STORYCLOUD

Transcript of Proceedings:

Grievance of First Officer Michael Danford, ATL 18-14

AIR LINE PILOTS ASSOCIATION, INT'L
and
DELTA AIR LINES CO.

VOLUME FIVE

December 2, 2020

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VIRTUAL ARBITRATION

CASE NO. 18-14

BETWEEN

AIR LINE PILOTS ASSOCIATION, INT'L

AND

DELTA AIR LINES CO.

VOLUME FIVE

DECEMBER 2, 2020

REPORTED BY:

DAMIEN STONEBERGER

STORYCLOUD

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Also Present:

Michael Danford, Grievant

Katy Hampton, Remote Technician

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DECEMBER 2, 2020

THE REPORTER: We're now on the record. It's 10 a.m.

THE ARBITRATOR: Thank you very much. Mr. Seham, you would proceed?

MR. SEHAM: Yes. We're calling our next witness, Theodore F. Shults, S-H-U-L-T-S. Arbitrator Burdette, would you like to swear the witness?

THE ARBITRATOR: I will. Thank you. Mr. Shults, would you raise your right hand, please. Do you swear or affirm that the testimony you're about to give in this case will be the truth, the whole truth, and nothing but the truth?

MR. SHULTS: I do.

THE ARBITRATOR: Thank you very much. And can you certify for us also there is nobody else in the room with you?

MR. SHULTS: I can certify that.

THE ARBITRATOR: And do you have any documents that are not a part of the exhibits in this case in front of you? Do you have any documents in front of you that are not part of the exhibits in this case?

MR. SHULTS: I do not.

THE ARBITRATOR: Okay. All right. With that, I

think we're ready to proceed. Somebody's got some feedback going on there. We probably need to make sure that people are muted that are not speaking.

MR. SEHAM: Yes. I was going to get -- I was actually going to ask the same, I'm getting a lot of feedback. And if everyone could go on mute until they're called upon to speak, that might improve it.

THE REPORTER: I'm trying to determine the source and I'm not -- in fact, I'm not immediately seeing it.

THE ARBITRATOR: Looks like everybody is muted except Mr. Shults and Mr. Seham at this point, I think. Is everybody --

THE REPORTER: Are you still experiencing the feedback?

THE ARBITRATOR: I don't think so.

THE REPORTER: Okay. That's all.

THEODORE F. SHULTS, J.D., M.S.,

having been first duly sworn, testifies as follows:

DIRECT EXAMINATION

BY MR. SEHAM:

Q. I'm still hearing a little bit, actually. Yesterday, apparently it helped that I lowered my volume, but then it's hard for me to hear. But I've lowered my volume a couple of notches, so hopefully that will work. But we'll proceed with our

examination. Sir, can you give us a brief description of your education?

A. Yes. I basically obtained an undergraduate degree in biology, then went off to the University of Kentucky and studied toxicology at the -- and -- and then got a master's degree in toxicology. Part of that process I was called as an expert witness in a couple of cases and then I got an interest in law and then I went off to law school at Brooklyn Law School and graduated in August '83.

MR. SEHAM: Okay. Let me ask the monitor, there are -- that there were portions of that that were garbled to me as -- are you picking everything up? Damien?

THE REPORTER: Sorry. Someone had muted me. I'm picking up everything clearly. If I don't hear anything, I will speak up to get a clarification.

Q. Okay. Okay. All right. It's -- very good. Then I'll rely on that. In terms of your career, sir, have you had any experience with respect to the function of the medical review officer in the context of employee substance abuse testing?

A. Yes. I basically got involved with the laboratory testing business in -- in, you know, coming into North Carolina and then after that, I basically

started training physicians of -- of clients of the laboratory on how to comply with the federal drug testing program. And then that led to a training program which then led to a certification program, you know, I was -- I was approached by SAMHSA and Joe Audrey who was the head of that at the time and said, you know, we -- we certify this laboratory, but we're not certifying the MROs. It's politically a difficult thing for us to do, so if you would like to do it, we'll help. So I said, okay. So -- and then -- then right then I started the training and certification program and I had been doing that for about 30 years now. So I've trained probably over 10,000 doctors and we've got probably around 3,000 now that are currently in good standing. That means they meet all the requirements of the Department of Transportation. So I've got some experience with -- with that MRO community.

Q. Are you associated with the American Association of Medical Review Officers?

A. Yes. I'm the founder of it and currently the chairman.

Q. And what service does that organization provide?

A. Well, we're one of the -- one, we're the only

organization right now that's been approved by HHS and DOT and the NRC to provide both the training and the examination of four physicians to become qualified as medical review officers. There's another organization, MROCC, I think they are involved primarily with the training and then there's another group that spun off of that -- that -- or -- or the American College of Occupational Medicine that does the training. MROCC does the -- the exam. So -- but -- but -- so there are really just two of us out there, but we're -- we're, you know, we've been the originator of this thing and probably the dominant provider for a number of years.

Q. Now in the context of substance abuse testing, what is the role of the medical review officer or MRO?

A. Well, what you find in federal testing, it's not simply what the laboratory results are. In other words, you know, with -- with this program, at least, the federal level is designed as a deterrent program and a safety program to reduce or deter the use of illicit drugs. And the problem therein is that some of these drugs have both elicit and elicit of application. You know, I mean, there's an awful lot of amphetamine used out there that's under prescription. It's used as Adderall as, you know, and then -- then there's --

clearly aren't. You know -- you know, it's cocaine, for example.

A medical review officer does two things. First, what they do is, they -- they verify that this is ac -- this laboratory result is actually a violation and actually was a violation of the rules which you can't tell just by the lab results. And with the -- with another -- in order to do that, they have to reach out to the donor and discuss the results with them and ask them if they have any explanation or any prescription for the drugs that are being used. And of course, the other thing that -- that -- that -- that's a little bit not -- not obvious at first is the fact that in this area, every time you're dealing with some individual's drug testing use or not use, you're -- you're dealing with private medical issues. So even before the ADA and all of the other HIPAA compliant issues were out there, the -- the process was the laboratory would reach out to these -- these donors and ask them about it. And it just seemed wildly inappropriate. So the MRO is actually someone, you know, if it's not the MRO who is it going to be? The cured doc, the VP of operations, you know, the HR people. So what they do basically become an extension of the company, acting as your agent to determine whether or not this actually is

a violation of the policy or not.

Q. In the context of Part 40 testing where an MRO review is required and yet does not take place, can the tests be reported as a verified positive?

A. No. It basically is going to be canceled. In other words, like it didn't even happen. I mean, a good example is a number of years ago we had a physician impersonator out in California who was saying he was an MRO and he was going around, he was -- he was doing all the MRO work. And when it turned out he didn't actually have an MD, you know, he had -- he had other problems, but that was one of them. The court -- when we went to court to say, hey, are there, you know, can we uphold what he's already verified as positive? They said, no, the MRO plays a significant element of this program and the fact that he doesn't have an MD is a significant deficiency, and whether he did it right or wrong is irrelevant. So they had to repeat all of the tests that he had verified.

Q. Okay. Is MRO review required in the context of Part 40 testing for ethyl alcohol?

A. No, it's not. And the reason is -- is that once this program started, the issue became if it's all about safety, how come we're not testing for alcohol? So Congress basically told DOT, thou shall test for

alcohol. The fundamental difference between alcohol and the other drugs is that it is basically how much, it's not is it there. Remember, you know, alcohol is -- is a legal component. It's ubiquitous, it's all over the place. So it's not a question of, do you have alcohol? Do you have some in your system? It's, are you impaired? And fortunately, I like to joke that alcohol likes to cooperate. In other words, if you have a good measurement of alcohol in the blood or the saliva or, you know, or the breath, you basically can correlate that to the person's status.

So the -- the -- the first issue that came up was, well, you know, what is that cutoff level? So DOT came up -- and you get a -- a bunch of people in the room to talk about alcohol. You can have two groups, and I've done this a number of times with corporates -- corporations. You'll have a group of what I call the Teetotalers. In other words, zero tolerance, any alcohol and you're -- and you're -- and you're not good to go. And then we have the, what's the big deal crowd who basically are social drinkers or maybe even heavy drinkers, but they don't see it at the same way. But DOT split the baby. They basically came up with two cutoff levels. They said, if you are above 0.2 or above, you have to be taken out of service.

Now, we're not saying that's a violation, but you're removed from service. If you're above 0.04, then you are in a violation. That basically means you're impaired. And about 80 percent of the people, at that level, are impaired. So that was the basis of the -- of the rule. And what they also said was, we don't care if you're drinking Scope, we don't care if you're drinking if this is a prescription, we don't care if you're drinking vodka. This is basically -- it's all about how much. So they said -- in that case, we don't need an MRO for that function because, again, it's a quantitative value and it's not -- it's not a biomarker, it's not a clinical evaluation. It's -- it's basically the raw alcohol and -- and -- and -- and again, quantitatively measured.

Q. Now, can you give us your background in the field of forensic toxicology?

A. Sure. I mean, I've done a number of different -- I've had a number of different jobs. I mean, first of all, when I was actually at the University of Kentucky, my research was the area of cocaine and performance and race horses. And, of course, I got involved, you know, with just the toxicology degree as an expert witness in what was supposed to be a horse doping case down in Louisiana.

It was not a horse doping case, but that's what got me interested in going into law. Since going into law, you know, I got out and I was -- I was hired by the US Army as an intern at the Pentagon and I helped them with their urine drug testing program. I also worked in the US Attorney's Office. Not so much because I was -- at that point, I was still a law student, but -- but because of the toxicology background. And, of course, in -- in the Eastern District of New York, half the cases in there were just basically white product cases. They're either cocaine or heroin cases, and that probably hasn't changed a whole lot since.

So that -- that was my beginning. I then relocated to North Carolina and eventually ended up working -- I had -- did a number different things here, but I ended up working for the laboratory that basically managed to get the first -- the first laboratory to do DOD testing, Department of Defense testing, for Fort Bragg, you know, down the road here for their urine drug testing program. And then I also have gotten involved with dealing with their clients and dealing in the private sector and helping develop the standards in the laboratory for how this testing needed to be done. You know, one of the early lessons I got it -- with the horses is that, you know, the -- the horse racing

chemist said, if you're going to call the winner of the Kentucky Derby out because of a drug violation, you better make sure your ducks are lined up because you're going to be in court the rest of your life. And so we were very sensitive about making sure that all the T's are crossed, or all the I's are dot -- dotted and that we could go in there and support the result. In fact, my first job at CompuChem was to be sort of their coordinator of the expert testimony at Fort Bragg.

So I got involved with a lot of just expert testimony in the forensic side of this thing. And, of course, it involves the chain of custody, the SOP, Standard Operating Procedures, the validations of the studies, etc, etc. You know, I was -- my -- my boss -- the president of the CompuChem asked me, as we were getting into this and more and more private sector testing, he said, hey, Ted. Let me ask you, what's our exposure for this? Do we have a liability? I said, you know, I don't think I can answer that, but I can do this. I can do a survey of the -- of the experts in the field and see what they feel. If they are with us, I think we're good. And that's -- and that led to a journal article called, The Legal Defensibility of Drug Testing.

And I went out and I literally met most of the

leading forensic toxicologist at the time and say, okay. What is the best way of doing this? And -- and again, the consensus was the GC mass spec was the way to go. And, of course, that became the -- the de facto at -- at -- the -- the methodology that served pretty well for -- for the last 20, 25 years. I've also been hired or brought on by the National Institute of Justice. NIJ is kind of the clearing house for technical stuff for the Department of Justice. Basically, it was a -- a lead of -- in -- in -- in reviewing grant applications. You know, you have people coming in to try to get federal grants to develop this -- that and this, sort of that methodology. And it was an interesting job, it was a challenging job, but that was also dealing with, you know, is -- it -- does this methodology work?

You know, is it -- is it going to be useful, etc, etc. So I did that for awhile. And I've been involved with the, you know, again, a number of other sort of technical side issues as -- as they developed. You know, one of the issues that came up in -- in the urine drug testing program was the validity testing, you know, how do we -- how do we determine whether we're looking at real urine or we're looking at water or we're looking at substituted? And that's been the

great Achilles heel of urine drug testing, is that so much of this stuff is really artificial urine.

And I remember at the time getting the fax machine coming on and basically Samsung came out with a rule that said, well, you know, below a certain level of creatinine, this is going to be a -- this is going to be a violation. This is going to be an adulterated or a substituted specimen. And literally 20 minutes later, my phone started ringing from some of my MROs, who knows a little bit about this, you know, they're kidney, nephrologist, etc. Physiologists were saying, hey, I don't -- where did they get that number from? I don't think that's right. So I started raising the flag saying, hey, guys, how -- where -- where's the homework? You know, where's the due diligence on coming up with that cutoff level.

And after five years of fighting and five year -- and Delta had a bad experience with this too. They had a -- a flight attendant, no fault of their own, who basically send it up with a -- with a violation. And it turned out, you know, she was a typical person you'd be worried about. She was a Japanese-American who flew from Japan to Los Angeles, drank -- the -- the medical director said drink a lot of water, which she did. She got off the flight and she gave a urine specimen, and

it was -- the creatinine and creatinine is a breakdown of muscle. You know, she's a Japanese woman who doesn't weigh 100 pounds. She's hydrated, she comes in, you know, she's not going to have a high creatinine level to start with. So she was below the cutoff level and then all hell broke loose, and that went into trials, etc. And that really was the first time that the HHS standard was shown to be faulty. But it took -- it took a almost an act of Congress to fix it. But anyhow, so that -- that was another thing that I was sort of involved with. I was getting my head beat, left and right, for saying that, hey, this may not be right. And again, I don't think they were chasing -- approaching the whole problem from the right direction. But that is what it is -- what it is. And, of course, it's been adjusted now and from 5 to 2, and I haven't heard a peep since then. So again, that's some of the -- some of the experience. I'm sure I'm leaving stuff out.

Q. Let me ask you. Are you familiar with the Society of Forensic Toxicology?

A. Oh, sure. Sure. Now, I've been a -- I've been a -- an active member of that for, you know, 15 years or so. I also -- I served on their Steering Committee. I served on their Strategic Planning

Committee. I've done a number of presentations there. Again, that's sort of I would say the -- the premier society for forensic tox. And I was --

Q. I'm sorry, I cut you off. I apologize.

THE REPORTER: I'm sorry. It was forensic what?

THE WITNESS: Toxicology.

Q. Are you familiar with the American Board of Forensic Toxicology?

A. Once again, that -- I -- yeah, I am familiar with it. That's the board that actually certifies toxicologists. I -- I certify MROs, but they certify the forensic toxicologist and the laboratories that do forensic toxicology in the criminal arena primarily. Not so much urine drug testing labs, but all these state labs that do, you know, what -- what -- what's this white stuff? What's this evidence, you know, etc., that kind of thing. And -- and also postmortem work is often wrapped up into that. So they certify the labs to do that. So I served on that board for 10 years or nine years, but I -- I -- I kind of got term limited out. But again, I learned a lot, I enjoyed it a lot. But every -- every -- every -- every -- every month there was a new issue that would come up in these labs.

Q. You were a director of the ABFT boards?

A. Yes, I was.

Q. Okay. Does someone who engages in forensic toxicology such as yourself have to stay current in ongoing developments with respect to testing methodologies?

A. Yeah. As a practical matter, you would -- you'd have to -- I mean, it's -- remember, you know, my day job, I mean, I'm -- I'm basically training MRO's all the time. So I'm constantly looking in the literature trying to find out what's going on. You know, I get -- we get phone calls here at my office, you know, two or three times a day, raising an issue about what's this drug? What is that? You know, a -- a -- and so, I -- I -- I do try to stay up in all of that. I also still keep my hand involved with development of new methods and -- and -- and stuff like that. So, you know, that -- that -- that -- that's -- that just a day in the life.

Q. Okay. And do you have -- something I overlooked. Have you served in any capacity with the NRC, Nuclear Regulatory Commission?

A. Yeah. I've been on -- I was -- I had been their technical consultant on their fitness for duty program. I've been -- it's a contractual position, and I was just reassigned. I'm -- I think I served for

like nine years, then -- then -- the contract were -- they ran out of money. And so the contractor lost in the -- so I was -- I -- I still was on the -- on the hook for them, but not -- not in a formal matter, but it was just re-upped earlier this year. So I'm back -- back in -- in -- in good graces over there.

Q. Okay. This next question may overlap with some of the material you've provided us, but I would want to divorce it out as a separate question. Has your work involved or -- yeah, has your work involved the review of the development of new substance abuse testing methodologies?

A. Yes. And I -- I -- I -- I -- I do that all the time. I was involved with that on the oral fluids side of it, looking at that. I'm actually now looking at breath testing for THC. And again -- and I'll tell you something. You know, one of the big issues in this case has been dried blood spot testing. I was really excited about that a number of years ago. And I will tell you why I'm not so excited anymore. And -- but anyhow. But -- so I do -- I do look at all of that and, of course, we always have, you know, the MRO program, we also talk about emerging novel drugs, novel substance abuse drugs. You know, one of the things that we're looking at now trying to put fentanyl into

the panel. You know, drugs that really are pro -- pro -- problematic.

Then there's a whole -- the whole constellation of drugs like synthetic cannabinoids. LSD is making -- is raising it's head again. So you've got all these things, is it -- and one thing you've got to realize in substance abuse area and toxicology, you can't stand still. You've got to keep moving with it. And -- and that's -- that's what I've done, and I've -- I've enjoyed it fortunately, but it -- it -- it -- it -- it -- it's -- it's -- it's always something, and I was fast -- how fast I can fall behind.

Q. A few very specific questions. Are you familiar with a company known as eScreen, and have you worked with them?

A. Yeah.

Q. And what capacity?

A. eScreen was one of my clients for a number of years. I -- I -- the eScreen was run by of -- of -- an MRO named Murray Laby (phonetic). And Murray was really an entrepreneurial doc. And we -- we be -- we became friends. But it also, he developed this me -- methodology. He felt that one of the problems with drug testing, the way -- when I was first -- when I was in the lab, I'll tell you something. If we got a

negative test out in five days, we thought we were doing great, you know. And the marketplace was always cheaper and faster, cheaper and faster. So the laboratories have really improved again. But Dr. Laby realized that one of the great -- a game changer would be to have an instant test.

So you could do the testing, you know, at -- at the clinic or at your doctor's office, and then be able to get the negative back to the client very quickly. And so, he developed a method -- a -- a -- a device. It's basically an Internet device. So it looks like a Mr. Coffee machine, but it basically just takes the cup, you put it in this machine, you -- you -- you get online, and -- and then it will basically will have a camera that would read the strips and give the result to the collector as to whether this is -- is, a, positive, b, negative or three, it had to go to the laboratory for further testing. So they put a certain percentage of them went to the lab just for as a quality assurance program. And his issue was, there was really no device like this in the FDA.

So, you know, if you'd coming up -- if you want clearance or pre-clearance, you basically have to find something, a conforming product that you could basically tag a log on. If not, then you basically

have to go through an awful lot of -- of legwork to sort of meet their sort of regular -- the data requirements. So I was retained by him to help them with the eScreen get FDA clearance, which -- which we did. But again, it was -- it was an interesting experience because that was my first real endeavor with developing something new at the FDA.

Q. Have you had any affiliation with the organization National Medical Services in Pennsylvania?

A. Yes. That's one of the leading forensic labs, not urine drug testing or -- or -- or substantive, but they basically are -- Fred Readers (phonetic) was a -- a well-known toxicologist who set that lab up about 40 years ago. And they basically do really cutting edge kind of -- kind of work out there. They retained me a couple of years ago because they ran into a problem. They were being sued for doing ethyl glucuronide testing. And -- and --- and --- the -- the -- the nature of the suit was not that their testing was inaccurate, but rather that they didn't -- they didn't -- they didn't represent the fact that they can't tell where the alcohol came from.

So there were a whole series of cases that came up a couple of years ago of people who basically said, hey, I have this ethyl glucuronide, but it was

basically from inadvertent use. It wasn't because I used it. And in fact, one of my colleagues who I still stay in touch with today, a fellow by the name of Dr. Koontz, who runs CRL laboratory, told me at a meeting, he said, Ted, I don't think they got the cutoff on this thing right. He said -- I -- you know, I'll tell you something. It -- all I have to do is take a sip of communion wine and I'll have a positive. I said jeez. And I -- of course, this was all set by medical boards and/or legal boards, you know, doing kind of monitoring of impaired professionals. And so, of course, you know, their contract was like, Mike, if you had any positive, you were out. You know, that was gonna be it.

So there was a very aggressive nurse at the -- in New Jersey who basically said, I'm not -- I didn't violate this. I don't care what they say, this is wrong. And she basically did a couple of tests with Purell, you know, the hand sanitizer. And basically she said, Purell gave me a positive. Well, so what -- that was picked up by the -- by the Wall Street Journal, and they ran with it. And as soon after they ran with it, next thing you know, we've got lawsuits falling out of the sky all around the place. They -- me too, me too. It was -- I -- I -- you should've seen

it. I mean, they were -- that was Purell, it was a rotten banana. It was soy sauce, it was all these sources of alcohol that are out there.

So again, I -- I was brought in to try to help. And my position was simply look, this is not about is it there or not. The question is where did it come from? And that's something no laboratory can tell you. I don't care if it's alcohol or if it's cocaine, they can't tell you where it came from with maybe one exception. But -- but that really is it. I mean, it really is something that -- and then of course what happened was, as the case went on, many of these people had completely relapsed. You know, it was -- it was something that was -- it was interesting because I know what the strategy of the defense firms and I'd actually never testified in that case, but that was -- that was one of the cases that was out there.

So I got an awful lot of expe -- experience with ethyl glucuronide and ethyl sulfate. And in fact, Dr. Koontz and I had another case in -- in -- in, I guess it was Wisconsin, where it was a urine alcohol test. And one of the issues came up was, you know, where did the alcohol come from? And that was -- that the -- the -- urine alcohol was so high, the issue was, how come this guy isn't impaired? And then of course, we -- we

-- we -- I came to the conclusion. Well, it's because this guy was an experienced drug user, he also knew he would be getting called, and he added something to the urine to just increase the alcohol content. I mean, it was absurdly high, but in any event -- okay. So that's been my experience with -- with ethyl glucuronide.

And then -- oh, finally, there's one other case in Tennessee where this -- a school teacher was basically -- it looked like she was impaired. And so -- and -- and she was -- she did drink. So they -- they basically pulled her from -- from this -- from the -- from the classroom and sent her to the clinic. And you know what they did? They sent her out and they did an ethyl glucuronide test on her urine. And the results that came back from the clinic was this is the highest level we have ever seen. Well, you know why? She's a social drinker. This wasn't about accidents. I mean, she had, you know, millions, hundreds of thousands of nanograms of ethyl glucuronide in her urine. So that was kind of, again, an absurd result, but just people who just know a little bit, but don't know the rest of the story.

Q. You've been using the full names and we've been cheating during a lot of this proceeding and referring to EtS and EtG because we can't pronounce the

longer versions. So I just wanted to clarify that with respect to your work at National Medical Services in Pennsylvania, that involved you being a consultant with respect to litigation-related to EtG and EtS testing?

A. Yes.

Q. Okay. And you may have referred to the National Institute of Justice. Could you tell us what that organization is?

A. Yeah. I mean, they're basically of a -- I think I said the clearing house for the technology that the -- the Department of Justice uses. And one of the things that they also do is they try to review -- they're sort of the SAMHSA version of DOJ. You know, they're the ones that have to vet out new -- new technologies and what's acceptable and what's not acceptable for the Department of Justice. So -- and they also had some money to kick around a few years ago in terms of grant money. So they put out -- you know, if you've got a new technology, let us know, submit a proposal, and we'll have experts review it. And so it was interesting because I -- I was -- I was brought in as one of the experts.

Sometimes there's usually like three of us in a room, but sometimes I was the lead, sometimes I was just on the team. But again, there were all kinds of

-- of, you know, miniaturized GC mass specs, you know, really interesting kind of devices, some which had promise, some which were just basically a pipe dream. But we basically had to sit down and determine what would the -- what they should fund and what they shouldn't. You know, so that -- that was it. Then when I -- you know, I had to -- that's -- that was more work than it was worth. But again, it made me -- sort of forced me to keep up with what the technology is out there.

MR. SEHAM: Okay. I'll ask monitor or Damien to bring up Union Exhibit 81.

(Union Exhibit 81 marked for identification.)

Q. And if you could just slow motion scroll through it so that the witness can see the 12 pages or maybe medium motion.

A. Well, I'm kind of familiar with this, so I -- I think that --

Q. Well, the question is, is this your curriculum vitae?

A. Yes, it is.

Q. Okay. And we can take that document down now. And I know to take a pause. So just for your information, sometimes when we're putting up an exhibit there can be a glitch or an interruption in audio, so

I'll take a pause once in a while here. My next question is, have you testified as an expert witness previously?

A. I have.

Q. Can you give us some detail, please.

A. Well, I probably testified about 25 times down or 22 times down through the years. A number of them actually are back -- were -- were actually back in the horse business. And I'm -- I'm going to mention this because I think it has some relevance to this. You know, when I left for law school, I figured I'm done with -- I'm done with equine. I'm not going to go -- I'm not going to get -- get back into that. But my -- my professor who was kind of an expert in this field, sort of kept track of what I was doing. And a couple of years ago, I -- we connected again and he said, hey, I -- we -- we think we really need you to help us with what the laboratories are doing. So I said, well, I've been out of it for awhile, but I'll be happy to take a look.

So after the 20 years, I got back in, I felt like Rick Van Winkle. And I'd tell you, I was really surprised at what I saw. In other words, when I was in the laboratory, we were -- we were trying to increase the sensitivity of -- of the instrumentation. We were

using what would almost be Middle Ages by today. Now we're using thin layer chromatography, we're using a GC. We did have a GC mass spec, but we barely could get it running most of the time. This is -- remember this is the late 70s that -- the -- when I finally left. And we knew that the -- the -- the -- the trainers were using drugs below the cutoff level.

So what happened -- and again, I didn't see any of this, but by coming back in, you know, just being introduced and sort of abruptly, it was like, holy cow, how did you get here? What -- what -- what the -- what the racing chemists were doing was, as -- you know, in this -- in the field of toxicology, it's fabulous. Not only we have new drugs, but we're always improving the sensitivity. There's always new analytical equipment that comes out there. So if you told me that we could routinely test the picogram level or even the nanogram level, I'd say that's a pipe dream, but it's not, it's -- it's real. So the problem is -- is that what -- what the racing chemists really adopted like a foster child was the new technology.

So, as I said, they kind of went down the rabbit hole of getting lower and lower cutoff levels without an appreciation for the fact that you don't -- at some point, you don't know what you're measuring anymore.

In other words, there's a background noise for most of these things. I think we've probably all seen the literature or at least the articles and, you know -- you know, some -- some newspaper about how the fact that most of money in this country is contaminated with cocaine, and now it's contaminated with methamphetamine. And then -- and we've got that contamination issue going on all over there. You know, I -- I -- there's no environmental testing laboratory or -- or university that has an environmental group that doesn't send the kids out to the local hot waterways to scoop up some water and come back and test it for what they find, you know, and they find all kinds of metabolites, all kinds of drugs in it.

So the issue is, what point you don't know what you're testing, what you're looking for anymore and what point -- is this not physiologically relevant? And I -- and I had a couple of meth cases that really struck me as being outliers. You know, we had a couple of horses that basically showed up were very low, I mean, picogram levels of meth in their urine. And I said, you've got to be kidding? Of course I was -- it was -- it fell on deaf ears, you know, even though I -- I put the literature together. I kind of showed that we've increased the sensitivity, and we have this

background contamination, and eventually these lines are going to cross.

Fortunately, a couple of years ago, we also had a situation where three horses showed up in Toronto, and basically, all three of them -- this is for a race, so all three of them were tested, all three of them came up for methamphetamine. Now, that -- that's a great story because the -- the stewards and the vets at the -- at -- at -- at the -- at the track kind of figured something doesn't seem right here. One is that, these three horses came from three different trainers and three different farms. So there was -- usually, there's a common connection, and so that was -- that was -- that was number 1. Number 2, none of these horses had any history or their trainers had any history, so they all had clean records, so that also raised some speculation as to what's going on here.

So I said, listen, there's got to be a connection to have all three of these come up positive, particularly all of them at this picogram level. So the -- finally, I heard that these horses all were -- all came together in a -- in a horse van and the same van. I said, okay, stop the presses, somebody go out there and swab that trailer down and see what you find. And sure enough, guess what? That -- that van, I think

it's like from Breaking Bad, I think at some point that -- that was actually used as a -- as a meth lab, because there was meth all over it. It's -- the walls, the ceiling, the floors, and you'll hear about this every once in a while in child custody cases, where the children come up positive. It's not because their parents are giving it to them, but they were in a contaminated environment.

So again, I -- I love that case because it got published in the Canadian Vet Journal that these three horses had gotten, you know, positive for just standing around in -- in -- in -- in this horse trailer. I don't know if -- I don't think it affected their performance much or -- or at all -- or at all. But again, that's sort of vindication for the fact that, you see what I'm telling you? You've got to be careful about how low you go with these things. And I think we've always appreciated that in the human side of -- of testing. You know, of course we see that now a lot with THC, you know, what's the cutoff level, how high or how sensitive should it be? We always had the issue of passive ventilation, passive -- and we've also established cutoff levels. Everyone complains about it, says we're missing a bunch. Yeah. But you're also missing a lot of headaches, you don't need to have too,

so that -- that's my sense. Again, not that I'm -- I'm for, you know, for trying to beat the test, but at the same time knowing -- to me, it's about trying to stay out of trouble.

Q. When you say headaches, are you referring to potential --

A. Yes.

Q. -- false positives?

A. Yeah. Yeah. False positives and -- and -- and being -- being able to validate. How do you go out and validate that you're not testing for background noise? You know, it's -- it's a challenge. It can be done, but it's a big -- it's a -- it's a big challenge.

Q. Without going into all the specifics at this time, my intent is just to ask about the areas in which you've testified as an expert. Have you testified as an expert with respect to internal laboratory testing procedures?

A. Yes, I have. I had a couple of those cases. And of course, for many years, I -- you know, part of what my job was is to go out, you know, and -- and actually audit the laboratories to make sure that they were in compliance for -- for private employers. So I had a pretty good idea of -- of what to look for, what to expect, and what's acceptable and what's not

acceptable. And -- and again, in -- in terms of laboratory analysis, there have been -- I've -- I have, I mentioned -- yeah, I'm going to mention that ethyl glucuronide case for the -- from -- from the teacher. There have been -- there have been a couple of others like that. But most of the time it's been just safety issues, cause and effect, that -- that type of thing. I have to kind of look over the cases again because there's --

Q. Okay. So you have testified concerning the interpretation of alcohol results --

A. Oh yeah. Yeah.

Q. -- and biomarkers?

A. Oh, yeah. Yeah.

Q. And then you've also testified as an expert witness with respect to MRO practices?

A. Yes.

Q. Okay. Have you ever -- in any of these cases, have you ever not been qualified as an expert witness?

A. No.

MR. SEHAM: Okay. Mr. Arbitrator, we tender Ted Shults as an expert in forensic toxicology as it relates to substance abuse testing, and with respect to the field of MRO Review.

MR. KASSIN: Arbitrator Burdette, what we would ask you and the board members to take note of is what the witness has just testified to in terms of only having a master's degree, as well as the primary focus of what his work has been, has been the training of MROs. And we'll have some questions on cross that will clarify this issue, but with the understanding of what his background is and for the board to view his testimony in that light.

MR. SEHAM: There could be rebuttal to that, but I'd rather proceed. May we proceed, Arbitrator Burdette? You're on mute.

THE ARBITRATOR: Yes. You may proceed. Sorry.

Q. Thank you. In order for a laboratory to be permitted to conduct forensic drug testing for a DOT regulated industry, is there any certification requirement?

A. Yeah. All the formal testing has to be by a certified laboratory and that's something that the National Laboratory Certification Program administers, the NLCP. And it's a pretty comprehensive quality control and quality assurance program.

Q. And in order to be certified and I believe the certifying agency is SAMHSA, S-A-M-H-S-A?

A. Yes.

Q. And in order to be certified by SAMHSA, what must a laboratory demonstrate?

A. They need to demonstrate basically proficiency, validation, accuracy, precision. They basically have to submit their sust -- standard operating procedures, those are reviewed. They all have to submit to a -- a -- a on-site inspection by three experts or more, depending on how big the laboratory is. They also have to be sub -- subject to blind proficiency testing, which comes through SAMHSA. It used to be -- the employers would send it in under DOT, but now it's basically just -- just NLCP. And the -- the initials there, National Lab Certification Program, they are kind of the contractor for SAMHSA that administers this.

Q. Okay. And are these -- I'm sorry. Go ahead.

A. So as I said, it's -- it's -- it's a -- it's a rigorous program. And again, you know, I hear a lot of complaints from the lab that it is very rigorous. But at the same time, I think the upside to all of it, is that you don't see much litigation against these certified laboratories for false positives and I guarantee you if they didn't have that in place, we would.

Q. Is a strict adherence to laboratories

protocols embodied in the SOP required?

A. Yes.

Q. Is there any laboratory certification program or independent overview specific to PEth testing for alcohol abstinence?

A. No, not -- not in the United States.

Q. Are you familiar with the third-party proficiency oversight program as applied to forensic testing under Part 40 for the transportation industry?

A. I'm not quite sure -- wha -- what you're referring to with that. I mean, that, you know the proficiency testing -- I know what the proficiency testing is, but if you're referring to it as the blind test, yes. The DOT had in their regulations a requirement that employers had to send blind specimens, which means they're basically not real specimens, but they're known -- known values and they're sent to the laboratory and they're blind in the sense they look like any other specimen that would come in. They basically abandoned that I think in 2019 because of the cost, but they also figured they could rely on SAMHSA and the NLCP that tests the same laboratories, you know, with blind specimens just to maintain their certification.

Q. Okay. Is there any similar blind sample

testing specific to PEth testing for alcohol abstinence?

A. Not that I know of.

Q. Okay. Are you familiar with the urine based immunoassay and gas chromatography mass spectrometry or liquid chromatograph mass spectrometry utilized by SAMHSA certified laboratories to conduct substance abuse testing in DOT regulated industries?

A. Yes.

Q. And could you give us a brief overview of how those two methodologies interrelate in terms of the testing process?

A. Well, the concept is, you know, immunoassays are basically an antibiotic antigen test. These are competitive tests where basically you take your specimen, you add a reagents to it. And basically depending on the reaction that you're going to monitor some way or another, you're going to tell whether or not the prohibited substance is in there or not. You know, what was nice about the immunoassays is that they can be automated and they can be very of cost effective. You know, I don't think we'd have large scale drug testing without the immunoassays.

The downside with immunoassays is that they're not 100 percent. In other words, you get cross-reactivity.

You know, for example, with the amphetamines, the -- during the cold or flu season, there an awful lot of false positives that come out of the labs because once again, the antibody can't distinguish between something like Sudafed and amphetamine. Again, they're very structurally similar kind of molecules. So that's when the idea was okay, well, if we get a positive, we're going to not going to act on it, but we're going to send that specimen to the GC mass spec as an independent sort of check on the immunoassay. And they both have to be positive for -- in order for it to be positive. And a GC mass spec -- I mean, just for the, you know, kind of a just a quick synopsis of it, is a gas chromatograph basically takes a mixture of drugs and separates them. And that's what I used when I was in the lab. It basically is like a racetrack.

You inject it into a column depending on the chemistry of that particular substance and the packing material, it travels down the column at a certain rate. So we have some compounds coming off fast, some coming off later. And the measured -- from the time you inject to the time it comes off is called a retention time. So that's how the gas chromatograph identifies it. So now when you hook a mass spectrometer onto it, it basically takes those things one at a time as they

come off the gas chromatograph and they basically, you know, molecules are too small, you can't see them, but you can break them into pieces. So that's what the mass spec does. It breaks them into pieces or, you know, electronically or chemically, basically and -- and then what you can do is you can look at the pieces, because each one of these things are ions. Each one them has a mass energy ratio and they'll travel down a field in a certain kind of way.

So basically that's how you look at it. You look at the -- the pieces and then the computer will put it back together for you and tell you what the structure of the compound that you're looking for. So again, I think that's why these things, you know, if you combine those two things together and make that, you know, we've -- we -- it's basically a -- it's not a question of is it there anymore? It's a question of, you know, you know, maybe other questions that sample handling may be an issue. There are other issues, but basically that's why the -- the two things were -- were the -- the combination of A and B, you needed to have a -- a positive test report.

Q. Okay. And how long have the current methodologies of immunoassay as a screen and gas chromatography, mass spectrometry as a confirmation

been approved for use in DOT regulated transportation industries?

A. Since the beginning. I mean really, you know, when the rules first were developed, the GC mass spec and immunoassay, the -- the two-step methodology was in place with the very first set of proposed regulations from SAMHSA. And of course, they would an adopted by DOT and the NRC.

Q. Okay. And was there a use of these methodologies even prior to the DOT program in 1988, '89?

A. Yes, they were. I mean, immunoassays has probably been around I want to say probably from the -- at least the late '70s, maybe early '80s. And then of course, but those were used and of course they were used singly and they were used, you know, for like an -- in maintenance clinics and things like that just to monitor the patients. But again, they didn't -- didn't have the same sort of forensic weight as a mass spec. And as the mass spec came along, you know, I -- I tell you at least in '83, I had -- was pretty well established and not as sexy as it is today, but it was -- was an established methodology, at least in the early '80s.

Q. Are SAMHSA -- I'm sorry, did I cut you off or

were you?

A. No, I'm done.

Q. Okay. Are SAMHSA certification requirements satisfied by a laboratory's mere adoption of these two prescribed methodologies or is something else required?

A. Well, you know, you still have, you know, just -- listen, you can have a mass spec, but you can do it wrong. You know, you basically need to have standard operating procedures, need to have your personnel trained. You need to have sample handling procedures in place. And these things are pretty rigorous. You know, you can't mix up specimens. You can't lose specimens. You know, you basically have to make sure that the specimens don't degrade. So there are a lot of other things other than just having the methods on -- on the shelf, is how do you use them, you know.

And again, I've, you know, a number of years ago we had a situation where a laboratory was making its own methamphetamine on it's gas chromatograph. It didn't know it at the time other than the fact that, you know, actually an MRO raised the issue first, that, hey, this -- this -- this can't be right. And then of course, the -- it was the A and B bottle that identified that. When they sent off the split specimen, it came back

dead flat negative and they realized to their grin that, you know, they were using the mass spec, but the -- the temperature that they were running at, they had a compound in the urine that was -- looks a lot like methamphetamine, it was actually Sudafed. So people take Sudafed, you know, and then that Sudafed was actually being converted to meth. Again, I will spare you the chemistry on all of that. But it was sort of a kind of a wake-up call that just because you're using a method doesn't mean you're going to get it right. I mean, the -- the -- the -- the GC mass spec looked perfect other than it wasn't from the urine which was being made on the column as in -- in -- in any kind of environment that they were in.

Q. Now, this may -- forgive me. This may overlap a little with some of your introductory testimony, but are you familiar with the scope of the SAMHSA inspection process?

A. Yeah, I am. I mean, there -- there are different sections of it. And basically, they -- they go -- they start with, you know, inspection of the laboratory facilities, the security of the facilities, you know, the methodology, the SOPs. You know, each one of these SOPs also have to be validated. There's a whole validation protocol that needs to be followed.

And again, they also have a number of other proficiency tests they need to -- they call open for efficiencies. In other words, you get this box in the mail or -- or by courier and you know they're from SAMHSA, you know these are for testing. So that's the first step. So you see how you perform on that. And the performance of each lab is compared to each other. And then you get -- occasionally you'll get a blind specimen that you won't even know it's a blind. It's supposed to be blind anyway, and it goes through the laboratory and they see how you perform with that.

So all of that is -- is part of the overall -- overall process. And again, if -- if you don't perform within a certain plus or minus range, you know, they're going to come in and inspect it. And of course, now with the split specimens, you know, you have this -- this -- this additional check that the laboratories, you know, the MROs will if -- if the donor wants there B specimen to be tested, the MRO is directed to get that facilitated. It's -- it has to be at a different lab. And -- and if those results don't jive, in other words, you get a complete flat negative at the second lab and something in the first lab that makes it look like the first lab has a first positive, SAMHSA will come out and inspect it and try to figure out what

happened. Again, relatively rare things, but that's all part of the process.

Q. Okay. And how often are these SAMHSA inspections conducted? Annually, quarterly?

A. I think they're quarterly, and I think it also depends on how big your lab is. I mean, there's a big difference between a lab that does 3,000 specimens a day and some of the big ones now that do 15,000 specimens a day. So, you know, of course, their fees go up and the number of inspectors go up, and they review almost every non-negative. They just go in and look at all of that of since the last inspection. And typically, they'll always find some issues. There will be something by the way, we don't like the way you're doing this. And so they have to take some corrective action to smooth that out. So again, this is why I think ultimately, it's the very reliable results from any certified laboratory.

Q. Yeah. And forgive me if you covered this. Well, actually let me -- by way of background in terms of the reference you made to split specimen. The splitting of the specimen, where does that occur? Does that occur at the laboratory or sometime prior to that?

A. No. It has to happen at the collection site. So when the collectors collect the specimen, whether

it's an oral fluid or a urine test right now, they basically put it into two vials and they label one an A bottle and the other a B bottle. And then they -- they put them together with a single chain of custody, and then send it off to the laboratory that has been specified by the client.

Q. And is there --

A. They put tamper evidence seals over both of them. So when they get to the laboratory, one of the first things the lab has to do is validate that they got the two specimens and/or that they've got, you know, the seals intact. And so -- so when the donor who has -- the only person who can order the B specimen under the DOT program is the donor. So the donor when they say, I want that B specimen tested, then the MRO goes ahead and has that facilitated.

Q. And is the -- if I can refer to laboratory A and laboratory B, is laboratory A the recipient of these specimens, is it permitted to open the B bottle that's reserved for the second laboratory?

A. And in fact, when that happens, that basically ends up as a fatal flaw. So fatal flaw is essentially a kind of a canceled test. So you'll have situations where, you know, first of all, the laboratory will -- will spill -- spill the B bottle or

there will be no B bottle there. So again, until the donor asks for it, if a donor asks for it and they can't produce it, that's -- the game's over. It's kind of like they say is a fatal flaw.

Q. Okay. So if Laboratory A produces a positive result that is verified, but the split sample is unavailable for testing, what is the result?

A. Canceled.

Q. Yeah. Are SAMHSA regulated laboratories required to preserve the samples they have tested for retesting?

A. Yes.

Q. For what period of time?

A. For three years. Anything that's non-negative. Non-negative is basically kept at the first laboratory and they also have to be kept at the second laboratory with the same period of time.

Q. Okay. Now, you've referred to blind sample testing process at SAMHSA certified laboratories. What happens if a SAMHSA certified laboratory produces quantitative results that are at variance with the blind samples and the anticipated quantitative levels of those blind samples?

A. To some degree, the question of how significantly different are they. Now, if they are,

you know, again, they compare them to the other laboratories that have done this. But if they are really far outliers, the first -- one of the things that you're going to -- they're going to ask the laboratory how did -- what do you think went wrong here? Here's what your result is. Here's what the results should have been. So they'll put the ball back in the court of the lab and hope that they can sort this out to some degree. But they would in any event, will follow up with an inspection. And if they find some systemic problem, you know, they can basically, you know, suspend the laboratory or de-certify it. A relatively rare phenomenon, but it's something that the laboratories do not want to have happen.

Q. Are you familiar with the term quality assurance data --

A. Yes.

Q. -- as it is used in the context of laboratory-based forensic testing?

A. Absolutely. So again, quality assurance data is something that the laboratory does internally, and they do it in a number of different ways. Typically, the way these large specimen handling operations work is they basically batch specimens into -- into certain numbers. In other words, depending on the

instrumentation they're using, it may be a batch of 10, it may be a batch of 25 or 115. In those batches, they have to have a number of calibrators, they have to have a number of proficiency tests, and they have a number of knowns until -- there's knowns and the unknowns. Basically, what you're looking for is -- with their -- with their calibrators is, how well are those calibrators reflecting what's actually been sent to the laboratory.

And so all of that basically is statistically analyzed to determine how -- how accurate or reliable the result is. And if they don't work, you know, that -- that -- that's going to -- they're going to put the -- the program on hold. The laboratory is supposed to take some corrective action. And that's what -- that's what to some degree what the certifying scientist does in all of these laboratories. They look over the QC data to see that all the numbers, the negatives are negative, the positives are positive, and the calibrator is within range. If they approve that, that's when they release the batch result. All the results go out for that batch. If not, if they fail, then they have to redo -- redo the whole batch.

Q. Are certified laboratories required to produce their quality assurance data to confirm the

accuracy of their testing methodologies?

A. It's all open to inspection. I mean, you know, a SAMHSA inspector comes in there, they're going to see all of it.

Q. Okay. Are you familiar with the term validation, as it is applied to forensic testing?

A. Yeah. And that's really a very important concept. You know, the validation is basically validating, showing that what you think you're doing, you're actually doing. Is this actually work? Does this method actually apply? You know, how does -- how are we going to do that? So there are all kind of protocols for validating. And it -- basically, it's -- it has to do with everything. How do you know that you're not losing a specimen? How do you know that you're measuring this accurately? Is there degradation? Is there a interference? Are there, you know, other issues in here? So each one of these methods, and even established methods have to be validated. And again, usually, a laboratory, particularly, if it's starting up a new method, has basically a validations, you know, kind of master plan. You know, how are we going to do this and what are we going to do? How many specimens we're going to run, and -- and what are the results we -- do we expect. So

you'd be able -- should be able to show someone who's not in the laboratory that this actually is what you say it is. And to some degree, that you're not even fooling yourself, you know, because I've seen that happen too.

MR. SEHAM: Arbitrator Burdette, can we take a five-minute break at this time for hand washing?

THE ARBITRATOR: Absolutely.

MR. SEHAM: Okay. Thank you.

THE ARBITRATOR: We're off the record for five minutes. We'll be back on at 11:00 your time?

MR. SEHAM: All right. Thank you.

(OFF THE RECORD)

BY MR. SEHAM:.

(Union Exhibit 51 marked for identification)

BY MR. SEHAM:

Q. If we could bring up then Union Exhibit 5. Excuse me. Did I say -- 51, 51. My apologies. I misspoke, 51. There we go. So just for the record, we're show -- can we get the -- can we get that full page showing? Okay. So for the record, what we are showing the witness now is a document titled ANSI/ASB Standard 036, First Edition 2019, Standard Practices for Method Validation in Forensic Toxicology. And the question is, sir, are you familiar with this document?

A. Yes, I am.
Q. Okay. What application does it serve?
A. Well, this is the guidance to laboratories in the forensic community that are not part of the NLCP or do clinical work to basically sort of establish the standards for their forensic work. So they can have a number of criteria and basically sort of outline what the expectations are. They've actually framed this a minimum expectations for validation studies.
Q. And are ANSI and ASB recognized as the leading industry regulators in terms of setting these standard practices for method validation?
A. Yes. In the toxicology -- in the toxicology community, they are.
Q. If I can ask Katy to turn to the fourth page, which has the title Table of Contents. And here, I -- we're going to focus on the eighth section. So we can just blow up the middle. There we go. I think that's it. Yeah, that's excellent. Thank you, Katy. So I'm going to go to 8.2 which reads Bias and Precision. Can you give us a brief overview of what bias and precision signify in the context of method validation?
A. You know, the simplest way of explaining bias is that is a propensity to overestimate or underestimate a measurement consistently. So, you

know, you may have a bias that increases the value of everything or a bias that decreases the value of everything. So those were things are measured and statistically analyzed. And then, you know, you -- you take it from there.

Q. And precision?

A. Precision is -- all right. Let's assume that you have little or no bias. Then the question is, if you repeat the specimen, how often do you get the same number? The precision is how accurately can you replicate what you've studied. So that's another element of it. So you need to have both, you know, an analysis of bias and also an analysis of -- of -- of the precision that you have.

Q. Okay. Moving down to the next reference, what is a calibration model in the context of method validation?

A. The calibration model is trying to determine what your linear range is, you know, in other words, how -- what -- what's the low and high of what your instrument can handle in terms of doing it. And so what you need to do is basically develop a kind of get in your head what the range you want. So then you develop calibrators at the low end, the middle, and the high-end. And then you infuse those into your test and

then you run them. And what you really want to do is when you plot those results out, you want to have kind of a straight line. Now, you want to be able to show, you know, that you're going to get, you know, that if the number -- that the number is actually reflects what you're looking at in a linear way.

Now, can you have some -- some -- some -- some methodologies like immunoassay for example. That's not linear. It's sigmoidal. In other words, you get a low swoop and then it cuts above the -- the cutoff level and then it levels out again. But what you want in the GS mass spec, and on a lot of these instrumentation is -- is -- is having linear. And you want to know what the high-end is and what the low-end is. You know, a lot of laboratories, they can't measure above a certain number. In other words, you reach 10,000, and you'll see in some of these reports, particularly with drugs, is that they'll be greater than 10,000. Now, maybe a 100,000, but you can't tell because you've -- you're not under your range of linear results.

Q. Okay. Moving down to 8.4, references carryover. And you described the significance of that measurement in the context of testing method validation.

A. Yeah. That's always a fun one. In other

words, most of these instruments, most of the analysis are done automated now. So you've got automated devices that, basically, you put all your specimens in a rack or in a carousel, and, basically, you -- you take them one at a time, and a needle comes down or some sampling device comes down, take a part of that specimen out and then -- and put it into your instrument. Now, the carryover is, if you have a very heavily -- heavy dose of a drug or heavy concentration of a drug in one, that even though these instruments are supposed to have a wash between each one of these things, the washing may -- may not be efficient.

So you'll find -- is that, you know, in the ideal world, what you'd want to do is run a negative between every positive. But that's just practically as -- as -- it -- it increases your costs tremendously, so I don't know if any lab that does that anymore. But -- but -- but the idea is that the carryover is identifying, to what degree is this not the -- the -- the result from your specimen, but the -- the -- the heavy -- the high positive that just came before it.

Q. Okay. And moving down again to 8.5, what are interference studies?

A. Interference studies are also, you know, again, are -- you know, when you're looking at --

looking at either immunoassay or GC mass spec, there are cross-reactive compounds or compounds that will interfere with your analysis. And this is more -- more exquisite in -- in GC mass spec. You may have some other compounds that show -- that send off similar ions or identical ions, and they will overlay with what you've got. So you basically need to separate each one of these -- these -- these ions appropriately so you don't have that carryover or -- or the interference factor going on.

Q. And the next reference is 8.6, ionization suppression/enhancement. What does that refer to?

A. Yeah. Again, a very similar kind of problem. There's some compounds you can put in these specimens that will basically suppress the signal. In other words, you'll miss it because it's basically either absorbing it or -- or chemically breaking it down, or whatever. So that's suppression. And enhancement is you basically have something in there that's doing the opposite. It's adding to it. So you have an enhancement. And that all depends, really, to a -- a lot of complex -- complex variables with that. You know, it's sort of medium dependent. You know -- you know, what are we talking about? Are we talking about blood? Are we talking about urine? So you get -- you

get -- and -- and what analysis? What are your derivatizing agents? There are an awful lot of variables with that. But basically, that's what it is, that -- that they recognize that there are other things that can be interfering with your specimen in terms of either making it disappear or making it -- making it seem like there's more than there is.

Q. And could you explain the reference at 8.7, to limit of detection in the context of validation of new testing?

A. Yeah. And this is an essential thing. And it -- it basically is, at what -- what statistical number do you have that basically, you know, you've got what -- what I would call a signal? In other words, what you're looking for is a signal. And then in the background -- look, with all these instruments you've got what's called noise, just the background stuff that's going on. So the question is, if you've got a drug and -- and it's supposed to come off and be a minute and 15 seconds, and then -- and then -- so you're waiting around for a minute and 15 second, and blip, you got something. The question is -- you've also got a lot of little blimps. And what's the ratio between the big blip and the little blip? So you need to be able to have a ratio of probably, you know, a

four-fold increase between the signal to what's called a background noise. And that was what the issues you run into when you get to an LOD, is that you just basically have too much background noise which can't be cleaned up. It's a theoretical limit on -- on how you can differentiate what you're looking at from what's just in the environment.

Q. Okay. And this reference at 8.8, the last in the section, the lower limit of quantification. What's the significance of that in the context of validation of new testing?

A. Similar, but different issue. In other words, when you just want to try and find something qualitatively, you can get a lot more sensitive. But if you're trying to actually measure how much it takes, there is a -- it's a higher level. You need to have a little bit more, not just what your limit of this -- what this instrument can do, but you need to have a comfort zone between the LOD and the LOQ, the limit of quantitation. Because if you want to have a quantitative value, it can't be the same as the LOD. I mean, it's just not going to -- it's just -- well, theoretically, it shouldn't be. So you need to have, you know, a -- a -- a comfort level between those two things.

So the LOQ, and in fact, in some of these programs, even in the NLCP, they define the LO -- LOQ and LOD of being -- having to be -- if you have an LOD, you need to have an LOQ that's 40 percent higher than that. Again, you know, you -- you can get much higher. Or the flip side is probably more -- more realistic. If you've established your LOQ, then the question is, you know, you need to have it -- be able to go down four-fold to get to your LOD. Again, a little bit more theoretical than you need. But, again, just to explain what that is all about. But the limit of quantitation is -- is a number that is -- is -- that -- it's typically used for most of -- most clinical labs and most -- most forensic labs. And the LOD is kind of like your theoretical outlier that you -- that -- that's -- this is pushing the -- pushing the metal -- pedal to the metal, this is the best we can do and this is what we're going to find.

Q. Thank you. Do you have any opinion as to whether any confidence can be placed in the dried blood spot PEth testing conducted by USDTL without the validation criteria we have just read?

A. Well, you know, I'll tell you something. No, I don't see how you can. I mean, the -- the -- the validation studies for this particular DBS is critical

because it really isn't have any -- any outside proficiency testing, and it's not an FDA-approved test. Now, the FDA justifies it saying, well, you know, these are not complex and they're simple and these are lab developed and tests. But that's really not the truth either anymore. This is not a simple test, this a complicated test. So you need to have even more validation as to how this is done.

And I -- I -- I'm going to go all sidetrack here for a second. You know, when DBS first came out, I was really excited about it. I was all in. I said this is great. And I -- my thought was that this could be used for looking at THC, that you can take blood specimens and then get a good quantitative value of what's in the blood. And the more I got into it, it's like, gee, this isn't -- this isn't -- this -- this is like Theranos. This is like just a drop of blood. The more you get into it, the more you see problems. And I -- just in a nutshell, I got to tell you something. There's a reason why there's only one lab that's doing this, because they're the only ones who's got the guts to come out with this. There's just -- the DBS thing has got more variables than you can shake a stick at. And the more I have gotten into this particular case, the more I've realized that it was a good thing I

steered away from it. Because, again, you got all kinds of variables with the dried blood spot testing and you need to have those all validated, one way or the other. Of course, we'll probably get to -- into it in a little bit, but, you know, like -- you know, how much blood do you have? What's the hematocrit? You know, what's -- you know, all -- all -- all those variables. So -- and I don't want to get ahead of myself too far, but that -- that -- that's my thought about it.

Q. Okay. Well, you made a reference, and I was going to ask you about this later, but you made a reference to Theranos. Could you elaborate on what that is a reference to?

A. I think we all remember the young lady, Elizabeth Holmes, who basically was promoting this concept that all you needed is a drop of blood and you could do all these clinical tests in the world. And what really struck me about that, and I almost was retained to try to do an evaluation of that, but the thing fell apart before I got in -- got into it, which, again, I was kind of -- felt fortunate. But it was -- because something was like, how could this be? How -- how is this -- what was -- what was amazing to me was how many, what I considered to be smart people, fell

for that hook, line and sinker. So basically --

Q. You may be presuming too much knowledge on your auditor's part. So I don't know that anyone knows who Elizabeth Holmes is and what the background is.

A. Elizabeth Holmes was an entrepreneur that was promoting this -- this technology that basically was the idea that you don't need to draw blood. She had a phobia of needles. She didn't like to get a blood draw. And she figured, look, this is so simple. All we need is a drop of blood and we -- we've developed a method here that can do all kinds of clinical tests, from A to Z, and give you a very quick result with no fuss, no muss, no sample handling, and no needles. You know, you could do this at home, you can send it in to the lab. And again, it was -- it was like it was too good to be true, as with most of these things are. But they -- but what -- what surprised me was that you had labs, you know, you had like CVS, you had even some of the big clinical labs saying they're looking into this.

And then I think CVS committed a lot of money to it, and so -- so did Walgreens. And they raised a couple of a hundred million dollars or so to -- to finance this thing. And it basically was built on a dream. It basically was fraudulent. But, again, this is something that, you know, the -- the FDA was kind of

given the runaround. They were -- they were -- they were going to look at it, but they never got a chance to really take a hard look at it. And, of course, the whole -- the whole house came crumbling down. You know, it's an interesting story. But, again, it was the idea that we can do this all with just a drop of blood. So I had -- I felt like there was a similarity here because this is something that -- DBS sounds very sexy. It sounds really attractive. And what could be wrong other than when you get into the details. And it's the details where these things get to real -- really be tricky.

Q. Okay. Now, you've given us an overview of validation criteria recommended by the industry regulators, starting from bias and precision on down to lower limit of quantitation. Based on the limited information that you've received or specifically the litigation package from USDTL, do you have any concerns that any of the validation criteria have not been satisfied?

MR. KASSIN: Mr. Burdette, let me object for a second. I think the foundation of question in this situation should be, has he reviewed the validation information on the PEth test at USDTL, and after that, he shouldn't be rendering an opinion without having

established a foundation as to what he has reviewed.

Q. I can rephrase the question. Based on the information that you have received, do you have any concern as to whether USDTL satisfies precision requirements?

A. I can't because I have --

MR. KASSIN: Hold on. Let me just restate the objection. I mean, I'm looking at his opinion letter on Union Exhibit 50, and he can say, "I state -- he says, "I can state with high degree of certainty even without the opportunity to review laboratory analytical results, quality assurance data, standard operating procedures for the labs." So he wants to render an opinion, I think the foundation has to be, what have you reviewed? I mean, it's a rather broad question based on what you reviewed, but at least as of his opinion letter of January 30, 2020, he hadn't reviewed any of that. So before he starts opining without a foundation, let's find out what the foundation, if any, is.

Q. I think the standard approach is to ask for the opinion and then to ask what he based that on, but rather than prolong the debate on the issue. Well, let me ask him to -- let's go back to Union Exhibit 51. If we could turn, it would be the 13th page of the PDF

which is paginated at the bottom page 8. Okay. And I'm going to refer the witness to 8.2.2.3, under general, that addresses percentage of CV, and I'm looking at it, the second paragraph, shall not exceed 20 percent. And then a reference in the second line there for certain analytical methods e.g. blood alcohol analysis should require a much lower coefficient of variation, less than or equal to 10 percent CV. Is this -- could you explain what CV is and what these percentages referenced?

A. You know, the coefficient of variation is basically, you know, kind of -- is a -- is a hybrid between, you know, bias and -- and -- and precision. You know, how -- how -- you know, what -- what's the variable between you run a number of specimens, how -- what's that number going to be? It's usually marked in a percentage basis. And the -- and the issue that I have is I don't have any CV data. I have no idea what their CV is for any of this. I don't think any have been provided. So, you know, to -- to the degree that -- you know, my -- my view was that, just based upon what I see, I have a problem with this, you know, because I haven't seen any of the supporting -- support for the precision or accuracy, or even with the CVs are of these things, you know, that -- that -- that are

being done here.

Q. If you could turn -- if I can ask Katy to show us Union Exhibit 16. Okay. For the record, what we're showing here is a USDTL litigation package for Choice Lab referencing specimen ID for Michael Danford. If we could move down to the fourth page of this document. And if you can magnify that a little bit.

Now, here, we're showing, sir, an initial test with a 69 quantitative result and a 98 for a second quantitative result using the same specimen. Is there an indication here that there's any difference in the testing methodology used between this initial test and the second test?

A. No, this should be -- you should prefer -- you should have results within 10 percent, and this clearly is going from 70 to -- to -- to 90.

Q. Does that -- so does that present concerns with respect to whether validation for precision has been satisfied?

A. Yeah. So yes, it does. And -- but -- and let me just emphasize this. This isn't about, is it there? This is not a qualitative test, this is a quantitative test, and these quantitative results are out of whack. So that's one reasons why I have a problem with the precision. If you can't get the

precision down, don't go around reporting out quantitative results.

Q. Okay. I'm going to go through a few exhibits and I'm going to do this quickly, so we don't take inordinate amounts of time. And the question for each one is going to be whether you consider these to be reputable sources for toxicological analysis. And we could put up first, Union Exhibit 1.

A. Oh, yeah. This paper to me was a real eye opener. This -- this, to me, I think is one of the most significant exhibits you've got, in terms of a description from our European friends on how you should be doing this, and what you need to do to validate this DBS stuff. Again, it's a very thorough paper. It's -- it's -- it's comprehensive. And -- and again, it -- it -- it -- it, to me, raised a lot of issues I wasn't even aware of. So I would say that this -- I think this is a very useful thing to -- to look at.

MR. SEHAM: Okay. And if you could now put up, Katy, Union Exhibit 26.

(Union Exhibit 26 marked for identification)

Q. Are you familiar with this study, the effect of temperature on the formation of ethanol by Candida Albicans in blood?

A. Yes.

Q. Okay. Is that a reputable toxicological analysis?

A. It is.

MR. SEHAM: Okay. And if you could move to Union Exhibit 27, Katy.

(Union Exhibit 27 marked for identification)

Q. Are you familiar with this? I'm going to abbreviate the first word to PEth in Blood as a Marker of Chronic Alcohol Use: A Systematic Review and Meta-Analysis.

A. Yeah, Also a very, very, very useful paper. And -- and remember, again, these are looking at, you know, again, a different sort of use or -- or -- or -- or qualitative as opposed to quantity. I mean, I'm not raising any issues. I don't think, in my opinion, that phosphatidylethanol is -- is -- is -- is -- is not a marker for alcohol. The question is how much and how did you measure that?

Q. Okay. If we could bring up, Katy, please, Union Exhibit 50. Okay. Do you recognize this as an expert report that you submitted in this matter?

A. Yes.

Q. And if we could go down, please, Katy, to page 4 of this document. Now on page 4, you referenced eight negative tests utilizing the EtG methodology, and

then a ninth EtG that was deemed a "positive" at the quantitative level of 112, and then -- that might have been actually 117. But then the following is accompanied by, or the following reference is accompanied by an EtS negative on the same date. Now, did I read that correctly in terms of the testing sequence?

A. Yes.

Q. Yeah. Okay. Now, can you --

A. So --

Q. I'm sorry.

A. Go ahead. Go ahead and ask the question.

Q. So I was going to ask just in terms of foundational questions. Can you describe the EtG methodology?

A. EtG methodology can -- is -- is -- can be done in a two-step process. It can be done on an immunoassay and then have a GC Mass Spec follow up with it. EtS, very similar. I'm not sure -- I'm not that familiar with the immunoassay of it, but I know you can do it with a GC Mass Spec. So I assume there's an immunoassay for it out there too.

Q. Okay. Is EtG or ethyl glucuronide a sensitive test?

A. It's exquisitely sensitive, but that's the

problem with it, it almost works too well. That's at least I think a lot of medical boards found out. You know, again, you've got this thing of people suggesting that they got it from a rotten banana, you know, the fermentation from fruit. You know, so it doesn't take a lot, it takes very little. And then you can remember, alcohol is all around us. I mean, you bake bread, I mean, that -- what you're smelling is a -- is a -- is a form of alcohol, you know, so you've got all these things going on that's the source of it.

And as I said, this was the big headache that NMS had because I think that, you know, they relied on the medical boards to establish what the cutoff was, but then they turned around since you couldn't sue a medical board because they have immunity, the plaintiffs in this thing went after the laboratory and the laboratory said, hey, we didn't tell you where it came from. We just told you it was there. And I don't think it was anybody questioned the fact that their -- their actual analysis was right, is a question that they weren't -- they're not being in charge with -- with interpreting what the results were. And again, I think that was a -- it's a smart thing for a laboratory not to interpret where it came from, but just say here's what we found. You interpret it, you know, and

that's kind of what MROs do. So to -- to that -- to that -- to that degree, so --

Q. Okay. Katy -- I'm sorry, I don't mean to interrupt.

A. I'm sorry.

Q. Katy, we can take that exhibit down so we can have more of the Brady Bunch visual. I know you've touched about -- on it in passing in your testimony up to this point, but in this immediate context, can you define for us what the term cutoff level means in the context of forensic substance abuse testing?

A. Yeah. It basically is an artificial law and at which you basically make a -- a determination. Above a cutoff means you're going to do one thing, below a cutoff means you're going to do something else. Typically it means above a cutoff it's going to be reported as a positive, and below it's going to be a negative. And those things are set not by the theoretical limits of the instruments, although, you know, historically that had been the case for many -- because we didn't have them -- we didn't have a very good sensitivity. But now with the kind of almost unlimited sensitivity that's out there, all these methods have cutoff levels, you know, even EtG. I mean, even in hair. I mean, I just saw an article that

told -- told me that the EtG cutoff in hair should be like 30 nanograms per -- and remember, in hair we're talking about weight to weight, not -- not weight to liquid or -- or, you know, so you're basically talking about picograms per -- per milligram or nanogram. So any event that -- that the -- so the cutoff has -- and then there's always been a big debate about that.

I remember in the early days of the federal program, paradoxically, the issue was they didn't want to have too sensitive a cutoff for THC because they thought they wouldn't have any workers left. They thought everybody would be knocked out. It turned out that wasn't the case. That the actual cutoff that they used in the early days in this program, was so insensitive, nobody was getting caught. So they had to ratchet it down. So again, that -- that -- that's what -- that's what it is. Again, it's a policy decision, but it's an essential one.

And that was one, again, one of -- one of my criticisms of the horse racing industry. They basically just didn't follow the science. They basically followed the instrumentation and they just pushed the instrumentation as far as it could because there weren't that many positives, and so the laboratory that could find a positive was like, you

know, waving a flag. The problem was that -- that it could have been an innocent thing like the -- the three horses in the trailer, or -- and now we're finding that the -- that the -- the stalls, you know, are contaminated, the grooms are contaminated. So, you know, so that was the idea. That's too sensitive. And I'll tell you again to reiterate this, you keep lowering these cutoff levels, and you get everybody positive. You can knock everybody out of these rehab programs if you wanted to with just -- just -- just -- just going through the sensitivity that the instruments are capable of doing now.

Q. You referenced the federal program Part 40. Are the concept of cutoff levels used across the board for all the substances tested under that program?

A. To my knowledge, yes.

Q. Yes? Okay. And then under that federal program, in terms of cutoff levels, can laboratories choose their own cutoff level under the federal program, or are those fixed cutoff levels for each substance?

A. You know, it's a -- the federal program's a two-edged sword. I mean, you cut -- this is what they want, and this is what you have and cannot, with the exception of the NRC. The nuclear regulatory program

built a rule that is saying, our cutoff levels are you can go lower than that if you want, you just can't go higher. So they said this is sort of the minimum standard. But if you -- if a utility wants to ratchet down, they can. And the early days of the program, some of them did, most of them now basically have just settled on the existing established cutoff levels. But in the DOT program and the HHS program, no, you're stuck with what they tell you it is and that -- and that's it, which in some ways is helpful for the laboratory since they, you know, can have just one validation and basically, you know, regulate it at -- at there for -- for the same for across the board.

Q. With respect to EtG alcohol testing, is there similarly a uniform cutoff level that's used?

A. Well, here the problem is, is that there are a number of different specialty boards that established what that is, and -- and maybe even some private employers, but most of the time I see this in medical boards, legal boards, and -- and -- and employers. And generally, there's, you know, in the early days they were doing 100, then they were doing 200, and then after this the -- the -- the Fukushima and the class action suits against NMS, most of the -- most of the medical boards have come back and have raised the

cutoff level to maybe 500 or 300. I mean, did -- so there's -- I don't -- I don't think I can identify what the consensus is for that. And again, I'm not pooh-poohing ethyl glucuronide, it's really very useful, but it's exquisitely sensitive. And if you're going to go way down, you're going to get everybody, and then -- and you -- then just because of the nature of alcohol.

Q. Okay. And in your experience, what's the most common cutoff used in terms of differentiating between a negative and a positive?

A. Somebody told me that they -- they think it's around 250 or 200 or something like that.

Q. Now, what cutoff level did Quest laboratories apply to Mr. Danford's test?

A. I don't recall. I don't recall what their cutoff level was.

Q. Okay.

A. Although I do know that the big problem with this testing from the very beginning was the fact that they didn't make a creatinine correction. In other words, this is the other variable with -- with -- with -- with EtG, and this has been the problem in -- in drug testing. If you -- you can -- you can -- your urine varies in its concentration fourfold over the day

without doing anything. Just from the morning urine, to the afternoon, to the evening, you'll see a big difference in the concentration. The more concentrated that urine gets, the higher the creatinine is. And the more -- the higher the creatinine is, and the more concentrated it is, the higher any drug -- drug or metabolite is going to be.

Most drug users go the opposite direction. They want to dilute their urine. They don't want to concentrate it because that increases the chances of detection. But so frankly, the -- the whole -- the whole bug-a-boo with this case is that this -- this creatinine level was above average, was above the norm, and it should have been corrected. And then if it was corrected, it would have fallen -- as I recall, and I remember what the numbers, I don't want to guess, but I'm thinking -- I'm -- I recall that it would have fallen below what the cutoff level was at the Quest lab.

(Union Exhibit 52 marked for identification)

Q. Okay. Now let's -- we'll come back to the creatinine because you -- you're anticipating me a little bit. But what I'd ask Katy to do is bring up Union Exhibit 52. Are you familiar with this analysis led by Michael G. McDonell?

A. Yes.

Q. And you would consider this a reputable publication?

A. Absolutely, yeah.

Q. Yeah. If we could move down to the sixth page of this document. Okay. I think I need just to -- well, actually, maybe slightly up just a little bit. That's fine where we are. If we go to the last paragraph, there's a statement here, I'd say four lines down starting with "therefore." Are you with me, sir?

A. Let's see. Thank you. "Therefore, cutoffs of 200 nanograms per milliliter and above are recommended for use in settings where minimizing false positives is essential." I don't disagree with that.

Q. Okay. Would you go so far as to say you agree with that?

A. Yes.

Q. Okay. Thank you. So I'm going to -- if we can take that down so I can see the full gallery of people again. So you were explaining, if I could have again briefly, creatinine is a protein or is a phosphate --

A. Breakdown for that -- yes. And -- and you basically produce a constant level of it, which is actually a reflection of what you're going to find in

your blood. And everyone, it's generically determined as to what the creatinine level and blood is. And so basically, when -- when you go into -- for doing a -- a urine drug -- urine test or you go in for just a clinical evaluation of your kidneys, one of the things they want to look at is what your creatinine and clearance is. So it's -- everybody has got kind of a constant level of it, you know, having a high or low creatinine level kind of give you an idea of -- of whether the kidneys are functioning properly or not. So once again, we have a -- a way above average here for Mr. Danford, which I think is just due to not kidney problems, but basically just of significant dehydration.

MR. SEHAM: Okay. In order to ask the next question, I have to set up -- confirm that I have the right page referenced in the document. So I'd like to ask for a five-minute break so I can make the transition smoothly. Okay. Thank you.

THE REPORTER: We're now off the record at 11:37 a.m.

(OFF THE RECORD)

BY MR. SEHAM:

Q. Okay. Very good. Now, I'm going to ask Katy, if you could bring up the document that I

identified during the break. Okay. So we're looking at, just for the sake of the record, Company Exhibit 9. It looks like it's page 112 in terms of PDF numeration. It's 111 in terms of hand scroll at the bottom. If we can magnify that a little. Okay. And again, for the sake of the record, I'm noting an EtG quantitative result at the bottom of 117 nanograms per milliliter. A creatinine measurement at the top of 256.9 mg/dL. And the question, sir, I have for you is, putting to one side the appropriateness of using 100 cutoff, 100 nanogram per milliliter cutoff as the definition of positive. Putting that to one side, does the information on this page raise any questions as to whether quantification in this case should be deemed as in excess of 100?

A. No.

Q. In terms of creatinine concept.

A. Yes. But you -- you need to -- with these types of tests, you need to adjust how concentrated the urine is. So if you adjust that 250 -- 254 over what an average creatinine would be, maybe like 120, that -- that 117 would be significantly lower. It probably be about 80 or so. Again, I'm just -- just -- just roughing it out. So again, that -- that -- that I think is -- is one of the fundamental issues with this.

And of course, it's also suspect, although not definitive, that there's no ethyl sulfate in this -- in this specimen. Usually these things go hand in hand, like brother and sister. And so for whatever reason, we have this marginal if -- if -- or arguably negative ethyl glucuronide and then there's no ethyl sulfate.

Q. Okay. So let's lay some further foundation for that. Your chart in your expert witness report refers to the EtS test on May 1. Could you describe the background of ethyl sulfate and what are the advantages or disadvantage of the EtS methodology as compared to EtG?

A. Yeah. These -- both of these things, EtG and EtS, are basically, you know, relatively minor metabolites of alcohol. So they're direct markers of alcohol. But again, alcohol is everywhere. So the question is how much? So EtG is -- is basically a sugar molecule hooked up to the ethanol. And so what happens with EtG, the -- the difficulty with it is that you can -- if you bring it into the laboratory, you can basically have it eaten up by bacteria. So you need to put some sort of -- either freeze the specimen quickly or get rid of it because the EtG will disappear. The benefit of EtS is that it doesn't. It's a sulfate. It is not going to be digestible by most bacteria that

you're going to find in urine, so it's much more stable on the shelf than EtG. So both of these things, you know, again, kind of go hand in hand. So this is -- this just jumps out at me that there's no EtS here at all.

Q. Is that a common -- is that a common practice to test a single urine specimen for both EtS and EtG?

A. It -- it is. I mean, again, you know, again, Quest does an awful lot of this stuff. They know what they're doing. So, you know, I would say that -- again, I'm not sure I could testify that every lab does it that way. But, you know, EtG, EtS are both -- both, you know, very helpful to have together because once again, they're just -- again, it's not definitive, but it suggests there's something going on here.

Q. Where the EtS is negative, does that suggest any interpretive approach to the EtG?

A. Yes. Well, again, you could probably, you know, I don't know what their cutoff for EtS is. But whether -- the theory would be, if that was positive, they'd also have to make the creatinine correction for that. And I'm not even sure what their cutoff -- they don't post what their cutoff is for EtS. But in any event, the fact that they didn't report any, which means, you know, that it was whatever that cutoff is,

it's below that. But they did report the EtG. Because again, they're starting with, I would say, a -- a somewhat overly aggressive cutoff of 100 in all of this to start with. And again, I don't -- I don't know. You know, again, this may be worthwhile in -- in a setting where you just want to flag something, but it's not going to be something that's going to be a -- a decision-maker. So that -- that's -- that's my --

Q. Okay. So how would you characterize the EtG and EtS results based on this May 1 urine collection?

A. Well, I would call them negative and that's that.

Q. Both the EtG and the EtS?

A. Yeah. Of course the EtS -- the labs agreed -- you know, saying it's negative. So I'm not -- but the EtG, I think that I would say that my sense is if -- if they -- if they were told that they need to do a creatinine correction on this which I think is good practice, that would've -- it would be negative as well, or they could just raise it to the more standard of a 200 nanogram cutoff.

Q. In terms of basic forensic principles in the toxicological environment, when two different testing methodologies are applied to a single sample yielding one positive and one negative, how is the overall

result treated?

A. Suspect. I wouldn't say it's canceled. I wouldn't say it goes away, but again -- and again, there may be variables if you look at the -- at the -- at the process a little bit more carefully. There may be differences in metabolism. There may be some reason -- remember that the EtG is only borderline even at -- at a very sensitive level. So the EtS, you know -- would've -- would've been normal or would've been just a negative also. So again, I don't -- I would not want to say that my -- my view is that, I would view these as negative tests. But again, per se, just because one's positive and one's negative. I mean, for example, if the EtG was 300 and there was no EtS, I'd be fine with it. I'd be good with that. But again, the EtG being at that low level is suspect already. And then it's further suspect by the fact that it doesn't have it's -- it's sister, ethyl sulfate nearby.

Q. Well, I was referring to in terms of forensic practice recognized in the broader field as reflected in Part 40, if there's a positive immunoassay, far in excess of cutoff, but there's a negative gas chromatography mass spectrometry result. How is that result treated?

A. In -- in all federal testing when there's a

discrepancy when you have a two -- two method methodology and one of them comes up negative, that's it. We're -- we're done. We're not going to move on with that. So regardless of what the drug is, and -- but if it's there's -- if it's a dual method, even a screening confirm and if the screener confirm doesn't work, that goes away. That step -- that becomes a canceled test.

Q. We've now discussed the EtS and EtG test based on the urine collection of May 1, 2018 for Mr. Danford. We now move to the PEth testing conducted using dried blood spot specimens that were collected on May 9th. And can you briefly describe, and this may overlap with prior testimony, but just to have some context here, can you briefly describe the nature of a PEth test?

A. Yeah. PEth phosphatidylethanol is a component of the cell membrane in red blood cells, along with about 50 other fatty -- fatty -- fatty acid esters that -- that faithfully make the -- make the structure of what the cell membrane is. And it turns out it was discovered a number of years ago, that in the presence of alcohol, that phosphatidylethanol, and a phosphate -- phosphatidylestrate basically generates this phosphate -- well, it generates this metabolite of

-- of -- of-- of alcohol, the phosphatidylethanol. Again, relatively low levels, but again, there's a good correlation between the phosphatidylethanol and exposure to alcohol. But it's all relative and how much exposure and what -- what -- what we are measuring here.

Q. Okay. Katy, you could drop that document so we can all see each other. What is the detection window of a PEth test?

A. Well, the detection window depends on how much you consume. But I basically, I think we're looking at, you know, maybe a -- a week or so of -- of -- of -- of being a positive test for, you know, given the -- the numbers that I see out there in the literature right now, I also understand that the -- that there's a elimination half-life, about 5 to 10 days, depending on what literature you look in. So that -- that's kind of where we're at with this.

Q. Okay. The May 9th specimen collection in 2018 for Mr. Danford consisted of obtaining dried blood spots. Is that the customary manner in which PEth testing is conducted?

A. The only place I know that does it is US Drug Testing Lab. I mean, I know that the Europeans have been looking at this, and they're the ones that have

come up with all kinds of things. But they're even -- their interested in this and application is not for forensics, it's for clinical testing. So that's -- that's so -- the -- even there and -- and I understand that there's now a proficiency program in Sweden, but the Europeans tend to be ahead of us on some of these things. They are in this area, but even here, this is not a forensic test for them. This is something that would they would use, for a clinical application. And dried blood spot testing, is used rout -- routinely with neonates, because you don't have to poke the kid and you get -- you get some -- you get a -- you get a qualitative result is what they're looking for in terms of metabolic issues.

So again, it has a lot of -- a lot of merit. It just isn't the appropriate or correct collection device to use for PEth testing for alcohol. And in fact, there are new devices out there that kind of eliminate the issues that made dried blood spot testing almost obsolete. There's a new gizmo out there that's a volumetric pipette that basically eliminates the issues that we're going to be talking about in a minute, with a hematocrit effect. So again, this is sort of outdated and again, never really wildly adopted, even though I know a lot of laboratories looked at this.

Now again, some laboratories are still looking at it and maybe still doing it, but not for alcohol. For example, I know a laboratory that's doing it for looking at testosterone levels in athletes. And I know that we are all -- Doping Association was looking at it, for again, steroids, but not alcohol because it's not -- it's not the appropriate thing because ethanol -- phosphatidylethanol is again, a different kind of animal than these others. First of all, there are about 40 different homologues of this thing, which means they are identical with one or two carbon differences. So there are a lot of variables with this thing. And of course, when you get into it and you'll see the papers that I talked about, and how -- and how you validate these things, there's all kinds of problematic issues with the dried blood spot.

First of all, I wasn't aware that you have the thing called a volcanic effect. In other words, if the two drops or one drop, it doesn't fill out the whole spot, you get a high concentration. But the most significant and an issue with this is that with an individual that has a high creatinine level, they probably have high hematocrit. You know, how many red blood cells are there, because it's being -- they're being pushed together, because they've lost a lot of

water. Now, all the methods basically say that at a minimum, you need to figure out what that hematocrit level is to get an accurate dried blood spot test. And nobody could tell me based on everything I've seen on what Mr. Danford's hematocrit level was even though we know he was dehydrated and we know we have this excessive amount of creatinine. So there's neither no adjustment, no attempt to do. And there's all kinds of papers on how you can estimate it or how you can deal with it. But it just was ignored in this case. So again, I think that that's one of the reasons why we had the ethyl glucuronide and -- and also the phosphatidylethanol.

Q. Okay. So other laboratories are using venous blood or whole blood for their PEth testing?

A. Yeah. Most of the time it's just a whole blood specimen, you know -- not -- you know -- you know -- so it is venous blood but it's all, you know -- not as opposed to plasma, they're basically looking whole blood.

Q. I may use the acronym DBS for dried blood spot. Is DBS PEth testing approved by the FDA?

A. Not for PEth testing. And I'm not -- and I'm -- and again, I'm -- I'm sure it's probably been cleared for test -- testing for clinical testing for,

you know, neonates and other clinical parameters, you know. But again, I don't think anyone looked at -- at PEth testing in any kind of rigorous kind of manner, and -- and if they did, they probably wouldn't approve it.

Q. Katy, we could post Union Exhibit 11, please. For the record, we are looking now at Union Exhibit 11, Dried Blood Spot Collection Instructions. Sir, are you familiar with this document?

A. Yes, I am.

Q. All right. And do you know if USDTL has any training or certification program for collectors of dried blood specimen samples?

A. I don't believe they do.

Q. How does that contrast with the United States Department of Transportation training requirements for Part 40 collections?

A. Well, it's interesting because one of the weak spots in all drug testing is the collector. You know, and I think DOT has been struggling with this since the beginning of the program. And DOT has a rigorous thing and this is just -- just catching urine. This is not a really complicated thing. You know, just, you know, have somebody go out there and get a urine, you know, and then -- and then -- and that

requires a great deal of -- of -- you need to have mock collections being supervised by somebody who knows what they're doing, keep -- maintain the records of those collections, and if they screw up, they basically have to be retrained again. So again, it's a kind of a rigorous regiment for just being a -- a -- what I call a urine catcher. And of course, you know, their challenges is not, you know, any -- challenge is also the paperwork and all of that. So again, to have something where there's none where something is -- is somewhat more complex as this is a little bit, kind of, surprising.

Q. Okay. All right. If you could -- focusing back on Union Exhibit 11. After the description of the materials that are contained in the USDTL kit, it goes on to say in the first full sentence, "Dried blood spot collection is a donor performed collection. It may be beneficial for the collector to assist the donor or perform the collection completely in some cases. In either case, it is imperative to follow the steps carefully to ensure a proper specimen collection." Why, sir, is it imperative that a collector follow the protocol set forth by a laboratory in terms of obtaining the testing specimen?

A. Well, if they don't, you're going to have all

kinds of unknown variables. You're not going to know what happened, you are not going to know that this was done with any kind of precision. And as I said, the literature indicates there all kinds of issues that happened with -- with a dried blood spot. So, you know, and even -- even for -- you know, a donor can do it. And again, remember what we're talking about here. We're talking about a -- having an accurate how much is it, not is it there. So, you know, for clinical testing, it's like, is it there or isn't it there in mo -- in most cases. And so here, you know, having somebody who's just going to wing it or basically, you know, kind of do what they want without any kind of monitoring or training. You know, it really just opens a -- a can of worms for everybody in this. The labs, the company, the -- the -- the -- the -- the providers. This really is just something that adds a whole degree of level of uncertainty that's really remarkable. So --

Q. If you could move down to -- and Katy, I should ask first, move down to point number 10. There you go. And thank you. Here, I'll focus on the latter part, which is all bolded and proceeded by note in capital letters. "Note: Allow the collection paper to wick blood out of the puncture. Do not press the

finger against the collection paper, and do not layer successive drops." Why is it important to wick the blood out of the puncture and not press the finger against the collection paper?

A. Well, first of all, you'll have a better sense of what the -- how much blood you have. Now, if you are going to press something, you don't -- really you've lost idea of what the volume is going to be. Second of all, if you touch this thing with your skin, you -- who knows what else you're introducing to it. You know, you've got -- you know, you've got alcohol on your fingers. You know where -- I don't -- not -- not necessarily just from, you know, the sanitizer, but you -- you've -- there are a whole lot of other variables involved with that. So again, it really is something that the ideal world, you basically just have the blood fall free and drop onto this card and then, kind of, be -- hit it in the center and then hope it -- hope it -- it fills -- fills the circle. So once again, and remember with Mr. Danford, I bet that blood got thicker than my blood at the moment or -- or your blood. I mean, it's again, it's kind of concentrated because again, he's relatively dehydrated.

Q. Would you concur with USDTL's characterization of this collection protocol is

imperative to the integrity of the collection and subsequent testing process?

A. Oh, sure. Yeah. No, I -- I do agree with that.

Q. Now, the latter part of the bolded language we were just reading references -- there's an injunction there, "Do not layer successive drops." Why is the avoidance of layering successive drops important?

A. Well, because again, it may not spread out on the card and -- and you're basically going to double the amount that you're testing. So, you know, if you got one drop, that's one thing. But if you have two drops, well again now you've got double the amount of red blood cells there and probably -- and theoretically, double the amount of -- of phosphatidylethanol that you're going to be analyzing. You know, given the same -- the -- the -- the same distribution of -- of the blood on that paper. So again, these are -- and -- and then when you stop and think about that for a second, that in some ways is what's going on here.

Even if there's -- let's assume it's just a single drop. Because that blood is more concentrated, you're getting more red blood cells in that, you know, the --

then the paper isn't going to be able to figure it out. They're just going to absorb what it gets. So that's why I think that this is -- it is imperative. But again, there are more than just that issue that's here. But that is an issue of not being able to touch this thing. And certainly, you don't want to double it up because that's just clearly going to be increasing or -- or increasing variability into your quantitative results.

Q. Okay. Does that relate in any way to the volcano effect that you were referencing earlier?

A. Yeah -- yeah. No. It -- it is. It kind of, you know, you think about a volcano, you've got a hole in the middle and you've got this sort of crust around the outside and then -- then -- then the lava flow outside of it. So it's not an -- it's not an even distribution. You know, it's not something like, you know, if you -- you just took like an ink and put it on there, you know, you'd have the ink and -- and the ink would separate into its parts, but it's nothing like you see with -- with blood on these paper things. Now, you will have this -- again, something has been described as a volcano effect and it has some, sort of, illustrations there of kind of what some of the issues are in terms of when you have the satisfactory and when

you don't have a satisfactory collection.

Q. If we could, Katy, slide down to point 11. In the second half, it says, "Avoid 'milking' the finger as this will cause more interstitial fluid to surround the puncture and will speed clotting (will stop -- excuse me, will slow/stop the bleeding). Do not layer successive drops." Why is the avoidance -- in your view, why is the avoidance of milking the finger by the specimen collector or by the donor important?

A. Well again, that's a -- just another area of variability. In other words, if you actually going to squeeze the finger, kind of like milk it, you know, you're basically going to take a lot more extra cellular fluid as opposed to what you want, the red blood cells. And again, it just changes the dynamics and the hemodynamics, of the whole -- the whole -- the whole shooting match. Again, I don't -- I don't know what all the results are going to be because I don't -- I don't know -- taken a hard look at that. But again, that they've -- they've made the point that you -- that -- that's not -- that's a no, no. That you really shouldn't do that.

Q. Okay. If we could, Katy, move down to point 15. Now, just for the record, I'll read that quickly. It says, "Place specimen card in drawing box, seal the

box with a long specimen seal from the bottom of the Custody and Control form. If you don't have a Custody and Control form, there is a tamper-evident seal provided in the collection bag. The seal should reach around both ends of the box and effectively fasten both ends shut." Is this use of a drying box into which the card is sealed consistent with the DBS protocols with which you are familiar?

A. Well, one of the things that I -- I've -- I've had a concern about is that it seems that every paper I've written -- read has emphasized how important it is to have a three-hour drawing time. And, I -- you know, again, whether that's in a box or not in the box, but I think that was -- that's an essential thing also to have here. And then that, you know, and again, I have a hard time visualizing a lot of these collections sites, setting aside three hours to watch -- watch paint dry, and that's kind of what you're doing with this. So again, I don't -- don't have the expertise on terms of other methods of -- of drawing these things or what you ship them in, but again, I think that time is -- is a -- is a main issue here. The other issue that I think that's come up has been the idea of -- they also emphasize don't use plastic, yet they send a plastic bag to put these things in. Which again, it's

like co -- confounding to me. I'm not quite sure where we're going with all that.

Q. Okay. Well, you're anticipating me again. So let me try to catch up with you. Katy, if we could slide down to point number 19. And I think this was what you're referencing. Here there is a special reference in bold at the bottom of point number 19, "Caution: Do not place inside an airtight plastic specimen bag." Would you consider this protocol as imperative to the integrity of the testing process?

A. That's an essential, because again, they're talking about the how -- how significant it is to make sure these things are dry. If you're going to put it in a plastic bag, I mean, come on. I mean, that's going to just -- that's going to slow down or stop the -- whatever drawing is going on. So again, that just to me is -- is -- I mean, I agree with that statement.

Q. Okay. Are you familiar with the use of desiccant pouches or sachets in the context of DBS testing?

A. Well, once again, the whole idea of this is just like when you get your pill bottle from the pharmacy, you know, you're going to have a desiccant in there because you don't want to have moisture, you know, mixing in with your -- with your medications.

And that's the same thing here. You want to get the moisture away from it. So you're going to want to include something that will keep -- make this thing as dry. And again, even though it may be dry here, but you know, you -- you send this, you know, off to -- to the Post Office or FedEx truck, you know, there -- there may be moisture in the air, you collect this in the summertime, it's -- it's a lot more humid, so, you know, the desiccant thing is -- is an important element to this.

MR. SEHAM: Okay. Katy, if you could take down this document and put up Union Exhibit 53.

(Union Exhibit 53 marked for identification)

Q. Just for the record, it's a treatise or a study entitled, "Dried Blood Spots-Preparing and Processing for Use in Immunoassays and in Molecular Techniques" with the lead author being Nico Gruner. Are you familiar with this study, and if you are, is it a reputable source?

A. Yeah. I've read it and I think it's a reputable source.

Q. If you could, Katy, if we can move down to, let's see, page 5 of this document. Let's see if I have the right page. It might be page 4. And if you could move down further, I want to -- yeah, perfect.

Under this heading of storage and transportation of dried blood spots, point number 4 reads, "Exclude the filter cards from further processing if the desiccant packs and/or the additional humidity indicator card changes to a pink color." Could you explain that, first of all, this process of desiccant packs changing to a pink color?

A. Well, once again, you want to make sure that this stuff is dry and stays dry. So you have -- this is an indicator, this is just to help for the -- the collectors and/or the laboratory personnel to assure that, okay, it -- it arrived here with the desiccant, and it looks like it's been dry because we haven't seen any -- any color change with the -- with the thing that changes color in humidity.

Q. And do you agree with this statement that filter cards that arrive with the desiccant pack that's changed to a pink color should be excluded from further processing?

A. Yes. I mean, you know, if you -- you're going to write rules, you might as well follow them.

(Union Exhibit 54 marked for identification)

Q. All right. Yes, if we could bring up Union Exhibit 54. Are you familiar with this study?

A. Yeah. This is an interesting -- yeah. I am.

This is the --

Q. Go ahead.

A. It is an interesting study because, you know, I mean, I have, I -- I -- I monitor my glucose levels as well being a diabetic. So again, this is something -- this is what we're looking at here. You know, the A1C test is basically a way for your physician to see how well you're controlling your sugar levels. You know, as -- if you have excess sugar in your blood, it basically hooks onto the -- to the hemoglobin or -- or the red blood cell. And then that -- it's proportionate to how -- how high the blood sugar is for a -- for a period of time. So even if you knock it down, it takes about 30 days for that to clear. So this is an interesting thing to show, you know, how the -- you can have basically different results, depending on where you're collecting it from. And this is not even for phosphatidylethanol, this is for A1C, you know, red blood cells with hemoglobin with glycosylated.

Q. And then you consider this report, Union Exhibit 54 to be a reliable toxicological source?

A. It is. And -- and in fact, I -- I -- I conceptualize all of this in terms of A1C, because we're looking at a red blood cell artifact, you know.

And then -- so the idea of, you know, how fast can you push this one way or the other kind of lead into the next topic we're going to talk about. You know, that -- that this thing is -- once it's in your system, it's in your red blood cells, how fast does it disappear. So again, just thinking about in terms of -- of A1C, this was an interesting thing showing that you get different results depending on, you know, a humid environment or not a humid environment, et cetera, et cetera. And, you know, you'd be misclassifying a whole group of patients here as being diabetic when they're not or vice versa. But most of the time it's -- it's the -- the -- the misdiagnosing them as being Type 2.

Q. Okay. We can take down that exhibit, Katy. Now, you have described the EtG test as exquisitely sensitive. Would you describe the PEth test in similar terms?

A. Yes. But not at traceable amounts, it takes a little bit more than a trace to be phosphatidylethanol. But the EtG, it -- all it does is take, you know, I mean, literally a very minimal amount of alcohol.

Q. Okay. Are you familiar with the references to PEth having a detection window of one to three weeks?

A. Yes.
Q. Okay. Is that following cessation of the alcohol exposure?
A. Yes. And again, it -- it really also depends on, to some degree, what, you know, how much -- how was -- how -- how -- how much alcohol was in this first place. So that -- that will also be -- but I think one to three weeks is a fair characterization of what the expectation is with phosphatidylethanol.
Q. And Katy, if we can move back to -- okay, hold on. Before we do that. Yes, let me ask this question. In view of the EtS and EtG results that we've discussed, relating to the May 1 urine collection for Mr. Danford, could the PEth test utilizing the DBS spots collected on May 9th, indicate the consumption of alcohol prior to May 1?
A. So the EtG is positive on May 1st, and then you have a -- a dried blood spot done on May 9th.
Q. Correct
A. And that's probably --
Q. What I'm referring to is having an EtS -- the May 1 results being EtS as a negative, EtG at 117 with a creatinine of 259.
A. Uh-huh.
Q. And if that -- if that occurred on May 1, do

you have an opinion as to whether a PEth test utilizing DBS on May 9, eight days later, could reflect consumption of alcohol prior to May 1, prior to the EtS and EtG results?

A. I don't think it could. I don't -- I don't think you've gotten, you know, the -- that kind of tail on it. And particularly, since you just have a marginal level there, and we also have history, you know, looking prior to that, of having negative EtGs.

Q. Okay. Katy, if we could move -- and yeah. Well, exactly right, you hit it just right. Maybe if we could magnify that just a tad. And I'm going to refer in the chart down to May 15th. So if you could slide down a little bit, so we can get 11 towards the center. Yes. Thank you. Perfect. Your chart indicates here a negative hair based EtG test on May 15th. That's on the chart test number 11.

A. Uh-huh.

Q. Are there any significant characteristics concerning a hair based EtG?

A. Well, it really was until I saw this result that I kind of bought into the idea that Mike was telling the truth. I mean, again, you know, I get all -- as -- as -- as we all do, you get all kinds of stories. But this really just -- just jumped out at

me. This is not possible -- this is not possible. If that PEth test was right, that -- you're not going to get a negative EtG in hair, you know, on the 15th. You know -- you know, kind of like, you know, just -- just a, you know, 7, 10 days later, you know, in -- in hair. Because, again, it's exquisitely sensitive and you've got -- it's a permanent record too, that hair. So you've got that going for you. So that -- if that's what you're going for, that would be what -- what my thought would be. But I don't have any concerns about it because, again, it's -- it's negative, and again, it's a pretty straightforward test.

Q. Okay. Now, moving down to test number 12 on your chart, which reflects a PEth whole blood negative. In your opinion, is it possible to have an accurate positive DBS PEth test on May 9th and a negative DBS PEth test on May 15th, six days later?

A. Not really. Again, once again, I have this -- this problem with the fact that, you know, you've got -- you have a -- you have a -- a half-life of -- of -- of -- of 5-10 days. And then how are you going to turn over all your red blood cells in that -- in that period of time? So again, this is something where, again, this is a -- a DBS, but it's been run twice, and again you're getting a negative result, which again is

inconsistent with that -- the positive result you got earlier.

Q. Okay. Now, the test at number 12 was whole blood. If we move down one --

A. Right. Right. Now, we're going to dry blood spot again. Yeah. Okay. Yeah. No. Clearly the whole blood is what -- what -- what jumped out at me. This is something that -- this is a very reliable kind of methodology to use and which we -- which unfortunately we should have been using here too, because again, you eliminate all of those variables with the dry blood spot stuff. So this is, again, I know it's a pain to poke somebody, and I know it's, you know, kind of a -- involved with getting a phlebotomist, etc, etc, but it saves an awful lot of aggravation. Because we had so many variables with that DBS stuff. So here we have a -- a -- a good PEth negative test that, which again is inconsistent with what we found earlier.

Q. Okay. So now we're moving, we move down to 13. We're back to the dry blood spot. Negative at cutoff, negative at LOD, which I'll submit to you is at 8 nanograms per milliliter. Is it possible, in your opinion, to have an accurate DBS PEth test on May 9th and a negative PEth test on May 16th at an LOD of 8?

A. I would -- I'll tell you one of these has to be wrong. And my guess is that it's going to be the one that was done on the 9th. Again, because this one it looks -- you know, again, it's just a -- just a repeat. It's done -- it's run twice and you have a -- and you go to limited detection, you know, now it's not even how much, it's can we see any of it? Is there any there? This report says no, you don't see it at all.

Q. Okay. And you may have addressed this in passing, but I would like to hear it again in the context of these specific results. Could dehydration reflected in a high creatinine level of 200 or higher impact the accuracy of DBS PEth testing?

A. Absolutely. And of course, the problem here is that we don't even -- because the -- the -- the high creatinine suggests a high hematocrit just because of physics. You know, you drain off a lot of water out of somebody, they're going to have a more packed cell volume for red blood cells. The problem is, there was no estimate of what -- what the hematocrit level is here. And if you go back and look at some of those recommendations for validation studies or other -- other literature, you're going to find that there are a number of ways of sort of estimating that just to minimize the hematocrit effect that's going on with

DBS. Again, it's not even for forensic, but just for clinical tests. So here none of that was done. We don't even know what the hematocrit is other than we -- it should be high because the creatinine is so high.

Q. Can a high hematocrit level impact the drying process?

A. I suspect so although I don't have any studies to show that one way or the other.

Q. Well, if the drying process requires additional time, can there be a resulting impact on blood fermentation?

A. Sure. Sure. The question is, how does the collector know that they need additional time? You know, that's how -- how they would do that. But again, I think that that's why they gave him a minimum of three hours. But again, it may be longer. But again, I don't know how the -- the -- the, you know, the collected -- collection site is going to know that they're going to need another hour or two to -- to dry this out.

Q. Do you have any opinion as to whether DBS PEth testing should be used for forensic purposes or at least as -- as it existed in 2018?

A. I -- I do now. I might say -- I wouldn't -- I would not go near this for a DBS test.

Q. Any final comment on whether Mr. Danford's termination based on a purported failure to abstain from alcohol should be based on the May 9th DBS PEth test?

MR. KASSIN: Objection. Hold on a second. That's really for the board to determine. I think Mr. Shults has expressed his opinions and I think the board can weigh it in the scope of all the testimony of the case.

Q. Well, this is a forensic -- well, I can rephrase that. I think that's frankly a picayune objection, but I'll rephrase it in order to avoid any controversy. Do you think -- do you have an opinion as to whether any determination as to whether Mr. Danford failed to abstain from alcohol consumption should be based on the May 9th DBS PEth test?

A. I do. And I don't think it should be conclus -- a conclusion that there was a violation of his contractual agreement.

Q. What conditions would you attach, if any, to his return to flight duty?

MR. KASSIN: Objection. Sorry. Again, that's a board issue. This individual is not a doctor. He's a toxicologist with limited experience and a master's degree. I mean, he's not in the position of advising the board as to how -- how the Delta ALPA monitoring

program and DPAC program should be interpreted. I mean, that's something that's fully invested in the board and it's not up to this witness to opine on that.

Q. Well, if I can lay -- I think the foundation's already been laid, but let me re-lay it. Sir, you've had -- you certify and train medical review officers, correct?

A. Yes.

Q. Okay. Are medical reviews officers frequently in the position to have to evaluate substance abuse issues or use of ancillary drugs that triggered positives or false positives and make a determination as to whether an individual is ready to reenter a safety sensitive position?

A. Yes. And they're also charged with opining as to whether or not they feel there's a significant safety concern with even the abuse of prescription medications.

Q. So I would ask the question again, but we'll pause to see if the objection is made once more. But what conditions would you attach, if any, to Mr. Danford's return to flight duty?

MR. KASSIN: Again, I'm going to object. I mean, that is not the purview of a medical review officer. And we had testimony from this witness as to the

limited role of medical review officers under Part 40 of the DOT regulations. He's not a medical review officer, he's not a licensed physician, and he's not -- and again, beyond all of that, this is something that the board considers within the scope of its jurisdiction. I assume that Mr. Shults has given the board his relevant opinions, and we'll -- we'll talk more about those in cross-examination. But it's not up to him to tell the board what sort of conditions to assert, or whether even conditions are appropriate, or whether reinstatement is appropriate.

MR. SEHAM: Well, if I could respond briefly, the objection is based in part on Delta counsel's testimony, which of course has to be not considered as to what the role of an MRO is. Now, we have an individual who is the president of the lead organization responsible for certifying MROs in this country, educates and certifies MROs throughout this nation, and is therefore fully familiar with those practices necessary in terms of MROs vetting the return to duty.

Now, this termination in this process was at least in part, substantial part, not just because there was a quantitative result that purportedly indicated a failure to abstain, but also because there's an

argument that Mr. Danford should have submitted himself to further inpatient treatment. I think as the testimony of Captain Graham indicates, and as the termination letter indicates, the termination would not have occurred if Mr. Danford had humbled himself and returned to an extensive inpatient program. So that is in our view, or certainly appears to be in terms of Delta's presentation to be a pivotal issue as to whether these test results warranted insisting, demanding that Mr. Danford return to inpatient treatment on pain of termination if he did not.

So the question to this individual who is a qualified expert on MRO procedures, is whether in his view, in order for this person to return -- Mr. Danford to return to a safety sensitive position, whether in his view it would be required that he return to an inpatient program. I think that's a core issue in this proceeding, that this individual -- we've laid the foundation at the beginning and again recently, that this individual is qualified to render an opinion on that. And with that, we'll leave it with Arbitrator Burdette to make a ruling on whether we can ask that final question.

MR. KASSIN: One second. I mean, counsel has just introduced another element, and that is the level of

qualifications of this witness in addictionology. He's not a medical doctor. He's not a psychiatrist that specializes in addiction medicine. He's not a doctor that specializes in addiction medicine. And again, so he lacks qualifications to address that element. On top of that, I just renewed by objection to him. This is an issue for the board to decide.

MR. SEHAM: I didn't hear anything new just then, so I'll let it go at what we said before and request that the arbitrator make a ruling, and we will respect whatever that ruling is.

THE REPORTER: You're muted, Arbitrator Burdette.

THE ARBITRATOR: Thank you. I'm sorry about that. I'm going to sustain Mr. Kassin's objection. I think that we've got other sources for that information and the board will take it under advisement.

MR. SEHAM: Okay. I have no further questions and we pass the witness.

THE ARBITRATOR: Thank you very much. Mr. Kassin?

MR. KASSIN: Sir, let me -- let me just ask. In terms of the board preference, I think if we took like a ten-minute break, we can go ahead and do our cross-examination at this point. And I'm anticipating approximately an hour. Maybe it may go a little bit longer. It just depends on the answers to the

questions. So it might be, don't hold me to the hour. So we could -- we can do that or we could take a lunch break if that's the board's preference. We're open to whatever the board wants to do.

THE ARBITRATOR: I'm fine with just proceeding ahead with a short break if everybody else is. Okay. Yeah?

MR. KASSIN: Okay. That'll be fine so we shall return at, is it 32? So about approximately 42 minutes after the hour.

THE ARBITRATOR: Okay, let's just make it 45. We'll make it easy.

MR. KASSIN: Thank you. I appreciate that. Thank you.

THE ARBITRATOR: All right. Thank you.

THE REPORTER: We're off the record. The time is 12:32 p.m.

(OFF THE RECORD)

THE REPORTER: We are back on the record. The time is 12:46 p.m.

THE ARBITRATOR: Okay. All right. Mr. Kassin, proceed.

CROSS EXAMINATION

BY MR. KASSIN:.

BY MR. SEHAM:

Q. Sure. Mr. Shults, I want to clarify something. I noticed in our Union exhibit book there are two exhibits. There's Union Exhibit 81 that I believe you testified about, which is your curriculum vitae. And there's also Union Exhibit 49. Is that the same curriculum vitae?

A. I'll have to take a look.

Q. Yeah, and don't do that right now. I just wanted to clarify which one you want to rely on or are they both the same? Let's call that a housekeeping matter we'll get to later.

A. Okay. Well, pick either one, either one will work.

Q. The way of your background, as you mentioned you are an attorney, correct?

A. Yes.

Q. And you have a master's degree in toxicology?

A. Yes, uh-uh.

Q. But you do not have a doctorate degree in toxicology?

A. That's true -- that's true.

Q. You've never served as a laboratory director?

A. Well, almost, but I -- I'd actually turned a position down.

Q. But you so --

A. No, actually I have not run as officially as a lab director.

Q. Okay. And you're not a qualified laboratory inspector for SAMHSA drug testing laboratories?

A. I am, but I just don't do it.

Q. Okay. So you've never done a SAMHSA inspection?

A. Not a SAMHSA inspection, but I've done them for the NRC.

Q. Okay. Your experience as far as working with laboratories is primarily the Equine drug research laboratories at the University of Kentucky, when you were a master's student?

A. Well, that's -- that was where I started, but I've -- since then I've worked at Roche Biomedical Laboratories in Burlington. I've worked for CompuChem where the lab director of USTL has -- has spent some time. I've worked with a number of other laboratories as a consultant. So -- so that help -- help clarify that.

Q. Sure. When you were at CompuChem, you were corporate counsel, right?

A. Well, I had multiple hats. I was brought on eventually as corporate counsel, but again, I played a role in developing what the methods were for doing the

testing. And I was supposed to be the new sheriff in town. The idea was -- the reason they brought me in was because they were getting their -- their ears boxed in by the lawyers down at Fort Bragg. So they needed to have somebody come in and defend their results in these court marshals and administrative proceedings and that was my primary job. Then when this federal government started requiring drug testing, they sent me out to the railroads to kind of convince them to use our lab, which was not a hard sell since most of the railroad docs -- directors were running the program and most of them were ex-military. So I said, look we're DOD certified and that's all I had to do. So that led to me to say, hey, how would you like to be our marketing director? I said no, you need a corporate counsel here. They said, okay, we'll make you the corporate counsel and that's how you make yourself a job.

Q. I missed on your CV your time at Roche. When was that period of time?

A. When I left -- after I left CompuChem. I was -- I was hired by Roche Holding up in New Jersey to come in and kind of work with Roche Biomedical over in Burlington to try to help them get their act together to move into the marketplace. So that -- I worked

there for about six months or -- or maybe a year working with them again. Visiting their laboratories and kind of helping them with it. Again, I -- I, you know, didn't put that on my resume, but again, it -- it eventually that day -- and I also kind of like laid framework for what's now LabCorp out here in the park. So I mean, I've been involved with it very heavily although I didn't put that on my resume.

Q. Okay. And you talked about the organization you founded that certifies MROs. But isn't it true only a licensed doctor can be an MRO?

A. That's true.

Q. And you're not a doctor, correct?

A. That's correct.

Q. And you're not an MRO?

A. That's right.

Q. So MROs are used in the review of DOT required drug tests and you talked about their role in the part -- under Part 40. What -- if someone has a positive drug test, what would the MRO ask them, and what do you train the MROs to ask?

A. Well, basically they're going to follow the DOT procedures and calling them and asking them if they have an explanation. If they have a prescription for the drugs that they were positive for? And then of

course there'll be other issues that will come up, you know, in terms of whether they, you know, are -- are -- you know, if they're using prescription medications. You know, whether or not the MRO feels that they're safe to return to duty or not. So those are the -- those are the kind of tasks, but basically, once they've identified a prescription then it goes -- they also have to produce evidence that -- that they -- that that is a legitimate prescription and then it was filled. And that once that's done, the MRO then can turn that around into a negative test and then make the second decision. Is this person safe to go back to work?

Q. Okay. And the information that the MRO relies on and that they're informed of when there's a positive drug test under the DOT regs, it's just a summary telling them what the drug is -- what the result of the test was?

A. The -- all the lab results, you know, from all of these certified laboratories are supposed to go to the medical review officer. And basically, that's it. I mean, when -- if they get a certified result from a certified laboratory they can rely on that. And then they move onto the next step as to whether or not, you know, the -- there is an alternative medical

explanation.

Q. Right. But the MRO does not request or look at the litigation package as part of their review?

A. No. But they do if -- if there's an issue that comes up. And basically, they're the ones that have to order the litigation package. And if the donor says this is a screw-up, I'm not -- I didn't do that drug. I don't know what you're talking about. And then they come back, the MRO says, listen, you need to get me all the litigation package. The DOT regs say that the laboratory has to turn it over, but it's facilitated through the MRO. So and again, you know, the MRO does not have to be a toxicologist. You know, that -- that -- that's the other thing I should point out. But again, it is helpful to know one or at least be able to have a good relationship with the laboratory.

Q. So you anticipated one of my questions, which is that an MRO does not have to be a toxicologist.

A. Right.

Q. Okay. And as you pointed out, alcohol is not something that requires a prescription and therefore it's not reviewed, alcohol tests -- DOT alcohol tests are not reviewed by MROs?

A. That's correct.

MR. KASSIN: Okay. I'd like for Katy, could you bring up Company Exhibit 26, please?

(Company Exhibit 26 marked for identification)

Q. And if you could kind of screen down so we can see the date of this program. Okay. And Mr. Shults, this is the cover page of a presentation that you made on alcohol testing presentation number 6 in Charlotte, North Carolina for the MRO training and certification course?

A. Yes. Uh-huh.

Q. And if you can look at -- Katy, can you bring a page 3 there, please? And can you blow up the bottom slide number 57 on phosphatidylethanol. And make it a little bit bigger, please. Okay. Slide 57 is from your presentation at that program, correct?

A. Yes. Uh-huh

Q. And then you say, "Phosphatidylethanol, the newest biomaker for chronic alcohol use," correct?

A. Yes.

Q. And you said, "The diagnostic sensitivity for PEth was 99 percent," correct?

A. Yes.

Q. Define sensitivity for us.

A. Sensitivity or -- I guess going to be specificity, but sensitivity is how -- how low -- how

-- how sensitive is it up to pick this up. And it may not be, you know, looking at it now, it may be I should've said specificity. You know, that it really just picks up alcohol and nothing else. But remember, look at the line above it. I said, you know, is this being used for a clinical or forensic test.

Q. So sir, I know that there may be things that your counsel are going to want to point out for you --

A. Okay.

Q. -- in redirect. So we're going to be here a long time if we could just -- unless you can just focus on what I'm asking you.

MR. SEHAM: I'm going to object to that he was being responsive to the question, and that it -- perhaps Delta counsel didn't like the answer, but having posed the question, the witness should be allowed to answer what he meant by that final bullet point. So I object to the interruption, and I would ask the Arbitrator Burdette rule that the witness answer as he was proceeding to do.

THE ARBITRATOR: I will say that Mr. Shults, you should confine your answer to the question that was asked by counsel and your counsel will have an opportunity to clarify anything that you wish to later on when he has an opportunity to redirect. So.

MR. SEHAM: Thank you.

Q. And Mr. Shults, the slide actually says the diagnostic sensitivity for PEth was 99 percent, correct?

A. Yes. Uh-huh.

Q. And it's fair to say that sensitivity is the ability of a test to identify a true positive?

A. That's a separate criteria. True positives, true false positives, you know, but it is -- it's -- it's -- it is extreme -- extremely sensitive. So that's -- that's what it says. Doesn't read more into it or less.

Q. Okay. And so for a monitoring program, for somebody like Delta that has a monitoring program or these impaired physician monitoring programs, when you're saying that the diagnostic sensitivity for PEth was 99 percent, that means that out of 100 tests, 100 people that have been drinking, it's going to catch 99 of them, correct?

A. At the risk of going out of bounds here. This is not talking about dried blood spot testing. This is talking about whole blood testing.

Q. Okay. But what I said -- you would agree with what I said on PEth testing, with your qualification. I understand that's your testimony, but

in a monitoring situation, out of 100, you're going to catch the 99 of those 100 who were drinking?

A. Okay. That's fine with me. That's, you know, that's -- I'm not so sure that's exactly what I meant there, but that's certainly an interpretation.

Q. Okay. I'd like you to -- Katy, you can take that down, and I'd like to go back to Union Exhibit 50, and go to that table of result on page 4. There you go. And if you could pull that up, so we could kind of get the whole table in there from number 1-16 if that's possible. I may have to shrink it. Mr. Shults, can you see that okay?

A. It needs to be blown up maybe one more step.

Q. If you blow it up, and you can -- there you go. So the preface to this is on page 3, and Katy, if you could just pull it back to the bottom of page 3 and then we'll come back to page 4 very quickly. The very last line on page 3 before the footnote is, "All of the testing done -- this is for Mr. Danford, "Pre and post PEth DBS test are presented on table 1." That's what that says, correct?

A. I believe that -- that's all the ones that I relied on for this opinion, I think there's one that I may have left off. I think there's a hair test that was out there that I considered to be a negative test,

but was not included in here.

Q. Okay. But let's just focus on what this document says. Right there on the bottom of page 3 in black and white. In expressing your opinion, you say all of the testing done pre and post PEth DBS test are presented in table 1, correct?

A. Correct.

Q. Okay. Who provided those tests to you?

A. Mr. Danford or Mr. Seham or even the prior counsel may have sent me some -- most of these tests.

Q. Okay. And Katy, can we go back to page 4, please? And if you could kind of get it down. There you go. You got down to 16. I just want to have everything up there as much as we can. That's close enough. And it sounds like you were prepared for this question, Mr. Shults. If you look between test number 13 on May 16th and test number 14 of August 2nd, it's missing the June 20th, 2018 hair EtG test, correct?

A. And I think that was my error. I mean, I just think that I just didn't -- didn't include that and in reviewing it, I realized it was out, but again, it was pretty much late in the game. In fact, I just learned it -- I just realized it yesterday. So that's kind of where I'm at so just keep it straight as I can.

Q. Okay. Katy, can you take us to page 2 and

towards the bottom there's in bold letters, the word opinion. Mr. Shults, the very first line starts out, "Even with the inability to review laboratory documentation or request a retest or confirmed split specimen, I believe this case presents clear laboratory error that has resulted in the unjust dismissal," etc. And then below that it says, "I can state this with a high degree of certainty, even without the opportunity to review the laboratory analytical results, quality assurance data, and standard operating procedures," correct?

A. Yes.

Q. So you prepared this letter without reviewing the laboratory analytical results, the quality assurance data and the standard operating procedures, correct?

A. I have not seen an SOP. And again, I have seen no validity data. And I did look at the lab documentation package for this result based upon the immunoassay and GC mass spec.

Q. But at the time that you wrote this, had you written at the -- had you reviewed the labs litigation package?

A. Yes.

Q. Okay. Why did you say you didn't have the

opportunity to review the laboratory analytical results?

A. I think when I was talking, you know, this -- let's see. This was -- this opinion came out in January and at that point, I may not have got -- have reviewed it. So I do think that there's a -- you have a legitimate point there. But I would say that the problem -- what I think what I'm trying to get at was the problem here is not the analysis per se of this specimen, but really the collection procedure. All -- my testimony has all been about the DBS procedures.

Q. Okay. So your testimony is not directed at the procedures at USDTL once they receive DBS sample, correct?

A. Correct.

Q. Okay. So with respect to the May 1, 2018 urine test that Mr. Danford had, that was analyzed at Quest, are you saying that Quest made a laboratory error?

A. No. They basically just followed the instructions that they received. And basically I think that their procedure is to do a creatinine correction for these things. And again, they don't determine what the cutoff level is either. My sense would be that they would have a -- a higher cutoff level and do a

creatinine correction for this, in which case this would have been a negative.

Q. Okay. And we understand what your testimony was. And if I understand your testimony at this point, and I do want you to make sure I'm understanding it properly. You're not saying that USDTL made a laboratory error once they received the DBS sample?

A. I just don't have enough information to know that. Their -- their chromatograms look good. Their -- the QC on their lab package looks good. But that's not what this case is all about. You know, my sense of it is --

Q. Well, just answer my question please and this will go a lot easier. So I think you've got there. And I believe the point that you made in your testimony was that you have not reviewed the validation data for the PEth testing that you USDTL has done; is that correct?

A. That's correct.

Q. And you've not reviewed the validation data at Quest for the test that it did on May 1st; is that correct?

A. I'm more familiar with Quest operations than I are with USDTL.

Q. Okay. So you are familiar with their

validation data for the test that they ran on Mr. Danford's urine for the EtG?

A. No, but I don't need to know that.

Q. Okay. Did you review the validation data for the Expertox test on his June 20, 2018 hair test?

A. No.

Q. Okay. I think that we have established with your testimony a couple of core facts, and one of those facts is that EtG is a biomarker, correct?

A. Yes.

Q. And it's fair to say that PEth is also a biomarker, correct?

A. Yes.

Q. And there are scientific peer-reviewed articles available that establish that PEth is a highly sensitive and specific biomarker for alcohol consumption. Is that fair to say?

A. Yes.

MR. KASSIN: Okay. Katy, can you switch us from the exhibit we're looking at to Company Exhibit Number 27, please?

(Company Exhibit 27 marked for identification)

Q. Okay. And to show us, this is the Javors article on PEth. Are you familiar with this article?

A. Yes.

MR. KASSIN: And Katy, could you bring us down to under abstract, there's a paragraph that says results.

Q. And in this article, you had had some testimony about the half-life of PEth?

A. Right.

Q. Javors determines that the half-life of PEth is a range of 1 to 13.1 days, correct?

A. Right.

Q. And Katy, can you bring us to page 7. There's a little bit more detail about that on page 7. And I'm looking for right below the synthesis article heading, there's one half-life of combined PEth. And do you have the capability of highlighting the second sentence that begins the mean half-life of combined PEth for us? Just that one sentence there. Thank you. So this study concludes the "mean half-life of combined PEth was 4.6 plus or minus 3.5 days with a range of 1 to 13.1 days," correct?

A. Yes.

Q. And Katy, you can take that down and can you bring us to -- just to take that down for now. Mr. Shults in your testimony, you talked about the half-life of PEth and we just established with this scientific study that it could be a range of anywhere from 13.1 days. You do not know what Mr. Danford's

half-life was for PEth, do you?

A. No.

MR. KASSIN: Okay. Katy, can you bring up Company Exhibit 28, please.

(Company Exhibit 28 marked for identification)

Q. And, Mr Shults, this is the Ulwelling article on PEth blood test in the security environment. Are you familiar with this one?

A. I don't think so. This is a little bit more -- more recent paper, but I don't -- I don't think I -- I might -- I may have seen it, but I'm not -- off the top of my head I'm not.

Q. Okay. I guess the point that I was going to try to make is that the scientific literature, and I'm specifically referring to the Ulwelling article, agrees with your statement that you had in your slide for that presentation in Charlotte, that PEth is a highly sensitive and specific biomarker for alcohol consumption.

MR. SEHAM: Is that a question or is that just testimony?

Q. Well, I'm just going to ask him -- if he's not familiar with the article, I'll just let the article speak for itself. And Katy, you can take it down. And you've alluded to this in some of the

questions that I've asked you, but specifically Mr. Seham had asked you several questions about normalizing creatinine. And isn't it true that Quest Laboratories, as a matter of practice, does not normalize creatinine when it's doing the testing of the urine?

A. That's my understanding and -- but they report creatinine results out. And again, I've seen some MROs who -- who will do that correction themselves.

Q. Right. And it's also fair to say that none of the United States laboratories that do that urine testing for EtG normalize for creatinine, do they?

A. But they often report the creatinine level out, but you -- I agree that they don't.

Q. Okay. I believe you made some reference to the fact that the PEth testing and specifically, you were talking about USDTL, but the PEth test is not an FDA approved test, it's a laboratory developed test?

A. Yes.

Q. The laboratories that you've worked for in the past, don't they have laboratory developed tests of their own?

A. I believe some of them do. Most of them -- yeah, go ahead.

Q. Yeah. And isn't it true that the FDA has

nothing to do with laboratory developed tests?

A. Historically, they made it -- they came out with an opinion a few years ago, which I understand is under review, that for simple tests, they're not going to get involved, but this is hardly a simple test.

Q. Okay. But they are not involved in reviewing the laboratory developed test for PEth testing, either for USDTL or other labs that you alluded to in your testimony, correct?

A. Correct.

Q. You did mention that you -- it was your opinion that USDTL was the only laboratory in the United States that does dried blood spot PEth testing; is that correct?

A. For PEth.

Q. So you're not aware of any other laboratories that do that?

A. Right.

Q. Okay. And what laboratories are you familiar with that do PEth testing in whole blood?

A. I think the -- the -- most of the clinical labs will do it. Quest obviously will do it. LabCorp will do it. I -- I think probably CRL will do it. So there are a number of labs that will do it, but it's not -- again, it's a whole blood test.

Q. Okay. I didn't -- in the context of this case -- I know it's an interesting case, the Theranos case, but in the context of this case, I didn't make the connection from your testimony as to what you were saying. Are you saying that Quest is perpetrating a fraud with its EtG testing?

A. Not Quest, USDTL. In other words, the other ones using the dried blood spot. It's not Quest that's using a dried blood spot. The -- that similarity between Theranos and this -- this -- this test is nothing other than it's one spot of drop -- one -- one -- one -- one spot of blood. You know, in one case, they can test for everything. In the other case, they can test for phosphatidylethanol with -- at some -- at some peril.

Q. That's a pretty broad statement to accuse USDTL of perpetrating a fraud, so --

A. I'm not saying it's a fraud, but what -- what -- what -- what -- what -- what is similar to this is that a lot of smart people bought into Theranos until the whole house fell apart. And this is a thing where I'm afraid that the laboratory itself may be fooling itself with this DBS stuff. Again, I can't put myself in their shoes, but that's my impression. And it also strikes me is that there -- there's a reason why

they're the only lab that's doing it.

Q. Okay. So before you just answered, I thought your earlier answer was that USDTL was perpetrating a fraud. So let's just be clear on that. Is it your opinion --

A. I'm not say -- I have no evidence that anyone's defrauding anybody. I think you can be fooling yourself, which I see a lot, but -- but I don't think there's an -- an intent to defraud anybody here.

Q. Okay. And how long, to your knowledge, has USDTL been doing PEth testing?

A. I don't know.

Q. Okay. Are you aware of any peer-reviewed scientific articles that establish the -- establish false positives?

A. No.

Q. Okay. So for the -- never mind. You talked a little bit about hair testing for EtG and cutoffs. And you said that you had read an article recently that talked about a cutoff at 30. Can you tell us that article, please?

A. Yeah. It's actually on your clients or on USDTL's website. It basically -- when you Google low level and -- glucuronide in hair, the USDTL comes up with a paper that's a summary of the literature out

there. And one of them deals with this -- the idea of the -- it's an Italian study, I think, that looked at a lot of drinkers and basically looked at the level of EtG in their hair. And they said the Society of -- the Society of Forensic Hair Testing recommended a cutoff of 30 or so nanograms per millimeters. So that's where I got it from.

Q. Okay. Tell us what your understanding is of the monitoring program that Mr. Danford was in at Delta Airlines and the monitoring program that Delta and its union, the Airline Pilots Association, had put together? What's your understanding of that program?

A. Well, I have sort of a peripheral understanding of the HIMS program and the idea that, you know, this is an idea of getting folks back into the system by giving them support and treatment as appropriate. And again, I -- I -- I've been asked to speak at these HIMS meetings a couple of times. But I -- I've -- I've always had a conflict. But again, I -- I'm -- I'm -- I'm -- I think it's a great thing. I'm -- I'm all for it. But the problem is, is this.

Q. Okay. And do you understand that airlines have a legal responsibility to exercise the --

A. Oh, heaven, I sure do. And -- and I understand how difficult this is and I'm very

sympathetic to the airlines and I'm very sympathetic, you know, to the idea that it's very difficult to basically determine compliance with -- with alcohol and even these other drugs and it's more so every day. But at the same time, I also know of -- of -- of, you know, again, the equitable issues in terms of fairness and -- and -- and supportability. So it's -- but again, I'm not -- I -- I -- I know how important it is and I don't want to have anybody flying a plane around that's either using drugs or is at relapsed or close to relapse. And I've -- I've been -- I've been exposed to this for a long time. Well, my first -- our first big client at CompuChem was American Airlines. There was a famous medical director who -- who added that program up. A guy by the name of Dr. Wick. But I don't want to go -- spare you the details on all that. But --

Q. Okay. So you do understand that one of the objectives of the Delta and ALPA agreed upon HIMS program is to keep impaired pilots out of the cockpit?

A. You bet.

Q. Okay. And another primary objective is to help people and help them maintain their careers, correct?

A. Yes.

Q. And to do it -- do you understand with

alcoholism that relapse sometimes occurs?

A. Oh, it occurs more times than not. No, I do understand that.

Q. Okay. And in order to keep impaired pilots out of the cockpit and help people maintain their careers, you have to have a way to identify people before it gets too late, correct?

A. Correct.

Q. Okay. You talked about programs that have a higher cutoff than the 100 nanograms per milliliter that's used by the Delta ALPA program for its EtG testing. Tell us what programs those are.

A. Most of the state medical boards have adjusted their cutoff for compliance for, you know, people who have conditional licenses to the 200 or 300 level. I want to say North Carolina, but there may be some others. I just don't -- I don't monitor it all the time.

Q. Okay. So only one that you could -- that you think might have one is North Carolina?

A. Yeah. I -- I could Google it in a minute and you could do it too.

Q. Okay. We're not going to refer to Google during your testimony. So you did look at -- as part of your testimony, you looked at the exhibit that had

the -- from Quest laboratories that had the summary of the results from the May 1st urine test for Mr. Danford. And then you went on to talk about him being dehydrated on May 9th for his PEth test. How do you know he was dehydrated for his PEth test on May 9th?

A. I don't know for sure. But again, I don't -- we didn't -- we don't -- nobody knows what his -- his -- his hematocrit is or -- or what his creatinine level was because it wasn't measured. But, you know, I'm assuming whatever the medical condition was that got him in -- in -- in -- into the dehydration did not clear overnight. But again, I don't know. It could've been.

Q. Okay. And you had a good bit of testimony referring to a couple of exhibits as Mr. Seham showed you about collection process, but you were not present for the collection process of the dried blood spot on Mr. Danford on May 9, 2018, were you?

A. That's correct.

Q. And even in a hypothetical situation where somebody puts hand sanitizer on a dried blood spot card, that hand sanitizer doesn't have PEth in it, does it?

A. It has alcohol in it. And the enzymes in the blood cells have the enzyme available to transform that

alcohol into PEth. And I understand that, you know, some of these cards are impregnated with a denaturing agent, but that's not the denaturing agent that will stop that process.

Q. So you're saying that hand sanitizer does have PEth in it?

A. No. Hand sanitizer has a good deal of alcohol in it. It's almost all alcohol. So it doesn't take much of anything for that to show up as a significant amount of PEth if given the right conditions.

Q. Okay. You talked about a couple of the PEth tests that were run, that were self tests by Mr. Danford on May 16, 2018. What was the level of detection those were run at?

A. Oh, I -- off the top of my head, I don't know. I think it was probably the -- the PEth testing I think was -- I don't know, I don't know.

MR. KASSIN: Okay. Arbitrator Burdette, can I have five minutes? I think I'm getting close to finishing my cross-examination.

THE REPORTER: You're muted arbitrator, Burdette.

THE ARBITRATOR: Thank you again. We'll go off the record for five minutes.

MR. KASSIN: Okay. Thank you, sir.

THE REPORTER: We're now off the record at 1:23 p.m.

(OFF THE RECORD)

THE REPORTER: We're back on the record at 1:27 p.m.

MR. KASSIN: We have no further questions. Thank you, Mr. Shults.

THE WITNESS: Thank you.

MR. SEHAM: I'm sorry. Just a few questions. Katy, if we move to Union -- excuse me, Company Exhibit 9. And it was that same page you were on before that, the handwritten 111. Perfect. If you could blow that up a little bit, and excuse me while I close my door here.

REDIRECT EXAMINATION

BY MR. SEHAM:

Q. Okay. Mr. Shults, looking at this report from Quest, does it say anywhere here that Quest is reporting alcohol consumption?

A. No, it doesn't.

Q. Is the information presuming that this is provided to the customer, is the customer, including the customer MRO, provided with the necessary information to normalize the result based on creatinine?

A. Well, they have to know what it is to start with and they have to know, you know, what goes over what and what numbers you're looking at. So, you know, I don't think that -- I don't see it on -- on this report on how to do that.

Q. No, no. I'm saying if someone knows the process, is the creatinine information --

A. Yes. Yes. You've got -- you've got that on the top line there of it being at 256.9 milligrams per deciliter.

Q. And if you could move to -- Katy, if you could move to Union Exhibit 75. And if you could magnify it sufficiently so that the witness can -- can read it. Tell us when -- there you go. So this is an ExperTox test using EtG performed on hair with the collection being June 20, 2018. Do you recall whether Mr. Danford provided you with this test result?

A. He did indeed provide it and for reasons I don't recall now. I either forgot it or omitted it from my report and I apologize for that. Because there's no reason why I couldn't have in sold -- folded this in. I mean, they reported out a very low level of EtG of -- of 4.8. And then at the bottom where they have their notes, they basically say, they suggested cutoffs, is that, you know, a positive being above a 7.

And so that to me is why I don't think this is -- this -- that had a whole lot of probative value.

Q. This reference to approximately three-month time frame. Is that a look back reference? In other words, this is the measurement.

A. And here's the problem with hair testing. You know, I know an awful lot about hair testing. I've worked with both Psychemedics and the other -- other lab, Omega Labs with their hair testing program. One of the things about hair testing is you're basically taking a strand of hair and cutting an inch and a half off. But then the question is, where are you going to segment it? Are you going to do the -- just a few strands or the whole thing? And of course then you get a dilution factor. So I'm not quite sure what their process is because I'm just not that familiar with -- with their -- with their hair testing techniques or -- or procedures.

So basically, all I can tell you is that based upon their own guidance is that they're considering a positive to be something -- what does it say here, greater than seven picograms per milligram. And here they've got a 4.8. So once again, I -- there's sort of a disconnect between what the labs are telling you and what they're reporting. So again, it's -- it's -- it's

helpful information, but at the same time, I'm not so sure, you know, what -- what the -- what the value of that is if you're going to ignore it.

MR. SEHAM: Very good. No further questions. Thank you.

MR. SHULTS: I do.

THE ARBITRATOR: Re-cross?

RECROSS EXAMINATION

BY MR. KASSIN:

Q. Mr. Shults, we're looking at Union Exhibit 75. If you had that document, it should have been included in your report, correct?

A. Yes.

Q. And you chose to leave it out of your report?

A. No. I -- I -- I probably just omitted. I -- there's was so much data in this -- in this -- in this case. I think I just -- was just an error on my part, not an intentional. And I -- I had to remember this because, you know, as -- as you suggested -- I mean, Mr. Seham mentioned it to me last night, he said whatever happened to that? And I said what? And then I had to go back. Oh, yeah, this. So -- and then I do remember saying, well, this has no real probative value. But again, I -- I -- it would have been easier for me to put this in and avoid this issue, to tell you

the truth. So that's -- that's where we're at. It's not Mike's fault, it's my fault.

MR. KASSIN: No further questions.

THE ARBITRATOR: Thank you. Any further, Mr. Seham?

MR. SEHAM: No, Arbitrator Burdette. Thank you.

THE ARBITRATOR: Thank you very much. Okay. Mr. Shults, you may be excused. Thank you very much for your time and participation.

MR. SHULTS: Thank you, sir.

THE ARBITRATOR: Okay. Mr. Seham, do you have anything? Do you have other witnesses, or?

MR. SEHAM: I have no other witnesses. I do have a couple of housekeeping issues in front -- we're on the cusp of closing our case, but there may be three issues I wanted to raise. Back on October 30th, I sent an e-mail both to Arbitrator Burdette, and Mr. Kassin, and Ms. Samuda, about our inadvertent introduction of a testing exhibit through Dr. Joseph Tordella, concerning his patient. And that we had multiple test results based on collections on May 28th. We put in an EtG test. We meant to also include a PEth test, also requested by Dr. Tordella. So I never -- what I had asked Delta counsel was to stipulate to the admission of the exhibit that we had attached, and my preference

being not to have to call back Dr. Tordella to confirm that he commissioned that test. I never heard back on that, so I don't know where we are in terms of that exhibit.

MR. KASSIN: Give me one second, please. Arbitrator Burdette, there's been a lot of emails since then. I think that if Mr. Seham wants to put that in the record, and with that explanation that he's just provided, there's no need to call Dr. Tordella back. The board can consider it for what it's worth.

THE ARBITRATOR: I agree.

(Union Exhibit 84 marked for identification)

MR. SEHAM: Thank you very much. The second housekeeping matter was that there had been a request that Mr. Stepanian, for -- there was a reservation of rights to cross-examine Mr. Stepanian, and there was a request for information in that same email of October 30th. Pursuant to Delta counsel's request, we identified the relevant court as being the 255th Family District Court of Dallas County, Texas, before the honorable Judge Beauchamp, and that the hearing dates that were requested were identified as October 27th, 2017, January 26th, 2018, March 16th, 2018, September 7th, 2018. There was a request that the toxicologist be hired, be identified, and the attorney -- the

attorney was Karen Bellingham, of Bellingham Law, and the toxicologist was Dwayne Fuller, of V-A-N -- this is his organization, apparently V-A-N-T-H-C-S Toxicology B113, I think that's his suite number, 4500 South Lancaster Road. On October 3rd, together with the Union Exhibit 84 was PEth test results that were Mr. Stepanian. But we never heard back from Delta counsel. It's our view that if we're closing our case, that means the reservation of cross-examination has been waived since we provided this information back in October.

MR. KASSIN: Everything that Mr. Seham just referred to is under review, and what we'll do is reserve the right to recall Mr. Stepanian for rebuttal, if we decide to do so. We're still under review.

MR. SEHAM: Well, I have to say, we don't consider that acceptable, that this is a working class man who opened up his life records. There was a reservation made back in October 30, 2020. And the case has to come to a close, this person can't be left twisting in the wind. If we provided this information October 30th, 2020, and we never received any response at this point with our closing our case, that reservation of right to further cross-examine our witnesses is waived. That would be our position.

THE ARBITRATOR: I understand your position. And Mr. Kassin, I would encourage you to come to that -- come a conclusion pretty quickly. From the board's perspective, and the board has had a brief executive session already about this. I'm not sure that there would be anything further that would be very elucidating to the board by further testimony from Mr. Stepanian. That's the boards -- that's the board's view of it. But I'm not in a position to dictate to either counsel how you perceive to present your case, so you'll present your case in the best manner that you can. I understand where we're at and I am sympathetic to Mr. Seham's comments, and that we probably -- there will be very little gain by bringing him back again. But that's up to Mr. Kassin and company.

MR. SEHAM: The final housekeeping matter that I have relates to where we go from here. So my understanding, and please, Mr. Kassin, correct me immediately if I'm wrong. But that we have two further dates, and those dates next week had been reserved for Dr. Howard Taylor's testimony; is that correct?

MR. KASSIN: The dates next week have been reserved for rebuttal testimony, and that will include testimony from of Howard Taylor, PhD, or Dr. Taylor. And we are analyzing what additional rebuttal that we will need.

We are going to provide counsel and the arbitrator with the names of three additional doctors, I believe, hopefully by tomorrow who may be presenting rebuttal testimony. We'll get you their curriculum vitaes and/or biographies as appropriate. But we have to make these decisions and we haven't made a final decision on that at this point. But we'll try to have a final decision so that everybody can know what we're looking at for next Tuesday and Wednesday. We would like to see after a break today, we're trying to track down a couple of witnesses to get them in here today for rebuttal, for our rebuttal case if that's acceptable to everybody. I know we'll need -- what is it? It's 1:40 Atlanta time, 12:40 your time, Central time, we'll need some time.

THE ARBITRATOR: Would it be appropriate to take a lunch break at this time, Mr. Kassin and --

MR. KASSIN: There you go. Yeah. That would be helpful if we could have an hour and 20 minute lunch break. So that would be getting us back together at 2:00 Central, 3:00 Eastern. We'll have a report for you and hopefully we'll have located a couple of witnesses.

THE ARBITRATOR: Okay. Go ahead, sir.

MR. SEHAM: Well, the reference to the fact that I

was going to make this statement and reservation of rights even before I knew it was going to be four doctors as opposed to one doctor. But as the board is aware, Delta conceded that it had the burden of proof in this case. We didn't have any expert testimony concerning the PEth test in their case in chief, and now we're going to be met with a deluge in rebuttal of information that should have been presented in the case in chief. So as we close our case, our position is that we are entitled to surrebuttal and some period of time to prepare given that we are meeting a deluge of expert witnesses. The company has had our information for a year or for the better part of the year and now we are going to have under a week of prior notice. So that's all to say in our view, we're closing our case today, but we reserve the right to present further testimony in surrebuttal.

MR. KASSIN: That's the right of counsel.

THE ARBITRATOR: Yeah, absolutely. Okay. All right, let's get back together at 2:00 Central, 3:00 Eastern and we'll go from there. We're off the record until then. Thank you.

THE REPORTER: We're off the record at 1:43 p.m.

(OFF THE RECORD)

MR. KASSIN: Arbitrator Burdette, our first

rebuttal witness will be Dr. Thomas Faulkner and I'm hoping that he's in the waiting room.

MR. SEHAM: Is the other witness going to be testifying about EtG/EtS or PEth, because I'd like to let our technical adviser go if we're not slated for that kind of witness.

THE ARBITRATOR: No. Well, the second witness we're hoping to be Captain Harry Miller and he is to testify about his role in the DPAC program and his interactions with Mr. Perez and Mr. Danford and he will mention the word EtG and PEth and --

MR. SEHAM: Oh no, I'll back up.

THE ARBITRATOR: Mr. Seham, he's not a scientific expert. He is the pilot DPAC rep at Delta.

MR. SEHAM: All right. Then we will release our technical adviser, he has other conflict or other issues.

THE ARBITRATOR: Okay. Do we have Dr. Faulkner?

MR. FAULKNER: Hello.

THE ARBITRATOR: There he is. Okay. Dr. Faulkner, would you please raise your right hand? I'm going to swear witnesses. Do you swear or affirm that the testimony you're about to give in this case will be the truth, the whole truth, and nothing but the truth?

MR. FAULKNER: I do.

THE ARBITRATOR: Thank you very much. And can you affirm for us that there's nobody else in the room with you? Very good. Thank you. And do you have access to any documents that are not exhibits in this case?

MR. FAULKNER: No, sir.

THE ARBITRATOR: Thank you very much. And Mr. Kassin, you may proceed.

THOMAS FAULKNER, M.D.,

having been first duly sworn, testifies as follows:

DIRECT EXAMINATION

BY MR. KASSIN.

BY MR. KASSIN:

Q. Thank you. Please state your full name for the record.

A. Thomas Bond Faulkner.

Q. Okay. Dr. Faulkner, do you serve as a senior aviation medical examiner?

A. I do.

Q. And are you also qualified to be a HIMS aviation medical examiner?

A. I am.

Q. In addition to your separate roles as a senior aviation medical examiner and HIMS aviation medical examiner, are you also have a role with Delta Airlines?

A. I do.
Q. And what is that role?
A. I'm a Contract B, the Director of Health Services regarding the pilot working agreement contract.
Q. Okay. Is that a separate and independent role from your work as a senior AME and HIMS AME?
A. It is.
Q. And under your agreement with Delta, are you permitted to see pilots as a senior aviation medical examiner and HIMS AME?
A. I am.
Q. Okay. And are pilots that come to see you made aware of the role that you have with Delta as Director of Health Services?
A. They are from before they meet me, but also I have a disclaimer or a statement in my waiting room regarding my role with Delta.
Q. Have you served as Mr. Danford's HIMS AME since July of 2018?
A. Yes.
Q. Okay. I'd like for Katy to bring up a copy of Union Exhibit 75. And Dr. Faulkner the connection which your role as Mr. Danford's HIMS AME, did he provide you with copies of alcohol tests that he had

taken before seeing you?
A. Before seeing me?
Q. Yes, sir.
A. I believe I did get records from Dr. Harper, who was his previous HIMS AME.
Q. Okay. Did Mr. Danford ever provide you any of the tests that he took after he had his positive PEth test with Delta on May 9th, 2018?
A. No.
Q. And looking at Union Exhibit 75, that's a EtG hair test that was collected on June 20, 2018. Did Mr. Danford ever provide you with a copy of this June 20, 2018 test?
A. No.
Q. Did he ever show it to you?
A. No.
Q. If he had given it to you or showed it to you, would you have passed that onto the Federal Aviation Administration you connected with your application for a special issuance for him?
A. Yes.
Q. And why would you have done that?
A. As a HIMS AME, if you will, I serve as a monitor for the pilots' recovery and their participation in the HIMS program, meeting the

requirements. That includes the biological random testing, to include any tests, positive, negative, dilute. You -- you submit all the tests that have been done.

Q. Okay. And in connection with the test that Mr. Danford may have taken after his positive May 9th, 2018 tests, these would be tests that were self tests, not the test that Delta DPAC had him do or the Talbott Recovery Center. Were you aware that he did some testing on his own?

A. I do know he did testing on his own, especially after the positive test for Delta.

Q. Okay. And at any point, were you provided information on those and shared that information with the Federal Aviation Administration?

A. I -- I did.

Q. Okay. At any time, did you provide advice to Mr. Danford to not share Union Exhibit 75 with either Captain Graham or Captain Burns in connection with his appeal hearing or his contract grievance?

A. No.

Q. In your role as a Senior AME or HIMS AME, would you ever give any pilot advice as to how they should interact in terms of their employment relationship with Delta or any other carrier for other

pilots that you see?

A. Well, let me qualify that. No, unless they were in a HIMS program, a company-directed HIMS program. In this case, Mr. Danford and I had an understanding I was not -- this was not part of the Delta HIMS program. We were working as a general aviation pilot on this. So -- but typically, that's -- that's -- the information like this that I gather, I wouldn't tell anything to share, unless they were showing non-compliance with a company-directed HIMS program.

Q. But just to be clear, he had never shown you what we've identified as Union Exhibit 75?

A. No.

MR. KASSIN: Thank you, sir. That's all I have for your questions.

MR. SEHAM: I'd like to take 10 minutes, please. I don't think I have -- I may have no questions but more than a handful, but I want to consult with my client. Can I have a few minutes, Mr. Arbitrator?

THE ARBITRATOR: Absolutely. You may.

THE REPORTER: We are off the record at 4:09 p.m.

(OFF THE RECORD)

THE REPORTER: We're back on the record. The time is 4:13 p.m.

THE ARBITRATOR: Thank you.

MR. KASSIN: Mr. Burdette, there -- there was one question that I meant to ask Dr. Faulkner that I forgot. Would the board give me permission to ask that? It's reference Union Exhibit 35, which is the Dr. Sager memo.

THE ARBITRATOR: Sure.

BY MR. KASSIN:

Q. Okay. Katy, can you bring up Union Exhibit 35, please? Dr. Faulkner, what I'll represent to you is that this is a memorandum, Dr. Sager at the Federal Aviation Administration. And what I wanted to do was show you some of the tests that he listed in his memorandum. And Katy, can you bring us to page -- second page of that exhibit? Let's see. Actually, I meant to start at the bottom. I'm sorry. At the bottom of page 1. Dr. Faulkner, there's a list of tests that Dr. Sager refers to. The first one is on the bottom of page 1. It's a laboratory test dated April 26th, 2018, which indicates the negative EtG tests. And then Katy, bring us to the top of page 2, please. And then there's a series of other tests. There's the May 1st, 2018 test positive for EtG at 117 nanograms per milliliter. There's a lab test dated May 9th, 2018, which indicates the pilot had a positive

PEth of 98 nanograms per milliliter. There's a hair test dated May 15th, 2018 which was negative for EtG. There's a test dated May 15th, 2018 for PEth which was negative. There's a PEth test dated May 16th, 2018, which was negative. There's a negative EtG test for urine collected on August 21st, 2018. There's a negative EtG test collected on September 12th, 2018, and there's a negative EtG test collected October 5, 2018.

So all the tests that I just listed and referred to on Dr. Sager's memo, are those tests that you provided to the FAA?

A. I believe so, yes.

MR. KASSIN: Okay. That's the question I had, Arbitrator Burdette. That's all I have. Thank you.

THE ARBITRATOR: Okay. Thank you very much. Mr. Seham?

CROSS EXAMINATION

BY MR. SEHAM:

Q. I hadn't anticipated asking this question, but Doctor, why do you say I believe so as to the tests you provided to the FAA?

A. He's referencing them. I put them in the report as part of the package. I -- I would stand by that I did submit those to them.

Q. So you had a specific recollection that all those tests were supplied to you -- were supplied by you to the FAA?

A. Right. Now, I -- I got -- I will say also the FAA also had -- because we -- as part of the process with HIMS, you do request the file that they have on the airman. And so I get those files that had a lot of other information. I do not -- I can't speak for Dr. Sager in terms of when he's going through that list, if he's mentioning some other things. I -- I don't have his file here in front of me. But I put in -- as I think I indicated earlier, I put in -- as I put in my briefing letter on him, what the concern was of positive tests, negative tests, and then what I've been getting since I've been following him. So I would say that I -- I submitted all that to tell the story to the FAA about before I was monitoring him and after I was monitoring him.

Q. Well, I'm sorry. You referenced a concern. What was your concern?

A. I have no concerns. I would -- I'm just trying to think. I would've been in his file since laboratory tests, including the ones that caused issue here for the positive test, the PEth test that conflicted, and what I had since I've been following

him.

Q. Okay. Well, I just thought I heard in your testimony that you identified the positive PEth test of May 9th and a concern arising -- I think the term you used was concern arising from the subsequent negative tests. Do you recall testifying to that effect?

A. I could have. I -- do you have someone who can read that for me?

Q. Well, did you have -- so you're saying now that you had no concern with respect to all these negative tests coming after the positive test?

A. No. And -- and again, I'm not a toxicologist. I put down what was tested in the past. So as I -- I -- I shared with Mr. Danford there, you have positive tests, you have negative tests. I -- I will just pass on to the FAA what the tests are there and try and explain since I've been working with him, we had negative tests, but I give it to the FAA to review all the information I have, that was provided to me, and make a decision.

Q. Well, did you make any recommendation to the FAA one way or the other as to whether he should obtain a special issuance?

A. In my working as HIMS with general aviation AME, I did recommend that he be certified based on the

information I had from -- since he worked with me.

Q. Okay. Certified for a first-class medical?

A. Correct.

Q. Okay. Were there any restrictions as to how he applied that first-class medical, that you can recall?

A. No.

Q. Okay. Now you say you serve as a DHS? And actually, let me back up. So your recommendations were not based on the test results that you submitted?

A. My recommendations were based on, since I've been working with him I believe in late July, getting the testing, getting the aftercare. I believe I also had him seen by Dr. Lynn again. We had doctor care reports from Dr. Prewitt, that my work with him was supportive of his getting medical certified.

Q. Okay. And the testing you say refers to testing starting in July of 2018?

A. Well, that's when I started working with him. I think the first test actually that I was overseeing was in August.

Q. Okay. Now, you said -- are you the current DHS for Delta Airlines?

A. I am.

Q. And were you at this time in 2018 -- through

the course of the year 2018, did you serve in that capacity as well?

A. I did.

Q. And what are your responsibilities as DHS for Delta Airlines?

A. Well, under the -- again, under the contract of the pilot working agreement, it's several-fold. One is to act as a resource for pilots to use for medical certification, answer their questions. Can I fly on this medication? Can you help me get my medical certification back or maintain my medical certification? And then if a pilot has been out for more than four months for -- consistently for a medical reason, and/or is issued a special issuance, I review their cases to make sure that they had met the FAA medical standards to -- and -- and full information was shared with the FAA, and then recommend that they be returned to work. And then the final issue is for fitness for duty evaluations. If the pilot is not being seen by me as his AME, I do get involved as a medical representative for what we call a Section 15 fitness for duty evaluations.

Q. So in this context, with respect to Mr. Danford, you would not have performed any Section 15 function, you would've been disqualified?

A. Correct. He was not in active Delta employment at that time. He was not in active Delta employment.

Q. My question is, would the company have -- if they had a Section 15 issue, would you have been disqualified from considering that?

A. If I had seen him, if I had worked with him as his AME, yes, I would.

Q. Okay. And when did you start working with him as his AME?

A. I believe I saw him -- I don't have it in front of me. I'm going to say July 2018.

Q. And in the event you're disqualified as the DHS in the context of the Section 15 analysis, who would undertake that Section 15 analysis?

A. I wouldn't know. Who -- I know they have several other doctors that they use for that, I believe.

Q. Okay. So Delta never came to you to inquire as to the medical qualifications of Mr. Danford; is that correct?

A. No.

MR. SEHAM: Okay. No further questions.

THE ARBITRATOR: Any redirect, Mr. Kassin?

MR. KASSIN: No, sir. Thank you.

THE ARBITRATOR: Okay. Thank you very much, Dr. Faulkner. You may be excused.
MR. FAULKNER: Thanks. Have a nice day.
THE ARBITRATOR: Thank you. You too.
MR. KASSIN: Arbitrator Burdette, as we mentioned, our next witness is Captain Harry Miller. We're going to check and see if he has some flexibility to start earlier. What's the best way to communicate with everybody? An email again?
MR. SEHAM: Yeah. I guess so.
THE ARBITRATOR: Yeah.
MR. KASSIN: Otherwise, we'll see you at 5:00, but we'll try to do it earlier.
THE ARBITRATOR: Okay. That would be good.
MR. KASSIN: Okay. Thank you.
THE ARBITRATOR: Thank you.
THE REPORTER: Are we going off record? Is that what I understand?
THE ARBITRATOR: Yes. Off the record.
THE REPORTER: Off the record at 4:23 p.m.
(OFF THE RECORD)
THE REPORTER: Okay. We are on the record. The time is 5:02 p.m.
MR. KASSIN: Arbitrator Burdette, the company at this time calls its second rebuttal witness, Captain

Harry Miller.

THE ARBITRATOR: Okay. We haven't sworn him yet. Right? Have we?

MR. KASSIN: No, sir, we have not.

THE ARBITRATOR: All right. Captain Miller, would you raise your right hand, please, we're swearing witnesses. Do you swear or affirm that the testimony you're about to give in this case will be the truth, the whole truth, and nothing but the truth?

MR. MILLER: Yes, sir. I do.

THE ARBITRATOR: Thank you very much. And will you also attest for us that there's nobody else in the room with you?

MR. MILLER: That is correct. There's nobody here.

THE ARBITRATOR: Okay. And that you don't have any documents in front of you that we would be referring to other than the exhibits in this case?

MR. MILLER: That's correct.

THE ARBITRATOR: Thank you very much. You may proceed, Mr. Kassin.

CAPTAIN HARRY MILLER,

having been first duly sworn, testifies as follows:

DIRECT EXAMINATION

BY MR. KASSIN:

Q. Sure. Please state your full name for the

record.

A. Harry Miller.

Q. Okay. And Captain Miller, what's your position with Delta Airlines?

A. I am a 8350 captain.

Q. Okay. Have you ever held a position in Delta's management?

A. I have.

Q. And what was your most recent position in Delta management?

A. I was the International Chief Pilot in Atlanta, for Delta.

Q. Okay. And during what period of time were you the International Chief Pilot for Delta in Atlanta?

A. August of 2015 through end of October of last year, 2019.

Q. And as the International Chief Pilot in Atlanta, what was involved in that? In other words, your duties and responsibilities.

A. Well, I had the -- the management of the international based pilots, even though sometimes I would work on the domestic side. I had those, and for standards for the international pilots also. If there was anything related to any of the international destinations that -- that need to be addressed, I did

that. And also worked on the HIMS program and the DPAC program for the Atlanta based pilots.

Q. Okay. Still focusing on the International Chief Pilot duties. Approximately how many pilots were you responsible for?

A. Well, Atlanta at the time was 5,000 plus pilots, and international we were over 2,000.

Q. And you mentioned that you also worked on the Delta HIMS or the DPAC program. Can you tell us what you did?

A. I was in charge of the monthly meetings for all the Atlanta based pilots. Every -- every month they have to see the chief pilot. So I was in charge of that, and also in charge of the monitoring. I attended many of the meetings at the Talbott Recovery, and also at MARR, when we had a pilot in treatment at those facilities.

Q. And what are your responsibilities in terms of pilots that would be in the Talbott Recovery Center, is there something called the Midterm Meeting that you were involved in?

A. That's correct. It was a mid-phase -- midterm meeting that -- usually the pilot's treatment is roughly 30 to 35 days. And somewhere in the first two to three weeks we would have a -- a midterm just to

see how the pilot was doing in treatment.

Q. And there was some reference in earlier testimony on the case about Big Wednesday. Was there something that you did once a month, and what was it called?

A. Yeah. That was called Super Wednesday. We did that over on the Delta campus at OC building, OC 3. And what that did, it helped relieve a lot of my duties. Because if we had 50 some pilots -- Atlanta based pilots that needed to basically have a monthly meeting with their chief pilot, it was able to do one group meeting, and we would normally have anywhere from 25 to low 30s attend that meeting. And it really cut down on my time, paperwork, so forth, you know, throughout the month, because I would've had to have done, you know, meeting -- almost a meeting -- meeting in half-a-day for all the -- all the pilots.

Q. Okay. In that role overseeing the DPAC pilots for the Atlanta base, were you familiar with what we refer to as the Contract A?

A. That's correct. I am.

Q. When would pilots sign the Contract A?

A. Contract A would be signed right if they're graduating from -- from TRC, that would usually be within a day or two of their release.

Q. Okay. And are you also familiar with what is referred to under the substance abuse policy for pilots, the Contract B?

A. I am familiar with the Contract B.

Q. And when would a pilot enter into a Contract B?

A. That would be considered a Last Chance Agreement. So that would be -- Contract B would be given to a -- to a pilot that has either relapsed on a Contract A and has had to go to the MARR facility for treatment, or if a pilot had an on-duty positive, he would go -- immediately bring him to a -- into a Contract B, he would bypass the Contract A, so to speak.

Q. You were a primary point of contact for the Atlanta based pilots from the Delta management side. Did you also work with the ALPA DPAC committee members?

A. I did.

Q. And what was your working relationship with the ALPA DPAC members?

A. I think we had a very good relationship. There was many of -- many of times that, you know, I would get that phone call at late night needing to address a situation. We were on a, so to speak, speed dial with each other and we worked hand in hand

throughout the whole process.

Q. And for the work that you did with the DPAC committee, over the years, did you ever receive any rewards or recognitions from ALPA for that work?

A. I did. It was -- actually, I was given the Toni Curry Award last November.

Q. Just briefly, tell us what that is.

A. That is an award given to volunteers and mentors that have worked with alcoholics, specifically pilots in alcohol recovery. And they give that award out once a year. And I was very fortunate to receive that. Toni Curry was a woman that worked specifically towards the end of her life with a lot of recovering pilots. And she was very well-known for her compassion, working with alcoholics for many, many years. I think she passed away in 2012.

Q. All right. We've also had some discussions in this case about the annual HIMS conferences. Are you familiar with those and did you ever attend any?

A. I did. I've -- I've been to, I believe, two of them over the course that I've been in management.

Q. And during those HIMS conferences, would there be training sessions on issues related to what you were doing to help the pilots?

A. Yes. And all that -- all the HIMS is -- is

really pilot specific and there'll be breakout sessions on new ways of different treatments, different rules, regulations, FAA requirements. It's usually a three-day.

Q. Okay. And is there also something called the Pilot Assistance Network?

A. PAN, is what we call it. It is Pilot Assistance Network that helps deal with pilots who are struggling in everything. Not so much -- they -- they do -- do the alcohol stuff and we do get some -- some that end up in the DPAC program. But it's also dealing with pilots having hardships either with the family -- family issues. They'd go through the PAN group, also.

Q. And would the PAN group have conferences, and would you attend those?

A. Yes, they did. They were doing their conferences -- the last few years, they were doing them in Atlanta and I'd -- I would attend, try to -- to go over there for at least a day to -- to sit in.

Q. Okay. One of the key participants in the pilot's recovery and we've heard about is the HIMS AME. Are you familiar with the role of the HIMS AME?

A. I am.

Q. And generally, how would you describe it? And would you have any interaction with the HIMS AMEs

for the DPAC pilots that you were responsible for?

A. I did. And they -- they were kind of orchestrating the whole recovery process for the pilot being -- some pilots need certain other things than -- than others do. But I -- I consider them kind of like the orchestra leader on -- on getting the pilot back to -- back to flying. So I worked with Dr. Harper Senior, Dr. Harper Junior, and we have two more doctors, Koworsky and Dr. Faulkner that we worked with. In Atlanta when Dr. Harper got to the point that he had -- he was very busy and we had to kind of form out a couple of other -- just another.

Q. Now, could you let the arbitrator and board members know what your understanding is of the monitoring program that's been agreed to by Delta and ALPA for pilots that are in DPAC?

A. Well, you know, it starts with monthly meetings obviously with -- with the chief pilot which I thought I have dealt with, and obviously monitoring the progress of how they were doing. Also, they're required to -- to have a minimum of 14 random tests a year. Sometimes that is over 14 by -- by a few or more, that can be generated by Choice Labs who -- who does the service for us. But that's the main part of it right there.

Q. As part of their Contract A, do the DPAC pilots agree to be subject to the random testing including PEth testing?

A. Yeah. I believe that's in -- under Section 13 of the -- of the -- of paragraph 13 of the Contract A.

Q. Okay. And are you -- were you familiar with the types of tests that would be used for the monitoring program?

A. The two most primary tests were the EtG urine, EtS urine, and also the PEth test, which was blood.

Q. Are you familiar with what the cutoff was for the EtG test, the urine test?

A. EtG, EtS was both 100.

Q. And do you know why it was picked for 100?

A. Any pilot that enters into a Contract A or attends DPAC program has to abstain totally from alcohol, and that's why it's such a low number.

Q. Okay. And do you know what the cutoff was for a positive test on a PEth test?

A. Yeah. A positive would've been anything 20 and above.

Q. Okay. And in terms of the monitoring program, were you like the point of contact if a pilot

received a positive test result?

A. In monitoring, that's correct.

Q. Okay. So once you were notified of a positive test result in monitoring, what steps would you take from the Delta management side?

A. Anytime we had a -- anytime we had a positive test, then we had to remove them from flying, if they were flying at that point. If they were between recovery, leaving TRC up to flying, I didn't have to deal with the safety issue of -- of removing them from flying at that point. But anytime -- anytime that we had a positive test and the pilot was flying, then he had to be removed.

Q. Okay. And you mentioned Choice Labs just a minute ago, what was their role?

A. Choice Labs would be Michele Gable. And what she does is -- the pilots, by the 25th of every month, they have to send Michele and Choice Labs their schedule for the following month. And in turn, she puts that into the computer, which in turn generates the random testing dates.

Q. Okay. You mentioned that you got notified when there was a positive test, but would Choice Labs notify you anytime a pilot was randomly selected for a test?

A. No.

Q. Okay. So no reason for you to be involved at that point?

A. No.

Q. Okay. If you got notified of a pilot that had a positive test and you had to contact him to remove them from flying, were you the person that would speak with them and let them know that they had a positive result?

A. Yes. I -- I had to make the phone call and in turn, I had to remove them from flying. And in turn, I would be -- have to let the regional director know that -- that we were removing somebody for flying because of that.

Q. So you reported to the regional director of flight ops?

A. That's correct.

Q. And during this period of time, do you recall who that was?

A. Through my term, it was Chris Frederick. And then he rotated out, and then there was Wayne Cochran, and then Bryan Dickerson.

Q. Okay. Did you ever have situations arise where a pilot has taken a urine test, random urine test, might have had a positive EtG but a negative EtS?

A. Yes. It doesn't happen often, but three or four times a year, yes, it does happen.

Q. Okay. And how were those situations handled?

A. What we would do -- what I would do without -- first of all, we got to think of safety. So if a pilot was on a trip, they have to come off the trip. And at that point, we have to schedule them for a PEth test to verify if -- if they had been drinking.

Q. Okay. And if the PEth test was negative, would you get notified?

A. If the PEth test was negative, yes. Yes. Correct.

Q. I'm sorry, I didn't hear you.

A. Yes. Yes. I would be notified.

Q. Okay.

A. Negative. And then at that point, I would return them to fly.

Q. Got it. And if it was positive, were you notified then too?

A. I was.

Q. Okay. And I mean, just briefly, once -- if you got notified of a positive, what was your responsibility in terms of what you had to say to the pilot at that point in time?

A. Well, that's never a good conversation, but

at that point, then I'll have to talk with the pilot, told him that he tested -- tested positive on the PEth test and that he is now removed from flying and that if he was on a Contract A, then he would have to attend the MARR facility for -- for treatment, 90-day treatment.

Q. Okay. I'm going to shift gears on you a little bit and I want to talk about Captain Michael Perez. And was Captain Perez one of the DPAC pilots that was in your group in Atlanta?

A. Yes, he was.

Q. And do you recall whether he had an assessment at TRC and whether you were part of the meeting with him at some point in that assessment process?

A. Yes, I was part of that.

Q. Okay. By way of background, what's generally involved in a TRC assessment? I mean, how long did it take and what's your understanding of it?

A. Yeah. It usually last three, could last four days. And basically what it is, is blood work. The majority of it is blood work and then obviously, interviews, counseling and so forth to try to get a little bit of a background on what the pilot's been doing.

Q. Okay. And do you recall what triggered the need for Captain Perez to have an assessment at TRC?

A. Yes. He had a DUI. I believe he was in an accident at that point.

Q. Okay. And do you recall what his breathalyzer results were at the scene of the accident when the police met with him?

A. I remember Dr. Bedi talking about that, during the -- during the assessment that it was -- I believe it was 0.2 -- over 0.2.

Q. Okay. And at some point -- so you mentioned overhearing Dr. Bedi. Do you recall the questions that Dr. Bedi would ask Captain Perez and your reaction to it?

A. I remember Dr. Bedi asking Captain Perez how he felt when he was driving and leaving that concert that -- it was a concert, and I think he rear-ended somebody in the parking lot. And I remember Dr. Bedi mentioning to him, so Mike, how -- how did -- how were you feeling? And -- and he made the comment that he did not think that he was drunk or didn't think he was -- could not drive.

Q. Okay. And Dr. Bedi's response, if you recall?

A. Dr. Bedi's response was that, Mike, you were

close to three times the -- over the limit, and that if you felt that you did not feel that you were -- you still had control of your senses and the ability to drive, that you probably have alcohol dependency because pretty much anybody in this room with that high of a blood count would be rather affected, and staggering, and unable to achieve that kind of function.

Q. Okay. Do you recall who was the HIMS AME for Captain Perez?

A. That would've been Harper Senior.

Q. Right. And as you've already described to us in terms of general background, Captain Perez would've been subject to alcohol monitor testing as part of his recovery process following leaving TRC?

A. Correct.

(Company Exhibit 29 marked for identification)

Q. Okay. I want to ask you about a urine test that he was given on March 3, 2016. And I'd ask Katy to bring up Company Exhibit 29 at this point. And you should see, Captain Miller, in the screen in front of you Company Exhibit 29. And Katy, can you can you scroll it down towards the bottom where we're going to see the results. A little bit further. Right there will be fine. That shows essentially a positive for

EtG at 167 nanograms per milliliter, negative for EtS. So that's one of the splits that I had asked you about earlier. First of all, I mean, were you ever shown this document before?

A. I was -- have not seen this document.

Q. Okay. But were you notified either by Choice Labs or by Captain Perez about this test result?

A. I remember getting a phone call not from Choice Labs, but from Mike that there was a split, negative-positive, and that he was concerned about it, and that they were asking him to go and get a PEth test. That's the only one -- I even knew about that.

Q. Okay. And he had signed his Contract A after graduating from TRC on December 18, 2015 and had not yet received a special issuance, which he later got on June 22nd, 2016. So was there any need for you to take him offline flying at that point?

A. No.

Q. Okay. And he told you he was going to get a PEth test. Were you ever informed of the PEth test results?

A. I was not informed by Choice Labs of it. I believe Mike called me, said that it came back negative, and it was -- it was good.

(Company Exhibit 30 marked for identification)

Q. Okay. Katy, I'd like you to pull up Company Exhibit 30 at this point. That's going to be a document that's also part of Union Exhibit 23 and it's on page 5 of Union Exhibit 23. And I'd just say that for purposes of the record as a cross-reference, but I thought it would just be easier to show this one page to Captain Miller as this exhibit. Katy, can you pull that up a little bit more just so we can get it -- thank you. And Captain Miller, were you ever shown this document before?

A. No.

Q. And did anybody from Choice Laboratories call you and tell you what the results was about the test that was given to him on March 16, 2016?

A. No.

Q. So did anybody from -- did Dr. Harper Senior call you and tell you what the results of this was?

A. No.

Q. Anybody from ALPA DPAC call you and tell you what the results were?

A. No.

Q. Anybody else from Delta that knew about it that -- did anybody from Delta tell you about it?

A. No.

Q. Okay. And with that result of 10 nanograms

per milliliter, using the 20 nanogram cutoff that DPAC used, would that -- would there have been any reason for anybody to tell you about it?

A. No.

Q. Do you have any knowledge as to why it was run at a limit of detection of eight nanograms per milliliter?

A. I have no idea why that was done.

Q. Okay. And following this test, I mean, are you aware that Dr. Harper Senior eventually submits a packet recommending Captain Perez for his special issuance and in fact he gets a special issuance on June 22, 2016?

A. I am familiar that he did, yes.

Q. Okay. Now, I would like to switch gears on you and ask you a couple of questions about Mr. Danford. And was he one of the pilots that you were responsible for out of the Atlanta base?

A. Yes.

Q. Now, he had a random urine test, on April 26, 2018 and it was negative. Did you get notified about that test at all?

A. I did not.

Q. Okay. On May 1st, 2018, he was given another random urine test and it was positive for EtG and

negative for EtS. Were you notified about that one?

A. I was.

Q. Okay. And what steps did you take after being notified of that?

A. At that point, I called Mike and told him that -- that he had a -- a split test and that he needed to come in and do a PEth test.

Q. Okay. And then did you remove him from flying?

A. I did.

Q. Okay. And he was given a PEth test. He did a PEth test, dried blood spot sample on May the 9th, 2018. Were you ultimately informed the result of that test?

A. Yes, I was.

Q. And that was a positive?

A. That was a positive.

Q. Okay. So you had to have a conversation with him about that test. Do you recall that discussion and can you tell us about it?

A. When I called Mike and told him that the PEth test was -- was positive, that -- that our policy is that at -- at that point, that he would need to -- to go to MARR because he relapsed and that -- that -- that basically was our -- our company position that he did

that. And the only other options would be if he did not want to go to MARR, then Delta is going to then make you either resign or -- or retire from the airline.

Q. Okay. And now, when you saw that result, did you think that he had had a relapse?

A. The number was high enough and that was -- we weren't talking about a number that was real close to -- to the cutoff at -- at that point that yes, I believed there was a relapse.

Q. Besides the discussion that you had with him where you had to call him and tell him he had a positive PEth test, did you have any other discussions with him before he received a notice of intent to terminate in July of 2018?

A. Yes. I had several conversations with him, many conversations with him prior to that time.

Q. And why? Why were you -- what was the purpose of you having all of those discussions with him?

A. I do not want to see him become unemployed. You know, he's been -- he's been with Delta many years. I -- I -- I wanted to save his job, bottom line. And I had a discussion with him and I was hoping that -- and I remember having a discussion with him saying, you

know, it's a lot easier to fight -- because he was saying he was not -- he was not drinking. And I said, you know, it's a lot easier to fight this if you have a job and just go to treatment. And I tried to -- many a times tried to get him to do it and not just me. ALPA did the same things.

Q. Okay. And you mentioned your responsibility in terms of reporting to the regional director. At the time that this was occurring, the 2018, who was your direct report?

A. That would've been Wayne Cochran.

Q. Okay. So you kept Captain Cochran informed of your efforts to talk with Mr. Danford?

A. Every discussion that I had with Mike, I -- I would report that directly to Wayne. Every -- every one.

Q. Did you ever have -- as part of these several discussions that you had with him, did you discuss with him that whether you thought he was in denial and how that relates to the disease of alcoholism? Can you tell us a little bit more about that?

A. Well, I -- I -- I really thought that he had -- one, had relapsed and was in denial because the PEth number was so high. And he just did not agree with me.

Q. If you were to summarize the Delta philosophy

in terms of working with pilots and trying to help pilots, in a couple of words, what would you -- how would you describe that philosophy?

A. We really try to save the man. Obviously, we tried to save the job. Even if a pilot was on a Contract B, basically a Last Chance Agreement and was to relapse, Delta goes so far as to even pay for another -- another set of recovery treatment. And that comes right out of Delta's operational fund. That's right out the bottom line. But we do that because we believe that we can save the man.

MR. KASSIN: Okay. Arbitrator Burdette, if I could just have a couple of minutes. I believe that I'm almost finished or finished with this direct examination.

THE ARBITRATOR: That's no problem. I'm sorry.

MR. KASSIN: That's all right. Thank you, sir. We'll be right back.

THE REPORTER: Off the record at 5:32 p.m.

(OFF THE RECORD)

THE REPORTER: We're back on the record at 5:35 p.m.

THE ARBITRATOR: Thank you.

MR. SEHAM: Yeah, I have some questions.

//

CROSS EXAMINATION

BY MR. SEHAM:

Q. Good evening --

A. Good evening.

Q. -- Captain Miller. What is your understanding of the term cutoff, in the context of biomarker testing for alcohol?

A. Well, to be honest with you, I just deal with numbers and the number being 100 for the EtG/EtS and the number being 20 for -- for PEth. And that's all I focus on.

Q. Well, if someone had a 90 quantitative result for EtG, would you treat that as a evidence of abstinence?

A. Like I said, I -- I just -- I just -- I just deal with a number. And then -- then 90 being -- would be considered a negative to me.

Q. Okay. And now, are you comfortable with the adjective dispositive? Are you familiar with that word?

A. I am not familiar with that at all.

Q. Okay. Did you -- well, let me use the term undisputable. Was it your understanding throughout your participation in this oversight of DPAC and HIMS, that a 100 quantitation nanograms per milliliter for

EtG was indisputable evidence of a relapse?

A. I don't have that knowledge.

Q. And did you have knowledge as to whether a 100 quantitative level for EtS was indisputable evidence of a relapse?

A. I do not have that knowledge, no.

Q. So who told you to take action based on those quantitative results?

A. That has been the process that we use and have been using for, I don't know how long, but way before me. And that's the numbers that Delta has agreed to and that's the numbers that -- that we use.

Q. Okay. Did anyone ever tell you that many laboratories use quantitations for EtG testing of 200 or even 500 nanograms per milliliter in order to avoid false positive results for absence?

MR. KASSIN: Arbitrator Burdette, this is Tom. I want to object. We tried to present this information as to how these numbers were arrived at through Captain Storbeck and got a number of objections. Captain Storbeck was the author of the policy and put a lot of effort and thought into it. And I think this is going beyond the scope of cross examination when you start asking about other laboratories -- I mean, the scope of rebuttal, I'm sorry. This is going -- this is going

beyond the scope of rebuttal when you start going into questions like that. But, you know, we made a good faith effort to present the background information for this and there were numerous objections for Mr. Seham for that with Captain Storbeck.

MR. SEHAM: And if I might respond, one of the -- first of all, the direct testimony went on at length about quantitative values and how that triggered specific actions. This is relevant to the question of was there a meaningful investigation of the relevant issues prior to termination? And that is one of the core elements. It's often referred to as one of the seven pillars of just cause, is was there a meaningful prior investigation?

THE ARBITRATOR: Okay. But how does that question get to -- I'm not following you, Mr. Seham. Is it in terms of how that question would relate to whether or not there was a meaningful investigation?

MR. SEHAM: Well, that this individual was advising Captain -- excuse me, First Officer Danford, that in essence, he had one of two choices, either to be terminated or accept his relapse as a fact. And we're trying to point out that that ultimatum presented by this witness was based on ignorance.

MR. KASSIN: It was based on the agreed-upon

program between Delta and ALPA. Like I said, we're glad to re-call Captain Storbeck to give more background information on how all of that came to be. But as this witness and others have made clear, both representatives from Delta and from ALPA made the significant effort to try to get Mr. Danford to go -- to go to re-treatment and the -- that was not -- their efforts were not successful. So that -- that -- this question doesn't get anywhere to -- to the point of whether there was a meaningful investigation.

MR. SEHAM: This witness, again, presented an ultimatum. He said I interpreted the results, I determined that he had a relapse. He interpreted the significance of the quantitative value of PEth. He approved of the PEth -- resort to PEth based on quantitative values of EtG/EtS. That was the direct testimony. If we're going to object now, then all his testimony ought to be struck.

THE ARBITRATOR: Yes. Mr. Kassin, let's let him proceed with his cross-examination and we'll get through this as quickly as we can.

MR. KASSIN: Yes, sir.

THE ARBITRATOR: Go ahead, Mr. Seham.

BY MR. SEHAM:

Q. Yes. Did you have any -- the question was,

do you have any knowledge of laboratories applying a 200 or even 500 quantitative value for EtS or EtG in order to avoid false positives?

A. I do not.

Q. Okay. And are you familiar with the term matrix as it's applied to EtS and EtG testing?

A. No, sir.

Q. And what was the substance used in the program to test for EtS or EtG?

MR. KASSIN: That's beyond the scope of rebuttal.

MR. SEHAM: Pardon?

MR. KASSIN: I'm objecting because that's beyond the scope of rebuttal.

MR. SEHAM: It has to do with the testing and it has to -- directly relates to the testimony elicited with respect to Perez. And it's premature, actually, to make that objection because we're going to lead to those issues and as to the issues of matrix and the consistency or inconsistency of Delta policy.

MR. KASSIN: This is not the witness to ask that of.

MR. SEHAM: The simple question is, he's making these decisions about whether someone gets fired or is considered in relapse, and I'm asking him the question, does he know what substance provided by the individual

as being tested for EtS and EtG.

THE ARBITRATOR: I think it's already -- excuse me just one second, Mr. Kassin. I think that's already in the record. We have the documents in the record, it didn't indicate what was tested, so --

BY MR. SEHAM:

Q. Well, there's some conflict there. Let me just ask, is it your understanding that EtS and EtG tests were performed on urine samples?

A. Yes. Yeah.

Q. Okay. Do you have any knowledge of the use of any other substance such as hair, or nails, or some other substance for the performance of EtS or EtG tests?

A. I do not. I do not.

Q. Now, you said that there were circumstances -- your testimony was that there were circumstances where there was an EtG positive and an EtS negative. And how did the program treat that mixed result?

A. At that point, then we would request a PEth test.

Q. Were there any concerns about the reliability of an EtG test if it was using the same urine sample as an EtS test that -- that resulted in a negative?

A. Not -- not that I understand, no.

Q. Okay. Do you have any familiarity with the reverse occurring, an EtS positive and an EtG negative?

A. I believe -- I'd have to go look back, but I believe that those have been reversed at -- at a time.

Q. Okay. And then what was the process where there was an EtS positive and an EtG negative?

A. The same, then we would require a PEth test.

Q. Okay. If we could turn to Union Exhibit 33. And on Union Exhibit 33, if we could turn to the Bates stamp -- you'll have to look at the bottom of the Bates stamp 001119.

MR. KASSIN: I'm going to object. This document is clearly beyond the scope of the rebuttal.

MR. SEHAM: It's to show that the testimony on direct is in error and the recent testimony on cross is in error, and that representations made by this witness and other witnesses are untrue. I would like to proceed with the questions. I'm entitled to this, especially because there's been no prior disclosure of this witness. I'm entitled to some latitude. This is a witness from whom it has been elicited testimony concerning quantitation, concerning what the process is for an EtG positive combined with an EtS negative and an EtS positive combined with an EtG negative, and I am trying to demonstrate that in fact there is no

consistent policy, and I would like to be able to proceed with that questioning.

THE ARBITRATOR: Go ahead. You can proceed.

Q. Okay. Now, Mr. Miller, this is -- as you see from this document, this is a test result for Michael Perez, correct?

A. Yes.

Q. Okay. And it was collected on -- sample was collected on December 7, 2015. Do you see that?

A. Yes, I do.

Q. And during that period, you would've been his chief pilot?

A. Yes.

Q. And this reflects an Et -- excuse me, an EtS positive. If you go down three lines from the break under tests, it says ethyl sulfate positive at 36 nanograms per milliliter, with a confirmation value being at 25. You see that as a EtS positive?

A. I see what that says there, yes.

Q. Okay. Do you know whether Mr. Perez was ever tested for PEth after this EtS positive combined with an EtG negative?

A. Well, it -- it looks like the date there, he was -- probably would have still been at TRC, so I -- I -- I -- I wouldn't have any dealings with any of this

right here.

Q. Okay. So you're not -- you're not aware whether there was a PEth test in response to this mix of EtS positive and an EtG negative?

A. No. And I'm trying to remember exactly when we signed his contract, but I don't think it was any -- that would've been had to be later in the month of December, not on the 7th or 8th. So I would've -- I would've never seen this.

Q. Okay. And now, perhaps it's the same, if we can move to 001115. And you see towards the bottom again, there is a report indicates a positive for EtS and a negative for EtG. You see where I'm reading?

A. Yes.

Q. Do you know whether there was ever a PEth test administered to Captain Perez in response to these test results?

A. I'm not aware of -- no. I would -- like I said, I -- I would've never seen this either.

Q. Okay. And if you can move to what was previously identified as Company Exhibit 30. It's your testimony that you were never advised of this test report that states that Captain Perez had a PEth positive test?

A. I was never advised by Dr. Harper or by

Choice Labs on that -- of that right there, no.

Q. Okay. And if we could go back to Union Exhibit 33 and go to 1108. You see here that there is a EtG test. And if you look under sample information to the right, it refers to nails. Do you know why Captain Perez had a nail-based EtG test on May 4th, 2016, initiated by Michele Gable of Choice Lab?

A. No, I do not know why that was done. No.

Q. Isn't it true that First Officer Danford attempted to familiarize you with test results based on nail tests -- nail-based tested that he had initiated?

A. He did tell me he was getting a nail test. Yes. That he -- I believe he said it was negative.

Q. And you decided to give that no consideration in terms of what his employment options were or with respect to your determination of relapse?

A. Well, what -- what I said was I passed that on to my director at that. But there again, we don't let people go out and do their own testing.

Q. Did you offer to have a nail-based test conducted under Delta's offices?

A. I did not.

Q. Did you tell First Officer Danford that the reason his nail test result was not going to be considered was because he had initiated it himself?

A. I do not --

MR. KASSIN: I'm going to object. There's no evidence that First Officer Danford had a nail test. I'm sorry. We're aware that he did a hair test in May of 2018, but not aware of an EtG nail test that he did in May of 2018.

Q. Did he ask you -- he spoke to you of taking tests using different body substances, correct?

A. He did. And that -- that -- that -- he did mention that and I couldn't remember if it was nail or hair, but I think he did -- did do one of the tests. Yes.

Q. Okay. All right. And did you ever tell -- did you ever give them the option to have these alternate tests, whether it was nail, or hair, or some other substance, or matrix?

A. I did not.

Q. No? Now, based on your decision or your determination that Mr. Danford had had a relapse, in part because the PEth test was high in terms of quantitation?

A. Yes.

Q. So might you have been embarked on a different path if the test had just been 20 or 21 nanograms per milliliter?

MR. KASSIN: Objection. Speculation.

MR. SEHAM: Well, he either knows the policy or doesn't. And if he know -- if he doesn't know, that's an answer.

MR. KASSIN: Now, wait a minute. That's pure speculation. What we're dealing with are the facts of this case and to start speculating is beyond the scope of this rebuttal.

MR. SEHAM: The testimony on direct was that he based his decision in part because of the quantitative value of the PEth, that it was so high. And that leads to the question, especially in a context where we have a 30 percent differential in the two PEth tests from the same matrix, from the same sample on the same day. The quantitative level is a significant issue here. So the question is, what is the policy if this witness testified that he based the relapse decision because the PEth test quantitative result was in the 90s. At a lower value, would he have considered himself to have a different option under Delta policy?

THE ARBITRATOR: You can answer that question. Let him answer it.

BY MR. SEHAM:

A. I'm dealing with a positive and negative and 20 would have been a positive. So I would have -- he

would have been -- the -- the same outcome would've been that he would have to go to MARR.

Q. Now, who told you that the quantitative level of a test indicated a relative quantity of consumption of alcohol?

A. There again, I'm just dealing with a number. So nobody. I mean, all I'm -- you know, past practice has been that, you know, that was brought to my attention when I took the job and that's the numbers that I look at. What's negative, what's positive, and go from there.

Q. Did anyone ever give you a policy document that stated that 20 nanograms per milliliter was the positive cutoff for PEth?

A. I don't remember if I saw the document or not, I -- I don't remember.

Q. Okay. Did anyone ever give you a policy document that cited 100 nanograms per milliliter as the positive cutoff for EtS or EtG?

A. I don't know if I saw the document or that it was given to me via phone, or in person by somebody.

Q. Is there any reference to quantitative values in Contract A?

A. No.

MR. SEHAM: If I could have five minutes. I just

want to check with my client to see if he had any notes.

THE ARBITRATOR: Okay.

MR. SEHAM: Thank you.

THE REPORTER: We're off the record at 5:56 p.m.

(OFF THE RECORD)

THE REPORTER: We're back on the record. It is 6:00 p.m.

BY MR. SEHAM:

Q. Captain Miller, I just have a few more questions.

A. Sure.

Q. After you received the PEth positive for First Officer Danford, did you have any conversations with his peer monitor?

A. Well, I can't -- I can't really remember if I -- in fact, I'm trying to remember who his peer monitor was. I don't -- I don't remember off the top of my head.

Q. Okay. Did you have any -- were there any reports at this time in terms of the trips he had recently flown that indicated that he had a performance issue?

A. No. There was none of that.

Q. Okay. Were there any reports from an AME, or

a psychiatrist or a psychologist indicating that Mr. Danford had an issue -- had a substance abuse issue?

A. No, not -- not at all.

Q. Okay. So the decisions you made to the extent you made any decisions was based on the PEth test?

A. The PEth test and the split test, correct.

Q. Okay. And you advised him that it would be easier to fight when he had a job -- while he still had a job. Was that your testimony?

A. My testimony was it would be better -- I didn't want to see him lose his job, period. And I knew the path that this was going was probably not going to be good. So I was trying to convince him that -- because he was talking about getting a lawyer and so forth, I was trying to convince him to go to MARR and do the process that you want to do while you're in treatment and have a job.

Q. All right. And you used the verb fight, correct? That it would be easier to fight while he still had a job, correct?

A. I can't remember what word I used.

Q. Well, you understood that he was going to get a lawyer to contest the test results, correct?

A. Well, he said he was going to -- looking to

have to get a lawyer. Yes. ALPA, you know.

Q. And you understood that he was denying that he had a relapse?

A. Yes.

Q. And in fact, if he had gone to MARR, he would have been expected to confess to a relapse; isn't that correct?

A. He would have been expected to participate in treatment. Yes.

MR. SEHAM: All right. No further questions.

THE ARBITRATOR: Mr. Kassin, anything else?

MR. KASSIN: No, sir. Thank you, Captain Miller. Oh, I'm sorry. Mr. Burdette. It's up to you.

THE ARBITRATOR: Captain Miller, you may be excused. Thank you very much --

THE WITNESS: All right.

THE ARBITRATOR: -- for your time and participation.

THE WITNESS: You bet, sir.

THE ARBITRATOR: Thank you.

THE WITNESS: Bye-bye.

MR. MILLER: Arbitrator Burdette, we'd like to reconvene on Tuesday, and we will be sending -- we have not made decisions on the doctors, other than Howard Taylor, who's the toxicologist PhD. But we will

endeavor to do that very quickly, but in the meantime, to give counsel a heads-up, we'll send to Mr. Seham and Ms. Samuda CVs or biographies of the three doctors we've been talking to.

THE ARBITRATOR: Okay. Very good. Does anybody have anything else before we close the record for this day?

MR. SEHAM: No, sir.

THE ARBITRATOR: Okay. Thank you-all very much. We'll close the record and reconvene on Tuesday, December the 8th, I believe, isn't it?

MR. KASSIN: Yes, sir.

THE ARBITRATOR: Okay.

THE REPORTER: We're off the record. The time is 6:04 p.m.

(Whereupon the proceeding concluded at 6:04 p.m.)

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REPORTER CERTIFICATE

I, DAMIEN STONEBERGER, hereby certify that the foregoing proceedings were recorded by audio by me, a disinterested person, and that the proceedings were thereafter transcribed to typewriting, by computer;

That I am neither attorney for nor a relative or employee of any of the parties to the action; further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially interested in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this December 2, 2020.

DAMIEN STONEBERGER
Digital Reporter, StoryCloud

SCOPIST CERTIFICATE

I, the undersigned, do hereby affirm:

That the foregoing electronically recorded proceedings were scoped by me to the best of my ability.

I further affirm I am neither certified or financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: December 21, 2020

Stephanie Morano

STEPHANIE MORANO

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