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 Six

December 8, 2020

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VIRTUAL ARBITRATION

GRIEVANCE OF FIRST OFFICER MICHAEL DANFORD

CASE NO. 18-14

BETWEEN

AIR LINE PILOTS ASSOCIATION, INT'L

AND

DELTA AIR LINES CO.

VOLUME SIX

DECEMBER 8, 2020

REPORTED BY:

DAMIEN STONEBERGER

STORYCLOUD

APPEARANCES

ARBITRATOR:

Mark Burdette

FOR THE COMPANY, DELTA AIR LINES CO.:

THOMAS J. KASSIN, ESQ.
SARAH AUFDENKAMPE, ESQ.
FORD HARRISON
271 17th Street NW, Suite 1900
Atlanta, Georgia 30363
404-888-3800
tkassin@fordharrison.com

CHRIS B. PUCKETT, ESQ.
DELTA AIR LINES, INC.
1010 Delta Blvd.
Department 943
Atlanta, GA 30354
404-715-1152
Chris.B.Puckett@delta.com

Also Present for the Company:

Brian J. Pickett, Company Board Member
Mike J. Doyle, Company Board Member
Patrick Burns, Company Representative

FOR THE UNION,
DELTA MEC AIR LINE PILOTS ASSOCIATION,INT'L:

LEE SEHAM, ESQ.
SEHAM SEHAM MELTZ PETERSEN
199 Main Street
White Plains, New York 10601
914-997-1346
lseham@ssmplaw.com

RACHEL SAMUDA, ESQ.
AIR LINE PILOTS ASSOCIATION, INT'L
100 Hartsfield Centre Parkway
Suite 800
Atlanta, GA 30354
404-763-5198
Rachel.Samuda@alpa.org

APPEARANCES, CON'T

Also Present for the Union:
Emilio Marcos, Contract Administration Committee Chairman
Kevin Morris, Union Board Member
Steve Mayer, Union Board Member
David Koch, Technical Advisor

Also Present:

Michael Danford, Grievant
Katy Hampton, Remote Technician

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DECEMBER 8, 2020

THE REPORTER: We are on the record. The time is 11:07 a.m.

THE ARBITRATOR: Okay. Now, we're going to put on the record that the grievant has an -- a technical expert today by the name of Dr. David Koch, spelled K-O-C-H. And I think, before we got on the record, Delta had expressed a desire to have a conversation about that.

MR. KASSIN: That's right. This may be more than way of a question. Maybe at some point, Dr. Koch can get his video going too. But the grievant has had an expert present throughout the hearing by the name of George Ellis. And as the arbitrator will recall, there was objections to the company having Howard Taylor present as a advising expert. Our understanding was that each side could have one advising expert during the course of the hearing who also would be free to testify. So, you know, I -- I just -- is -- is really probably more of a clarification for you, Arbitrator Burdette. Our underst -- you know, because we would have liked to have had another advising expert here that may have potentially been a rebuttal witness, but

we restricted it to one, believing that was what we were required. So my understanding was that Mr. Seham could have one and he has done so throughout the period of the hearing with Mr. Ellis --

THE ARBITRATOR: But he's not here today. Mr. Ellis isn't on today, right?

THE REPORTER: You are muted, Mr. Seham.

MR. SEHAM: Yes, I am. Well, yes. To start from the beginning there -- there was never any discussion about whether it was one or more. In any case, George Ellis would never, was -- was never intended to testify. He -- he will not be testifying, whereas Dr. Koch may be testifying if -- if that's required after.

THE ARBITRATOR: Just for clarity, Mr. Ellis is not on today, right?

MR. SEHAM: He's not available yet, but we can -- if he will become available.

THE REPORTER: Mr. Seham, your -- your audio is erratic and I'm unable to hear you clearly. Can you hear me?

MR. SEHAM: It would be Dr. Koch.

THE REPORTER: Mr. Seham, your -- your audio is quite erratic and I did not hear any of that. We may have to have you -- I think we should have you call in as well.

MR. SEHAM: Okay.
THE REPORTER: If we may go off the record for a moment to rectify this.
THE ARBITRATOR: Sure.
THE REPORTER: We are now off the record.
MR. SEHAM: What's the telephone number?
THE REPORTER: Oh, that's right. Chat is disabled. Hang on just a moment. I will give you that info. We're now off the record. The time is 11:11 a.m.
(OFF THE RECORD)
THE REPORTER: We're back on the record. The time is 11:13 a.m.
MR. SEHAM: And Damien, I have to start from scratch in terms of my response to Mr. Kassin on the technical advisors; is that correct?
THE REPORTER: Yes, sir, I apologize for that.
MR. SEHAM: No, no. Yeah. I'm not asking for an apology. I just wanted to clarify that. Mr. Kassin raises issues for the first time an issue about numerical limitation on technical advisors that we had -- we had never heard that before. But even to the extent there is a numerical limitation of one for technical advisors who are also testifying, George Ellis will not be testifying. We never intended to him to testify. The only technical advisor who would be

testifying potentially is Dr. Koch. In any event at this time, George Ellis is not available. We'd like him to be able to join if he becomes available. He just isn't at the time. But the only person who would serve a dual capacity of technical adviser and witness would be Dr. Koch.

THE ARBITRATOR: Mr. Kassin?

MR. KASSIN: I think with that understanding we'll be fine. We should've clarified that with you and that's on us to clarify that with you earlier on.

THE ARBITRATOR: Okay. Then let's proceed.

MR. KASSIN: Sure. I do not -- our first witness today is Howard Taylor, PhD or Dr. Howard Taylor, and I don't see him on the screen yet. If he maybe could be admitted into the waiting room.

THE REPORTER: He is in now.

MR. KASSIN: Okay.

THE REPORTER: Okay. Mr. Taylor, can you hear us? He's not -- he has not activated his system yet.

MR. KASSIN: And Katy, this is Tom Kassin. Once we get going, Howard Taylor, his first exhibit, we're going to refer to as his curriculum vitae and it's Company Exhibit 15. Just to make it easier for you to find and we're not going to go through the whole document, but you should be able to follow the pages as

we go through like education and positions and stuff like that, and we'll have you pull it up.

REMOTE TECH: Copy that. Thank you.

THE REPORTER: He still has not yet connected his camera or his microphone.

MR. KASSIN: Okay.

THE REPORTER: Is someone in contact with him?

MR. KASSIN: He's at a different location, but we may have to send somebody up there to go check up.

THE ARBITRATOR: Yes. Let's do that.

THE REPORTER: We're now off the record. The time is 11:18 a.m.

(OFF THE RECORD)

THE REPORTER: On the record, the time is 11:22.

THE ARBITRATOR: Okay. Dr. Taylor, would you raise your right hand, please? We've been swearing witnesses today.

THE WITNESS: Yes.

THE ARBITRATOR: 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?

THE WITNESS: I do.

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

THE WITNESS: There's no one else in the room.
THE ARBITRATOR: And do you have any documents that you could refer to that are not a part of this case?
THE WITNESS: No.
THE ARBITRATOR: Thank you very much. Mr. Kassin, proceed.

EUGENE HOWARD TAYLOR, PH.D.,
having been first duly sworn, testifies as follows:

DIRECT EXAMINATION

BY MR. KASSIN:

Q. Yes, sir. Please state your full name for the record.

A. My full name is Eugene Howard Taylor.

Q. Dr. Taylor, what is your professional specialty?

A. I'm a forensic toxicologist.

Q. Can you tell us what your current position is?

A. Yes. I have two positions. I'm a forensic toxicologist and co-owner of National Toxicology Specialists. And I also serve as a laboratory director for a clinical laboratory addiction labs of America, also in Nashville, Tennessee.

Q. Can you just explain to the arbitrator and board members what all those positions involve?

A. Sure. My -- the forensic toxicology we do -- we do workplace drug testing and monitoring of professionals in recovery by monitoring drug and alcohol testing. So that forensic testing is sometimes called a third-party administrator, who manage company's drug and alcohol testing programs. And in addition to that, I serve as an expert witness, particularly for the US Air Force. Much of my work involves testimony and consulting with courts-martials throughout the United States and the world. The -- that's the forensic side. On the clinical side, I serve as a laboratory director for Addiction Labs of America. It's a clinical laboratory. We do drug testing for addiction treatment -- treatment centers throughout the United States. So I hold both of those positions of employment.

(Company Exhibit 15 marked for identification)

Q. Okay. Your curriculum vitae has been submitted as an exhibit -- identified as Company Exhibit 15. And I was going to ask Katy to scroll through it with us. We won't go through the whole document, but I just want to highlight a couple key points. What previous positions have you held as a toxicologist?

A. Prior to starting National Toxicology

Specialists, I was a laboratory director for the National Reference Laboratory Substance Abuse Division. We were a SAMHSA certified laboratory that did forensic testing for workplace drug testing. We did about 3,000 specimens per day. Prior to that, I served as a -- in a clinical laboratory also with National Health Laboratories in Dallas, Texas for a short time. And then prior to that, I also was with the same company, National Health Laboratories -- National Reference Laboratory. I served as director of their clinical toxicology division. Prior to that, I was a tenured associate professor at the University of Arkansas for Medical Sciences in Little Rock. There I was in charge of the clinical laboratory for clinical chemistry and toxicology. I also taught medical students, pharmacy students, and med -- medical technology students. Prior to that, I was in a postdoc position at the University of South Carolina, the medical -- medical school there, in the department of laboratory medicine. I did a two-year fellowship in -- in Clinical Chemistry and Toxicology prior to moving to Arkansas.

Q. Okay. And are you board-certified and by whom?

A. Yes. I'm board certified in both forensic and clinical toxicology. The board certification

American Board of Forensic Toxicology, and also board certified by the American Board of Clinical Chemistry with a specialty in toxicology.

Q. Okay. And what professional licenses do you hold?

A. I hold a laboratory directors' license, the State of Tennessee for directing a toxicology laboratory, also a COQ or a certificate of qualification for the State of New York. Our laboratory once was going to apply for certification and it was necessary for me to become qualified as the laboratory director for the State of New York in toxicology.

Q. If you could briefly describe for us your educational background.

A. Yes. I have two undergraduate degrees. I have a BS in Chemistry and a BS Education in Mathematics from Armstrong State College in Savannah, Georgia, which is now part of Georgia Southern University. Then I went to the Medical College of Georgia, got my PhD in Biochemistry at the Medical College of Georgia.

Q. Have you been appointed as an expert in other judicial proceedings?

A. Yes. Most -- most all of my work in the --

in the court involves the Air Force. I've been appointed as an expert in over 200 military courts-martials and qualified as an expert in about 25 military courts-martials. And then I have an additional about 25 civilian cases that I've done. So I've testified about 50 times throughout my career, predominantly with the Department of Defense courts-martial.

MR. KASSIN: And Arbitrator Burdette, we'll let the rest of his curriculum vitae speak for itself. At this time, we would like to tender Dr. Taylor as an expert forensic toxicologist.

THE ARBITRATOR: Okay.

MR. SEHAM: No objection.

THE ARBITRATOR: Thank you very much, proceed.

MR. KASSIN: Yes sir.

BY MR. KASSIN:

Q. Katy, if you can take that curriculum vitae down. Thank you. Dr. Taylor, you know this case involves the termination, that Mr. Danford was a pilot for Delta Airlines and HIMS related program for alcoholic, had been drinking alcohol contrary to his agreement with Delta, and the requirements of his FAA Special Issuance. And he had a positive PEth test result as a result of a DBS or dried blood spot sample

taken on May 9th, 2018 as analyzed by the laboratory at United States Drug Testing Lab or as we've been referring to as USDTL. When were you first review -- I'm sorry. When were you first retained by Delta to review the results of the USDTL drug testing results for the May 9th PEth test?

A. I was contacted on June the 28th, of 2018 by -- by telephone.

Q. Okay. And what were you asked to do?

A. I -- I was asked to basically consult to review litigation package for the Quest Diagnostic Laboratories for an EtG urine test, and also to review the USDTL PEth testing that was done on -- on May the 9th to review those and then offer an opinion as to the accuracy of those test results and interpret -- interpretation of those results.

Q. Were you provided with the Quest data package, which is in the record as Company Exhibit 9 and the USDTL litigation package, which is in the record is Company Exhibit 10?

A. Yes. Yes.

Q. And once you received those documents, what steps or what things did you do next?

A. I -- I reviewed the documents for scientific validity or accuracy of the litigation package, the

chain of custody, quality control, and the appropriate analytical techniques. I had one concern relating to the two results. The screen result was 69 on the initial PEth screening tests and the confirmation result was 98. After looking at both results, I wanted to talk to Dr. Joe Jones at the laboratory to understand the uncertainty or the reproducibility of those results. I called him. We discussed that. He explained to me that the uncertainty or reproducibility precision, as we call it in the laboratory, is plus or minus 30 percent. And those values are certainly within plus or minus 30 percent of one another. So I was satisfied that the -- the precision was -- was appropriate and those results were in fact scientifically valid.

Q. So after you completed your analysis of the Quest May 1st, 2018, EtG results and the USDTL May 9th, positive PEth results, at some point, did you have a discussion with the Delta flight operations management?

A. Yes. I was involved in a conference call. It was probably a week or two after that. I -- I don't recall the exact date. And there was Mr. Puckett and also two or three members of the management from the flight -- flight ops at Delta. And we discussed the results and also the interpretation.

Q. And with respect to the Quest data package for the May 1st, 2018 EtG test results, what did you tell the Delta flight operations management people present on the call?

A. The litigation package was scientifically valid. As I said before, I reviewed the chain of custody, the quality control, and the methodology used by Quest Diagnostics in Norristown. I was satisfied that those were valid and accurate results. And then we discussed the PEth results. Would you like me to go and talk about that result as well?

Q. Sure. Did you advise him as to whether or not that EtG result of 117 nanograms per milliliter was positive?

A. Yes. It was positive, yes.

Q. Okay. Now, tell us also about your analysis what you shared with the Delta flight operations management team with respect to the USDTL May 9th, positive PEth?

A. I -- I reviewed the same issues in the litigation package, the chain of custody, quality control and scientific validity of the testing process. After reviewing that, I determined that was positive and that is consistent with the EtG result of May the 1st. As -- as we know PEth has a detection window of

two to four weeks roughly. And this certainly would overlap and be consistent with the initial EtG result from May the 1st and May the 9th indicating that active drinking had occurred.

Q. And did you inform the Delta management team that was your opinion?

A. Yes.

Q. Okay. What did you say to them?

A. The test is -- test is positive for both EtG in urine from May 1st and also positive for PEth from the May 9th, blood spot specimen test. In my opinion, it indicated drinking within the last two weeks, roughly. That's generally what we see in -- in our practice with -- with PEth. The -- the look-back period is typically one to two weeks.

Q. Okay. Now, the cutoff that was used by USDTL for that May 9th, 2018 test was 20 nanograms per milliliter. How widely is that cutoff of 20 nanograms per milliliter used in the toxicology field?

A. 20 nanogram per milliliter is a standard cutoff in the United States, Europe has a slightly different standard. But in the United States that is the generally accepted cutoff. And -- and there's a reason for that. The -- the idea is that we don't want to overlap any negative results or someone that's not

drinking. Typically someone that's not drinking has extremely low PEth value below the limit of quantification or limit of detection. So if we apply some of the uncertainty, as I said before, plus or minus 30 percent to that 20 nanogram per milliliter value. There's no overlap with the -- the very low PEth results that would occur from a non-drinker.

Q. Okay. After your telephone discussion with the Delta flight operations management and prior to coming to the system Board of Adjustment to testify today, did you make a site visit to the USDTL laboratory?

A. Yes, I did.

Q. Can you tell us when?

A. Yes. It was March the 12th of this year, 2020.

Q. What was the purpose of your visit?

A. Two -- two purposes. One was to actually observe the process for myself. I -- I currently serve as a SAMHSA inspector. I've inspected about -- certified laboratories about 50 times -- 50 SAMHSA inspections throughout my career. And I want to apply some of those same standards in looking at the USDTL results. So I observed the process. I also looked at the SOP, the Standard Operating Procedure to make sure

that it was scientifically valid and that the technicians were following the SOP. And also I looked specifically at the validation data because we're looking at dried blood spot tests. I wanted to really understand how the validation testing was done, what was done, and was that appropriate? And after spending a day at the laboratory, I was -- I was assured and convinced that the testing process was accurate and certainly defensible, very sound forensic process.

Q. Okay. And general background. Did you also look at their quality control procedures?

A. Yes, I did.

Q. Okay. And did you have an opportunity to review the original data from Mr. Danford's DBS sample, that was collected on May 9, 2018?

A. Yes, I did. I went back to the original data, not the litigation package, which is basically a summary of the data. But I looked at both the screening, run the actual results that were produced in the laboratory, the -- and also the confirmation results. For the confirmation results specifically, I was interested in something called carryover or contamination. Is it possible for one sample to be carried over into the next sample and make it positive? USDTL actually inserts a blank solvent, a solvent

blank, in between every single confirmation specimen. So that would assure that -- assure one, that there's no carryover contamination from one specimen to the next.

Q. Okay. So did you actually observe them -- the various steps of them actually conducting a test analysis of dried blood spot?

A. Yes. I -- I -- I followed a technician through the process, each individual step from receipt of the specimen to how these punches are done. The dried blood spot, they're -- they're three punches that are done. They're each three millimeters in diameter. And those are put into a test tube. And then the next dried blood spot, next specimen, would be spotted. But in between those, the technologist would use a Q-tip or cotton swab dipped in methanol to actually clean the pneumatic press that is used to assure, again, that there's no carryover or contamination from one specimen to the next. So in addition to watching the process and observing that, I -- I also looked at the instrumentation, what they're using. They're using an Agilent liquid chromatograph coupled with a Sciex mass spectrometer. And those are very appropriate, very standard instruments used in -- in many forensic laboratories in the United States. I also looked at

the Standard Operating Procedure manual to look at the methodology, how it was done, and to make sure that the technicians were following the -- the procedures. And -- and as I -- as I said, following each step along the way, I wanted to ensure that there was scientific and also forensic defensibility. Chain of custody was followed, the process was done appropriately, and then the validation data. I spent quite a bit of time looking at that to ensure that the validation was done properly according to current Standard Forensic Toxicology Guidelines.

Q. You testified just a moment ago about looking at what's referred to as carryover. Could you elaborate a little bit more on what that means and what you did to review their processes on carryover?

A. Sure. The -- one of the -- the big problems in laboratories, particularly high volume or high throughput laboratories, is this characteristic, what we call carryover. That is the contamination of one specimen and that may precede another specimen and may have a higher result. And that, that somehow would bleed into or carry over into the next specimen. USDTL takes several precautionary steps to ensure that does not occur. As I mentioned before, they use a swab dipped in methanol as a solvent to clean the pneumatic

press in between each single outreach specimen that is -- is processed. They insert a blank in between every confirmatory test result. In addition, they have an upper limit of quantification of 500. And anything over 500 would be subject or suspect with carryover. But of course since they use solvent blanks there, and they look -- they can look at the solvent blank and see that no carryover has occurred. It's a very sound and very defensible forensic process, as I said before.

Q. Okay. In connection with the carryover issue that you just described, did you have the opportunity to look at the sample that was run just prior to the DBS sample that Mr. Danford provided on May 9th, 2018?

A. Yes, I did. It -- it was -- it was well below the 500 nanogram per mL limit. And -- and in addition to blank following that sample was completely negative. There's absolutely no PEth carried over into that blank sample. And therefore, Mr. Danford's sample would not be subject to any contamination or carryover as we say, due to our previous result.

Q. Okay. You mentioned that you also looked at quality control safeguards that USDTL employed. Can you tell us what those were and your observations of them?

A. Yes. They use a single calibrator, a single

20 nanogram per mL calibrator. They use three controls. Three positive or three controls in which PEth is present, one below the cutoff, and two above the cutoff. And they also use a certified negative blood sample to prove that the matrix or blood has no PEth in it, in order to demonstrate that there's no production from any -- any just laboratory process, it might inadvertently add PEth into -- into the process. So a negative with three controls are included in -- in every run.

Q. Okay. So based on your first visit to the US Drug Testing Laboratory on March 12, 2020, and based on your background as a board-certified toxicologist and qualified SAMHSA inspector, what conclusions did you reach about that laboratory?

A. The -- the -- the process is sound. The laboratory has a very thorough and accurate forensic process, both in chain of custody, quality control, and the analytical methodology in which they're -- which they're using.

Q. Okay. I'm going to switch gears a little bit to you and talk about some of the testimony that we had from experts on behalf of Mr. Danford earlier in this case. And there was some concern expressed about the difference, the quantitative difference between the

initial PEth result of 69 nanograms per milliliter and the confirmatory PEth results of 98 nanograms per milliliter, and you testified you also had questions about that. Can you go into more detail about your analysis of the concerns that you had, which I think will address their experts also?

A. Certainly. So if we look at the initial result, the PEth result of 69, and as we said before, the reproducibility or uncertainty associated with that result is plus or minus 30 percent. So if we -- if we do the math, and I have a calculator here, if you'd like me to, we can say where the range of where the true value is. Of course, when you measure something, you don't really know what the true value is. You simply know what a -- a range it would encompass. And the same thing is done for the 98. If we look at 98 and say that -- that true value is plus or minus 30 percent of that actual value. There's considerable overlap between the 69 range plus or minus 30 percent and the 98 range, of plus or minus 30 percent.

So I guess the bottom line is the actual value probably lies somewhere between the two. Because we're -- again, we're looking at an analytical measurement in the laboratory. And one thing in a forensic process is you always want to define the uncertainty associated

with that measurement. That's very critical. So if I had seen a result of 69 and 690, well clearly those are two very far apart results and -- and there's no overlap between them. And I would be very concerned about that. But in this case, it's -- it's -- it's very simple to see that the -- the -- the average or the mean is -- is probably closer to the true value. And even if we look at the plus or minus 30 percent, there's tremendous overlap there. So if you need me to do the calculations, I certainly can.

Q. Would you please do that? I'd like to put that on the record. And I'd like for you to explain, when you do that, give us the range for 69 and then give us the range for 98, and what you can conclude from those two ranges?

A. Okay. And just to let everyone know, I have a old-fashioned calculator here with me and a pad of paper. So I'll very quickly do that calculation for you. Okay, so if we look at the range with 69 plus or minus 30 percent, that range is 48 to 90. 48 to 90. And if we do the same thing, plus or minus 30 percent of the 98 value, that range is 69 to 127. And you can see that there's considerable overlap between those two ranges.

Q. And what does that tell you?

A. Those -- that if -- if I ran that sample 100 times, let's say, I would see similar values between -- within that range that I just -- just showed you.

Q. Okay. What is the basis for use of the plus or minus 30 percent? In other words, how do you come up with that plus or minus 30 percent?

A. Sure. That -- that is something -- that is something that comes from the laboratories validation data. The -- the -- when -- when one analyzes the particular cutoff at 20 nanogram per milliliter, and analyzes that multiple times and looks at the mean and the standard deviation, a standard deviation is simply the spread of data. How -- how wildly or narrowly distributed is that data. They come up with calculations called a coefficient of variation. This is standardly used in a laboratory to -- to -- to look at the uncertainty. So in -- in looking at the 20 nanogram per mL cutoff, the CV or coefficient variation was approximately or slightly less than 15 percent. In the laboratory, we use two times the coefficient of variation as the range of uncertainty. And there are reasons for that I won't go into. But if you look at two times 15 percent, that range is plus or minus 30 percent. So it's strictly related to the laboratories validation data and they produce data that show that is

the uncertainty in their testing procedure.

Q. Okay. Again, we switch gears on -- with you onto another -- before I do that, let me just ask you, is there any question in your mind or your opinion as to the accuracy of the May 9th, 2018 PEth test for Mr. Danford conducted by USDTL?

A. No. In fact, if -- if we take a look at that uncertainty and apply it to the -- the cut-off, if -- if you noticed the range that I just discussed, 69 and the range is 48-90 and the 98 range is 69-127. Those ranges are nowhere near the cutoff. So this -- this -- this result, even with all the uncertainty from the laboratory, is not anywhere near 20 nanogram per mL cutoff. So I'm -- I'm convinced that this PEth is present, it's positive, and it's well above the cutoff.

Q. Okay. Next, I want to talk about some testimony from one of the experts called by Mr. Danford, whose name is Theodore Shults. And just as a preliminary question, do you personally know Mr. Shults?

A. Yes. I know -- I know Ted very well. We are -- we are colleagues. In fact, we had lunch together at -- at the last Society of Forensic Toxicology meeting in San Antonio. I know him very well.

Q. Now, he has submitted a report, Union Exhibit

50, which the company shared with you earlier before this hearing, correct?

A. Yes.

Q. Okay. And he had some testimony where he discussed comparing some self tests that Mr. Danford did on May 15, 2018 and May 16, 2018. And Mr. Danford also submitted a package of those tests to Delta at an appeal hearing on July 30th, 2018. And what I'd like you to do and I'd like to ask Katy to bring up Company Exhibit 20.

(Company Exhibit 20 marked for identification)

Q. And I want to look at page 1 of that document, Katy. And as you get to the middle of the page it -- there's the words negative and detection limit of 20. And I think if you'd just blow that up a little bit, you got it right there and lower it just a hair, there we go. We -- we got it. The point of -- so what Mr. Shults's opinion was that it was not possible for Mr. Danford to have a negative PEth test on May 15, 2018 and a positive PEth test on May 9th of 2018. Do you agree with that opinion?

A. I disagree.

Q. Okay. And in connection with what you are about to testify to, did the company ask you to prepare a chart on half-life?

A. Yes. I -- I prepared a demonstrative aid on half-life, yes.

(Company Exhibit 31 marked for identification)

Q. Okay. And that should be Company Exhibit 31, which is -- was distributed before the hearing to StoryCloud and to the board members, arbitrator, and counsel. So I'd like Katy, can you bring up Company Exhibit 31, please? And this is what I had --

MR. SEHAM: I have no -- I just want to state that I have no prior knowledge of this. If you say you distributed it, it must have been after the hearing started.

Q. Mr. Seham, I'm not sure what time. I know we did -- if you check you should be able to see it so -- but I will -- we're just looking at it now and we'll just go -- we'll -- it's pretty straightforward. So Dr. Taylor, on the -- the half life chart which is Company Exhibit 31, what is page 1 showing us and tell us what your calculations were?

A. Yes. I prepared two calculations based on -- one based on the 98 result and another based on the 69 result. So this -- this is using the 98 result. So much discussion has been about half-life and the application of half-life. So we know that the range of half-life is from 1-13 days. It's a very wide range

with the average being about 4.5 days. But the standard -- the standard deviation is about 3.5. So it's one-day half-life is very possible. It's -- in fact, it's within one standard deviation of the average. So if we apply one-day half-life starting at May the 9th. And you can see how -- just following the column down for one day using a one-day half-life at -- at May the 9th, it simply have the result each day -- every day have the result.

By May the 14th, we're down to three. And certainly that would easily produce a negative PEth test result on May the 15th. And then if we look over at two days. So let's assume for a moment that the -- the half-life is two days. Well, beginning again at May the 9th of 98, go two days later to May the 11th, it's 49 and a half, go two more days to May the 13th, it's 25, and go two more days to May the 15th, it's 12. So again, even with a two day half-life, we would be -- we would produce a negative test result, recalling that in the previous exhibit that the cutoff for the laboratory is 20. So this would produce a result well below 20 nanogram per mL, even if it's day 15.

So it's certainly reasonable to -- to -- to say that the half-life for Mr. Danford lies between one and two days, assuming that the value that we're starting

from is 98. I also did the same thing with 69. Is that the second page of this exhibit? There we go. So let's go back and let's just for -- for a moment assume 69, and again, just giving the benefit of the doubt to the widest range of possibility, somewhere between 98 and 69, applying the same logic with a one-day half-life beginning at 69 on May the 9th, then you can easily see by May the 13th we are well below the 20, that would certainly produce a negative PEth test on May the 15th. Let's go to the middle column, which is two days beginning again with May -- with May the 9th being 69.

And then we come to May the 15th, you can see that the May the 15th PEth result would easily be below 20 and produce a negative result. If we extend it all the way out to the three-day half-life beginning 69 on May the 9th, by May the 15th our value is 18. So again, even with a 20 nanogram per mL cutoff, that would produce a negative result. So certainly we can say the half-life for Mr. Danford is certainly between one and three days, perhaps closer to one to two days, and that's consistent with what we see with alcoholics. We know that alcoholics have a shorter half-life than do social drinkers. That's a well-known -- well-known fact. So certainly with a one to two day half-life,

either of those conditions would produce a negative PEth test on May the 15th.

Q. And we had some testimony briefly from Mr. Shults, but I wanted to -- are you familiar with the scientific peer-reviewed study done by Dr. Javors?

A. Yes -- yes.

Q. I'd like you to just briefly to look at Company Exhibit 27. Katy, if you could bring up page 1 of that. And then we're going to go over to seven. And under -- Katy, if you could just bring down to results and just blow that up a little bit. It's just a little bit further down under the results. Does this report you were saying in terms of the half-life of PEth being anywhere from 1 to 13 days?

A. Yes, exactly. The range is 1 to 13 and the average is 4.6. An inappropriate use of half-life is to use 4.6 for calculations. That's simply the average, that's not -- that's not Mr. Danford's half-life. In fact, we just calculated Mr. Danford's half-life of being between one to two days. So 4.6 cannot be used as an average. But the range again is 1 to 13 days.

MR. KASSIN: Okay. And you can take that down. And that's all I have on Company Exhibit 31 for right now. Let me put this back in place. Okay. Katy, if

you could go back to Company Exhibit page 3, and Dr. Taylor, I want to refer you to a self test that Mr. Danford presented to Delta. It was a hair EtG test done on May 15th, 2018. And we can bring that up, Company Exhibit page 3.

REMOTE TECH: Which Exhibit?

MR. KASSIN: I'm sorry, Katy, what?

REMOTE TECH: Which Company Exhibit? You said page 3, but which one?

MR. KASSIN: I'm sorry. Company Exhibit 20, please.

REMOTE TECH: Okay. One moment.

MR. KASSIN: Okay. So can you just blow it up a little bit more so we can all see it. It doesn't need much. There you go.

BY MR. KASSIN:

Q. Dr. Taylor, what assisted Mr. Shults's testimony in his report, states -- Union Exhibit 50, it was not -- his opinion was it was not possible for Mr. Danford to have a positive PEth test on May the 9th, 2018 and have a negative hair EtG test on May 15, 2018. And my question for you is; is that inconsistent? The negative hair EtG test on May 15th, with a positive PEth test on May the 9th?

A. No. It's not inconsistent and here -- here

is the reason why. So if you look at the date of collection of 5/15 and compare that to the PEth test -- positive PEth test that's May the 9th. The hair takes about two weeks for it to grow or penetrate through the skin. For example, if one uses a drug or alcohol and it's incorporated into the hair, the hair follicle is actually growing beneath the skin. It takes about two weeks, for that process -- for it even to penetrate the skin in order to be cut. Now if you notice, this is chest hair which grows even more slowly than does head hair. So two week period typically is for -- for head hair and chest hair grows about half as fast as head hair. So the -- the dormant period or look-back period is -- is even greater with chest hair. So if we subtract two weeks from 5/15, we can go all the way back to May the 1st, that we couldn't see anything. If -- if -- if he drank a ton between May the 1st and May the 15th, you couldn't see it because it's below the -- the skin. It -- it's unable to be detected because it has not penetrated the -- the skin in order to be cut. So this test proves that or doesn't -- doesn't negate or rebut the negative PEth test at all. There's not enough time for the hair to grow in order to be reflective of any drinking that might have occurred in that period that we discussed previously with the PEth

test.

Q. Okay. Next, I'd like to refer you to page 4, Company Exhibit 20. And Katy, if you'd just bring it to the next page. Okay. Dr. Taylor, this is the PEth test collected on May 16th, 2018. It's a self test Mr. Danford took and it's part of the packet that he gave to Delta at his appeal hearing. And it shows a screen cut-off of 20 nanograms. And up above it, it refers to it where it says test requests that it shows -- it was a -- a dried blood spot. Am I reading that correctly?

A. Yes.

Q. Yes. Okay. Essentially, Mr. Shults's point was that it's just not possible for Mr. Danford to have had a positive PEth test on May the 9th, 2018 and have a negative PEth test with a cutoff of 20 on May the 16th, 2018. Any brief observation regarding the May 16th test?

A. Well, we -- we've already shown that the -- the May the 15th test could certainly be negative if his half -- half -- half-life was one to two days and anything after May the 15th would certainly be negative if the May the 15th PEth -- PEth test was negative. So one done the subsequent day, that -- that makes perfect sense. If -- if the previous day was negative, I would expect the subsequent day to be negative.

Q. Okay. And then I'd like you to look at page 5 of Company Exhibit 20. And Katy if you could bring us over to that page. This was the last of the self test that Mr. Danford presented to the company at his July 30th initial appeal hearing. And it was also a dried blood spot collected on May 16th, 2018 and used a confirmation cut-off level of eight nanograms per milliliter. And it shows that it was negative and Mr. Shults's opinion was that this particular test with an eight nanogram cutoff being a negative, shows that it was not possible for the May 9th PEth test that Mr. Danford took to be a positive. Do you agree with that statement?

A. Again, if you go back to the -- the chart with the half lives, it certainly could be below eight nanogram per mL on the 16th of -- of May. So that is -- that is consistent with the May the 9th positive PEth test. Assuming a half life of one to two days, that -- that is certainly consistent.

MR. KASSIN: Now I want to switch your attention to what's been identified as Union Exhibit 75. And Katy, if you can bring that one up.

Q. It's a hair EtG test that was taken by Mr. Danford on June the 20th of 2018, that was not given to Delta Airlines. But I'd like to get your opinion on

some of the information that's contained on Union Exhibit 75. And Katy, I don't know -- can you blow that up just a hair more, but maybe not. It's looking -- actually I can see it pretty good. So as you look at Union Exhibit 75, Dr. Taylor, what's your initial -- or what's your initial, if you will, summary of the information contained here?

A. Sure. The -- the result is positive 4.8 picogram per milligram with a cut-off of 2 picogram per milligram. A very important thing to note on this report, is look at the date of collected on 6/20th. So now recall we -- we have enough time for the EtG present in hair to penetrate the skin in order to be detectable. So we -- we've -- we've surpassed that two week, sort of dormant or latency period, that if we went back prior to June the 20th, let's say subtract two weeks back to June the 4th, then our look-back period begins on June the 4th. So drinking would have to have occurred prior to June the 4th. If you look at that 4.8, a question becomes, is it possible to be -- to drink and have a result of 4.8? Is -- is that entirely possible? And there's a very nice study by Kronstrand -- Robert Kronstrand. He's a colleague that's in Sweden. And I believe we have an exhibit for that to -- to demonstrate that exact point.

Q. Sure. And Dr. Taylor, I'd like to refer you to what's been identified as Company Exhibit 32. And Katy, I'd like you to bring up the Company Exhibit 32 at this point, and you're probably going to need to blow that up.

(Company Exhibit 32 marked for identification)

Q. Is this the scientific peer-reviewed article by Kronstrand that you were referring to, Dr. Taylor?

A. Yes, it is.

Q. And can you point out to us the relevant information and if you could just -- if you could assist Katy and tell her where to go in that study?

A. Sure. If we could just show the abstract -- the portion of the abstract would be -- would be great. And let me grab my copy here so -- I -- I cannot see the copy very well on the screen. So I'm going to grab the -- the actual exhibit here from the exhibit list. Just a moment. And this was Company Exhibit -- which one, 32?

Q. 32, sir.

A. Okay --

Q. Company Exhibit 32.

A. -- I have it. So if you look at the abstract -- and maybe you can blow it up just a bit more to look at the abstract, please, particularly the last four

lines.

A. So be -- beginning with the sentence where it says, "We conclude." To -- to explain what the study was about, individuals drank alcohol. It says 16 or 32 grams to put that in perspective, a drink is 14 grams of alcohol. So 16 is roughly the equivalent of one drink or 32 grams of alcohol or ethanol is the equivalent of two drinks. So these individuals drank daily for three months, every single day for approximately 90 days. And what the study shows basically is that, it is possible to get a negative hair test with the drinking every single day because the results fall below the threshold for detection.

And to look at the sentence in the abstract, it says, "We conclude that persons who ingested 16 or 32 grams of ethanol daily for three months, presented with low concentrations of EtG in hair well below the proposed threshold for over consumption, 30 picogram per milligram." And to put that in perspective, the Society of Hair Testing is using heavy alcohol consumption, moderate to heavy consumption at 30 pg/mg. And then the last sentence is very important as well, in that abstract. It says, "In addition, none of those who ingested 16 g/day had concentrations over the proposed abstinence threshold of 7 pg/mg." So to put

that in perspective with Mr. Danford's test of June the 20th, his EtG hair test value of 4.8. It is certainly possible to drink. In fact, to drink every single day for three months, one drink and have a concentration less than seven picogram per milligram. So this study demonstrates that just because a negative hair -- a negative hair test does not rebut a positive PEth test.

And I'd also like to go in this article. It's page 4. If we could scroll down to in the upper left-hand corner, it's got page 4 of the article. Yes. That's it on the right-hand side, please. That's page 3, one more page, please. Yes, that's correct. And if you look below Table 3, the paragraph that begins another significant finding. And the -- the next sentence after that, which begins with the diagnostic specificity." The diagnostic specificity for EtG is theoretically very high since its formation is always associated with metabolism of ethanol. However -- and this is the important point. However, our results showed an EtG concentration below seven picogram per milligram does not exclude daily alcohol use. And thus the sensitivity is questioned for the purpose of monitoring total abstinence." So the question becomes, does a seven if -- if a result is below seven picogram per milligram, which is typically used as a cut-off for

hair testing, does a result below that prove abstinence? And the answer is, it does not. Because as we just demonstrated, one can drink as much as one drink every single day for three months and be below a seven picogram per milligram value. So the question becomes, if you are abstinent, then what values would you typically see in hair? And I think that's our next exhibit, which is the article by Pirro.

MR. KASSIN: Okay. And Katy, can you please bring up Company Exhibit 33?

(Company Exhibit 33 marked for identification)

Q. And Dr. Taylor, I would ask you, is this the Pirro exhibit you're referring to?

A. Yes, it is.

Q. Okay. And can you take us to the relevant portions of that study?

A. Yes. So let me -- let me explain the purpose of this study. So here -- here we are asking a different question. So if someone is abstinent, what would an EtG in hair look like or what values would we see in hair? So if we could go to the abstract, blow that up. The very last sentence of the abstract. Very last sentence of the abstract. And -- and let me explain what they did here. So in this -- in this instance, they -- they actually tested children. They

tested children because we know that these individuals were abstinent from alcohol. And they looked at the values that they got for EtG in hair. And it's -- and they found the values to be extremely low, approximately one, two picogram per milligram. And the take home message for this article is the last sentence. It says, "Cut-off value in the range of one to two picogram per milligram can be reliably proposed to support alcohol abstinence." If you recall on the ExperTox report, they used a cut-off of two picogram per milligram. That -- that cut-off is extremely well-founded because we're asking a different question. We're asking the question is Mr. Danford abstinent? And that question it can be answered that he was not because his value falls above that two picogram per milligram range. There's one other part of this article I would like to -- to -- to -- to -- to talk about. And if we could go to actually, it's -- it's upper left-hand corner page 232 of the article. I believe it's page 4.

Q. Actually I believe it's page 5.

A. Page 5, upper-left-hand corner. Page 2 -- and below this table -- thank you. On the right-hand side --

Q. Do you want to go back?

A. Right-hand side. No -- no, that was correct.

Q. See the rest of the table?

A. Just below the table on the right-hand side, where it begins with 0.5. picogram per milligram. Okay. So the -- the -- just to lead into that sentence what -- what that says, it says, "The LOD and LOQ values were 0.5 picogram per milligram and one picogram per milligram respectively. In agreement with Society of -- SoHT is Society of Hair Testing consensus for alcohol abstinence assessment, which recently fixed the minimum quantitative performance for such an investigation (LOQ values less than three picogram per milligram.) So to understand what the Society of Hair Testing is talking about here, they're -- they're -- they're using three different suggested cut-offs. The low end value of three picogram per milligram is for abstinence as we were -- had just shown. The values produced in this paper produced values between one and two picogram per milligram.

Then they use a value of seven picogram per milligram as a -- as a typical cut-off. Now, not all laboratories can go down as low as ExperTox. That's why they recommend using a seven milligram per -- seven picogram per milligram cut-off. So to say that someone has a -- a value below seven picogram per

milligram does not necessarily mean they're abstinent. We have to go below three picogram per milligram to -- to prove abstinence. And then the Hair -- Society of Hair Testing also uses a much higher cut-off of 30, which relates to excessive drinking, they call it moderate to heavy drinking. So the cut-off is very, very important to determine what question you're trying to answer. If the question is abstinence, you need to use the lowest possible cut-off. And I just want to be clear on what -- what the purpose of all these cut-offs were.

Q. Okay. And Dr. Taylor, you had initially started to go to Page 5 on the left-hand column. Could I direct your attention there, and what conclusions does the Pirro study reach in terms of what alcohol abstinence programs assessments should use?

A. Right. And that -- that was basically based on that -- that sentence that I just read. In -- in order for a laboratory to -- to use a hair test for the purpose of abstinence the -- the -- the value needs to be below three picogram per milligram. And that's exactly what ExperTox did. That -- that cut-off is well-founded in the literature for abstinence.

Q. Okay. Katy, can I get you to go two pages over. So you are on page -- page 7. Thank you. There

we go, and it's to the left-hand column. Can you just blow that up a little bit? Dr. Taylor, what is your take on the paragraph that starts for the alcohol abstinence assessment?

A. Yes. For -- for example, it says, "For the alcohol abstinence assessment our experimental data suggests a revision of the existing cut-off is advisable, that a cut-off as low as one picogram per milligram can reliably be proposed, at least for clinical purpose. Meanwhile, prudently higher values about two picogram per milligram can be maintained for legal and forensic controversies." Exactly what we're doing here. "Until consistent independent results will be collected to support the selection of a cut-off at such a low concentration." And again, that -- that's exactly why ExperTox is using the cut-off that they're using as opposed to the other laboratory which had a much higher cut-off of 20 -- for -- for other hair test results.

Q. Okay. Next, I want to shift our attention to Union Exhibit 50, which is the expert report prepared by Mr. Shults. And Katy, if you could take us to Page 5, please. Under interpretation results in that second paragraph, Mr. Shults refers to the non-negative ethyl glucuronide test referred to above, which is the May

1st EtG test that Mr. Danford had. Is non-negative in this context the same as positive?

A. Yes.

Q. Okay. And also on page 5, and as well as in his testimony, Mr. Shults made reference to normalizing the results from Mr. Danford's test results with the creatinine level. Do you agree with his opinion that test results should be normalized and do laboratories normally normalized results with creatinine level?

A. No. Well, I disagree with his conclusion. Laboratories do not typically normalize EtG results. To explain why normalizing is even relevant at all to drug testing or alcohol, relates really to -- to drugs that stay in the body a long time. The classic example is THC. So the question that's asked, because THC stays in the body for weeks, and in some studies even months, is this new use or old use? That we need to compare a previous point in time to a secondary value to determine if the person smoking marijuana again. And this is exactly what the purpose of normalization is to do is to take out the effect of how hydrated one is whether they're over hydrated or under hydrated or whatever. So we understand what that is. SAMHSA labs do not normalize results. Forensic drug testing laboratories, if they do normalize results and they're

used for the purpose of comparing two results. It's not possible to normalize a single result and provide any interpretation. The -- the bottom line for this -- this paragraph, the EtG test is positive. Whether you want to call it positive and normalized, it's still positive. There's no -- there's no -- the normalization does not change the fact that it's still positive.

Q. Okay. And we'll be coming back to Mr. Shults in a second, but I want to go over to Union Exhibit 57, which is the expert report from Dr. Skipper and go to page 4 where there's a -- a timeline, and there's a table on page 4. I think it's one more, so it should be one more page, please. And I'm focused on the May -- May 1st, '18 statement there. We just blow that up just a hair. But Dr. Skipper also talked about normalizing the results for creatinine. And on this particular -- he makes a similar comment to what Mr. Shults said that in terms of -- if you normalize that you come down to 46 nanograms per milliliter. What's your assessment of that approach?

A. Well, there's no way to interpret that. I mean, the -- the laboratory -- there's no laboratory that says a certain normalized EtG result results in a positive. Laboratories just don't do that. So Dr.

Skipper took a -- an arbitrary creatinine value, a random creatinine value, and used that for his denominator to -- to -- as the result. So the calculation is purely arbitrary. The laboratory does not do that. It's not customary to do that. The laboratory's procedure and policy say that anything over a 100 nanogram per milliliter is considered positive. So it's still positive. There -- there's no additional interpretation that would make this negative. It's positive to begin with. And you can normalize it all you want, but it's still positive.

Q. Okay. Katy, we're going to go back to Dr. -- I'm sorry Mr. Shults's Exhibit, Union Exhibit 50 and we'll go back to page 5 of that exhibit. And I want to go down to the bottom one third of that. The sentence starts out the compelling evidence of laboratory error are, and if you can take us -- here we go, yeah, you've got the whole thing, that's great. If you can just maybe blow that up just a hair. Maybe too much, maybe go back. Here we go. Thank you.

So Dr. Taylor, what I want to ask you about is these claims of laboratory error that Mr. Shults is testifying to and putting in his report. So first of all, he says, compelling evidence of laboratory errors are, and we we've talked about the differential between

those tests, self tests that were done on May 15th and 16th versus the PEth on May 9th and I'm not going to go back over that. And he also -- goes down towards the bottom. It says, "I can only speculate what the sources of error are here." By way of background, what are the errors that a laboratory can make?

A. Well, a laboratory can -- an error in a laboratory can happen one of three ways. The first error, it would be a chain of custody error. It's not the right sample. The second error could be an analytical procedure. It's not the right technique, it's the wrong procedure. The third way a laboratory can make an error is a clerical error. I found no evidence of error. I don't know what he's talking about. When he wrote this report, he had not or has not been to the laboratory. He had not even reviewed the litigation package at the time he wrote this report. So I -- I don't understand what he's talking about and I -- I disagree with that comment.

Q. Okay. To be specific as to what you were just referring to, you were talking about the USDTL test results of May 9th and the positive PEth for Mr. Danford, correct?

A. Right.

Q. When you looked at the Quest litigation

package, which is Company Exhibit 9, did you see any basis for laboratory error by Quest?

A. No.

Q. Okay. And -- at the beginning of page 5 and it will carry over to page 6, Mr. Shults talks about dehydration. "Dehydration results in increased concentration of metabolites in urine that is produced" and -- and what I really want to do is change our focus now from urine to PEth. "It also causes interference in -- and if you can flip to the top of the next page please, Katy, immunoassay test". Is a PEth test an immunoassay test?

A. No. No test -- none of the tests here were immunoassay tests. The EtG tests that was performed, the screen and the confirmation are not immunoassay. The PEth test is not immunoassay. Immunoassay reference is not relevant here.

Q. Okay. And then staying on page 6 at the very top there, it goes on to say, "Dehydration can also change the characteristics of blood and can cause interferences in dry blood spot tests and retention time in the mass spectrum chromatography." What was your reaction to that?

A. Well, the second part -- for the retention time and mass spectrum, mass spectrometry is absolutely

not true. There's no basis for that whatsoever. The retention time is one of the key criteria that we use for identification of a compound. And that is not true. That statement has no basis in fact. Dehydration -- an individual's -- an individual's hematocrit vary -- or male varies between about 42 to 52 percent. And as one drinks a lot of water, let's say, your kidneys filter it out so your blood stays very -- very homogeneous and preserves the -- the state of hydration. So if one is -- if one is severely dehydrated, well, the kidneys, what they -- how the body responds is to retain water. So you try to preserve that hematocrit in a -- in a very narrow range for survival.

Dehydration, it may cause one or two percent fluctuation in hematocrit. but it's certainly not going be that traumatic. So if we look at Mr. Danford's creatinine from the EtG tests from May the 1st, his creatinine was 254, I believe, approximately. The normal range for creatinine is about 20 to 320. So yes, it's a little bit toward the upper part of the normal range, but it's -- it's by no means diagnostic of kidney -- kidney disease or severe dehydration or something like that. Yeah. His urine was a little more concentrated. Yes. That's true, but certainly

not abnormal.

Q. Okay. And Katy, I'd like you to -- same page. I'd like to go down to Mr. Shults' opinion, starting with another important variable in the PEth DBS test, you can stop right there. So Dr. Taylor, can you see that? The statement having to do with the, what effect does hematocrit have on PEth? And statement that's underlined, "The physical characteristics of DBS sample are also potentially affected by the patient's hemoglobin, hematocrit level." And then there's, down below, also, "The relative amount of plasma in a disk punched from different spots can vary and particularly exaggerate when the hematocrit is extremely high or low." Your reaction analysis as a board-certified toxicologist for those statements?

A. Sure. Let's -- let's take -- kind of separate them and let's just talk about the effect of hematocrit. So there's some studies that say there's no effect of hematocrit. In fact, the study that Dr. Skipper referenced, we don't need to show that right now. But the one that he referenced specifically says there's no effect of hematocrit and there's no effect of the -- the spot, the punching of the blood spot. There's no effect. But -- but that particular study

had a very high cutoff for PEth. Other studies have said, well, yeah, there's some contribution for hematocrit, it can alter the result a bit. One particular study that I recall said that the change in hematocrit can alter the result by about 10 percent. So if we look at that analytical variability that we were talking about before, the laboratory USDTL says that 10 -- plus or minus 10 percent is incorporated in that plus or minus 30 percent. So that's simply something that's inherent in the blood spot procedure that adds a bit of variability into the result.

Other studies show, that again, that the plus or minus percent, may be a, what's called a pre-analytical variable. And that, in fact, may contribute or add to the plus or minus 30 percent. So some other studies says, well maybe the variability in the quantitative result may be plus or minus 40 percent based on individual hematocrit. But all the -- again, all of this is pre analytical variability. So the hematocrit, it may have some effect. Certainly it will. But how much an effect, it's fairly minimal. It's going to be well below anything that would alter this result significantly enough to cause it to be below the cutoff, for sure.

So the next statement about the relative amount

plasma disk is the -- the underlined statement in the second paragraph. USDTL does not do a single punch. They do three punches and those punches are randomly selected. So the idea of -- of punching out a sample that is far different and -- and unusual from the rest of the blood spot is compensated by the fact that they're taking three different punches and randomly sampling that blood spot. So yeah -- yes, even if there were changes by sampling three different times, you can overcome that -- that variability. So again, that's not -- not really an important factor. So I guess the bottom line is that hematocrit, the maximum affected it could have is plus or minus 10 percent of the result. Which again is not -- not very high, since we're already talking about plus or minus 30 percent in the analytical world.

Q. Okay. Next, there was testimony by Mr. Shults, he refers to it in the paragraph below. And Katy, if you could bring us up one more paragraph, the paragraph, this concentration effect. And he talks about the fraud perpetrated by Theranos, and we don't have the transcript of exactly what he said. I mean, my recollection of his testimony was he clearly was alluding to USDTL, maybe not so much Quest in terms of what they're doing with their DBS. And I mean, what --

is it --

MR. SEHAM: For the record, I -- I'd ask that counsel not -- I'm going to object to the characterization of testimony.

Q. We'll let -- Mr. Seham -- or Mr. Arbitrator, I'm sorry, sir. We'll let the record speak for itself. The question was simply is -- and I think, many of us are familiar with the Theranos situation and the documentary that's been done on it and other writings, but is that reference, the Theranos, an appropriate reference to the state of the science on PEth testing?

A. No. In fact, this is beyond inappropriate for an expert to say something like that, particularly since he's never visited the laboratory and at this point hadn't even looked at the litigation package. That -- that is completely inappropriate and frankly, I'm shocked that Ted would even go down this road. It's -- it's nonsense.

Q. Okay. Mr. Shults also opines, "The PEth DBS test performed here does not meet the fundamental requirements of a forensic test." Your reaction to that?

A. It -- it absolutely does. In -- in -- in a forensic test, one of the first things that you have to have is a chain of custody. There's chain of custody

of the specimen, there is chain of custody of the aliquots. Is the procedures that are used scientifically defend -- defensible and reliable and accurate. The answer to all of those questions is yes. Is there an SOP? Is the SOP consistent with what the technologist are doing in the laboratory? The answer is yes. Is the techniques and procedures forensically sound? The answer is yes. Has there been validation performed that's in accordance with standard guidelines for forensic testing? The answer is yes. Do all of those taken as a whole indicate this is a sound and appropriate forensic test? The answer is yes.

Q. Okay. He also makes several other claims that I want to go through them in a fairly rapid fashion. His opinion on the positive PEth test on May 9, 2018 was a false positive; do you agree?

A. No, there's -- there's no evidence of that.

Q. USDTL is a non-certified laboratory, do you agree?

A. Well, they are certified. They're certified by the College of America Pathologists for forensic drug testing. They're also certified by the State of New York. I think perhaps what he's referring to is the SAMHSA certification. As we know, PEth is not an analyte, it's covered in a SAMHSA certified -- as a

covered -- as an analyte it's even tested in SAMHSA. And if you look at alcohol for -- as just the breath alcohol, testing is not done in a SAMHSA laboratory, it's a breath test. So to apply or to even say that this is -- is not -- is done in a SAMHSA certified laboratory. Even if it were done in a SAMHSA certified laboratory, as an inspector, I don't look at this stuff because it's not relevant, it's not a SAMHSA test. So that -- that has no bearing whether the laboratory is certified by SAMHSA because it's not covered as an analyte. But I disagree, the laboratory is certified. In fact, they have the highest certification that they could possibly have. The -- the forensic urine drug testing certification is kind of the next level or next tier relative to SAMHSA and also certified by New York State as well.

Q. Okay. Another opinion he expressed his that USDTL used the laboratory developed tests for its PEth tests, and that's not FDA approved. Your reaction to that?

A. No -- no laboratory developed test is FDA approved. In fact, all chromatographic and mass spectrometry tests are not FDA approved. So if -- if -- if that's the requirement, you would put out -- every single forensic laboratory in the United States

would be out of business, including every SAMHSA lab because every test that is done by gas chromatography or liquid chromatography mass spectrometry, those are all laboratory developed tests in the SAMHSA laboratory and that would not be allowed. It's simply irrelevant. And -- and FDA approval has to do with testing that's run on automated instruments or automated analyzers, not chromatographic techniques.

Q. Okay. Mr. Shults referred to a number of scientific studies in his testimony, and what I wanted to do is go through each of those with you and ask you whether they're relevant to PEth testing and the issues in this case or otherwise gets your -- just get your thoughts on the relevance of what -- and accuracy of what he's pointing to. The first one he talked about was Union Exhibit 1. And I think, Katy for now I think you don't need to refer to these unless the arbitrator or counsel would like to look at specific pages. I think -- I think we can go through these exhibits rather quickly and just have everybody on the screen. And Dr. Taylor, do you have a copy of Union Exhibit 1 with you?

A. Yes, I do.

Q. What was the study about and is it relevant to what we're discussing in this case on the PEth

testing?

A. Yes. This is -- this is related to therapeutic drug monitoring and clinical toxicology guidelines for dried blood spot based test. And the -- the essence of this article is simply saying that you have to have a sound validation procedure in order to implement a dry blood spot test. As I said before, I -- I reviewed the validation data in its entirety at -- when I visited USDTL. I looked at the following things. I looked at precision, I looked at accuracy, I looked at linearity, I looked at limit of protection, limit of quantitation. I looked at something called crosstalk. In -- in the laboratory, world crosstalk has to do with an internal standard that you add to a sample. Is there contribution or could you produce a false result by adding internal standard? And the answer was no.

I looked at the internal standard, what they used. They used the deuterated internal standard. What that simply means is it's an altered PEth molecule that has the different molecular weight as what is commonly in the body. I looked at the type of filter paper that they were using, the Whatman 903 filter paper as described. I also looked at their interference data that they looked at several drugs to see if there were

interference. I also looked at the stability data that they had. The -- the -- there was some -- relating to the -- the sample coming in and was the sample stable or able to be analyzed within a certain period of time? And I also looked at a few other things I'm trying to recall off the top of my head.

I looked at ion suppression and matrix effect. That's a big thing that's -- that was talked about in this particular article, that you need to evaluate the matrix, the dried blood spot as -- as a matrix in doing your evaluation and look at the ion -- what's called ion suppression with that. The one thing that the USDTL did not do was evaluate hematocrit. And that's an important thing that was brought out in this particular article. So when I asked Dr. Jones about that, why they didn't do hematocrit, his answer was that they actually used their -- their validation data was based on using blood from 10 different people. So if we look at a variation of 10 different people, they certainly would have varied hematocrits. The only problem is they did not record those hematocrits. So I don't know exactly what the hematocrit was from those 10 individuals that they used to spike PEth into the blood samples. But other than that, the validation data at the laboratory is nearly identical, except for

a few minor things, what's -- what's in this article. So the -- the laboratory did what they were supposed to do with the forensic toxicology guidelines. And I would argue that their validation is as good as any -- any laboratories validation data.

Q. Okay. And you mentioned that this study addresses therapeutic monitoring. Is that distinguishable from something that is to determine whether someone's in compliance with an abstinence program?

A. Yes. This is looking to see if someone's taking a drug. It's -- it's slightly different.

Q. And what impact, if any, does volcanic effect have on therapeutic monitoring as well as on what we're doing with PEth testing?

A. Well, the -- the idea of being that the volcano effect of a different concentration in the center of the spot versus the periphery of the spot. So as I said before, the laboratory takes three punches randomly. It could be from the center, it could be from a side or -- or certainly not near the edge. So the decision points on making the -- the blood spot punch is that it cannot touch the periphery where there is no blood. So by taking three samples again, you're minimizing any effect that would be due to a specific

concentration of -- of PEth in a narrow area of the center or -- or whatever. So the volcano effect is really minimized by taking three punches.

Q. Okay. The next study that Dr. -- sorry. Mr. Shults referred to was Union Exhibit 26, which is the Chang study on the effect of temperature on the formation of the ethanol. Will you look at that study, please?

A. Sure. This -- this particular study has to do with blood. It's not related to dried blood spot. And to explain the difference or what -- what the study is even trying to talk about. So if you take blood and you add basically a yeast or -- this Candida Albicans is a yeast. If you add it to the ethanol -- add it to the sample. Of course, we know the way to produce ethanol is by fermentation. If you add some yeast, add some sugar and allow it to ferment you will produce ethanol. So the effect of -- of this study was trying to say that you need to be careful because if you have bacteria or -- or more preferably yeast in the sample, you can produce ethanol. Of course, this has no bearing on dried blood spot because dried blood spot has a preservative or basically a chemical in it that denatures any protein. I think Dr. Jones talked about this, the guanidinium salts, that as soon as that blood

spot hits the paper, any enzyme is inactivated, so there's no way to produce PEth by a blood spot that even has this particular yeast in it. Also we might note that if a preservative is included, typically that eliminates any -- any growth of yeast or bacteria. And there's a particular sentence that I would like to point out that's also relevant here. It's on page 1, 2, 3, 4.

Q. Can you bring up page 4 of Union Exhibit 26, please. Page 4, are you at the top?

A. Yes, that's it. And go down to the third paragraph from the bottom. It begins with room temperature. Yes. Right there, room temperature. Can you blow that up just a hair. Yeah. Okay. If you look at that sentence that begins that paragraph, room temperature, so even under all these absurd conditions, adding the yeast into a blood tube, it says, "Room temperature storage of all specimens gave negligible or no ethanol formation until day 5." All right. Even if -- let's just assume, even if there's contamination and there's there's ba-- there's yeast and it's been fermenting, the specimen was analyzed the next day. So the specimen collected on May the 9th was analyzed on May the 10th. So even if that were true, we are well within day 5. The yeast has to have time to reproduce

and to grow in order to produce ethanol as -- as you know, from -- from just fermentation. So all this study says is that it's possible, but it has no application to dried blood spot.

Q. Okay. Next, I'd like you to look at Union Exhibit 27 that was referred to by Mr. Shults. This is the Viel study of Phosphatidylethanol. And did you have a chance to review this article?

A. Yes. The only thing I would like to point out, it's in the abstract, if you could bring up the abstract and the very last sentence of the abstract. I -- I'm not sure what his point of this article was, and this -- to explain what this article even -- even is about, is there was a literature search for -- for PEth that -- just clinical interpretation and so forth, and -- and I think that the last sentence is -- is -- is very telling. It says, "The present analysis demonstrates a good clinical efficiency of PEth for detecting chronic heavy drinking. So this particular article reinforces the fact that PEth is the -- is the best marker for -- for detecting drinking. And that's really all -- all I wanted to say about that one.

Q. Okay. Next, let's go to Union Exhibit 52 Mr. Shults referred to.

A. Yes. And the -- the appropriate thing to

look at is on the second page of this article under conclusions. Yes, that's it exactly. So this -- this particular study used various cutoffs for detecting, you know, I know that's been a -- an issue of what's the cutoff and why do you use the cutoff and what's the implication of the cutoff and so forth. So this particular study, and I'll just read the conclusion, it -- it provides evidence of why Delta is using the cutoff that it currently uses. It says that, "An EtG-I -- is an immunoassay, is an EtG cutoff of a 100 nanograms per milliliter is most likely to detect heavy drinking for up to five days and any drinking during the previous two days. If he -- you -- and then the next sentence, "A cutoff of greater than 500 nanograms per milliliter are likely only to detect heavy drinking during the previous day."

So this obviously, in order to detect drinking or to have a good screening test, you want to use the lowest cutoff that's available. Now we know EtG has -- in urine has the unfortunate issue of hand sanitizer and inadvertent exposure to alcohol, that could certainly cause a positive result. But the idea for a screening test is you want to detect, have the high -- the best detection value, and this actually explains why Delta uses the -- the cutoff that it does. Why

choose a 100 nanogram per milliliter versus 500 nanograms per milliliter? Because obviously it has a longer detection window up to five days versus the 500, which is only likely to detect drinking within a day or two.

Q. Okay. The next study I'd like to -- Mr. Shults referred to was Union Exhibit 53 and I believe that's Gruner study; is that correct?

A. Yes.

Q. And did you have an opportunity to review Union Exhibit 53?

A. Yes. This has to do with using immunoassays for virus identification, particularly hepatitis and HIV. This is -- this is irrelevant for two reasons. First of all, no immunoassay was done in this -- in any of the testing, whether it's EtG or PEth so that's irrelevant, and also this is testing for viruses, not PEth, so again, it's just irrelevant.

Q. Okay. Next, if you could look at Union Exhibit 54. And tell us did you review this study?

A. Yes.

Q. Okay. And what, if any, relevance did you see in this study related to the PEth testing issues in this case?

A. It's -- it's irrelevant. This talks about

glycated hemoglobin or hemoglobin A1C. No relevance to PEth whatsoever. So this -- this has no bearing on anything. It's irrelevant.

Q. Okay. Union Exhibit 57, we talked about a little bit earlier. It's the Dr. Skipper expert report and I'd like you to look at page 10 and there's a study referenced in there by Dr. Skipper at the bottom of the page, the Kummer study. Are you familiar with that?

A. Yes.

Q. And I believe that we have identified the Kummer study as Company Exhibit 34, and can Katy, if you can put up Company 34, please. Dr. Taylor, what I will ask you to do is just -- basically you're familiar with the Kummer study and the reference by Dr. Skipper. What is your assessment?

A. Sure. If you look at the abstract, I -- I -- I think the abstract on the left-hand side if could blow that up a bit, it -- it has the relevant information that I was -- I was discussing earlier. That's fine right there. So if you look at the fourth sentence from the bottom where it begins, the quantification. So this is relevant to the issue of hematocrit. I discussed earlier that some studies say that there's no issue with hematocrit and this is the exact study that -- that I was referring to. So the

statement begins with, "The quantification of PEths in C-DBS, dried blood spot was not significantly influenced by hematocrit, punch location or spot volume." And -- and essentially this negates any issue of hematocrit. The -- the main drawback of the study though, as Dr. Skipper pointed out was that the cutoff was very, very high. But still it again calls into question if there is any effect by hematocrit at all.

Q. Okay. The next topic I wanted to go to has to do with some testimony from Dr. Joseph Tordella, and he had a pilot that he was assisting by the name of Matthew Dacier. If we can look at Union Exhibit 37, please. And we're going to look for the results on the other side of the bottom third of the page. So Dr. Tordella pointed out that his deposit that he was assisting had a low EtG result of 24 nanograms per milliliter, and that what he said is that he followed it up with a hair EtG test that actually took place on May the 28, 2020 and that's Union Exhibit 38. If we could just go over to 38 right now. And he was expressing some questions and his testimony will speak for itself, but the test that he did 10 days later after the positive PEth test on hair came back negative using a 20, picogram per milligram cutoff. Is that an appropriate test to do as a follow-up to a low EtG

test?

A. No. The -- the -- the -- the test that you referred to on the 18th was a PEth test, not -- not EtG, so --

Q. I'm sorry. Okay. Thank you.

A. Again, we have two issues here. The 28th is a fairly short time for the hair to grow out. It's possible, but we know that someone can drink as much as one to two drinks every day for three months and have results that are below seven picogram per milligram. So this cutoff is not appropriate to monitor abstinence. The ExperTox cutoff is the appropriate cutoff at two picogram per milligrams. Not -- not 20.

Q. Is --

THE ARBITRATOR: Mr. Kassin, can I suggest that we take a five-minute bio break if it's not going to impact your examination of Dr. Taylor.

MR. KASSIN: It would be more than appropriate if we could have 10 minutes. That'd be great.

THE ARBITRATOR: All right. 10 minutes. Yeah, we've been at this for two hours, so I think it's time we give people a little bit of a break.

THE REPORTER: We are off the record. The time is 12:55 p.m.

(OFF THE RECORD)

THE REPORTER: We are back on the record. The time is 1:05 p.m.

THE ARBITRATOR: Thank you. Mr. Kassin, proceed.

BY MR. KASSIN:

Q. Thank you, sir. Dr. Howard Taylor, I want to go back to Dr. Tordella for a second and his Union Exhibit 37, which is the PEth test, where he had a value of 24 nanograms. And as I understood his concern and the transcript will speak for itself. If he wanted to do further testing instead of hair EtG test, what would you have recommended to him?

A. I would've done an additional PEth test.

Q. In a moment I want to ask you for some conclusions, but before we get there, based on the research that you've done and your expertise as a board-certified forensic toxicologist, is there a scientific study, an article that you would recommend and speak to that gives kind of the current status or the science of PEth testing?

A. Yes. There's a very nice article by Ulwelling. It's a couple of years old that really gives a very good overview of the science and state of the art of PEth testing.

Q. We've put that Ulwelling exhibit into the record earlier in this case, it's Company Exhibit 28.

Could you refer to that? And Katy, could you please bring that up for us? It's Company 28. And you may need to blow that up just a little bit. Dr. Taylor, I want to ask you, could you point to the key sections of that you think that the arbitrator and board members should take into consideration?

A. Yes. If you turn to the third page, upper left-hand corner, little bit larger. Upper-left-hand corner is what we're looking for, second sentence. That's good enough right there. So if you look at the second sentence where it says to protect. So the sentence reads, "To protect against false positives however, PEth is currently considered to be an indicator of purposeful alcohol ingestion at values greater than 20 nanogram per milliliter." There's been discussion of 20, it's not standard, it's a laboratory developed test and just all these issues relating to the cutoff. And this explains exactly why the cutoff exists, why it is. So many of the laboratory toxicologists around the country have gotten together and used 20 -- consensus basically at 20 nanogram per milliliter is the appropriate cutoff. And the reason for that is, we -- we don't want to have the cutoff too low that we identify drinkers -- I'm sorry, non drinkers at very low concentrations. But we want to

have a cutoff sufficiently high that we can in fact reproduce that result if a value is greater than 20 nanogram per milliliter. That's exactly why the cutoff exists as it -- as it does.

Q. Okay.

A. The next one is on the page upper left-hand corner 1638. It's the one, two, three, four, fifth page of the article. And it's the second paragraph -- second area that begins with legal acceptance of PEth. Yes. Right there. That's fine, right there. Okay. So a question has become that PEth is non-standard, is not really accepted, is not used in judicial settings. And the -- the -- actually that's not correct. It is used -- widely used in administrative hearings across the US and a reference to that it's -- it's commonly used in situations such as this where you're trying to establish drinking or identify if abstinence is actually correct.

The next thing I want to talk about is the second paragraph under there. Just scroll it up about three lines. Right there. So it begins with the paragraph on the left-hand side, second paragraph, a positive PEth "A positive PEth finding greater than 20 nanogram per milliliter in the lower range, that is 20-80, indicates that the person has very likely consumed at

least 2.5 or more standard drinks for several days prior to the test or has been binged rather heavily." And the next sentence is key. It says, "While a low PEth value does not reveal the pattern of consumption, the unassailable conclusion is that the employee has consumed alcohol within the past month or so." The next thing I want to point out is if you could reduce the size of that and the lower right-hand corner of that page. That's probably good enough. Right there. Scroll down just a bit. On the right-hand side, it talks about interpreted guidelines. If you can scroll that down just a bit, please.

Q. Scroll up.

A. Down. Scroll to -- to -- scroll -- scroll up. I'm sorry. My apologies. Right -- right there. On the right-hand side where it has the different PEth, less than 20, 20-200. Could you scroll up or down just a bit more? My apology. There you go. One -- a little bit more, please. Right there is fine. So if you look at the different interpretation from this document, PEth less than 20, it says light or no consumption or abstinence. Values between 20 and 200, significant consumption. And then it identifies what the -- what that means. Moderate level of drinking averaging between two to four drinks a day for several

days a week. And then if you look at the last categorization, greater than 200 nanograms per milliliter, heavy consumption. And the very last sentence of that paragraph is telling. It says, "The literature is very consistent in concluding that PEth is a highly sensitive and specific biomarker for alcohol consumption." To understand what the difference is between sensitivity and specificity, so sensitivity is when the test is positive, the individual has been drinking. Specificity is when the individual has not been drinking, the test is negative. So this test, PEth is -- is very good and that it has both high sensitivity and specificity.

Q. Okay. Before we leave this particular study, Dr. Taylor, I'd like to refer you back to page 3 on the right column towards the bottom. And this has something to do that you testified about earlier when you were speaking to half-life.

A. Yes.

Q. Can -- Katy, it's the paragraph that begins, PEth production begins. You may have to go a little bit to the left, to get it in there. It's on the left column. There we go.

A. Right, right there is fine.

Q. That's fine. This has to do with the

half-life discussion and --

A. Right. That's good right there. Yeah.

Q. -- you explained the point about heavy drinkers or alcoholics and what their half-life is related to?

A. Right. Exactly. So if you look about -- on the left-hand side where the paragraph begins, PEth production and about halfway in the middle of that paragraph. Begins with the -- in the middle of that page, "The shorter half-lives tended to be found in studies involving alcoholics or heavy drinkers." In other words, when -- we know that from the Dr. Marty Javor's study, that the range of half-life is between 1 and 13 days with the average being 4.6. But that lower end of that half-life range is consistent with alcoholics. So this -- this statement is simply saying that the shorter half-lives are found in alcoholics. And that certainly supports our one to two day half-life that we've found for Mr. Danford.

Q. Okay. You had pointed to the end of the article about the literature being consistent on the value of using PEth testing. I'd like you to look at -- I'm sorry, Dr. Skipper's article which I believe is Company Exhibit 18. Are you familiar with that study?

A. Yes.

Q. What were some of the key points that Dr. Skipper made in his study regarding the value of using PEth testing?

A. Right. The -- the -- the purpose of this article was to evaluate individuals that had a low urine EtG concentration because as -- as we know, there are other things other than drinking alcohol that can cause a low EtG result. So the idea is to use the PEth test as a confirmatory test, and that -- that's generally how that is done. In fact, in our practice, what we do is exactly what Dr. Skipper recommends, is the -- the EtG is a -- is a screening test. We don't take action based purely on EtG. We follow it up with a PEth test, and that's what we would recommend.

Q. Okay. So to reach a conclusion in your testimony, you covered a good bit of ground with us this morning and early afternoon. But based on the evidence of the case that you reviewed, including the May 9th,2018 PEth test results for Mr. Danford as well as his earlier EtG result from May 1st, 2018, what conclusion do you reach regarding whether he has been drinking and in violating his abstinence requirement?

A. Yes. It's my opinion that he was drinking prior to the May the 9th PEth test. A two-week interval prior to that is the most likely a time. If

you notice in this case, it's quite unusual, in that we have three positive tests. We have a positive EtG test from May the 1st, we have a positive PEth test from May the 9th, and we also have a positive hair test from June the 20th. All three of those point to use in that two-week period preceding the positive PEth test. At least they're all consistent. Those all are consistent with drinking during that two-week period.

MR. KASSIN: Thank you. Arbitrator Burdette, if I could have 30 seconds, I believe that I'm complete with my direct examination.

THE ARBITRATOR: Okay. We'll go off the record while you check.

THE REPORTER: We're now off the record. The time is 1:17 p.m.

(OFF THE RECORD)

MR. KASSIN: Yes, sir. At this point, the company has completed the direct examination of Dr. Taylor.

THE ARBITRATOR: Okay. Mr. Seham?

MR. SEHAM: I'm ready to start.

THE ARBITRATOR: Okay.

MR. KASSIN: We request a lunch break if you don't mind.

MR. SEHAM: I don't object to a lunch break provided that I can have a break after I do my initial

examination.

THE ARBITRATOR: Okay. Absolutely.

MR. SEHAM: Yeah. Okay.

THE ARBITRATOR: Absolutely can. Mr. Kassin, how much time do you need?

MR. KASSIN: This is up to Mr. Seham at this point. I mean, I would suggest our usual hour or 45 minutes or so.

THE ARBITRATOR: Okay.

MR. KASSIN: I suggest an hour. Mr. Seham, what would you suggest, sir?

MR. SEHAM: I'm not objecting provided I can have a subsequent break, though. Yeah, that's fine.

THE ARBITRATOR: Absolutely. Okay. So we're going to go off the record for lunch at 1:19 Eastern time, and we'll be back at 2:19.

MR. KASSIN: Thank you.

THE ARBITRATOR: Thank you.

(OFF THE RECORD)

THE ARBITRATOR: Mr. Seham, the floor is yours.

CROSS EXAMINATION

BY MR. SEHAM:

Q. Thank you very much. Dr. Taylor, looking at your resume, I'm going to focus on the 20-year period, approximately between 1995 and 2014. What were you

doing during that period, that 20 year period of time?

A. I was -- I found a company called National Toxicology Specialists. I'm the president and founder of that company.

Q. Did that company operate a laboratory?

A. No.

Q. During that 20-year period, what direct employment did you have with a forensic or clinical laboratory?

A. I was a SAMHSA inspector. I performed SAMHSA inspections during that time. I did not operate a laboratory.

Q. Okay. My question was, and it will go faster if you listen to my questions and answer what I ask you. What I asked you was what direct employment did you have with a clinical or forensic laboratory during that period of time?

A. None.

Q. Is the answer --

THE ARBITRATOR: Repeat the answer, please.

A. None.

Q. Okay. Thank you. Now, please identify the published peer-reviewed controlled studies in which you have participated related to EtS.

A. You broke up just a hair. Did you say EtG?

Q. No, I said EtS. I asked you to identify the published peer-reviewed controlled studies in which you have participated related to EtS?

A. None.

Q. Could you please identify the published peer-reviewed controlled studies in which you have participated related to EtG?

A. None.

Q. I'm sorry, the answer is none?

A. Correct.

Q. Okay. You're breaking up a little for me too, but we will all bear with it. Could you please identify the published peer-reviewed controlled -- controlled studies in which you have participated related to PEth testing?

A. None.

Q. Okay. Does your laboratory of what you're the director now conduct PEth testing?

A. No.

Q. Are you familiar with the term abstainer, as that term is used in the context of -- excuse me, in the context of PEth, EtG, or EtS testing for alcohol -- alcohol abstinence?

A. Yes.

Q. Okay. So what does -- what's your

understanding of the term abstainer?

A. No alcohol.

Q. What's your understanding -- in the same context, what's your -- and actually let me back up. Abstainer means no alcohol over what period of time?

A. During the period of time you say you are -- you are abstained.

Q. Okay. So in the same context, EtS, EtG, and PEth testing for abstinence, what does the term teetotaler mean to your understanding?

A. No alcohol.

Q. Well, how is that distinguished from an abstainer?

A. An abstainer is one that has previously drunk alcohol, and a teetotaler is someone that does not drink alcohol. For example, my wife is a teetotaler, she does not drink alcohol, she is not under any program. So someone may be under an aftercare monitoring program at which they must not drink alcohol, but yet they have in the past.

Q. Okay. A teetotaler is someone who has historically not drunk alcohol?

A. Yes.

Q. An abstainer is someone who is just abstaining for a given period of time; is that correct?

A. Okay.
Q. Now, you reviewed the litigation package for USDTL with respect to the Danford PEth test, correct --
A. Yes.
Q. Let me finish the question, for the collection of May 9th, 2018, correct?
A. Yes.
Q. The initial test -- what was the reading of the initial test?
A. 69 nanogram per milliliter.
Q. The reading for the second test was what?
A. 98 nanogram per milliliter.
Q. Were the same instruments being used to test both -- on both those occasions, for the initial test and the second test?
A. I don't have evidence. I'll have to look at that. I think that is true, but since I had to move rooms, I don't have the -- the -- the documents in front of me.
Q. Okay. Well, the same -- the same type -- you don't know whether it was the same type of instrument?
A. It was the same type. I don't know if it were the identical instruments.
Q. Okay. Is there an assay or is the same -- was the same chemical methodology used for both tests?

A. Yes.
Q. The same controls were used for same -- for -- for both of those tests, correct?
A. Yes.
Q. In terms of being situated at a low, medium, and high level?
A. Yes.
Q. Okay.
MR. KASSIN: Mr. Seham, we're going to move those exhibit books over to where he is, so he could have them in front of him for your questions.
Q. And when you first got the results and saw the differentiation between the initial test, the 69 and the second test of 98, that did raise a concern for you, correct?
A. Yes.
Q. And why did it raise a concern for you?
A. Simply whenever you see results that are not identical, you ask a question, why -- why are they not the same number? And I wanted to understand the precision or reproducibility of the assay.
Q. Well, I mean, it's very common that there would be a slight variation of 5 to 10 percent between two test results the same day on the same sample, correct?

A. Yes. Sometimes screening uses a different procedure. For example, they may use a one-point calibration and the confirmation may use a multi-point calibration.

Q. Did that occur in this instance, the differences in calibration?

A. No, they did not.

Q. Okay. What's the standard variation at your laboratory when the same sample is tested twice with the same type of instrument using the same assay? What's the standard variation?

A. Plus or minus 30 percent.

Q. Plus or minus 30 percent at your laboratory; is that correct?

A. I couldn't hear the end of that question. Please repeat.

Q. The question was, you're saying at your laboratory, when you test a sample of the same sample twice using the same methodology on the same instrument, what's the average variation in results in terms of percentage?

A. The accepted range is plus or minus 30 percent.

Q. Okay. And who determines that plus or minus 30 percent?

A. The laboratory director.
Q. Sir, are you saying at your laboratory, for example, at your laboratory, have you ever tested the same sample twice using gas chromatography mass spectrometry?
A. I'm sorry, you're breaking up.
Q. At your laboratory, have you ever tested the same sample twice using gas chromatography mass spectrometry?
A. No. We use liquid chromatography mass spectrometry.
Q. Okay. Have you ever used that -- using that methodology, have you ever tested the same sample twice?
A. Occasionally, sometimes we do.
Q. And what's the variation that you've experienced between your initial test and your second test of the same specimen using the same methodology?
A. I'm not sure I've ever calculated it, but it certainly is within plus or minus 30 percent.
Q. And you would consider 30 percent acceptable at your laboratory?
A. Yeah. Yes. It's -- it's a clinical lab. The differentiation -- we use a little wider range in a forensic laboratory, but it's a clinical laboratory.

Q. Okay. What would be the range at a forensic laboratory?

A. Typically, plus or minus 20 percent.

Q. And is there any variation on that coefficient with respect to testing for alcohol?

A. It depends on the matrix. Urine, blood depends.

Q. Okay. With respect to blood --

A. To test alcohol --

Q. -- what would be the -- pardon?

A. I -- I want to make sure we're clear. To test actually alcohol, not PEth or some metabolite?

Q. Also testing for alcohol?

A. Oh, the -- the coefficient of variation is much lower. It's -- it's probably plus or minus 10. 10 percent in terms of --

Q. It's about 10 percent, correct?

A. Yes. It's -- it's very low because that particular assay is -- is a different -- different type analysis.

Q. And you say it's up to the laboratory director to determine what the tolerable deviation is, the coefficient deviation is from test to test?

A. Yes. That's determined in the validation data. And from that data the laboratory director makes

a call as to what is acceptable.

Q. And it was Joseph Jones told you that he had determined that 30 percent was acceptable?

A. Yes. Plus or minus 30 percent.

Q. And he provided you the validation studies on which he relied?

A. Yes.

Q. Okay. And what did those validation studies conclude as the causes of the 30 percent deviation or up to 30 percent deviation?

A. Well, there was no cause. That's simply the procedure and what the variation showed. The cause was not -- was not discussed.

Q. Well, before they conduct this testing, they actually put in a blind sample as part of their pre-testing calibration process, correct?

A. I'm not sure if USDTL does that or not. I don't know if they do a blind sample.

Q. Do you recall doing any review of blind samples that USDTL was using for internal control and analysis?

A. I don't recall. They use internal quality control. In other words, known or open controls, but I don't know if there was a blind. I -- I can't recall.

Q. Okay. Do you know whether there were any

outside agencies monitoring USDTL with a third-party blind sample program?

A. No. Proficiency program, no.

Q. No. Okay.

A. With respect to DBS, no.

Q. Okay. When did you -- you testified on direct about when you were consulted first by Delta Airlines concerning this case. Can you recall when that was when you were first consulted?

A. Yes. It was June 28th, 2018.

Q. And was that a telephone call or was that a meeting face-to-face? How did that transpire?

A. A telephone call.

Q. And how long did that telephone call take to last?

A. I don't recall. I would -- I would estimate 10 to 15 minutes.

Q. Okay. And that was with Mr. Puckett?

A. Yes.

Q. Who else was on the phone?

A. Only him in the first call.

Q. Okay. And then there was a follow-up call sometime after that?

A. Yes.

Q. And when did that happen?

A. It was a week or two after that. I don't recall the exact date.

Q. How long did that call go?

A. Again, this is an estimate, maybe -- maybe 15 or 20 minutes.

Q. And that was just with Mr. Puckett or was anyone else involved?

A. No. There were other individuals, two or three additional individuals from Delta Flight Ops Management. I don't recall their names.

Q. Well, did you ever speak to Captain Graham?

A. I may have. I don't know. I don't -- I don't -- I don't know. Again, the names were not important to me.

Q. Okay. So you had a call on June 28th of 10 to 15 minutes, you had a call -- you had a call a week or two later of 15 to 20 minutes. And when was your next interface with Delta representatives?

A. I don't know. I -- I would have to look at my -- my files.

Q. Was that weeks later or months later?

A. I don't recall.

Q. Did they ever ask you for a written opinion as to what your position was with respect to the reliability of any of the tests involved in this case?

A. No.
Q. But you gave them your -- you gave them your opinion as to the reliability of the tests in this case, correct?
A. Yes.
Q. And when did you give them your opinion?
A. I couldn't hear you. You're breaking up.
Q. When did you give them your opinion in terms of the reliability of the tests in this case?
A. Well, I guess there are two issues here. One is the reliability of the litigation package, and then second was the visit to USDTL in March of this year. So in the first instance relying with that the two -- one to two weeks after that July 28th initial call, I gave them my opinion that the litigation package was sound and appropriate.
Q. Okay. And then it was March 2020 when you actually went to USDTL?
A. Yes.
Q. Okay. I imagine you took notes as you went through your inspection -- well, of your review of their practices?
A. I'm sorry, you're breaking up again. I could not hear you. Please repeat.
Q. Let me -- I kind of changed my question

midstream. Did you take notes, written notes as you went through your review of USDTL in March of 2020?

A. I think I took one page of notes perhaps, maybe one or two.

Q. And you never provided a written report to Delta after March of 2020?

A. Correct.

Q. Do you know how many laboratories conduct PEth testing for forensic purposes?

A. They're a handful. There is LabCorp, ARUP.

Q. I'm sorry, LabCorp. What was the second one?

A. The second one is A-R-U-P out of Utah. Marty Javor's lab out in San Antonio and USDTL. Those come to mind.

Q. And of those four, would it be just San Antonio and USDTL that are using DBS or dried blood test approach?

A. Yes, correct. Yes, correct.

Q. Okay. Now, you relied or you referenced Company Exhibit 28. I don't think we have to bring it up right now, but an article by William Ulwelling, U-L-W-E-L-L-I-N-G, as a reliable source in terms of PEth testing information?

A. Yes.

Q. Okay. But that was not -- that article does

not reflect an independent study, correct? In other words, or indirect controlled -- excuse me, strike all that. That article, it does not consist of an independent controlled study, correct?

A. Right. It's a review article, correct.

Q. It's a review of other articles or other studies?

A. I'm sorry, I lost -- can you please repeat.

Q. I think we're agreeing, but it's a survey of other studies, correct?

A. Yes.

Q. Now, you said you reviewed -- let me back up so we have a comprehensible record. What is an SOP?

A. Standard Operating Procedures.

Q. Does every laboratory -- is every laboratory required to have one?

A. Yes.

Q. I think you referred to before the clinical testing versus forensic testing. Could you draw a distinction between the two or define for us your understanding of what those two terms mean?

A. I'm sorry, again. I did not -- I heard the last part, but not the first part.

Q. Clinical and forensic. What's the difference in terms of laboratory testing?

A. Sure. A forensic laboratory is for legal proceedings. A clinical laboratory is for diagnostic testing, diagnostic measurements.

Q. Diagnostic meaning to provide people with healthcare?

A. Yes.

Q. What areas does an SOP address?

A. It addresses all of the methodology. For example, receipt of sample is typically the first portion of an SOP. Accessioning receipt, chain of custody procedures, quality control procedures, the analytical testing methods, how it's done, how it's performed, how it's interpreted. It also addresses quality control. I think I mentioned that. And it also involves, how to determine if a test is positive, the interpretation of the results. What constitutes -- what criteria is for a positive result.

Q. You used a term that we might not all be familiar with, accessioning. What does that mean?

A. Receipt and processing of samples and aliquots.

Q. What is involved in the receipt portion of the accessioning? That you mean the receipt from the collection facility?

A. Yes. Typically by a courier or FedEx.

Samples are received, they're opened to look to make sure there's no -- there's no tampering. It's all intact. That the specimen identification number on the specimen matches the chain of custody or requisition form. The chain of custody is inspected for completeness, for accuracy to make sure that there are no blank spaces, no inappropriate spaces. Also reviewed are what testing is required and what comments may be made by the collector.

Q. Is the laboratory allowed to deviate from its SOP?

A. No.

Q. If it does deviate from its SOP with respect to a particular test, what is done with that test?

A. Again, I heard the last part, but not the first part. My apologies.

Q. If a laboratory does -- if it's discovered, let's make this personal. If you discovered that a sample has not been processed with respect to accessioning and receipt in accordance with your laboratory's SOP, what is done with that test result or what is done with that test?

A. It depends. There are two kinds of errors or two kinds of issues. One are correctable issues and others are fatal flaws. For example, if a date is left

off or a signature is left off, that may be something that is correctable. If the chain of custody number on the specimen does not match the chain of custody on the receipt, that would be a fatal flaw or if there's insufficient urine or insufficient sample, that would be a fatal flaw. So it depends on the nature of the issue as to what disposition would -- would occur with that.

Q. To give you a specific example, what if the packaging arrived in a form that's not in compliance with the SOP? For example, a torn seal.

A. That would depend. If the SOP says that a torn seal is a fatal flaw, the sample would be rejected and not tested.

Q. You recall what the USDTL SOP provided in terms of receipt and accessioning?

A. I cannot. I don't remember.

Q. Now, you determined -- it sounded like you made a dispositive determination with respect to Mr. Danford, that his sample would have a one or two day half-life. Did you make that determination?

A. Yes. And I heard about a third of what you said. I think it had to do with half-life. His half-life.

MR. SEHAM: Yeah. You know, I'm going to -- I'm

using my phone because that's what I was told to do at the storage. I'm wondering if I might experiment that with the patience of the arbitrator. If I might experiment going back to the regular Zoom approach. Well, let me just do that. I'm going to go on mute.

MR. KASSIN: Mr. Seham, I don't know that it's your problem. It might be the WIFI bandwidth where Dr. Taylor is. Would it be okay with the arbitrator if we took a short break and we'll have Dr. Taylor dial in just like Mr. Seham is. Because Mr. Seham, we're hearing you loud and clear without any --

MR. SEHAM: Okay.

THE ARBITRATOR: Okay. Let's take a five-minute break off the record, Damien.

THE REPORTER: Off the record. The time is 3:04 p.m.

(OFF THE RECORD)

THE REPORTER: We are back on the record. The time is 3:10 p.m.

BY MR. SEHAM:

Q. Okay. So to continue, Dr. Taylor, my understanding of your testimony on direct was that you made a definitive determination that Mr. Danfords' half-life for PEth is between one and two days. Is that correct, you made that determination?

A. I said between one and three and more likely between one and two.

Q. Okay, and that's interesting. You said between one and three. If we can bring up Company Exhibit 31. Now, on this first page, you did half life calculations based on a starting point of 98, correct?

A. Yes.

Q. And you just did one and two days. Why did you not do a calculation for three days? Is that because the result would be something that Delta would not want to see?

A. Absolutely not. Because the May 15th hair test was negative. And 12 -- the number 12, that clear -- clearly shows that it's below 20.

Q. Okay. And then the second page -- if you can move to the second page, you added the -- the third day and -- and your explanation would be because of the hair test, that you added the third day?

A. No, not the hair test because the 69 -- it just -- it just shows using the two different values. If you picked 69, what would the calculation looked like, if you pick 98, what would it look like. Really the -- the 69 is just for illustration.

Q. And so why did you not include that illustration for the -- for the first page -- for the

98?

A. Well, I can certainly do the calculation right now if you'd like.

Q. No, no. I'm not asking you to do that. I'm asking why -- why did you omit that in the first page?

A. Because at -- at two -- at two days it was below -- it showed that it was below 20.

Q. Mr. -- excuse me, Dr. Taylor. We -- we can take this down so because I can't see Dr. Taylor with it up. What controlled studies that have been peer reviewed that you can you identify that analyze the half life of PEth?

A. The -- the best is Marty Javor's article that's already in evidence.

Q. Okay. Can you identify any others?

A. Yes. There -- there are many.

Q. There are many. I'm not asking you -- can you identify any others?

A. Yes. If I have access to my notes and my computer.

Q. Okay. I'm asking you right now as you sit here today in this moment, can you identify any other?

A. Not off the top of my head, not by memory. I would have to go back to my file.

Q. Very good. So with the -- with respect to

Javor's -- the Javor's publication, what is -- what is the conclusion that you recall from Javor's?

A. The average half life was 4.6 days with a standard deviation of 3.5. The range of values is from one to 13 days.

Q. And how many -- how many participants in that study?

A. I -- I would have to look at that paper again.

Q. Would you know whether it was hundreds or a couple of dozen?

A. Again, I would have to look at the paper.

Q. Okay. Well, you identified I think one factor with respect to what could impact half life, as I recall. My -- my recollection is the one factor you identified is a history of drinking or past drinking. Is that -- is that a factor --

A. Yes.

Q. What other factors impact?

A. Well, we -- we know that alcoholics have a shorter half life than do social drinkers. Many -- many of the studies involving half life were with social drinkers and they demonstrated value much -- much -- much greater.

Q. Yeah, sir, that was not my question. I said

-- my question was, aside from the level of alcohol consumption, what other factors are you aware of in published studies that impact on the duration of half life?

A. That's the most prominent one. I can't recall the others.

Q. Okay. Now, what you -- did you determine that Mr. Danford, is a -- is an alcoholic?

A. No.

Q. Did you determine that he was a heavy drinker?

A. No.

Q. In what proximity to the test does the drinking have to occur in order for it to impact on the half life?

A. That's a good question. Typically, we -- we talk about tolerance. Tolerance is developed or lost within a couple of weeks. So I cannot answer your question directly. I -- I -- I don't know the answer. But typically we -- when we talk about influence on elimination rate or tolerance, we -- we typically talk about a two-week period.

Q. Well, do you know of any published study that addressed that in the context of PEth testing, the proximity of the alcohol?

A. I do not. I--I do not.

Q. On what -- you concluded that -- you concluded that Mr. Danford had a shorter half life or had a half life at -- at the shorter end of the spectrum identified by Javor's and others because of your conclusion that Mr. Danford was drinking; is that correct?

A. No. I -- I evaluated the data and showed, based on the test results that I had evidence that I had, his -- his half-life would be between one and two days. I -- I -- I do not have the actual litigation package or -- or raw data from the May the 15th test. So I don't actually know that number. I just -- I simply know it's below 20. That's all I know. So I estimated -- so I estimated the range of half life based on the data that I had.

Q. What data did you have?

A. I had a May the 9th PEth test and May the 15th PEth test.

Q. And that's the date on which you based your determination of Mr. Danford's half life?

A. Correct.

Q. So your determination -- your determination of Mr. Danford's half life was based on your assumption that the May 9th test was accurate, correct?

A. Yes.

Q. Okay. Mr. -- excuse me, Dr. Taylor. If you could -- we can bring up Company Exhibit 20. Okay. All right. So if we can scroll down a little bit further. I do -- actually -- actually stay there -- stay there for now. Go back to where you were. Do you recognize this -- this document as being a LabCorp PEth test result, correct?

A. Yes.

Q. And this was from Michael Danford?

A. Yes.

Q. And the specimen was collected on May 15th, 2018, correct?

A. Yes.

Q. Okay. And LabCorp as distinguished from USDTL, uses venous blood or -- or whole blood for testing, correct?

A. Yeah.

Q. Okay. And if you could -- if you now scroll down, please. It -- it says here after -- it references the detection limit, 20 nanograms per milliliter. It says, "PEth levels in excess of 20 nanograms per milliliter are considered evidence of moderate to heavy ethanol consumption. However, alternate explanations should be explored following any

positive finding. Please note that while PEth is considered relatively insensitive to incidental ethanol exposures, the possibility remains that an individual elevated PEth level may result from incidental or unintentional ethanol exposure." So do you -- do you disagree, Dr. Taylor with LabCorp's representation here that alternative explanations should be explored following any positive finding with PEth?

A. I -- I don't disagree. I do disagree that there is any data to support that it's -- that incidental ethanol exposure can cause a positive PEth test. There's nothing to support that statement.

Q. But you don't disagree with the statement that alternative explanations should be explored following any positive findings?

A. Yes, that is -- that is certainly appropriate.

Q. Okay. Well, if we can turn to Union Exhibit 75, please. You know what, I -- I -- you can take that down, actually, I think I already addressed that. Does the laboratory developing -- let me back up and make sure we all are comfortable with the terminology. A laboratory developed test, that's sometimes referred to by the acronym LDT, correct?

A. Yes.

Q. Okay. And what is an LDT?

A. A laboratory developed test.

Q. Okay. Perfect. No controversy there. But asking beyond that, as distinguished from what? What is laboratory -- why do we have that term? What are we distinguishing an LDT from?

A. Sure. A -- a -- a good example, a comparison would be an immunoassay. An immunoassay are purchased reagents from a company that are manufactured and sold in mass to laboratories to do rapid screening on automated chemistry analyzers. Those tests were not developed by the laboratory, but by a manufacturer, as opposed to a -- a chromatographic test, which involves a piece of equipment, a -- a liquid chromatograph, a mass spectrometer. The makers of mass spectrometers and liquid chromatographs do not supply a -- a method that is standard to be used with their equipment. They leave it up to the user to develop their own. And various users have -- some have better ideas than others. So they develop what they consider to be a very good assay that requires validation. That's the important step to make sure that a laboratory developed test is accurate and reliable.

Q. Does the developer of an LDT have any obligation to validate pre analytical standards?

A. Not -- not necessarily. No. Some of those pre analytical variables -- you're referring to pre analytical like the collection process?

Q. Yeah. Anything that falls within that spectrum of pre analytical including that. Yeah.

A. Right. They -- they may dis -- they may discuss how the collection is to be done, but they don't necessarily have to validate that to go out to a collection site and observe someone doing it and say they did it a 100 times correctly or something like that. So they may --

Q. I'm sorry. That's not what I'm asking. I'm asking you in terms of the standards. I mean, as to what ought to be done?

A. Yes. The laboratory determines what standards are appropriate for a collection of a specimen. Yes. How -- how much volume is required, the chain of custody procedure, the -- the shipping procedure. Yes. All -- all of that is determined by the laboratory.

Q. And are those incorporated in an SOP?

A. They may or may not.

Q. Now, are you -- with respect to your own laboratory. And I'm sorry, if you could tell me what -- the name of your laboratory again?

A. Addiction Labs of America.
Q. Addiction Labs of America. Under the -- are you familiar in terms of the program at your laboratory, with
the term or the objective quality results?
A. Quality results or quality control?
Q. No, quality results. Is that a term that you use at your laboratory in terms of program objectives, quality results?
A. Well, that -- that would be the objective of any laboratory. I'm not -- I'm not sure I'm following what -- what you're asking.
Q. Okay. We'll move on. I think you had testimony concerning adjustment of quantitative results based on creatinine. And is it your testimony that no laboratories do that?
A. No. I didn't say that. Some laboratories do it. I mean, I -- our -- for example, our laboratory adjusts everything, but some things have no meaning. And -- and the reason some things are adjusted is because the -- the program that makes that calculation is -- is something that's a third party that we don't have any control over. We -- we do -- we do not use EtG -- normalized EtG results for any purpose whatsoever. It has no interpretive value whatsoever.

Q. And but you -- so you would -- I didn't understand your testimony. You say your laboratory does use creatinine adjustment in some context?

A. Yes, in some context. For example, in my direct, I talked about using it for marijuana, very appropriate, Buprenorphine, Benzodiazepines. These are drugs that have a very long detection window of a week -- weeks to month. So the purpose of creatinine adjustment is to compare two values -- two points in time. For EtG the -- the -- the EtG is positive for only a few days, one to four days. So it wouldn't make any sense to normalize it to creatinine. It just wouldn't make any sense.

Q. Did you hear that -- you were present for the testimony of the director of Quest Diagnostics, Barry Sample?

A. Yes.

Q. Okay. Did you hear his testimony that to the effect that it would be appropriate for the customer to make a creatinine adjustment?

A. Well, a laboratory sends out results. The customer --

Q. I'm asking do you recall his testimony to that effect?

MR. KASSIN: Just let the witness answer.

A. The customer can do anything they want to with their result. Yes.

Q. Does the customer also set the quantitative value for your laboratory as to what is a positive and what's the negative?

A. No, the customer does not. The laboratory does, based on its validation data.

Q. That's the practice at your laboratory?

A. At all laboratories. The -- the customer may choose from a menu of different cutoffs, but the -- some cutoffs are -- are not appropriate or not available. It -- it depends on each laboratory. For example, in -- in my laboratory, we have one cut-off for each analyte. They're -- they're not multiple cutoffs.

Q. Okay. And why don't you have multiple cutoffs?

A. Because they're not necessary for what we do.

Q. Why are they not necessary? I mean, why would you not let a customer dictate cutoff levels for the testing that you conduct?

A. Well, what we typically do, we -- we -- we treat addicts -- we're addiction treatment centers. So for -- let me just use marijuana as an example. We tested a 20 nanogram per mill cutoff for marijuana.

The federal workplace testing is 50. We're trying to see if someone is using marijuana in treatment, not in a workplace setting. So we're going to use the lowest cutoff that we can for immunoassay for marijuana. The federal rules we -- we don't care about because they're irrelevant to us. We're looking for treatment, not for workplace testing.

Q. Now, back to the Javor's study. That study in -- that didn't involve whole blood distinguished from DBS; is that correct?

A. I -- I thought it was DBS, but I -- I could be mistaken.

Q. Okay. Then other than -- other than the alcohol provided to the subjects in the study, the participants were required to remain abstinent during the 22 day study period, correct?

A. Right.

Q. And the study included the use of spiked samples, correct?

A. I -- I believe so.

Q. And you recall that the imprecision rate ranged between 6 and 11 percent as between the spiked samples and the actual testing?

A. That -- that seems fair, yes. That's -- that's appropriate.

Q. And in most of the participants, PEth levels were detectable after two weeks of total abstinence; isn't that correct?

A. That -- that could very poss-- very well be possible. We know that PEth is detectable up to a month, up to four weeks. That -- that certainly is possible.

Q. Okay. Would you agree that published studies indicate that an EtG result can be generated by pralines?

A. Pralines, like the candy?

Q. Yes.

A. I'm not familiar -- I'm not -- I've not heard of that study.

Q. Would you agree with me that there are studies that an EtG result can be generated by non-alcoholic beer?

A. Possibly, yes.

Q. So there are studies that have reached that conclusion?

A. I -- I have heard of some. Alcoholic -- alcoholic beer contains a very low percent of alcohol, so alcohol is present in non-alcoholic beer. So that is -- that is possible.

Q. Okay. And would you agree that there are

published studies indicating that an EtG result can be generated by fruit juice?

A. I've not seen any studies to show that.

Q. And are you aware that there are published studies indicating that an EtG result can be generated by sauerkraut?

A. I am not aware of any study to support that.

Q. Are you aware of published studies indicating that an EtG result can be generated by soy sauce?

A. No.

Q. Now, an EtG -- you would agree that and you're aware of a published study that a EtG positive can result from the incidental use of hand sanitizer or mouthwash, correct?

A. Yes, that is possible.

Q. I'm trying to get an exhibit up here. Now, you consider the Javor's article to be a reliable source, correct?

A. Yeah.

Q. And the Ulwelling and Smith Guidelines for the use of PEth, do you believe that to be a reliable source as well?

A. Yes, I do.

Q. If we could turn to Company Exhibit 28. And I'd like to move to 1635, of that article. Yeah. Down

a little further. I'm going towards the top of the page. Yeah, perfect. You can stop right there. Thank you. I'm looking at the second column on page 1635. The first full paragraph that reads, "The EtG is subject to false-positive due to "extraneous exposure" to ethanol-based hand sanitizers when used 20 or more times a day, such as by medical personnel. Mouthwashes, when swallowed and the consumption of, "pralines, non-alcoholic beer, pharmaceutical products, fruit juice and sauerkraut". To effectively eliminate false positives, laboratories tend to use a high EtG minimum threshold of 250 nanograms per milliliter to indicate the intentional consumption of alcohol." Do you disagree with any of this information contained in that paragraph?

A. No.

Q. If we could bring up Union Exhibit 1. Now, did you review this document the Official International Association for Therapeutic Drug Monitoring as it related to PEth testing?

A. Yeah, but this doesn't relate to PEth testing. It's talking about dried blood spots for therapeutic drug monitoring, but yes, I -- I reviewed that. Yes.

Q. Fair enough and I stand corrected. Are any

of the validation criteria identified in this document? You've never -- let me back up. You've never engaged in a validation process for PEth testing, whether it was whole blood or dried blood, correct?

A. Correct.

Q. And within this article, are there any criteria in terms of the validation for a dried blood spot testing process that in your opinion, would not apply to PEth testing? And if you're of that opinion, if you could state the basis for your opinion.

A. Sure. Let -- let me pull the actual article because there's -- there's several of those points. Okay. I have the entire article in front of me. Let's start -- let's start with the -- this -- the next page. It talks about type of filter paper. And it talks about various -- various types. The USDTL uses Whatman 903. That's one of the commercially available papers that are discussed. So the first item would be appropriate.

Let's see. The next item that they mention -- going to -- to the third page, it talks about interferences originating from collection substrate and then talks about sample volume. The next page is where we're going here. Right up to that table, yes. The Sample Volume. The USDTL does not use a specific

sample volume. In other words, the card is -- is -- is filled with blood, but it's not necessarily a specific volume, so that does not apply. The drying and storage process really relates more to microbiological samples. As you know -- as we've talked about before, PEth testing is used for virus samples and microbiolo -- microbiological samples. While drying is important, that's not -- not crucial to a PEth test. And it -- it -- obviously, it's shipped in a -- in a box, so 24 hours of drying by the time it takes to get to the laboratory. So the drying and storage process is not as critical for a PEth test as it is for a microbiological test. The next issue there --

Q. I wanted you to identify as you went what you were relying upon. Do you know whether USDTL conducted any validation studies with respect to the appropriate drying process?

A. I did not see -- observe any, so I -- I don't know if they did. I -- I'm -- I am not aware of any.

Q. Well, to the extent that they either conducted a validation study or relied on somebody else's validation study, they would be obliged to comply with the results of that study, correct?

A. If it's -- if the laboratory director decides that that's an issue. You asked me originally what

sample -- what issues that I think did not apply. So in -- in my opinion, drying is not an issue that really is -- is essential to PEth testing. It's for microbiological testing.

Q. Okay.

A. Although if -- if the laboratory says to dry it an appropriate amount of time or needs to, you know, get on -- tested immediately after someone draws a sample of blood, that's -- that's up to the laboratory to decide that. But I did not review any data one way or the other to say it should be dried or should not be dried for a certain length of time.

Q. Okay. Well, would you agree though -- would you agree though that PEth -- however it's obtained -- it doesn't determine the time, dose, or frequency of use?

A. Correct.

Q. In terms of the quantity itself, correct?

A. That's correct. Yeah.

Q. And then would you agree that the -- yeah. Okay. And I'm sorry and I -- thanks for supplying that omitted element. Would you agree that there's no correlation between the quantitative result of the test and the level of consumption?

A. There -- there is some correlation, yes. The

higher the PEth value, the more alcohol that was consumed during that time period. Yeah. Yes. It's -- it's -- it's not a great correlation, but there is a correlation. Yes.

Q. Okay. Well, would you agree that 100 nanogram per milliliter does not reflect a consumption level five times higher than a 20 nanograms per milliliter result?

A. Yes, that's -- that's correct.

Q. Okay.

A. And I -- I -- I can keep going in this article if you'd like me to, but I -- I think -- I think we've kind of get the high -- the high points as well, and what would be -- things that would not be appropriate for PEth testing.

Q. Okay. All right. I'm satisfied. And would you agree that the DBS has a shorter history than traditional matrix such as liquid blood, plasma, serum?

A. Well, yes, partly. Dried blood spots had been used since -- since the 1960s. I -- I -- I did my PhD on Phenylketonuria, which was a -- is a devastating inborn error of metabolism. Every newborn in this country is tested for PKU and several other metabolic diseases. So this -- this has been done since the 1960s with dried blood spots. So it's -- it's

certainly not new technology, but it's not as old as testing blood or urine that could have been done for 100 years or so.

Q. Now, are you aware that the USDTL in its FAQ asserts that there are no other labs that do commercial dried blood testing -- excuse me. There are no other labs that do commercial dried blood spot PEth testing, so there are no labs for comparison with USDTL? Do you consider that an accurate statement?

A. Partially. You are correct there are no other commercial laboratories, but Marty Javor's lab is the laboratory that we use for any additional testing. If we want to retest a sample and send it to another laboratory, we -- we use his laboratory. So -- and that -- that laboratory is in San Antonio. It's a University of Texas laboratory, it's not a commercial laboratory. So that -- that is a true statement that the -- there are not other commercial laboratories, but there are other -- there are other laboratories for comparison.

Q. So what's the difference between a commercial laboratory and a non commercial laboratory?

A. It's not for profit.

Q. You made some reference about -- and if I'm misquoting you it's not intentionally, that there was

some factor of pre-analytical deviation up to 40 percent. Does that ring a bell in terms of your direct testimony?

A. Yes. There's a very good paper that was published a couple of years ago by an author named Ngyuen, N-G-Y-U-E-N, a Vietnamese name. And he discusses the -- the variability of PEth testing and discusses this -- the -- the analytical variability of plus or minus 30 percent, which we've discussed several times. The concern is or the question is, what variability does the collection process add to that? And I think you discussed or talked about the effect of hematocrit. So what his paper does is, it says, well, if we -- if we add all of the variables together, pre-analytical variables, analytical variables, how -- how much can that -- that value range and the point of his paper was plus or minus 40 percent is a very good estimate of all of the variables that you take into account for a dried blood spot test.

Q. And when was that test conducted?

A. 2018.

Q. 2018. And how many subjects did that involve?

A. It was more of a theoretical paper. I'm not sure if it was any -- were any specific numbers of

patients, or numbers of donors. It was discussing when you take apart all of the -- in forensic toxicology, we talk about something called uncertainty. And the way you measure uncertainty is you add up all of the things that you -- that have variability. Certainly the collection process has variability. The -- the analytical process has variability. And when you add every single variable that there is, they -- they describe and use plus or minus 40 percent as the imprecision or the range that one could see for a result.

Q. If we could bring up Union Exhibit 37. I guess I need this scroll to the second page. Okay. Here we go. I believe your testimony on direct -- first. Let me back up. What kind of test are we looking at here?

A. This is a PEth test done on a donor by the name of Matthew Dacier, collected on 5/18/2020.

Q. Okay. And I believe your testimony was that subsequent to this test that Dr. Tordella should have had his patient submit to another PEth test?

A. Yes.

Q. Okay. And why should he have done that?

A. Well, the PEth test is the best option available. A hair test -- let -- let's say the hair

test is positive. Well, that just tells you what you already know that this individual has been drinking. The PEth test of 24, if the hair test was negative, it doesn't rebut or refute this result. So the -- a hair test would add no additional information to which you already have. I would recommend the additional PEth testing.

MR. SEHAM: Okay. I'd like to take a break at this point and review my notes and talk to my client. Let's see. I'm trying to figure out how long of a test -- a break I want to take. Let say it's 20 minutes. Arbitrator Burdette, if it's acceptable that you we'll come back at 4:20. Excuse me, 4 -- what do I want? Yeah, 4:10.

THE ARBITRATOR: 4:10?

MR. SEHAM: Yeah.

THE ARBITRATOR: Okay. We'll go off the record until 4:10 Eastern Standard Time.

THE REPORTER: We are off the record at 3:49 p.m.

(OFF THE RECORD)

MR. SEHAM: Pass the witness.

THE ARBITRATOR: Okay. Mr. Kassin?

MR. KASSIN: Yes, sir. I have two questions for Dr. Taylor.

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REDIRECT EXAMINATION

BY MR. KASSIN:

Q. Dr. Taylor, are you aware of any scientific studies that show that there have been a false positive PEth test?

A. No. In fact -- in fact, we have -- we've done 4 or 500 PEth tests over the seven or eight years we've been doing them. We've sent out six or seven retests and there've been no -- they've all confirmed. And the same with Joe Jones told me that USDTL has had the same experience.

Q. Okay. Are you aware of any scientific studies that show that PEth results at or above 20 nanograms per milliliter due to anything other than intentional ingestion of alcoholic beverage?

A. No. I'm not aware of any study.

MR. KASSIN: Arbitrator Burdette, those are only two questions I had.

THE ARBITRATOR: Okay. Mr. Seham, anything else?

MR. SEHAM: No. No further questions.

THE ARBITRATOR: Okay. Thank you very much, Dr. Taylor, you may be excused from the witness stand.

THE WITNESS: Thank you.

MR. KASSIN: Arbitrator Burdette, we had planned that Dr. Taylor taking the whole day and we're pretty

much there. I would like to have the opportunity to resume our rebuttal in the morning at 10:00 a.m. Eastern Time. But I would tell the board and counsel, Mr. Seham, Ms. Samuda, I don't think that it will take more than an hour other than for potential surrebutal that Mr. Seham have.

THE ARBITRATOR: Okay. So what you're suggesting is that we may be done by noon-ish time tomorrow?

MR. KASSIN: Yeah. We certainly would, I'm hopeful that we'll certainly be done by noon-ish East Coast Time tomorrow and we'll have more time if that's necessary for Mr. Seham.

MR. SEHAM: Yeah. Well, in terms of surrebuttal, that would not take place tomorrow. We essentially heard the company's case for the first time today and we would need time to review it, just as the company had the better part of the year to review our expert report. So we would have to schedule another date for surrebuttal.

THE ARBITRATOR: Okay. Well, you and Delta will get together and discuss when that would be?

MR. KASSIN: Yes, sir.

THE ARBITRATOR: Subject to the availability at my calendar, which you can see in real time.

MR. SEHAM: Thank you.

THE ARBITRATOR: All right. So we're going to conclude for today and go off the record, Damien, at 4:13 Eastern Standard Time. We'll reconvene tomorrow morning at 9:00 a.m. Central and 10:00 a.m. Eastern.

(Whereupon the proceeding concluded.)

* * *

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 8, 2020.

_____
DAMIEN STONEBERGER
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 24, 2020

_____
STEPHANIE MORANO