of things, but we
5 : 2 9 P M 12 can't give you a fresh start on the day. Right? And I think
5 : 2 9 P M 13 it's prudent for everybody to do exactly that.

5 : 2 9 P M 14 So I'm going to direct you, of course, not to
5 : 2 9 P M 15 discuss this case with anyone and not to do any research. Be
5 : 2 9 P M 16 here bright and early 9:00 tomorrow morning. I will charge
5 : 2 9 P M 17 you, and then you will deliberate.

5 : 2 9 P M 18 Have a good evening and travel safely.

5 : 2 9 P M 19 (Whereupon the jury was excused from the courtroom.)

5 : 3 0 P M 20 THE COURT: Please be seated. I'm going to direct
5 : 3 0 P M 21 each counsel to come up to Ms. Ravenel. I want you to make
5 : 3 0 P M 22 sure all the exhibits are in, because, tomorrow, with the way I
5 : 3 0 P M 23 do it, after I do my charge, I tell them to go back and select
5 : 3 0 P M 24 a foreperson. I ask you if there are any objections to the
5 : 3 0 P M 25 charge other than the ones already raised.

5 : 3 0 P M 1 If you indicate to me there are not any more
5 : 3 0 P M 2 issues, then they are directed that, when Miss Eunice walks
5 : 3 0 P M 3 back there and gives them the exhibits, they begin
5 : 3 0 P M 4 deliberating. So I don't want a delay while y'all are trying
5 : 3 0 P M 5 to figure out if the exhibits are -- I want them ready to go.

5 : 3 0 P M 6 So tonight before you leave, you come up. Each
5 : 3 0 P M 7 of you sign off that it's -- all of your exhibits are there and
5 : 3 0 P M 8 available.

5 : 3 0 P M 9 We understand that?

5 : 3 0 P M 10 MR. ASHMORE: Yes, sir.

5 : 3 0 P M 11 MR. LEVENTIS: Yes, Your Honor.

5 : 3 0 P M 12 THE COURT: Okay. See y'all tomorrow morning.

13
14 * * * * *

15 CERTIFICATE

16 I, Tana J. Hess, CCR, FCRR, Official Court Reporter
17 for the United States District Court, District of South
18 Carolina, certify that the foregoing is a true and correct
19 transcript, to the best of my ability and understanding, from
20 the record of proceedings in the above-entitled matter.

21
22
23 

24 Tana J. Hess, CRR, FCRR, RMR
25 Official Court Reporter