AIR LINE PILOTS ASSOCIATION, INT'L	)	**GRIEVANCE NUMBER ATL 18-14**
AND	)	**ARBITRATOR MARK BURDETTE**
DELTA AIR LINES, INC	)	

POST-HEARING BRIEF ON BEHALF OF MICHAEL DANFORD

Respectfully submitted

/s/ Lee Seham
Lee Seham, Esq.
Seham, Seham, Meltz & Petersen, LLP
199 Main Street – Seventh Floor
White Plains, NY 10601
(914) 997-1346

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INTRODUCTION

The Delta HIMS program is in danger of collapse. In the absence of a showing from this System Board that those innocently accused will be protected, voluntary participation in the program will evaporate.

In the instant matter, Delta determined that Mr. Michael Danford failed to maintain his abstinence, and terminated his employment, based on a single test result applying a methodology used by no other commercial laboratory in the United States. No pre-termination investigation was conducted with respect to the reliability of the test nor was *any* consideration given to a welter of information – prior tests, piloting performance, psychological/psychiatric reviews, peer monitor evaluations, subsequently conducted testing evidence – that supported a finding of continued abstinence. The FAA, which did consider this evidence, re-issued Mr. Danford's first class medical certificate without requiring re-entry into a treatment program based on its determination that the single test failed to establish a relapse.

The evidentiary record presents a singular case. Virtually everything that could have gone wrong with the evaluation process did go wrong, including, but not limited to:

* In defiance of laboratory recommendations and the opinion of its own witnesses, Delta treated the single test result as dispositive, rather than as one source of information within a broader clinical analysis;

* Delta selected a "positive" cutoff level rejected by other airlines and the United States government due to its tendency to produce false positives;

* Delta failed to apply a two-test confirmation process recognized by the toxicological community and by the National Transportation Safety Board as indispensable to the forensic testing process;

* Delta stripped Mr. Danford of a split sample testing process that it had promised to him as a safeguard of testing reliability;

* The single test result on which Delta relied was based on a dried blood specimen collected in violation of protocols the laboratory described as "imperative" to the "integrity" of the test result;

* The laboratory failed to provide supplies to the collection site that it considered to be a mandatory component of the specimen collection and transportation process;

* The laboratory intentionally deviated from protocols established by the manufacturer of its testing materials without validating that the deviation would not impact quantitative results;

* Neither the laboratory nor any of Delta's witnesses presented any documentation establishing scientific validation of the "cutting-edge" methodology applied;

* The laboratory's test results confirm non-compliance with basic validation standards identified by the laboratory's director as applicable;

* The laboratory has no internal policy requiring investigation of inconsistent test results (positive and negative) from the same donor on the same day;

* Delta refused to give any consideration to the Grievant's negative test results, from the same laboratory using the same methodology, that were inconsistent with the quantitative test result upon which Delta relied.

When HIMS Peer Monitor Captain David Dodge attempted to present evidence in favor of Mr. Danford, Delta's response was to "shoo me off" because "the PEth test don't lie." (Tr. 605). While Captain Dodge described HIMS as a "very important program," he saluted Mr. Danford for having the "integrity to stand up and say … I did not drink." (Tr. 608-09).

This case is not just about Mr. Danford; it is about the viability of the HIMS program. It is about pilots with substance abuse problems who, with a growing sense of trepidation, must consider whether they will self-identify or just keep flying as best they can. The failure to reinstate Mr. Danford, under the facts presented in this case, will slam a door on those who need and want help, but who also seek assurances of due process and fair treatment.

STATEMENT OF FACTS

Michael Danford has been flying since he was ten years old. He served honorably in the United States Navy and flew as a Delta pilot for over eighteen years on the MD-88, Airbus 330, 757/767, 727, 737, and L1011. In over fourteen schools, he passed all training events with flying colors. He never failed a check ride. He was never disciplined in any manner. In short, Mr. Danford was an exemplary employee who displayed unsurpassed airmanship. (Tr. 653-56).

On January 5, 2017, while off-duty, he was arrested for driving while intoxicated. He paid a fine and was not required to appear in court. (Tr. 656). Notwithstanding the absence of any physical health issue related to alcohol, he entered Delta's alcohol recovery program as a volunteer. (Tr. 656-57).

The program included a 42-day stay at the Talbott Recovery Center (TRC), a facility located in a high-crime area with pervasive drug use and car break-ins occurring in the immediate vicinity. (Tr. 664-65). While there, he was housed with an overt racist and convicted felon who boasted of beating victims into submission during robberies. (Tr. 659-662). His requests for a change in accommodation were denied; instead, he was forced to confront his criminal roommate, which served only to further aggravate the unsettling environment. (Tr. 662-64). After a 15-minute interview, the TRC medical director summarily diagnosed him with a pointed warning that any challenge of the diagnosis would be futile. (Tr. 665).

Notwithstanding these difficulties, Mr. Danford fully cooperated with the TRC program and received the following evaluation upon his completion of that program:

> Mr. Danford's prognosis for long-term recovery is good. He was attentive to the process, often contributing insightfully in groups, recognizing patterns and the need to be more honest with oneself and others. The main potential for extra caution for Mr. Danford identified at this time is his relatively new relationship and the emotional potential therein.

(UX63). The referenced "new relationship" related to Artis Todd, a Delta flight attendant who is a teetotaler and with whom Mr. Danford has had a stable and exclusive relationship since 2017. (Todd, Tr. 611-13).

Prior to his return to the flight line, Mr. Danford was required to sign a form document referred to as Contract A, which required him to abstain from drinking alcohol during his remaining employment with Delta. Pursuant to Contract A, Danford was required to submit to a program of peer monitoring, psychiatric and psychological examination, AA meeting attendance, monthly Chief Pilot meetings, and random testing for abstinence from alcohol. The document makes no reference to the quantitative values that would be treated as a positive. Contract A provided that noncompliance with its terms "may" result in disciplinary action, up to and including termination. (CX3). However, Delta's Flight Operations Policies and Procedures Manual (FOPP) provides that a volunteer participant in the HIMS program who suffers an alcohol-related relapse "will not be suspended or terminated provided that relapse is limited to one occurrence." (CX4, Section G.1 at 5-6).

Mr. Danford returned to the flight line and performed three international trips in the spring of 2018 without incident or complaint. (Tr. 668-69). From early November 2017 through

the end of April 2018, he submitted to a series of eight monthly random alcohol tests, all of which yielded negative results. (CX1).[1]

On May 1, 2018, Mr. Danford was required to provide an additional urine specimen pursuant to the random alcohol testing program. The specimen he provided was split into two specimen bottles – bottles A and B – so that, in event of a positive test result, Danford could have the B bottle sent to a second laboratory as a means of challenging the initial result. (Tr. 673-74; CX9 at 7(collection form)). The urine contained in bottle A was tested by Quest Diagnostics Laboratory (Quest) utilizing two distinct chemical methodologies – ethyl sulfate (EtS) and ethyl glucuronide (EtG).

The EtS methodology measures sulfur molecules that may be produced by alcohol consumption. Danford's EtS test for the May 1 urine collection was negative, supporting a finding of abstinence. (Kassin, Tr. 10; Sample, Tr. 323-24). EtS has a higher stability than EtG and may be considered the more reliable biomarker. (Shults, Tr. 849-50).

The EtG methodology measures ethyl-glucuronide molecules that may be produced either by an individual's consumption of, or exposure to, alcohol. EtG at significant levels may be produced by an individual's use of hand sanitizer or mouthwash, or his consumption of a long list of common items, including pralines, non-alcoholic beer, pharmaceutical products, fruit juice, sauerkraut, or soy sauce. (Jones, Tr. 71-72, 188; Sample, Tr. 352; CX28 at 1635). Laboratories, therefore, generally use a "minimum threshold" of 250 ng/mL to indicate the intentional consumption of alcohol. (Jones, Tr. 1112-13; CX28 at 1635).[2] Nevertheless, Delta

[1] The random alcohol tests were conducted on November 8, November 28, and December 14, 2017, and on January 4, February 12, March 9, March 27, and April 26, 2018. (CX1).

[2] Even the cutoff of 250 ng/mL may be too low. Dr. Gregory Skipper testified that most forensic laboratories apply a positive cutoff of 500 ng/mL and that, in order to exclude false positives, a 1,000 ng/mL cutoff is required. (Skipper, Tr. 516-17).

instructed Quest to apply a cutoff of 100 ng/mL to indicate a "positive" test result. (Sample, Tr. 323, 328). Delta's aggressive approach is distinguishable from other airlines, which apply an EtG cutoff for positives of 150 or 200 ng/mL. (Storbeck, Tr. 269). Quest reported a quantitative EtG of 117 ng/mL for Mr. Danford's urine sample. (CX9 at 112).

Michele Gable, Director of Operations for Delta's testing program, described Danford's EtG quantitative result as "not considered a true positive because the EtS was negative." (UX66 at 1).[3] Quest's test results also reported that the urine sample had a very high creatinine level of 256.9 mg/dL, indicating that the specimen was unusually concentrated due to Mr. Danford's dehydration. (CX9 at 112; Danford, Tr. 673). Average creatinine for human urine is approximately 100 mg/dL. (Jones, Tr. 200; Skipper, Tr. 519). Applying a process referred to as "creatinine normalization" would have reduced the effective quantitative result of the May 1 EtG test to below even the 100 ng/mL cutoff level selected by Delta. (Jones, Tr. 200-01; Skipper, Tr. 519; Shults, Tr. 848).

In response to the EtG test result, Mr. Danford made requests to Michele Gable and Delta Chief Pilot Harry Miller that his split sample be tested. (Tr. 677-78). Under the federal program applicable to airline industry drug testing, where a split sample test fails to confirm the presence of the target metabolite, or even if the split sample is simply unavailable for testing, the original test is cancelled. (49 CFR § 40.187(b); 49 CFR §§ 40.187(e)(1); 40.201(e)). Mr. Danford's requests to have his split sample tested were denied. (Danford, Tr. 677-78; UX66). Instead, Ms. Gable instructed him to submit to a blood-based test for phosphatidylethanol (PEth).

PEth is an abnormal phospholipid formed in the presence of ethanol. (UX50 at 3). Typically, PEth tests are performed on whole blood; however, Mr. Danford was instructed to

[3] Ms. Gable also characterized Delta's EtG 100 ng/mL cutoff level as creating "nuisances." (Danford, Tr. 676).

provide a dry blood spot (DBS) specimen for testing at United States Drug Testing Laboratories (USDTL). According to USDTL: "There are no other labs that do commercial dried blood spot testing, so there are no labs for comparison." (UX19 at 1).

The collection facility to which Mr. Danford was directed did not have the necessary DBS collection materials, which Ms. Gable was required to ship. (Tr. 678). While USDTL asserts that it maintains a specimen collector certification program, it is not mandatory and no training was provided to the individual who collected Mr. Danford's specimen. (UX12 items 4 and 5; UX14 items 4 and 5; Jones, Tr. 108-09).

USDTL sets forth DBS collection protocols in a document that states that adherence to the protocols is "imperative to the integrity of the collection and subsequent testing process." (UX11). No document detailing the mandated DBS collection protocol was referred to by the collector during Mr. Danford's May 9 collection nor was he provided any oral instructions with respect to the collection process. (Tr. 685-86).

The May 9 DBS collection failed to comply with several "imperative" requirements. In bold lettering, the protocol mandates that certain practices must be avoided, including "milking" the finger to produce blood, direct contact of the finger with the DBS card, the layering of successive blood drops on the card, and the enclosure of the card in an airtight shipping bag. (UX11 at Steps 10, 11, 13, 19). A paper shipping envelope distributed by USDTL highlights that these errors must be avoided. (UX67; Tr. 691). Nevertheless, every one of these "imperative" collection standards was violated: Danford's finger was milked and squeezed through the entire process; the collector filled the circles via a "continuous finger painting" process; the card circles were filled by successively layering blood drops; and the completed DBS card was immediately placed in an airtight, plastic specimen bag. (Tr. 683, 684, 687, 689). The immediate enclosure

of the specimen in an airtight, plastic specimen bag fails to comply with the card manufacturer's protocol requiring a 3-hour drying process. (UX15 at 7-8).

USDTL mandates that the specimen "MUST" be shipped with a desiccant pouch to preserve the integrity of the specimen. (UX19 at 3). However, the supplies that USDTL provides to the collector do not include a desiccant pouch and, consequently, Mr. Danford's DBS card was shipped without this safeguard of testing integrity. (Jones, Tr. 181-82; UX20; Danford, 684-85).

USDTL describes its application of DBS PEth testing as "rather cutting edge." (Jones, Tr. 186). Nevertheless, the laboratory has performed no validation studies with respect to numerous issues that have been identified as impacting PEth quantitative analysis, including: the specimen collection process, sample volume effect, hematocrit effect, creatinine level effect, volcano effect, USDTL's failure to provide a desiccant pouch for shipping and its failure to adhere to the drying protocol prescribed by the DBS card's manufacturer. (UX12/UX14 item 3 (specimen collection); UX12/UX14 item 13; (sample volume effect); UX12/UX14 item 14; (hematocrit effect); UX12/UX14 item 15 and Jones Tr. 188; (creatinine level effect); UX12/UX14 item 16; (volcano effect); Jones, Tr. 180 (non-use of desiccant pouch); UX15 at 7-8; Jones, Tr. 156 (deviation from manufacturer's drying procedures)). Jones also admitted that USDTL has conducted no validation studies on the impact of sample creatinine levels on PEth quantitative analysis. (Jones, Tr. 188).

USDTL reported two quantitative results: 69 ng/mL and 98 ng/mL. (Jones, Tr. 76; CX10 at 5). The two varying results were produced despite the use of the same sample card,

same type testing instrument, and same controls for both tests. (Jones, Tr. 1083-84).[4] USDTL reported the test result as "positive" for PEth based on its application of a 20 ng/mL cutoff.

On May 14, Chief Pilot Miller advised Mr. Danford via telephone that his DBS PEth test result was "positive" and, as a result, he was obligated to return to in-patient treatment at Metro Atlanta Recovery Residences (MARR) the next day or be terminated. (Danford, 693-94). Entry into the MARR program would have required Mr. Danford's acceptance of an internment of 90 to 180 days. (Graham, Tr. 443).

Mr. Danford responded that he had not been drinking and requested Miller's assistance in obtaining a medical review of the test result. Miller declined Mr. Danford's request without explanation. (Tr. 695). Miller expressed his view that, even if Danford had not consumed alcohol, he needed to go to the MARR treatment facility and "fight" it from there. (Danford, Tr. 702, 758; Miller, Tr. 952-53).

On May 15, Danford contacted Michele Gable, who endorsed Danford's proposal of seeking additional testing to demonstrate that the May 9 DBS PEth test had been in error. Gable advised him that he needed to have the second test conducted that same day and that the test be performed at the testing laboratory's limit of detection (LOD) of eight ng/mL. (Tr. 696-97). Referring to the prospective results, Gable promised that "we'll take a look at it." (Tr. 697).

That same day – May 15 – Danford initiated a whole blood PEth test with LabCorp and entered on the collection form that he requested testing at the LOD of 8 ng/mL. (Tr. 698-99;

[4] The industry standard for the scientific validation of testing methodologies provides that the coefficient of variation (CV) for a quantitative test should not exceed 20%; however certain analytical methods (e.g., blood alcohol analysis) should be subject to a coefficient of variation of less than 10%. (UX51 § 8.2.2.3.1 at 8; Taylor, Tr. 1086-87). Dr. Taylor testified that, in his experience, that typical variation at a forensic laboratory is 20%. (Taylor, Tr. 1086).

UX70). LabCorp reported a negative test result applying the standard cutoff of 20 ng/mL. (Tr. 699; UX71).

At the recommendation of the collection site personnel, Danford also submitted, on May 15, and again on June 20, 2018, to EtG hair tests due to its six-month detection window. ExperTox Laboratory subsequently reported results consistent with total abstention from alcohol consumption over the prior six months. (Danford, Tr. 700-01; UX72, UX75).

The next day – May 16 – Danford submitted to a DBS PEth test to be sent to USDTL. This time, the specimen collector complied with the collection procedures that USDTL deemed "imperative to the integrity of the collection and subsequent testing process." (UX11; UX73; Danford, Tr. 703). The May 16 DBS specimen tested negative at both the cutoff of 20 ng/mL and the LOD of 8 ng/mL. (UX74; Danford, Tr. 704-05).

Jones testified that it takes "many weeks to a couple of months" to replace the blood cells carrying PEth. (Jones, Tr. 35). According to USDTL, PEth has a half-life of approximately 4.5 days, which means the level of PEth in the blood decreases by half every 4.5 days. (Jones, Tr. 128; UX19 at 2). Thus, it would have been expected that if USDTL had accurately reported a 98 ng/mL or 69 ng/mL quantitation for Danford's DBS PEth quantitative test result of May 9, the May 15 and 16 tests conducted just six and seven days later, respectively, would also have produced a detectable result. In short, the May 9 and May 15/16 tests could not both be accurate assuming an average half-life of 4.5 days.

When Danford attempted to present the May 15 and May 16 test results to Michele Gable, she would no longer speak to him. (Danford, Tr. 706). Chief Pilot Miller told him that he could present the test results at his post-termination arbitration if he cared to. (Danford, Tr. 706-07).

The "decision-maker" with respect to Mr. Danford's termination was Captain Jim Graham. (Kassin, Tr. 11; CX2). Danford presented the above-referenced testing evidence to Captain Graham at his pre-termination hearing, upon receipt of which Captain Graham promised to give the test results "very careful and due consideration and have them looked at by experts and would make a determination." (Danford, 709; CX20). Graham reneged on this commitment and declined to consider the evidentiary value of the tests purportedly because there was "no way for us to understand exactly how the test was done." (Graham, Tr. 450). Graham, however, never explained to Mr. Danford that he would not credit the results or that consideration of the results depended on Delta's scheduling of the tests. (Graham, Tr. 709).

Graham terminated Mr. Danford based on his conclusion that Mr. Danford had knowingly consumed alcohol. (Graham, Tr. 454). Graham conducted no investigation other than to apply the testing protocols as he understood them to exist; in his view "there was no reason to" conduct an investigation. (Graham, tr. 458). Thus, at the time of the termination, Graham had no knowledge as to the forensic reliability of the EtG testing process but nonetheless accepted the EtG methodology as providing a "reliable result with respect to the abstinence or non-abstinence issue." (Graham, Tr. 460-61). He did not consult with a Medical Review Officer or any other medical doctor. (Graham, Tr. 461-63). Nor did he engage in any pre-termination consultation with Michele Gable or representatives of either Quest or USDTL. (Graham, 472-73).[5] He did not consider any of the numerous available sources of clinical information, including, but not limited to, Mr. Danford's peer monitor, psychiatrist, psychologist or performance record. (Graham, Tr. 477-78).

[5] Dr. Jones testified that apparently no one at Delta had contacts with USDTL representatives concerning Mr. Danford's test results until 2020. (Jones, Tr. 188).

Despite his knowledge that Mr. Danford contested Delta's determination that he had suffered a relapse, Captain Graham made no effort to initiate a review pursuant to Section 15 of the Pilot Working Agreement, which provides a mandatory process for resolving disputes relating to a pilot's physical fitness. (Graham, Tr. 473, 476-77; JX1 at Section 15). Graham testified that Mr. Danford would not have been terminated if he had accepted Delta's unilateral relapse determination and entered re-treatment at MARR. (Graham, Tr. 484).

As a result of the testing commissioned by Delta, the FAA asked for the return of Mr. Danford's first class medical certificate. The FAA subsequently re-issued Mr. Danford's first class medical certification, without requiring in-patient treatment, based on its determination that full consideration of the clinical and testing data cast doubt on the reliability of the May 9 DBS PEth test result. (UX35).

ARGUMENT

I.

BURDEN OF PROOF: DELTA BEARS THE BURDEN OF PROVING RELAPSE

Pursuant to the Pilot Working Agreement (PWA), a pilot cannot be terminated without the Company establishing just cause. (JX1 at Section 18.D.1). Since termination constitutes the capital punishment of the workplace, the burden of proof that must be borne by the Company is a heavy one; the evidentiary predicate for termination must be established by clear and convincing evidence in order for Delta to prevail. *Delta/ALPA,* Gr. No. ATL 16-05 (Arb. Richard Kasher, 2018) at 43 (Delta and ALPA "agree that there must be 'clear and convincing' evidence and 'just cause' to support the imposition of discipline.")(Attachment A).

Contract A does nothing to eliminate the applicability of the just cause standard to Mr. Danford's termination. Rather, it permits Delta to argue that just cause may be established if

there is clear and convincing evidence that Mr. Danford suffered a relapse. The standard seven elements of just cause still apply[6], including the requirement that Delta prove that it engaged in a meaningful pre-termination investigation. *See Delta/ALPA*, Case No. NWA 2710-08 (Arb. Frederic Horowitz, 2018) at 7 (even in the context of a last chance agreement (LCA), the Company bears the burden of proof of establishing just cause by proving that the Grievance breached the LCA and related policies as alleged)(Attachment B).

II.

DELTA'S FAILURE TO CONSIDER ANY CLINICAL EVIDENCE PRECLUDES A FINDING OF JUST CAUSE

Much of this brief will, perforce, address mind-numbing issues relating to forensic toxicology. However, for two reasons, Delta's failure to give *any* consideration to the available clinical evidence preclude a finding of just cause irrespective of any test results. First, because of the unanimous opinion of both the toxicological experts and laboratories holding that test results should be considered as just one source of information in a more comprehensive clinical analysis. Second, as confirmed by both Dr. Skipper and the FAA, the clinical evidence in this case overwhelmingly supports the conclusion that Mr. Danford did not have any relapse.

As discussed in the remainder of the brief, even according disproportionate weight to Delta's proffered test results of May 1 and May 9, the evidentiary record establishes that the testing data could never satisfy Delta's burden of proof. Among other factors discussed below, which disfavor a finding of relapse, are the following: (1) the negative May 1 EtS result, (2) the May 1 EtG result would be considered negative at standard cutoff levels, (3) the May 1 EtG result would have been considered negative even at the non-probative Delta-selected cutoff of 100 ng/mL if the quantitative result had been normalized for creatinine, (4) EtG, in general, is

[6] *Enterprise Wire Co.,* 46 LA 359 (Daugherty 1966).

non-probative of the source of alcohol, (5) the May 9 PEth test result is inadmissible due to collection errors USDTL has deemed "imperative to the integrity of the collection and subsequent testing process," (6) USDTL's application of a "cutting-edge" PEth DBS testing process that has never been scientifically validated, (7) USDTL's deliberate deviance from the manufacturer's DBS testing protocol without scientific validation, and (8) the uncontroverted evidence that USDTL has produced inaccurate test results during the relevant time period, and has no system in place to investigate false positives.

At most, Delta's testing evidence produced a clinical question as to whether Mr. Danford might have had a relapse. The PWA provides a binding method for resolving such disputes related to a pilot's physical fitness. That process involves a physical fitness review by a Delta-appointed Company Medical Examiner (CME). If a pilot wishes to dispute the CME's findings, he may retain a Pilot Medical Examiner (PME) for the purpose of obtaining a second opinion. If the CME and PME reach differing conclusions with respect to the issue of the pilot's fitness, they are empowered to jointly select a Neutral Medical Examiner (NME) whose analysis and decision is final and binding. (JX1 at Section 15). The process is better suited to carefully balancing the interests of aviation safety with the imperative that a pilot's career not be improperly terminated. Without such a balance, aviation safety will be compromised by deterring pilots with substance abuse problems from entering the HIMS program due to their concerns of unfair treatment and the absence of any medical review process. In view of Delta's failure to avail itself of the mandatory contractual process for resolving disputes relating to pilot's fitness for duty, the grievance must be sustained.

A. Bio-Marker Testing Data Must Be Considered Just One Source of Information in a Broader Clinical Analysis

Even the purveyors of EtG and PEth testing services readily acknowledge that their test results must be treated as one data point in a broader clinical analysis of whether an individual has relapsed. As Quest Laboratory's Director of Science and Technology Barry Sample testified:

> And we all – you know, we recommend that a Medical Review Officer be used, not just for federal testing or it's required or in certain states where it's required, *but for all tests, particularly in interpreting positive results.* But that's ultimately a customer or an employer decision.

(Sample, Tr. 350-51). Dr. Sample's testimony is consistent with Quest Laboratory's adjuration that:

> Quest Diagnostic recommends clinical correlation and/or healthcare provider review when interpreting EtG and EtS results.

(UX79). Dr. Gregory Skipper concurred that, the analysis of any EtG result under 500 ng/mL requires the application of "clinical acumen." (Skipper, Tr. 517).

LabCorp similarly cautions, in the context of whole blood PEth analysis, that "alternative explanations should be explored following any positive finding" and that "the possibility remains that an individual elevated PEth level may result from incidental or unintentional ethanol exposure." (UX2). When Dr. Howard Taylor was asked whether he disagreed with LabCorp's position that "alternative explanations should be explored" following any positive finding with PEth, he responded: "I – I don't disagree." (Taylor, Tr. 1104).

Dr. Gregory Skipper concurred. He described PEth as a "good marker" with "meaning and purpose." He cautioned, however, that the PEth methodology is "still not totally understood." (Skipper, Tr. 520). Dr. Skipper testified that, like the EtG biomarker, the use of which has been subject to repeated review and revision as its shortcomings were gradually

identified, PEth "has to be used with caution and be interpreted in the light of clinical data. You can't just rely on any lab test to be perfect." (Skipper, 520-21).

USDTL Laboratory Director Jones tacitly agreed with the views of LabCorp and Dr. Skipper. The most that Jones could say for the DBS PEth result was that it was "consistent" with someone who has not been abstinent. (Jones, Tr. 101). On cross-examination his answer was downgraded to alcohol consumption being a "reasonable explanation" for a positive PEth test. As he conceded to Dr. Tordella, when confronted with conflicting DBS PEth tests results, Jones's limited function was to report laboratory results and refrain from making any clinical determinations with respect to whether an individual experienced a relapse. (Jones, Tr. 170; Tordella, Tr. 375-76 – "I'm just a lab guy … I don't come up with the diagnosis. That's your job."). In other words, a relapse determination is the province of a Medical Review Officer (MRO) or other healthcare professional.

Under the federal program[7], the MRO acts as "an independent and impartial 'gatekeeper' and advocate for the accuracy and integrity of the drug testing process." 49 CFR §§ 40.123(a). Confirmed laboratory results cannot be released to an employer in the absence of prior quality assurance review by the MRO to determine if he can "verify" that the confirmed positive test result actually reflects substance abuse. 49 CFR §§ 40.123(b); 40.129(a). The MRO verification process must include an interview of the tested employee that affords the employee the opportunity to present a legitimate medical explanation for the test result. 49 CFR §§ 40.133(a); 40.137(b). The MRO's pre-verification review must include, where necessary, a review of clinical evidence. 49 CFR §§ 40.139(c). Where a legitimate medical explanation for a

[7] Arbitrators have found that adherence to federal testing standards to be a requirement of just cause even where the application of these standards was not required by law. *See, e.g., Litton/ Ingalls Shipbuilding*, 90/22751, 967 BNA LA 30 (Nicholas Jr. 1991) (finding "essential fairness" required adherence to federal testing guidelines even in the absence of "mandatory application").

confirmed laboratory positive exists, the MRO must verify the test as negative. 49 CFR §§ 40.137(d). As reflected by the testimony of Dr. Sample, Dr. Taylor, and Dr. Skipper, such an MRO review should have been conducted in the instant matter in order to properly interpret the raw data provided by the laboratories' reports. No Delta representative ever explored whether there might be an alternative explanation for the May 9 PEth positive, much less a qualified MRO.

The vital importance of due process in the grievance and arbitration process, and, in particular, the need for a meaningful pre-termination investigation is well established. As one leading commentator summarized:

> Discharge and disciplinary action by management has been reversed where the action violated basic notions of fairness or due process. This was true, for instance, where the employer gave employees no chance to be heard but discharged them summarily upon learning that they had been convicted of larceny by a court. In other situations, too, **the failure of management to make a reasonable inquiry or investigation before assessing punishment** was a factor (sometimes the sole factor) in the arbitrator's refusal to sustain the discharge or discipline as assessed by management.

ELKOURI & ELKOURI, *How Arbitration Works* at 673 (4th Ed. 1985)(footnotes omitted)(emphasis supplied). As Arbitrator Daugherty held in his seminal case establishing the seven tests for just cause, a fair investigation conducted "prior to the termination" is essential for a showing of just cause. *Enterprise Wire Co.*, 46 LA 359 (Referencing tests 3 and 4). Fundamental due process errors cannot be rectified simply by affording the grievant, at some distant date, the right to an arbitration hearing. *McCartney's Inc.*, 84 L.A. 799, 804 (1985).

The mere fact that alleged substance abuse is involved does not relieve the employer of its obligation to properly investigate the matter prior to termination. *Misco, Inc.*, 89 L.A. 137, 144 (1983) (reinstatement of employee discharged for bringing controlled substance onto company property ordered reinstated, in part, due to employer's failure to conduct an adequate

pre-termination investigation). Nor are these procedural obligations in any way diminished simply because medical issues are central to the decision-making process. *American Iron & Machine Works Co.*, 19 L.A. 419 (1952).

In *American Iron*, the grievant had been terminated upon the recommendation of the company doctor who had concluded that he was prone to back injury. *Id*. at 418. While Arbitrator Maurice Merrill agreed that such a conclusion, if properly arrived at, would constitute just cause for termination, his analysis did not stop there:

> Obviously, the "proper and just" or "just" cause for discharge cannot be the simple recommendation of the company's physician. **So to hold would be to vest in him the uncontrolled discretion which the contract forbids to management**. His recommendation must be based upon reasons, grounded in physical fact, which render it proper to bring the employment to an end. And his mere statement that these conditions exist cannot be conclusive, because to give them such conclusive effect would also vest him with an unlimited discretion. **His conclusions and facts upon which they are based must be subject to examination and rebuttal**, at least to the extent of determining whether his recommendation is candid and within the bounds of reason.

Id. (emphasis supplied).

The pertinent question, therefore, is whether Delta engaged in a meaningful pre-termination investigation of the relevant clinical evidence. In the absence of such an investigation, Delta cannot be said to have made a substantively fair decision, or to have provided the procedural due process to which Mr. Danford was entitled.

B. Delta Engaged in no Pre-Termination Review of the Clinical Information That Supported a Finding of Abstinence

The context in which the relevant biomarker testing occurred must be carefully considered. This matter does not involve a reasonable cause or post-accident test. There were no pilot performance issues or workplace misconduct. There were no health issues.

Indeed, the clinical evidence in the record overwhelmingly supports a conclusion of continued abstinence, including:

* The positive Talbott Recovery Center assessment (UX63);

* Mr. Danford's neuropsychological and raw scores that presented no evidence of mental disorder related to substance abuse. (Skipper, Tr. 509-10);

* Mr. Danford's consistent compliance with every aspect of the Contract A program (e.g., group meetings, continuing education, reporting for tests)(Dodge, Tr. 599-601);

* His exemplary participation in the peer monitoring program and the enthusiastic support of Peer Monitor David Dodge (Tr. 598-609);

* His stable and exclusive relationship with Artis Todd, a Delta flight attendant and teetotaler (Tr. 611-14);

* The positive assessment of aviation psychologist Dr. David Prewett, including his support for the re-issuance of Danford's first class medical certificate (Tr. 713-15);

* The positive assessment of aviation psychiatrist Dr. Steven Lynn, including his support for the re-issuance of Danford's first class medical certificate (Tr. 713-15);

* An 18-year tenure with Delta devoid of any history of discipline or misconduct (Graham, Tr. 467-69; Danford, Tr. 653-56);

* A perfect training record (Graham, Tr. 467-69; Danford, Tr. 653-56);

* Zero performance complaints (Graham, Tr. 467-69).

Nevertheless, notwithstanding the adjurations of the laboratories and the experts, Delta steadfastly refused to engage in any consideration of this evidence. The terminating officer did not consider any of the available sources of clinical information, including, but not limited to, Mr. Danford's peer monitor, psychiatrist, psychologist or performance record. (Graham, Tr. 477-78).

Graham conducted no investigation. He simply accepted certain quantitative results, not stipulated in any policy document submitted by Delta into the evidentiary record, as dispositively establishing a relapse. (Graham, Tr. 458). At the time of the termination, Graham had no knowledge as to the forensic reliability of the EtG testing process, but nonetheless accepted the EtG methodology as providing a "reliable result with respect to the abstinence or non-abstinence issue." (Graham, Tr. 460-61). He did not consult with a Medical Review Officer or other medical doctor. (Graham, Tr. 461-63). Nor did he engage in any pre-termination consultation with Michele Gable or representatives of either Quest or USDTL. (Graham, 472-73).

By contrast, the FAA took into consideration the totality of the available clinical and testing evidence and determined that the May 9 PEth test did not provide definitive evidence that Mr. Danford had experienced a relapse. (UX35 at 3).[8] The FAA re-issued Mr. Danford's special issuance without requiring him to re-enter treatment. (Danford, Tr. 716).[9]

The grievance should be granted on the grounds that Delta failed to engage in a meaningful investigation prior to its termination of Mr. Danford.

III.

TWO-TEST STANDARD:

DELTA MUST ESTABLISH THAT *BOTH* QUEST'S ETG TEST AND USDTL'S PETH TEST ESTABLISHED A RELAPSE

The principal question before the System Board is whether there is the requisite level of certainty that Mr. Danford actually drank alcohol in violation of this Contract A obligation. As

[8] Delta made much of the fact that the FAA currently prescribes PEth testing for pilots who are recovering alcoholics. (CX17). However, the FAA does not prescribe *DBS* PEth testing – which only USDTL uses on a commercial basis – and has not treated a positive PEth test result as dispositive evidence of relapse.

[9] Significantly, Captain Storbeck testified that he was previously unaware of any "circumstance under which a part 121 pilot was re-certified by the FAA following a relapse without retreatment." (Tr. 257-58). Storbeck's testimony further confirms that the FAA was satisfied that Mr. Danford did not experience a relapse.

alleged by Captain Graham in his termination letter: "Your use of alcohol violated the provisions in your Contract A" and, consequently, terminated Mr. Danford due to his "failure to maintain abstinence as you were required to do…." (CX2 at 2). As Delta counsel argued in his opening statement, the tests "established a failure to maintain complete abstinence. [Mr. Danford] was at this point in violation of his contract A." (Kassin, Tr. 10).

As argued in Section II above, a finding that Delta satisfied its burden of proof is precluded by the Company's studied refusal to consider any of the relevant clinical evidence. However, even if the Board were to consider upholding a termination based exclusively on laboratory test results, it is an axiom of forensic toxicology that any legal reliance on test results should be based on two tests applying distinctive testing methodologies.

In *Federal Aviation Administration v. Bosela*, NTSB Order EA-4928, 2001 NTSB LEXIS 67 (December 13, 2001), the National Transportation Safety Board (NTSB) addressed the scientific suitability of a laboratory developed test (LDT) designed to determine whether pilots and other airline employees had adulterated their urine specimens with the adulterant nitrite. The NTSB observed that the consensus of both the FAA's and the Respondent's experts was that a "'two-test system using separate aliquots and separate technology,' is a 'constituent element' of scientific suitability…." *Id*. at *7. Put another way: "a two-test, two aliquot-approach is necessary to ensure a scientifically suitable test that can be relied upon to yield valid, accurate results." *Id*.

The purported architect of the DPAC program, Captain Storbeck, recognized the applicability of the two-test forensic concept:

> it's inappropriate and not in the best interest of anyone involved to have a system that's relied upon one particular type of test.

(Storbeck, Tr. 249). The intent of the two-test program is to "protect the pilot" by having "two positive tests, one confirming the other." (Storbeck, Tr. 263-64). USDTL Laboratory Director Jones agreed that in an "ideal world, you'd want two completely different analytical methodologies…." (Jones, Tr. 64).[10] According to the termination letter, the DBS PEth test was administered to "confirm" that Danford "had been drinking." (CX2 at 2).

Thus, even assuming the legitimacy of an investigatory approach that disregards all countervailing clinical evidence, Delta cannot satisfy its burden without demonstrating that *both* the EtG and DBS PEth tests, as administered, constituted sound forensic evidence of a relapse. As addressed in Sections IV and V below, respectively, this evidentiary standard cannot be satisfied by defining a quantitative result as a "positive" in defiance of the standards of the forensic testing community or by utilizing a "cutting edge" testing methodology without the requisite evidence of scientific validation.

IV.

QUEST'S ETG TEST DID NOT PROVIDE PROBATIVE EVIDENCE OF RELAPSE

A. Quest's EtG Test Was Not Designed to Establish Non-Abstinence

Delta's failure to engage in any pre-termination review of the relevant clinical evidence is greatly aggravated by the limited objective of EtG testing under the DPAC program. Delta's testing regime was *not* designed to achieve the forensic objective of proving abstinence (the equivalent of the Part 40 federal program's forensic objective of proving unlawful substance use), but to ascertain whether there was a *possibility* of a relapse.

[10] As Jones testified, each matrix has its advantages and advantages. (Jones, Tr. 271). On occasion, different matrices may produce different results without the cause being fully known. (Jones, Tr. 271-72; UX19 at 11 bullet 1).

Captain Chris Storbeck, presented by Delta as the originator of its substance abuse policy, explained that a core element of the program was "managing risk" for the Company. (Storbeck, Tr. 222-23). In achieving that objective, the program has been entirely successful, since there has never been an incident involving an impaired pilot. (Storbeck, Tr. 236-37).

Safety is not just a laudable, but an essential goal. So too is preventing a misdiagnosis that would unjustifiably destroy the career of a pilot. Unfortunately, Delta's EtG/EtS testing was designed to accomplish the first goal without consideration of the latter:

> One of the issues that you deal with when you start trying to use various forms of metabolite testing like EtG and EtS is that, you know, a positive, for example, on one test **may or may not indicate drinking** depending on the sensitivity of the test.

(Storbeck, Tr. 245). Delta's testing program cast a wide net designed to haul in not those who had relapsed, but anyone who had been exposed to alcohol in any form. Delta's EtG cutoff level was part of a program designed to identify "possible relapses." (Storbeck, Tr. 249).

Here again, the evidence from both sides of the aisle confirmed that the EtG methodology simply does not provide reliable evidence with respect to the issue of abstinence. By the conclusion of Delta's case-in-chief, it had been established that an EtG positive can be triggered by "incidental exposure" to hand sanitizers, mouth wash, and other products found in daily usage. (UX19 at 5, item 4; Jones, Tr. 188; Sample, Tr. 352 "well documented").[11] Delta's rebuttal expert at first professed ignorance concerning a wide spectrum of products that could generate a false EtG "positive." However, when Dr. Taylor was confronted with a published article he had lauded, he conceded that such ubiquitous items as pralines, pharmaceutical

[11] As Dr. Sample conceded, the Delta-devised EtG test does not establish the source of the ethanol, "and the possibility of 'incidental exposure,' and post-collection specimen changes needs to be considered when interpreting results." (Sample, Tr. 350; UX78). Jones concurred that EtG can actually develop within the specimen while it is in transit. (Jones, Tr. 43).

products, fruit juice, and sauerkraut could trigger false positives. (CX28 at 1635; Taylor, Tr. 1112-13). He also agreed to the accuracy of article's characterization of commonly enforced laboratory standards for ETG testing:

> To effectively eliminate false positives, laboratories tend to use a high EtG minimum **threshold of 250 ng/mL** to indicate the intentional consumption of alcohol.

(*Id.*).

Nevertheless, Delta directed Quest to disregard the 250 ng/mL forensic standard in favor of a cutoff set at less than half that quantitative level. Thus, Mr. Danford's May 1 urine specimen yielded an EtS negative and an EtG "positive" of 117 ng/mL at the 100 ng/mL cutoff level "requested" by Delta. (Sample, Tr. 323, 328).[12]

Captain Storbeck acknowledged that Delta's designation of Mr. Danford's quantitative result as a "positive" was not only in defiance of forensic laboratory practice, but also constituted a sharp deviation from airline industry and federal government standards:

> other airline programs that I'm aware of typically used 150, 200. … DOT testing was for like truck drivers and stuff like that was like 400…

(Tr. 269). In sum, other airlines and the United States Department of Transportation would have treated Mr. Danford's May 1 EtG result as a negative and no PEth testing would ever have

[12] Sample conspicuously resisted Delta counsel's effort to characterize the EtG result as a "positive" in favor of merely acknowledging the quantitative value:

Q: And based on the laboratory analysis, there's no doubt that Mr. Danford's urine sample of May 1, 2018 was positive for EtG?

A: What I would say there, there is no doubt that the specimen identified as being provided by Mr. Danford was reported positive EtG concentration of 117 nanograms per mL.

(Sample, Tr. 324).

occurred. Significantly, the FAA's own evaluation of Mr. Danford's fitness to fly gives no consideration of the May 1 EtG result as evidencing relapse. (UX35).

The use of EtG testing in the manner directed by Delta compels two conclusions. First, the failure to apply EtG in a forensic manner precludes any finding that the two-test requirement has been satisfied. Second, Storbeck's acknowledgment that Delta uses EtG testing for a clinical, rather than forensic, purpose reaffirms the necessity of treating it as one data point in the overall evaluation of Mr. Danford's clinical status. Indeed, Dr. Sample acknowledged that Quest's service was only that of providing a quantitative result that required interpretation. (Sample, Tr. 350-51).

The terminating officer, Captain Graham, testified that the PEth would not have been conducted but for the "positive" result produced by Quest. (Tr. 466). Whether normalized for creatinine or not, Mr. Danford's EtG test should have been deemed a negative and no PEth test should have been administered, as would have been the practice at any other airline. The grievance should be sustained on this basis.

B. Quest EtG Test Result, Normalized for Creatinine, Further Confirms Abstinence

Forensic urine testing for substance abuse is based on finding a defined quantitative level of metabolites within an aliquot of urine. There is no dispute within the evidentiary record that the quantitative results are directly affected by the relative dilution/concentration of the urine specimen, which is reflected in a urine sample's creatinine level. (Skipper, Tr. 519). Naturally occurring creatinine levels may fall within a broad range of 20 ng/mL to 300 ng/mL. (*Id.*). According to Quest, the creatinine level of Mr. Danford's specimen was 256.9 mg/dL, indicating that the specimen was unusually concentrated. (CX9 at 112).

Dr. Gregory Skipper, who has been employed by the federal government to develop SAMHSA advisories on the use of EtG[13], testified that, because urine concentration can "quite dramatically" affect testing results, a "normalization" process must be applied in order to properly interpret the laboratory's quantitative analysis:

> It's called normalizing the value to see what the value would be at a creatinine level of 100. So it would be in this case, since the creatinine level was 257, it would be 257 over a 100 times the 117 [ng/mL Quest result], which gives you 46. So if his urine concentration had been average instead of highly concentrated, in other words, if he drank a little more water and had more of a normal urine concentration at the time of this collection, the EtG level would have been 46.

(Skipper, Tr. 519; UX57 at 4). Put another way, "if he had a little more normal urine concentration, it would've been reported as a negative." (Skipper, Tr. 520). Forensic Toxicologist Theodore Shults agreed that the application of a standard creatinine normalization would render the quantitative result of 117 ng/mL a negative even at Delta's industry-defying cutoff of 100 ng/mL. (Shultz, Tr. 851).[14]

Delta witness Dr. Jones agreed that creatinine level was a "relevant consideration" in interpreting a quantitative EtG result. (Jones, Tr. 200). In reviewing the higher EtG result of 138 ng/mL for Captain Perez, accompanied by a creatinine quantitation of 264.2 mg/dL, Jones testified:

> So in this case, if I were interpreting this, I would say it's positive. It's supposed to be negative, but it's positive. But it's 138, which is a low value to start with. And the creatinine being elevated like it is, kind of just mental math, I'm cutting that in half, so now we're at 60, 70, 80, somewhere in there. And so this is – a reasonable explanation would be the use of other products containing ethanol as a reasonable explanation.

[13] (Skipper, Tr. 502).
[14] Shults also testified that any EtG result below 200 ng/mL should also be considered a negative, with or without creatinine normalization. (Shults, Tr. 851).

(Jones, Tr. 201-02; UX34). Thus, when analyzing comparative alcohol biomarkers for a research article published in April 2020, Dr. Jones and his five toxicologist co-authors wrote, "EtG and EtS concentrations were normalized to a creatinine concentration of 100 mg/dL." (UX82 at 1104). Similarly, Company Exhibit 18, another comparative review of alcohol biomarkers submitted into the record by Delta, confirms that the proper forensic analysis of the significance of EtS and EtG results requires that the results be "normalized to creatinine 100 mg/dL." (CX18 at 3, Table 1).

As previously discussed, Quest Laboratory Director Dr. Sample testified that his laboratory recommended that a Medical Review Officer be employed "particularly in interpreting positive results." (Sample, Tr. 350-51). Regrettably, as with the setting of Quest's cutoff levels, he recognized, "that's ultimately a customer or an employer decision." (*Id.*). He agreed that, with respect to creatinine normalization, "Medical Review Officers or other people that are reviewing and interpreting the results may use such a ratio …" (Sample, Tr. 325-26).[15]

The lone holdout with respect to the relevance of creatinine normalization was Delta rebuttal witness Dr. Taylor, who testified on direct that "laboratories do not typically normalize EtG results." (Tr. 1047). When asked on cross-examination about laboratories' use of creatinine to adjust quantitative results, he testified:

> Some laboratories do. I mean, I – our – for example, our laboratory adjusts everything, but some things have no meaning. And – and the reasons some things are adjusted is because the – the program that makes calculation is – is something that's a third party that we don't have any control over.

[15] Significantly, Quest reports creatinine level to its customers on the same page on which it reports the EtG quantitative result, thereby providing the necessary information for Delta's MRO or DHS to perform the creatinine normalization analysis. (CX9 at 112; Shults, Tr. 910).

(Taylor, Tr. 1107). Taylor's somewhat muddled testimony did have an illuminating conclusion, i.e., that, after a laboratory produces its quantitative result, it is left in the hands of a "third party" to interpret the results.

Quest knows that characterizing a 117 ng/mL quantitative result as a "positive" result is not the forensic norm. Quest also knows that creatinine normalization of a quantitative result is a common interpretative practice. Knowing these facts, at Quest "we recommend that a Medical Review Officer be used" to determine what the quantitative result actually means. (Sample, Tr. 350-51). One may view Quest's passivity to be a natural self-limitation of a laboratory's role or the forensic equivalent of Pontius Pilate. In either case, Quest's agnostic approach confirms the indispensable role of a Medical Review Officer. Having deliberately abstained from performing any medical review of the tests involved in this matter, Delta cannot be found to have carried its burden and the grievance must be sustained.

C. The Negative Result of the ETS Test Should Have Brought the Testing Process to a Close

Captain Graham testified that the DPAC program calls for a PEth test when there is a "positive" EtG, but a negative EtS result. (Graham, Tr. 445). However, Delta submitted no document to this effect much less any policy shared with pilot participants. While Contract A lists testing methodologies, it makes no reference to quantitative cutoff levels or the relative weight of tests when they yield conflicting results. Indeed, when asked about applicable quantitative cutoff levels, Captain Graham's response was: "I don't have any knowledge of the testing protocols or what happens – with the testing protocols." (Tr. 458-59). This from the man who oversaw the DPAC program. (Graham, Tr. 436-37).

We do know that, superficially, the testing process applied to Mr. Danford's May 1 urine sample adhered to what the NTSB described as "a two-test, two aliquot-approach … necessary to

ensure a scientifically suitable test that can be relied upon to yield valid, accurate results." *Bosela,* 2001 NTSB LEXIS 67 at *7. Consistent with this axiom of forensic toxicology, Quest conducted EtS testing as part of its "confirmatory analysis." (Sample, Tr. 322-23). However, there was no confirmation. Thus, even if, in contravention of established forensic laboratory and airline industry standards, Danford's EtG quantitative result were to be deemed a "positive," the testing process should have been treated as having produced a negative given the absence of an EtS confirmation. Graham testified that, under Delta's unwritten policy, the PEth would not have been conducted but for the "positive" result produced by Quest. (Tr. 466). Consistent with basic forensic toxicology principles, the failure of the EtS process to confirm the EtG result should have brought the testing process to a close with a "negative" report. The PEth test should never have occurred.[16]

This is not to say that Delta could not have engaged in further inquiries into Mr. Danford's fitness for flight. Indeed, the Company has unlimited discretion under Section 15 of the PWA to initiate such an inquiry consistent with the review process provided for therein. However, Quest's inability to confirm the EtG "positive" when its EtS analysis produced a negative should have ended the vagaries inherent in an extended testing process divorced from clinical analysis. It is foreign to the tenets of forensic toxicology to continue testing until the bell is rung.

[16] This approach would mirror the federal standard pursuant to which, where an immunoassay positive is followed by a gas chromatography/mass spectrometry negative, the final test result is treated as a negative. 49 CFR § 40.87(c).

D. Quest's Violation of its Standard Operating Procedures With Respect to Specimen Chain of Custody Requires Invalidation of the EtG Test Result

Dr. Sample testified that Quest's laboratories handle 10 to 11 million tests annually. When asked whether the average lab technician handles hundreds or thousands of tests per day, he responded: "I have no idea … I would not venture a guess." (Sample, Tr. 340).

The critical importance of properly documenting the internal chain of custody of a specimen was testified to, with some insistence, by Dr. Sample:

> Q: Is it acceptable practice for a technician to omit documentation of handling a specimen and just go from memory?
>
> A: No, it is not.
>
> Q: Or jotting down the handling of a specimen or an aliquot in a personal diary as opposed to official laboratory documentation.
>
> A: No –
>
> Q: How many times –
>
> A: Let me finish first.
>
> Q: Go ahead, I'm sorry?
>
> A: And – and that's part of the certifying review process to ensure that there aren't errors or omissions. And just since there can be correctable flaws. So it's possible to get a memorandum of – of correction, within the laboratory just as it is, you know, laboratory sending to collection sites to recover missing information.

(Sample, Tr. 339).

In the context of addressing a correctable error in the *collection site's* chain of custody, Dr. Sample identified a deadline of approximately one week. (Tr. 337). In terms of correcting a *laboratory's* error or omission with respect to its internal chain of custody, Dr. Sample provide the following testimony:

Q: [G]iven that multiple tests are being handled per day, is there any time limit on the capturing the correction in a memorandum?

A: Well, it will not – the results will not be reported prior to correcting the errors or omissions.

Q: Is that in the SOP? That standard that you just articulated?

A: I – I would have to see exactly what the SOP verbiage is pertaining to that. But yes, that's our – that's our – that's our policy.

(Sample, Tr. 340-41). But, that is not what happened with respect to the handling of Mr. Danford's specimen.

Mr. Danford's specimen was collected on May 1 and logged in at Quest on May 3, 2018. (CX9 at 112). The test was reported on May 9, 2018 and, in reliance on that report, Mr. Danford was ordered to report for a DBS PEth collection the same day. (*Id*.). What was not reported at that time was that, on May 5, 2018, a chain of custody handling step was omitted or incorrectly documented at the time of handling by a technician named Kayla Shultz. (CX9 at 45). Contrary to Quest's policy, the laboratory's results were reported without any prior correction of the error or omission. In fact, the error/omission was not documented until July 6, 2018, over two months after it had occurred. (*Id*.).

The impact on the testing process that may have occurred based on this chain-of-custody error cannot be known with certainty. What is known is that the error occurred at a laboratory that produced an EtS negative and an EtG "positive" from what was supposedly a single sample. What is also known is that the error occurred in the context of a testing process in which Mr. Danford was stripped of what is considered an indispensable guarantee of accuracy under the federal program – the testing of the split sample (see Section IV.E below).

In view of Quest's mishandling of Mr. Danford's specimen, and its violation of its own SOP/policy in addressing that error, Delta cannot carry its burden in this case and the grievance must be sustained.

E. Delta's Denial of the Opportunity to Have His Split Specimen Tested Invalidates The Quest Results, Particularly in Light of the Evidence of Quest's Chain of Custody Error

Split specimen testing consists of the collection of a single specimen, which is split into two specimen bottles. In the event of a confirmed positive test from the A bottle, the B bottle is then shipped to an independent laboratory.

Under the federal program, if the testing of the B bottle by the second laboratory fails to confirm the presence of the substance in question, the overall test is cancelled. (49 CFR § 40.187(b)). If, for any reason, the split specimen is unavailable for testing, then the test is cancelled. (49 CFR §§ 40.187(e)(1); 40.201(e); Shults, Tr. 816). Delta's program director, Michele Gabel, advised program participants that the provision of a split sample was an integral part of the program and served the purpose of allowing a test result to be "verified." (Danford, Tr. 674).

In accordance with the DPAC program and federal standards, on May 1, Mr. Danford provided a specimen that was split into two specimen bottles – bottles A and B – so that, in the event of a positive test result, Danford could have the B bottle sent to a second laboratory as a means of challenging the initial result. (Tr. 673-74).[17]

[17] Quest's litigation package contains a Quest specimen collection form confirming that the a "split" specimen had been collected. (CX9 at 7). Quest's photographs of the specimen confirm that the specimen was, in fact, split into two bottles. (CX9 at 115).

In response to the EtG test result, Mr. Danford made requests to Michele Gable and Delta Chief Pilot Harry Miller that his split sample be tested. (Tr. 677-78; UX66). Mr. Danford's requests to have his split sample tested were denied. (*Id*.).

Delta's failure to adhere to the standards of the federal program, or even to the Company's own standards as articulated by its program director, deprived Mr. Danford of a fundamental guarantee of testing accuracy. Under these facts, Delta cannot carry its burden of proof and the grievance must be sustained. *See*, *e.g*., *United Parcel Service Company and Independent Pilots Association* (Arbitrator J. Duff, 1992)(airline employer fails to satisfy "requisite standard of proof" in light of mishandling of split sample, despite absence of proof that split sample was adulterated)(Attachment C); *Pace Air Service, Inc. v. Administrator, Unemployment Compensation Act,* 1998 Conn. Super. Lexis 346 (Super. Ct. Conn. 1998)(despite the absence of any direct challenge to the procedures used in obtaining the drug test result, Superior Court upholds decision of Employment Security Board of Review to discredit entire testing process due to failure to comply with requirement of obtaining a split sample); *Delaney v. Commonwealth of Pennsylvania*, 535 A.2d 719 (Commonwealth Ct. Pa. 1988)(Despite the absence of any direct challenge to the procedures used in obtaining the drug test result, and the admitted narrowness of the scope of judicial review, court overturned State Horse Race Commission decision to impose fine where split sample had been improperly destroyed).

In view of Delta's unexplained denial of a testing safeguard that it had promised to Mr. Danford, the grievance must be sustained.

V.

USDTL's DBS PEth TEST IS INADMISSIBLE, UNRELIABLE, AND INCONCLUSIVE

A. USDTL's Failure to Validate its DBS Specimen Collection Process Invalidates the Test Result

It is undisputed that a "critical element" of laboratory practice is its adoption of a Standard Operating Procedural (SOP) manual from which the laboratory is not permitted "any variance." (Jones, Tr. 29). USDTL's SOP purportedly covers "everything" including the required steps for the collection of a DBS sample and subsequent receiving and handling. (Jones, Tr. 56, 151). USDTL nonetheless flouted the System Board's *subpoena* by refusing to produce a copy of its SOP or any portion thereof. (UX12 and UX 13 at item 1; Jones, Tr. 153-54). Nor was any portion of USDTL's SOP presented at the hearing notwithstanding Dr. Jones' representation that no deviation from that document is permitted. With respect to DBS specimen collection, therefore, it must be presumed that SOP-mandated procedures are replicated in the protocols USDTL distributes to outside specimen collectors.

USDTL is the only commercial laboratory in the United States that applies a DBS collection process to PEth testing. Moreover, as discussed further in Section V.C below, USDTL DBS collection protocols modify the manufacturer's prescribed collection protocols with laboratory-specific "innovations" that render the USDTL collection process quite literally unique. Consequently, the proper scientific validation of USDTL's prescribed collection procedures is critical to the test's admissibility.

USDTL's specimen collection validation data was sought pursuant to a System Board's *subpoena,* which commanded the production of:

> All documents related to validation studies conducted by USDTL with respect to the DBS collection procedures prescribed by the laboratory, including any documents related to incurred sample reanalysis (ISR).

(UX12 at item 3). USDTL's astonishing response was:

> A peer reviewed study that evaluated reanalysis over time may be found at https://academic.oup.com/alcalc/article/5 1/3/275/2888208. **USDTL has no other documents responsive to this request.**

(UX14 at item 3)(emphasis in the original). Thus, USDTL conducted no validation study for its own unique collection process nor any analysis of the impact of deviating from the procedures mandated by the laboratory. Remarkably enough, at the hearing, Laboratory Director Jones betrayed his mistaken belief that the article by Dr. Ludmila Bakhireva, referenced by the link embedded in USDTL's subpoena response, was a validation study conducted by USDTL personnel. (Jones, Tr. 154-55; UX15).[18] In fact, the focus of the Bakhireva study was limited to the question of the stability of PEth DBS results when re-tested after prolonged storage. The samples were obtained from previously phlebotomized samples that were subsequently pipetted onto DBS cards. (UX15 at 2). Thus, the study did not include any validation of USDTL-prescribed collection procedures nor did it involve samples collected outside of a hospital setting.

In view of USDTL's failure to validate its own peculiar specimen collection process, the test result cannot be deemed valid and the grievance must be sustained. As discussed in section V.C below, the failure to validate the collection process is doubly fatal in view of USDTL's deliberate deviation from the protocols set forth by the manufacturer of the DBS collection card.

[18] Notwithstanding USDTL's reference to the Bakhireva study in its subpoena response, Jones admitted during cross-examination that none of the authors were USDTL employees, that he could not recall the number of subject-participants and that, in fact, he had virtually no knowledge of the study: "I don't recall the research project." (Jones, Tr. 155-56).

B. The Specimen Collector's Failure to Adhere to Collection Procedures Deemed by USDTL "Imperative" to Ensure the "Integrity" of the Testing Process Renders the DBS PEth Test Result Inadmissible

Analysis of the actual implementation of the collection process, as it related to Mr. Danford's May 9 specimen, begins with undisputed evidence of the laboratory's abdication of any responsibility for controlling the proficiency of that process. While USDTL asserts that it maintains a specimen collector certification program, it is not mandatory and no training was provided to the individual who collected Mr. Danford's specimen. (UX12 items 4 and 5; UX14 items 4 and 5; Jones, Tr. 108-09). The failure to provide any training to specimen collectors is in sharp contrast to federal standards mandating the training and certification of specimen collectors. This training must include the trainer's direct observation of the trainee's performance of multiple mock collections. 49 C.F.R. §§ 40.33(a)-(c).

Dr. Jones' testimony focused on a denial of any liability for specimen collection violations rather than the acceptance of a shared responsibility for preventing such pre-analytical errors. Jones insisted that USDTL maintains an "arm's length relationship" with collection facilities over which it exercises "no control." (Jones, Tr. 110). According to Jones: "it's their responsibility" while incongruously agreeing that it was "imperative" that the collectors "adhere to the protocols for the collection set forth by USDTL in order to have confidence in the ultimate result." (Jones, Tr. 111).

The lack of training and USDTL's abdication of responsibility produced a foreseeable result: The uncontroverted evidence[19] is that the DBS specimen collection was collected in a

[19] Delta neither provided the testimony of the specimen collector nor provided any explanation for its failure to make her available to testify. The System Board should infer from this failure that her testimony would have confirmed the accuracy of Mr. Danford's testimony concerning the collection process. Elkouri & Elkouri, *How Arbitration Works*, Ch. 8.4.I. at 8-51 (7th ed. 2012) ("The failure of a party to call as a witness a person who is available to it and who should be in a position to contribute informed testimony may permit the arbitrator to infer that had the witness been called, the testimony would have been adverse to the position of that party."), *citing*

manner that breached USDTL's "imperative" standards. (UX11). Indeed, the critical importance of adhering to these standards was further highlighted, in most cases, by the protocol's bold lettering. The undisputed violations included the following:

* At step 10, USDTL admonishes in bold lettering: **NOTE: Allow the collection paper to wick blood out of the puncture. Do not press the finger against the collection paper and do not layer successive drops.** (UX11 at item 10; Jones, Tr. 57). Both requirements – direct contact with the card and layer of successive drops – were violated. (Danford, Tr. 688-89, 691). Indeed, the contact amounted to "continuous finger painting." (Danford, Tr. 683).

* At step 11, USDTL instructs the collector in bold lettering: **Avoid "milking" the finger as this will cause interstitial fluid to surround the puncture…"** (UX11 at item 11). Here again, the collector violated the bold print protocol by squeezing Mr. Danford's finger throughout the process. (Danford, Tr. 683, 687, 689, 691).

* At step 19, USDTL instructs the collector to place the specimen in a "non-plasticized envelope" and warns in bold lettering: **Caution: Do not place inside an airtight plastic specimen transport bag.** (UX11 at item 19). (Danford, Tr. 690).

Strikingly, the collection violated virtually every item on USDTL's bulleted list of "What to Avoid," including:

* Avoid "milking" the finger;

* Do not press the finger against the collection paper;

* Do not layer successive drops of blood;

* Do not touch the already filled collection circles;

* **DO NOT place the box in an airtight plastic specimen transport bag**

(UX67). The collection of Mr. Danford's specimen violated every one of these imperative prohibitions. (Danford, Tr. 691).

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among others, Southern Cal. Permanente Med. Group, 92 LA 41, 45 (Richman 1989)*; St. Charles Grain Elevator Co.,* 84 LA 1129, 1132 (Fox 1985)

The above are merely those violations of proper forensic procedures that *USDTL itself* described as imperative to ensure the integrity of the testing process. Other violations of accepted forensic practice include the fact that the plastic bag containing the USDTL collection supplies had been opened in advance of the specimen collection (raising additional questions concerning the non-sterile conditions of these supplies) and the possible use of an ethanol-based sanitizer in lieu of the isopropyl alcohol pad included with USDTL's supplies. (Danford, Tr. 684, 687). With respect to the former lapse, the use of previously unwrapped testing material has been cited by a federal administrative law judge as a factor in his decision to invalidate a test based on collection error. *See, e.g., FAA v. Alexander,* Case No. SE-18819 at 420 (J. William E. Flower, 2010)(Attachment D). With respect to the potential use of an ethanol-based sanitizer, the direct introduction of alcohol into a DBS specimen has been found to have a direct impact on quantitative results with the potential for high level false positives. (UX80).

Forensic Toxicologist Theodore Shults concurred with the USDTL protocols' pronouncement that it was "imperative" to the integrity of the testing process to adhere to these procedures. (Shults 861-62). For example, the layering of successive blood drops could double the amount of PEth that is analyzed thereby altering quantitative results due to a "volcano effect." (Shults, Tr. 862-63). The milking of the finger results in the introduction of cellular fluid into what should be purely red blood cell matrix. (Shults, Tr. 864; Skipper, Tr. 531-32). Shults found the lack of drying time and placement of the specimen in an airtight bag to be a "confounding" occurrence that violated an "essential" safeguard of the integrity of the test process. (Shults, Tr. 865-66). The failure to properly dry the card, as compounded by the introduction of the wet card into an airtight plastic transport bag, created a sustained humidity with the potential to alter quantitative results. (Shults, Tr. 866, 868-70; UX54 at 1 ("The results

suggest that collection conditions, particularly humidity, affect the quality of DBS-based measures.")).

Dr. Skipper – the only individual to testify in these proceedings who was recognized as a PEth testing expert[20] – also testified that blood thickness created by layering drops, the improper drying of the DBS specimen, and direct contact with the DBS paper all have the potential to alter quantitative results. (Skipper, Tr. 531-33). Dr. Skipper agreed with USDTL's admonition that strict adherence to the collection protocols is required in order to "have confidence in the results." (Skipper, Tr. 531).

Dr. Taylor, who, unlike Dr. Skipper, has never been involved in the study or development of PEth, referenced a study, the name of which he could not remember, indicating that pre-analytical variables could bring quantitative PEth variability up to 40 percent. Taylor pronounced this 40 percent quantitative variability to be a "very good estimate." (Taylor, Tr. 1119). Needless to say, no one knows for sure. And needless to say, this kind of guess work, when a man's career is at stake, is horrifying.

Where collection procedures designed to ensure the integrity of the testing process are violated, the ensuing test result must be deemed invalid. *See, e.g., FAA v. Alexander,* Case No. SE-18819 (J. William E. Flower, 2010); *American Airlines, Inc.,* Case No. M-246-91 (Arb. Marvin Hill, 1992)(Attachment E); *San Mateo County Transit District,* 96 LA 365 (1990)(Transportation employer bears burden of demonstrating by clear and convincing evidence that proper specimen collection procedure was followed); *Metropolitan Transit Authority,* 93 LA

[20] Delta's counsel pointedly disavowed Jones' status as an expert witness. (Kassin, Tr 123). Delta's only "expert," Dr. Taylor, acknowledged that he has engaged in *no* studies related to EtS, EtG or PEth and that his laboratory does not conduct PEth testing. (Taylor, Tr. 1080-81). By contrast, Jones recognized Dr. Gregory Skipper's expertise with respect to PEth testing. (Jones, Tr. 290). Dr. Skipper's resume and Jones' own article reflect Dr. Skipper's direct participation in multiple PEth testing studies. (CX55 at 11, 21; CX82 at 2, 5, 6 n.12).

1214, 1217 (1990)("Collection site procedures and chain of custody safeguards must be carefully followed to insure the reliability and accuracy of the final test result."); *Vista Chemical Co.*, 99 BNA LA 994 (Baroni 1992)(same). The federal courts have upheld arbitrations reinstating individuals to safety sensitive positions where mandated testing procedures have not been followed. *See, e.g., Southern California Gas Company v. Utility Workers Union of America*, 2001 WL 1020253 (9th Cir. 2001)(Upholding an arbitration award reinstating the two employees and rejecting the employer's protests that the arbitrator had relied on a legal technicality that defeated public policy: "If the procedures are not followed, a person is not deemed to have failed a drug test, under the regulations, and there is no prohibition to employing him."); *Atchison, Topeka and Santa Fe Railway Co. v. UTU*, 175 F.3d 355 (5th Cir. 1999)("Without a valid positive test result, Santa Fe had no grounds under the collective bargaining agreement for dismissing Richardson, and the PLB was within its jurisdiction in reinstating him.").

As the above cases have uniformly held, the burden does not rest on the individual to quantify the impact that the collection errors had on the result; the burden rests with the parties who have developed and control the process to demonstrate compliance with applicable procedures.[21] Moreover, as discussed in Section F below, the dramatic impact on quantitative analysis arising from varying collection processes was amply demonstrated by compelling documentary evidence the authenticity of which neither Delta nor USDTL made any effort to dispute.

[21] The best that Jones could muster, by way of a defense, is that "there's no evidence *at this time* that sealing a dried blood spot sample in an airtight bag would interfere with the test or produce PEth." (Tr. 173). Putting to one side the inaccuracy of that statement, as discussed further in Section V.C, the burden is on the *laboratory* to validate deviations from its own protocols and those prescribed by the manufacturer.

C. USDTL's Intentional Deviation From the Manufacturer's Drying Protocol Renders the Test Result Inadmissible

Even if the specimen collector had conscientiously followed the specimen protocols provided to her by USDTL, she still would have violated the specimen drying standards recognized by the DBS card manufacturer and even USDTL itself.

Again, USDTL conducted no studies to validate its collection process. Nevertheless, as discussed in Section V.A above, USDTL's response to the System Board's subpoena did reference the laboratory's reliance on an article cited as https://academic.oup.com/alcalc/article/51/3/275/2888208. (UX14 at item 3). The reference is to a peer reviewed study titled *Stability of Phosphatidylethanol in Dry Blood Spot Cards*, which references that:

> Cards were left to dry at room temperature for 3 h on a flat surface per manufacturer's protocol….

(UX15 at 7-8). The referenced manufacturer is the producer of the Whatman 903 Specimen Collection Paper, the same DBS collection card utilized by USDTL. (UX15 at 10; Jones, Tr. 46). Dr. Jones conceded, that a drying time of three hours is specified by the manufacturer when using the Whatman 903 card. (Jones, Tr. 156). Shults testified that a three-hour drying time is the standard applied in every forensic paper he has reviewed. (Shults, Tr. 864-65).

USDTL's approach to the drying requirement is decidedly schizophrenic but, in any event, does not comply with the manufacturer's standard. The USDTL collection protocol distributed to collectors provides no guidance related to the duration of drying. (UX11). USDTL's FAQ, however, demands that the collector "MUST" allow the card to dry for one full hour. (UX19 at 3, item 5). But then again, USDTL's marketing presentations insist that "NO DRY TIME" is required. (UX21; Jones, Tr. 182).

Dr. Jones conceded the deliberateness of USDTL's deviation from the manufacturer's extended drying requirement when he testified that the drying box was developed "because donors did not want to wait for one to three hours for the blood spots to thoroughly dry before you put the seal on …" (Jones, Tr. 58-59). Jones' glib explanation for USDTL's deviation from the manufacturer's standards is that donors would be exasperated by the wait time because they "had to get back to work." (Jones, Tr. 157-58). This is a salesman's explanation, not the explanation of a forensic toxicologist.

Irrespective of USDTL's self-contradictory guidance, Mr. Danford's specimen was placed immediately into a sealed plastic bag without allowing for any drying time at all, thereby breaching the requirement that the specimen be "set aside" so that it "can dry and then be shipped … in the afternoon FedEx shipment…." (Jones, Tr. 59). Thus, non-compliance with the Whatman 903 three-hour drying requirement was compounded by the immediate placement of the DBS specimen in an airtight plastic bag. This non-compliance with the express collection and shipment protocols in USDTL's SOP, which prohibit the use of an airtight plastic bag, should have resulted in the DBS specimen not being tested. However, in another indication of the laxity of standards at USDTL, the laboratory's receivers are not instructed to confirm that the specimens have not been shipped in violation of this protocol. (Jones, Tr. 161-62). Worse still, Jones admitted that USDTL would knowingly violate its own protocols in this regard and thereafter blame the client:

> we do accept the sample if it was to come like that because we don't know the conditions of the collection. … at the end of the day, the client is responsible for sending their specimens in the way that we ask them to.

(Jones, Tr. 275). Thus, even though USDTL deems it "imperative" that a specimen "must" not be shipped in plastic-lined container, Jones agreed that "the specimen would be tested anyway." (Jones, Tr. 276).

In sum, USDTL has never validated its DBS specimen collection procedures, knowingly permits the violation of its own "imperative" protocols, and knowingly violates the specifications of the DBS card manufacturer without supplementary validation. As with the collection protocol violations, USDTL's violation of the manufacturer's specifications, standing alone, renders the test result invalid. *Federal Aviation Administration v. Bosela*, NTSB Order EA-4928, 2001 NTSB LEXIS 67 (December 13, 2001).

The *Bosela* case involved a laboratory's determination to record the results of an initial dipstick test after a 10-second wait instead of the 60 seconds specified in the manufacturer's instructions. 2001 NTSB LEXIS 67 at *34. The NTSB affirmed the administrative law judge's determination that the laboratory's failure to "produce any written validation study about the suitability of using the [initial test] in a manner contrary to the manufacturer's instructions" signified that the test "was not validated in any meaningful way that could be reviewed." *Id*. at *9. The resulting invalidation of the initial test required the reversal of the FAA's license revocation, based on the alleged use of a nitrite adulterant, in view of the NTSB's holding that two valid tests were required to establish the use of a substance in violation of federal aviation standards. *Id.* at *7 ("a two-test, two aliquot approach is necessary to ensure a scientifically suitable test that can be relied upon to yield valid, accurate results.").

USDTL's disregard of essential forensic validation practices is beyond the pale. A test conducted in violation of a manufacturer's protocols, without any documented scientific

validation for the deviation, renders the resulting test invalid. The grievance must be sustained on this basis.

D. The Omission of a Desiccant Pouch in the Packaging and Transportation of the Specimen Renders the DBS PEth Test Result Inadmissible

Here again, the untrained specimen collector is condemned to failure. Not only does the USDTL-published protocol make no reference to the use of a desiccant pouch but, the supplies provided to the collector include no such item. (UX11 (listing supplies provided); UX19 at 8 item 4 (listing supplies provided) UX20 (bag of supplies); Jones, Tr. 181-82). Nevertheless, USDTL exclaims on its website that the specimen collector "MUST" allow the card to dry for a full hour and "MUST" include a desiccant pack.[22] In view of the fact that neither of these injunctions are incorporated in USDTL's specimen collection protocols card it is not surprising that neither of these critical collection procedures were complied with during Mr. Danford's May 9 DBS PEth collection. (UX11; Danford, Tr. 684-85). The omission is dispositive of this case in view of the fact that a desiccant pack turning pink, confirming the exposure of the specimen to humid conditions, requires the rejection of the specimen for testing. (UX53 at 4; Shults, Tr. 866-68). As confirmed in a reputable study of DBS testing led by the University of Duisburg-Essen, a laboratory must:

> **Exclude the filter card from further processing** if the desiccant packs and/or the additional humidity card changes to a pink color.

[22] USDTL's FAQ at page 3, bullet 5, states:

> Before placing blood spot cards in a sealed plastic bag, you MUST allow the card to dry for one full hour. Once dry, you place dried blood spot cards in a plastic bag but you MUST include desiccant packs to reduce the moisture in the bag.

(UX19).

(*Id*.)(emphasis supplied). USDTL, Forensic Toxicologist Shults, and the University of Duisburg-Essen agree – Mr. Danford's DBS sample never should have been tested without the requisite evidence that the sample had not be exposed to humidity. Here, once again, USDTL never conducted a validation study addressing the scientific suitability of omitting the procedural safeguard, which the laboratory's FAQ stated was mandatory. (Jones, Tr. 180). The grievance should be sustained on this basis.

E. USDTL Has Failed to Properly Validate Its Testing Procedures and Also Failed to Provide Any Documentary Evidence of the Limited Validation Conducted

USDTL operates a laboratory that has not been certified by the United States Department of Health and Human Services (DHHS) as part of the National Laboratory Certification Program (NLCP). (Jones, Tr. 102-03). Its testing and quality assurance protocols fail to incorporate safeguards deemed indispensable under the federal testing program. For example, USDTL does not adhere to a split sample testing procedure mandated under 49 CFR Part 40. (Jones, Tr. 106). As discussed in Section IV.E above, under the federal program and relevant arbitral precedent, the omission of this protection for the tested employee requires the cancellation of the test.

Similarly, the federal program requires a blind testing quality assurance program administered by a third party. USDTL, however, does not participate in such a proficiency program and grants itself an allowable deviation of thirty (30) percent. (Jones, Tr. 106-07; Shults, Tr. 805).[23]

Only a "handful" of laboratories in the country offer PEth testing of any kind. (Jones, Tr. 56). Moreover, USDTL is the *only* commercial laboratory utilizing DBS PEth testing. In fact, USDTL boasts of the singularity of its approach in a telling manner:

[23] Under CLIA guidelines, it is preferred that laboratory proficiency testing be conducted through a third-party program; however, with respect to DBS PEth testing, such a program does not exist because there are "just not enough of them being done…." (Jones, Tr. 67).

Q: Are you aware of any other labs splitting specimens for PEth or sending two specimen cards filled with dried blood for testing?

A: There are no other labs that do commercial dried blood spot PEth testing, so there are no labs for comparison.

(UX19-FAQ; Jones, Tr. 184). In a worrying characterization, Jones' described USDTL's application of DBS to PEth testing to be "cutting edge." (Jones, Tr 186).

USDTL's DBS PEth test is a "non-standard" laboratory-specific procedure that has not been cleared by the FDA.[24] (Jones, Tr. 30). Jones testified that USDTL is subject to "some very loose guidelines" in terms of oversight pursuant to the Clinical Laboratory Improvements Amendment (CLIA). (Jones, Tr. 31). Although USDTL's validation documents were reportedly made available to CLIA inspectors, there is no basis for asserting that they were approved or even reviewed. (Jones, Tr. 55). Indeed, even whether USDTL's DBS PEth assay was reviewed is unknown. (Jones, Tr. 117).

The critical importance of application-specific validation for DBS testing methods was highlighted in a 2019 study authored by PhD's from throughout Europe, the United States, Latin America, and Australia:

> Dried blood spot (DBS) analysis has been introduced more and more into daily practice. To assure the quality of bioanalytical methods and to assure that the results obtained with those methods are valid, it is of the utmost importance that newly developed methods are fit for purpose. Those methods must have undergone adequate method validation and are monitored through a suitable quality control (QC) program. Absence of DBS-specific method validation guidelines results in DBS-based methods lacking essential validation aspects resulting in reduced credibility. Validation requirements described in guidelines for the quantitative analysis of traditional matrices (i.e., liquid, blood, plasma, or serum) are not always easily translated to analysis of DBS. More, additional parameters, such a **volume** and **hematocrit** (HT) effects, which are not part of traditional guidelines, are often overlooked or not adequately assessed.

[24] A laboratory developed test (LDT) can be submitted to the FDA for approval; however, USDTL chose not to seek such approval. (Jones, Tr. 50).

(UX1 –S. Capiau, et al., *Official International Association for Therapeutic Drug Monitoring and Clinical Toxicology Guidelines: Development and Validation of Dried Blood Spot-Based Methods for Therapeutic Drug Monitoring* at 1 (2019)(footnotes omitted).[25]

None of USDTL's validation studies were produced at the hearing in this matter. Moreover, Jones conceded that USDTL has performed no validation studies with respect to volume effect, hematocrit effect, or volcano effect on the quantitative analysis of DBS PEth samples. (Jones, Tr. 304). The rationale proffered by Jones for failing to address these factors was **not** that they would have no impact on the quantitative result, but rather that they could not affect the quantitative result sufficiently to affect an abstinence determination:

> And so you get concerns about volcano effect and hematocrit effect, and those kind of things. In an abstinence test that's kind of irrelevant. A 60 and a 600 for a question that we answered here, it's the same result, it's positive, and we need a reasonable explanation. … **I've been using Purell, not a reasonable explanation. You're not supposed to use Purell.**

(Jones, Tr. 299-300).

Of course, having never conducted any validation studies with respect to these issues leaves USDTL in no position to quantify the impact of these various factors. Jones found the Capiau article "very interesting" and, having read it, remarked: "so there's probably some experiments that I'm going to do to just see what influence it may have." (Jones, Tr. 301). He thought that there may be a paper addressing the impact of these factors, but he could not remember the author's name. (*Id.*). In sum, USDTL maintains that a lack of validation studies with respect to a number of issues known to impact quantitative analysis is acceptable because a DBS PEth positive would still establish alcohol consumption **provided one does not use Purell.**

[25] Shults testified that the Capiau study laid out the appropriate criteria for validating DBS testing. (Shults, Tr. 836).

Taylor was not engaged in evaluating the validity of USDTL's DBS PEth testing process until nearly two years after Mr. Danford's test. (Tr. 1019). At the time of the visit, he was "assured and convinced" by USDTL that the testing process was accurate. But he conceded that there was no third-party proficiency program for USDTL's DBS PEth testing and had no recollection of USDTL using blind samples for internal control and analysis. (Tr. 1088-89).

Taylor never prepared a written report of his evaluation of USDTL testing procedures. He unconvincingly testified: "I think I took one page of notes perhaps, maybe one or two." (tr. 1092). As with USDTL's limited validation studies, Taylor's notes were never introduced into evidence.

Such an unprofessional approach to scientific validation was squarely rejected by the NTSB in the context of a laboratory developed test result proffered by the FAA as evidence of adulteration:

> [We] are troubled somewhat by the lack of any written validation study, or written results from a thorough and formal validation study, in this record. … Without a written validation study, or at least contemporaneous scientific notes describing it, we are now unable to reliably evaluate the validity of the qualitative procedure….

Bosela, 2001 NTSB LEXIS 67 at *9.

Jones boasted that USDTL's DBS PEth testing methodology was innovative and cutting-edge. Those are inspiring adjectives for a smart phone, not for a process that pretends to be both forensic and of such probative value that all clinical evidence can be disregarded (other than the use of Purell). The lack of *any* scientific validation of USDTL's testing methodology – even the informal Taylor notes – compels that the grievance be sustained.

F. The Evidentiary Record Establishes that USDTL Failed to Validate the Precision of its DBS PEth Testing Methodology

As discussed in Section V.E above, Delta has left the System Board utterly in the dark as to whether USDTL scientifically validated its testing procedures. No validation studies were provided. No written analysis of the validation studies was provided. Issues that admittedly have quantitative impact – hematocrit, volcano effect, sample volume effect – were never addressed. The evidentiary record does contain, nonetheless, some evidence with respect to the issue of precision.

Jones identified precision as one of the core criteria that USDTL was required to validate and referenced the standards established by the Scientific Working Group of Forensic Toxicology (SWGTOX) as establishing the "guidelines for validating a new test with [sic] the purposes of forensic toxicology." (Jones, Tr. 31). As Jones continued:

> Their name has changed now, it's ODAC, O-D-A-C. I'm not sure what it stands for, I just know there was a name change. But these are the criteria that are expected in a validation prior to release to the public.

(Jones, Tr. 31-32). Jones was nearly right: SWGTOX was disbanded in 2014 and replaced by the Toxicology Subcommittee of the Organization of Scientific Area Committees (OSAC), which updated and approved the ANSI/ASB Standard Practices for Method Validation in Forensic Toxicology. (UX51 at 3rd page of introduction).

Precision concerns the reproducibility of test results or, in the slightly more detailed language of the Standard Practices document:

> The measure of the closeness of agreement between a series of measurements obtained from multiple samples of the same homogenous sample. It is expressed numerically as the coefficient of variation (%CV).

(UX51, Section 3.12). A defined percentage limit is placed on permitted variation in results from the same sample:

> For quantitative procedures, two different types of precision studies shall be assessed during method validation: within-run precision and between-run precision.
>
> * * *
>
> The % CV shall not exceed 20% at each concentration. It is noted that certain analytical methods (e.g., blood alcohol analysis) should require a much lower coefficient variation ($\leq$ 10%).

(UX51, Section 8.2.2.3.1). Simply put, a laboratory that cannot produce results from the same sample within the percentage limits provided for in the Standard Practices document should not be reporting quantitative results. (Shults, Tr. 835-36). Forensic Toxicologist Shults testified, without contradiction, that the 10% precision standard should apply to PEth testing to determine alcohol use and that, without this degree of precision, a laboratory should not release its quantitative results. (Shults, Tr. 835-36).

USDTL conducted two tests on the same day, with the same sample, using the same controls, the same testing instrument, and the same chemical testing methodology. Nevertheless, one test result was 69 and the other 98 – an increase of over 42%.[26] USDTL's defense is that its technicians are simply not paying much attention to quantitative analysis with respect to the initial test:

> If it's above the cutoff, we're not so concerned about the quantitation. Number one the quantitation is irrelevant anyway, you know, as laboratory, we want to make sure that the number that goes out is a good number… [i]n the initial it's all about was it above 20 or below 20 …

(Jones, Tr. 63). Put another way, Dr. Jones was not very interested in USDTL's satisfaction of the validation criteria that he identified in his testimony as the applicable standard for validating an LDT. Hewing to his own path, Jones described USDTL's quantitative analysis as "a very

[26] Even if the percentage were calculated as the decrease of 98 to 69, the variation would be 29% -- in excess of the minimal precision standards established by OSAC and Dr. Jones. (UX51, Section 8.2.2.3.1; Taylor, Tr. 1086-87).

subjective thing" impacted by "little uncertainties" that "add up" to an assumed variability in quantitative result of "approximately 30 percent." (Jones, Tr. 96-97). He identified a couple of sources for this uncertainty such as "uncertainty of the pipettes" and "getting the punches of the exact same size." (*Id*.). Abandoning his original testimony, Jones eventually testified that USDTL had no obligation to satisfy industry standards as they related to precision: "There's no specific that, like, it's got to be within a certain percentage or it's got to be specifically this or that." (Jones, Tr. 99).

Dr. Taylor concurred with Dr. Jones' original testimony that USDTL had an obligation to validate its testing methodology in accordance with the standard guidelines. (Tr. 1022). For Taylor, therefore, the precision validation issue leapt off the page upon his initial review of the USDTL litigation package:

> I had one concern relating to the two results. The screen 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.

(Taylor, Tr. 1016). Dr. Taylor resolved the issue in USDTL's favor after Dr. Jones told him that the "uncertainty" of the laboratory's DBS PEth testing was plus or minus 30 percent "and those values were certainly within plus or minus 30 percent of one another." (*Id*.).[27] In other words, the methodology is okay because Jones told him it was okay.

But it was not okay. USDTL failed to satisfy the validation standards Jones himself identified as applicable. And Taylor, on cross-examination, conceded that typical quantitative variation at a forensic laboratory is 20 percent, while a 30 percent variation is range permitted to

[27] Giving USDTL even greater leeway, Taylor calculated the precision variation permitted as apply plus or minus 30 percent to both figures to get them within range of each other. (Tr. 1026).

a clinical laboratory. (Taylor, Tr. 1086-87). In view of USDTL's failure to meet this standard of reproducibility of test results, the grievance must be sustained.

G. Even if Properly Conducted, PEth Tests Are Not Conclusive

Even the proponents of the PEth testing have determined that its results are not conclusive and must be reviewed in the broader context of the available clinical data. Thus, the FAA itself determined that Mr. Danford's May 9 DBS PEth test result did not dispositively establish a relapse and re-issued his medical certificate without the requirement of re-treatment. (UX35 at 3). LabCorp[28], even when using the less experimental venous blood matrix, issues its PEth test results with the caveat that "alternative explanations should be explored following any positive finding" and that "the possibility remains that an individual elevated PEth level may result from incidental or unintentional ethanol exposure." (UX2). In one sense, the most damning evidence of the uncertainties inherent in PEth testing arises from an article nominally co-authored by USDTL Laboratory Directory Jones, but effectively disavowed by him at the hearing.

Again, at least nominally, Dr. Jones is the co-author of a PEth research article published on April 16, 2020, entitled *The Roles of Phosphatidylethanol, Ethyl Glucuronide, and Ethyl Sulfate in Identifying Alcohol Consumption Among Participants in Professionals Health Programs.* (UX82). Jones averred that his co-authors were reputable professionals who had provided him with a full opportunity to review the draft article before it was published. (Jones, Tr. 309). Jones also testified that he had not learned anything since the article's publication in the spring of 2020 that would cause him to disavow its contents. (Jones, Tr. 289).

The article, after reviewing a range of PEth cutoff levels applied by laboratories, states:

[28] LabCorp's pedigree derives from one of original laboratories certified by SAMHSA in 1987 and is where Jones received his own practical training. (Jones, Tr. 22-23).

> None of these cutoffs are supported by a strong evidence base; rather they represent differing sensitivity and specificity considerations. … absent an evidence-based consensus on abstinence cutoffs for PEth and EtS, we were unable to assess the sensitivities and specificities of the biomarkers.

(UX82 at 1106).[29] Dr. Jones disagreed with his own article in this respect. (Jones, Tr. 279).

The article further states that:

> it is unknown whether incidental alcohol exposures can produce suprathreshold PEth concentrations, given interindividual differences in PEth precursor homologues, phospholipase D concentrations or activities, and elimination rates.

(*Id.*). When asked on cross-examination whether he agreed with this statement, the astonishing testimony was "I'm not aware of any description of that. … I have not seen that. And – maybe I've missed it in the literature. Maybe it's there and I just missed it though." (Jones, Tr. 286).[30] Putting it mildly, Dr. Jones' standing as an authority on PEth testing must be deemed severely tarnished by his ignorance of the findings of a research article that bears his name. Small wonder, then, that Delta declined to proffer Dr. Jones as an expert.

Notwithstanding his occasional braggadocio, Jones' final assessment of the PEth cutoff level adopted by USDTL was strikingly diffident. He described the 20 ng/mL as being "arbitrarily chosen." He further explained:

> And then the question comes into are we picking up the individuals that we want to pick up, and are we picking up the individuals that we don't want to pick up? And 20 has kind of been – over time it has proved to be a decent cuff off. May it change in future, it may as more data comes out, or as situations come up, or if someone comes up with a mechanism, or a situation, or a scenario that'll explain blood level PEths.

[29] The Jones article's diffidence with respect to PEth reliability echoes that opinion of Dr. Skipper that there is no "definitive study to show us what the specificity is at whatever cutoff we're using." "There's been inferences and suggestions, but no clear definition." (Skipper, Tr. 528).

[30] Jones actually testified initially that he was not familiar with the term PEth precursor homologues. (Jones, Tr 283).

(Jones, Tr. 282). Jones' testimony as to the interpretation of quantitative results being susceptible to "changes in the future … as more data comes out" parallels the testimony of PEth expert Dr. Gregory Skipper.

As Dr. Skipper explained, commercial laboratories initially introduced EtG testing with a "positive" cutoff level of 100 ng/mL; however, most laboratories subsequently moved to a 500 ng/mL cutoff level to avoid the occurrence of false positives and related litigation. (Skipper, Tr. 517-18). The problem was that, at the time EtG was introduced, "we didn't understand it fully," and it was only later that "positives" arising from incidental exposure were discovered. (Skipper, Tr. 521-22). Dr. Skipper described the result as a "tragedy":

> So I saw that happened with EtG testing 20 years ago when it was first developed. We were relying on it, there were concerns that there could be false positives and it turns out there were. But in the meantime, people did lose their careers.
>
> * * *
>
> So with PEth, the same thing is going on. We are not totally sure what affects PEth testing.
>
> * * *
>
> [T]hese are newer tests that likely have great value, but … they've not been around as long and not been as thoroughly studied. And so it's even more important to be careful to have a physician involved to look at all the factors, and not just rely on the [laboratory] result as the final word.

(Skipper, Tr. 521-22, 536, 584).

Jones believes that USDTL's "arbitrarily chosen" DBS cutoff level is pretty "decent" though it may "change in the future." Dr. Skipper's logical reaction is that the results must, therefore, "be used with caution and be interpreted in the light of clinical data." (Skipper, Tr. 520-21). In other words, the path recommended by the FAA, LabCorp, Dr. Skipper and Dr. Taylor … but, eschewed by Delta.

In view of the broad consensus that, even when properly conducted, DBS PEth testing is a new methodology that does not yield conclusive results, the grievance must be sustained.

H. USDTL's False Positives and Lack of Internal Controls

Putting Mr. Danford to one side, three witnesses submitted hard documentary evidence that USDTL has produced false positive test results. The evidence includes documented test results indicating that false positives may be generated by particular collection sites and/or by USDTL's use of the derivative DBS matrix in lieu of whole or venous blood.[31] In this latter category is the evidence presented by Mrs. M.

1. The False Positive Test Results of Mrs. M

As Mrs. M testified, she was engaged in litigation that concerned her ex-husband's efforts to reduce the number of days per week that she had custody of her children. In order to enhance her position, she abstained from any consumption of alcohol from mid-July, 2017 through the present date. (Tr. 626-27). She presented no fewer than nine test results from three laboratories for the 2017-18 time frame confirming her abstinence. (UX40A; UX42A; UX4A; UX43A; UX44A; UX45A; UX46A; UX47A; UX48A). Two USDTL "positive" reports during her abstention, at 24 and 20 ng/mL respectively, prompted her to check the laboratory's DBS results against a laboratory using whole blood. (UX39A; UX41A; Tr. 628-31).

Mrs. M tested positive at 59 ng/mL based on a DBS specimen collected on February 13, 2018; however, she received a negative test result based on a whole blood specimen collected **the next day** February 14, 2018. (UX3A; UX4A). Similarly, she tested positive at 34 ng/mL

[31] As confirmed by the testimony of Dr. Jones, there is no basis for asserting that the specimens provided for the tests detailed in this section were from any sources other than from Mrs. D, Mr. S, and Pilot D, respectively. Prior to laboratory testing, USDTL requires documented confirmation that the specimen collector verified the donor's identity with government-issued picture ID. (Jones, Tr. 77-78). For the same reason, there is no basis for questioning the authenticity of specimens provided by Mr. Danford for testing subsequent to May 9.

based on a DBS specimen collected on May 4, 2018; however, she tested negative based on a whole blood specimen collected on **the same day**. (UX5A; UX6A). The sole objection presented by Delta with respect to this documentary evidence when initially presented during the cross-examination of USDTL Laboratory Director Jones was that, out of respect for Mrs. M's privacy, the Union exhibits had been redacted to remove her personal information. (Tr. 120). This objection was responded to by providing unredacted "A" versions of the exhibits in question.

There is no reason for doubting the credibility of Mrs. M. Her litigation has been settled and is over and done with. The result – reduced custody of her children – has left her "devastated." (Tr. 639). Her motive for testifying as an uncompensated fact witness was to prevent a similar harm from befalling others:

> My life has been severely negatively impacted by these false positive tests. My kids' lives have been negatively impacted. I -- I believe that there are many other people out there whose lives have been negatively impacted by this test and the false positives that it gives. … So I want to do everything I can possible to help anybody in a similar situation, because it -- it is difficult and life changing.

(Tr. 640).

2. The False Positive Test Results of Mr. S

Mr. S. was similarly involved in litigation related to child custody and his ability to drive a car with his children as passengers. (Tr. 354). In support of his position, Mr. S abstained from the consumption of alcohol and, with the assistance of his attorney, arranged a series of eighteen (18) biomarker tests during the period of October 27, 2017 through July 6, 2018, to demonstrate his abstinence. (Tr. 355-56; UX59). The testing methodologies and matrices included urine-based EtS, hair-based EtG, fingernail-based EtG, and DBS PEth testing at USDTL. (*Id.*). With the exception of the USDTL reports, every test result confirmed his abstinence. (Tr. 356-57;

UX59). In order to demonstrate the erroneous nature of the USDTL reports, in April of 2018, Mr. S created his own verification process to determine whether the DBS specimen collection facilities were committing errors that affected his test results. (Tr. 358).

A DBS sample collected on April 6, 2018 at the collection facility Forensic DNA and Drug Testing Services yielded a PEth result of 78 ng/mL positive according to USDTL; however, a DBS sample collected the very next day at Any Lab Test Now, and also tested by USDTL, yielded a negative result. (UX8; Tr 358-59). Mr. S presented his social security number and driver's license, respectively, to identify himself for the two tests. (UX8; Tr. 359).

Still more shocking, DBS specimens provided by Mr. S **45 minutes apart on the same day** at Forensic DNA and Any Lab Test Now, May 3, 2018, yielded USDTL results of 50 ng/mL and a negative, respectively. (UX9). And, yet again, DBS specimens provided by Mr. S **on the same day** at Forensic DNA and Any Lab Test Now, July 6, 2018, yielded USDTL results of 67 ng/mL and negative, respectively. (UX10). USDTL's test reports reflect that the same donor name and the same SSN identification were listed on the July 6 results. (*Id*.).

As with Mrs. M, there is no motive for Mr. S to testify as he did except to assist a man who, in his opinion, had been similarly victimized by a false positive DBS PEth test result.

3. The False Positive Test Results of Pilot D as Reported by Dr. Tordella

Dr. Joseph Tordella is a HIMS-trained physician who has worked as an AME for over 43 years and monitored over 1,000 pilots for substance abuse. (Tordella, Tr. 370-71; Jones, Tr. 169). Like Mr. Danford, Pilot D came under Dr. Tordella's monitoring program as the result of a DUI incident that was not associated with addiction. (Tordella, Tr. 371). Over the course of five years of monitoring, Pilot D had received 41 negative DBS PEth results from USDTL, all with a quantitative reading of 0 ng/mL except one with a negative result of 3 ng/mL. (UX18 at

1; Tordella, Tr. 373). Then, based on a DBS collection conducted on May 18, 2020, USDTL reported a "positive" PEth result of 24 ng/mL. (UX37; UX18 at 1; Tordella, 371-72). The result was not received by Dr. Tordella until May 28, 2020.

Dr. Tordella was shocked by the result and made immediate arrangements on May 28 for additional testing to support his belief that Pilot D had not suffered a relapse and that the May 18 test result was a false positive. (Tordella, Tr. 373; Jones, Tr. 169-70). These tests included both an EtG hair test and a DBS PEth test, both conducted by USDTL and both yielding negative results. (UX38; UX84; Tordella, Tr. 374-75). Dr. Jones advised Dr. Tordella that the quantitative result for the May 28 DBS PEth test result was 0 ng/mL. (Tordella, Tr. 375).

Dr. Tordella discussed his concerns with both Dr. Jones and Dr. Javors, the director of the DBS PEth testing laboratory at the University of Texas. Both Jones and Javors advised him that that half-life for PEth ranges from 4 to 10 days. (Tordella, Tr. 383). Consequently, the May 28 test result of 0 ng/mL "raised quite a bit of doubt" as to the accuracy of the May 18 PEth test result. (Tordella, Tr. 378). When Dr. Tordella queried Jones as to whether the May 18 DBS PEth result could be deemed to have established alcohol consumption, Jones responded:

I'm just a lab guy. … I don't come up with the diagnosis. That's your job.

(Tordella, Tr. 376). Jones agreed that he made comments to Dr. Tordella to this effect. (Jones, Tr. 170). Jones comment was resonant of LabCorp's injunction that "alternative explanations should be explored following any positive [PEth] finding," a warning that Dr. Tordella described as a "spot on." (UX4; Tordella, Tr. 379).

4. USDTL's Failure to Control for False Positives

Delta counsel interceded to prevent any examination of USDTL's laboratory director with respect to hard evidence of USDTL's production of false positives by insisting that Dr.

Jones was not appearing as an expert witness. (Kassin, Tr. 123-24)("Dr. Jones is not here as an expert."). Delta's objection was sustained thereby allowing Jones to evade providing any explanation for these false positives. (Tr. 127-28). This tactical "success" however must be treated as Delta's acquiescence to the probity of the evidence provided. Indeed, before Delta cut off the examination of its non-expert witness, Dr. Jones had already demonstrated USDTL's ability to confirm the authenticity of the documentation submitted by these witnesses. (Jones, Tr. 141-42; UX7). Delta's determination to make no challenge to the documentation provided by Mrs. M, Mr. S, or Dr. Tordella establishes that, during the same approximate time period as Mr. Danford's test, USDTL was producing multiple false positives for at least three other individuals.

Jones' testimony also confirmed that USDTL has no system of internal review to determine whether, based on its own calculation of PEth half-life, the laboratory is producing inconsistent results for a donor over a period time. (Jones, Tr. 129). Indeed, Jones confessed that there is no internal review even when separate samples from the same donor on the **same day** produce a positive and negative. (*Id.*). Thus, there could be numerous other instances of the inconsistent testing results presented by Mrs. M, Mr. S, and Dr. Tordella, but the unreviewed information is securely buried in USDTL's archives.

If USDTL professes to have had no notice of false positives, it can most charitably be described as a matter of willful ignorance. USDTL is the ostrich of laboratories with its head implanted deeply in the sand. The evidence of false positive results during the relevant time period, combined with USDTL's failure to implement internal controls for the detection and correction of false positives, requires that the grievance be sustained.

VI.

DELTA'S REFUSAL TO INITIATE OR CONSIDER ADDITIONAL TESTING PRECLUDES A FINDING OF JUST CAUSE

Even assuming the System Board could not find good reason to question a finding of relapse based on the totality of evidence presented above, the grievance should be sustained based on Mr. Danford's own testing evidence and Delta's discriminatory and dishonest response thereto.

A. Factual Background – Mr. Danford's Immediate Initiation of Testing

It was not until May 14 that Delta advised Mr. Danford that his May 9 DBS PEth test had produced a "positive" result. The very next day, Danford contacted Ms. Gable for the purpose of initiating additional testing that would confirm his abstinence. Gable endorsed the idea, specified the cutoff levels he should request, and promised, with respect to the result, that "we'll take a look at it." (Tr. 697).

That same day – May 15 – Danford initiated a whole blood PEth test with LabCorp and entered on the collection form that he requested testing at the LOD of 8 ng/mL. (Tr. 698-99; UX70). LabCorp reported at a negative test result applying the standard cutoff of 20 ng/mL. (Tr. 699; UX71). At the recommendation of the collection site personnel, on May 15 and again on June 20, Mr. Danford also submitted to an EtG hair test due to its six-month detection window. ExperTox Laboratory subsequently reported results consistent with total abstention from alcohol consumption over the prior six months. (Danford, Tr. 700-01; UX72; UX75).

The next day – May 16 – Danford submitted to a DBS PEth test to be sent to USDTL. The May 16 DBS specimen tested negative at both the cutoff of 20 ng/mL and the LOD of 8

ng/mL. (UX74; Danford, Tr. 704-05).[32] According to USDTL, PEth has a half-life of approximately 4.5 days, which means the quantitative level of PEth in the blood decreases by half every 4.5 days. (Jones, Tr. 128; UX19 at 2). Thus, it would have been expected that if USDTL had accurately reported a 98 ng/mL or 69 ng/mL quantitation for Danford's DBS PEth quantitative test result of May 9 had been accurate, the May 16 test conducted just seven days later would also have produced a detectable result. It did not. In short, the May 9 and May 16 tests could not both be accurate assuming an average half-life of 4.5 days.

Danford presented the above-referenced testing evidence to Captain Graham at his pre-termination hearing, upon receipt of which Captain Graham promised to give the test results "very careful and due consideration and have them looked at by experts and would make a determination." (Danford, 709; CX20).

B. Delta's Discriminatory Approach to Alternate Biomarker Testing Unfairly Denied Mr. Danford of Exculpatory Evidence

On March 16, 2016, Captain Michael Perez provided a DBS sample for PEth testing. USDTL reported that the test was "positive" based on a quantitative result of 10 ng/mL. (UX33 at 5). Delta Chief Pilot Harry Miller advised Perez that this was a "non-negative" and decided, therefore, to get AME Dr. Charles Harper involved. (Perez, Tr. 399, 403-04).

Dr. Harper initially suggested an EtG test using a hair matrix, but, due to the shortness of Perez' hair, changed his recommendation to a test using a fingernail matrix. (Perez, Tr. 405-06). On May 5, 2016, Perez provided a fingernail sample for testing at USDTL, which resulted in a negative test result applying a positive cutoff level of 20 pg/mg. (UX33 at 3). Based on the EtG

[32] Although the testing of the May 16 specimen at LOD 8 was conducted several weeks after the initial test at the 20 ng/mL cutoff, any decline in the quantitative result over this brief period of time would be insignificant. As Dr. Jones testified, the "stability" of its DBS specimens limits any decrease in the quantitative result to 10 to 15 percent on an *annual* basis, thereby permitting the re-confirmation of a result even one year later. (Jones, Tr. 131-33, 143).

nail test, Delta Chief Pilot Harry Miller told Perez that Delta was satisfied with the test and Perez was "good to go." (Perez, 407). According to Dr. Jones, the USDTL fingernail-based EtG test provided Delta with a detection window of up to approximately three months. (Jones, Tr. 206). As Jones admitted, each matrix has its advantages and disadvantages and sometimes tests using different matrices can produce different results without any apparent reason for the differing results. (Jones, Tr. 271-72).

Delta offered Perez an opportunity to exculpate himself with the alternative EtG matrix of fingernail testing.[33] Delta failed to offer such exculpatory testing to Mr. Danford and further refused to consider such testing evidence when Danford obtained it at his own initiative. Just cause cannot be established where such a discriminatory approach to discipline is applied, particularly where there is good reason to believe that Mr. Danford's test result would also have been below the 20 pg/mg positive cutoff level applied to Captain Perez.

C. Captain Graham's Dishonest Representation that Delta Would Consider Mr. Danford's Testing Evidence Precludes a Finding of Just Cause

According to the Company's own exhibit, Mr. Danford presented to Captain Graham (1) a May 15 LabCorp whole blood negative PEth test; (2) a May 15 ExperTox hair-based negative EtG test with a six-month detection window; and (3) a May 16 USDTL DBS PEth test result, which was negative applying a cutoff of 8 ng/mL. (CX20). Captain Graham promised to give the test results "very careful and due consideration and have them looked at by experts and would make a determination." (Danford, 709; CX20).[34]

[33] Delta made this offer to Perez notwithstanding the fact that he had had a positive EtG test, higher than that of Mr. Danford's, just three and a half weeks earlier. (UX34, Perez, Tr. 396-97).

[34] Graham never contested Mr. Danford's account of the commitment that Graham had made; therefore, credibility is not an issue. In the event the System Board deems Captain Graham's credibility an issue worthy of consideration, we draw the Board's attention to a recent decision by federal Administrative Law Judge Scott Morris, which found Delta liable under the AIR 21 whistleblower statute for having used compulsory psychiatric examination as a "weapon" to retaliate against Delta pilot Karlene Petitt for having raised safety issues. *Petitt v. Delta Air Lines, Inc.,* 2018-AIR-00041 (December 21, 2020). In his decision, Judge Morris characterized Graham's testimony as being of

Graham reneged on this commitment and declined to consider the evidentiary value of the proffered testing evidence purportedly because there was "no way for us to understand exactly how the test was done." (Graham, Tr. 450). Graham, however, never explained to Mr. Danford that he would not credit the results or that consideration of the results depended on Delta's control of the testing process. (Graham, Tr. 709).

Graham terminated Mr. Danford without any pre-termination consultation with Michele Gable or representatives of either Quest or USDTL. (Graham, 472-73). He consulted no one with a degree in toxicology, biology, or chemistry. (Graham, Tr. 457).

Graham's explanation for refusing to consider the testing evidence – that there was "no way for us to understand exactly how the test was done" -- rings particularly hollow in view of the fact that one of the exculpatory test results came from USDTL, the very same laboratory whose test result was the primary basis for Delta's termination of Mr. Danford. How the test was done? The document that Mr. Danford put in Graham's hand reflects that it was done in precisely the same manner as his May 9 test, i.e., a DBS PEth test conduct by USDTL. And, had Graham inquired further, he would have learned that the specimen collector for both the May 9 and May 16 USDTL tests had verified Mr. Danford's identity with picture ID. (CX10 at 8; UX73).

As discussed further below, the May 9 and May 16 USDTL test results cannot be reconciled without attributing to Mr. Danford a PEth half-life of less than half of the average value. Unquestionably, such testing data merited further review and the involvement of a medical professional. Delta's stubborn refusal to consider any of this evidence until *after* its termination of Mr. Danford is dispositive of this case. Once the axe has fallen, a Company will

"dubious credibility" and lacking "candor" (Decision at 42, 71). The Tribunal cited "many inconsistencies" between Graham's trial testimony with his prior sworn testimony in a deposition. (Decision at 71).

instinctively circle its wagons and deploy all resources to justify what it has *already* done. Consistent with the arbitral case law discussed in Section II.A above, such post-hoc rationalization cannot satisfy just cause.

Far worse, in our view, is the deception in which Captain Graham engaged. If he had but said to Mr. Danford what he suggested at the System Board hearing – i.e., that Delta had to control the testing process – then additional testing utilizing a matrix with a several month detection window could easily have been arranged. Mr. Danford sought no such arrangement because he left the pre-termination with Graham's false assurances ringing in his ears.

In *American Airlines, Inc.*, Case No. M-246-91 (Arb. Marvin Hill, 1992), the company made a commitment to cancel a drug test result based on reported specimen collection issues only to later renege on this commitment. Arbitrator Marvin Hill found that the grievant had justifiably relied on this commitment in forsaking further efforts to obtain further test results that would provide evidence of his abstention from substance abuse. (Attachment E at 32). The company's withdrawal of this commitment denied the grievant of the opportunity to obtain "very strong evidence" of his innocence. (*Id.*). No just cause may be found when a terminating officer's misrepresentations deny the grievant of such an opportunity.

VII.

DANFORD'S SUBSEQUENT TESTING CONFIRMS HIS ABSTINENCE

A. Danford's May 15 and May 16 PEth Tests Constitute Clear and Convincing Evidence that the May 9 PEth Test was a False Positive

According to USDTL, PEth has a half-life of approximately 4.5 days, which means the level of PEth in the blood decreases by half every 4.5 days. (Jones, Tr. 128; UX19 at 2). Thus, it would have been expected that if USDTL had accurately reported a 98 ng/mL or 69 ng/mL quantitation for Danford's DBS PEth quantitative test result of May 9, the May 16 test conducted

just seven days later would also have produced a detectable result. More specifically, even if the subsequent PEth sample had not been collected until nine days after the May 9 collection – May 18 – the expected result would have been approximately 24.5[35] or 17.25 ng/mL.[36] Thus, according to USDTL's own representations concerning PEth half-life, a DBS collection two full days earlier, on May 16, 2018, should have produced a quantitative result two to three times the applied cutoff of 8 ng/mL. Thus, the May 9 and May 15/16 tests could not both be accurate assuming even a below average half-life of 4 days. (Shults, Tr. 874-75).

Delta's counterargument is to assert that the System Board should ignore USDTL's pronouncements concerning its own testing methodology and apply, instead, a half-life of 1 to 2 days. The evidentiary record does not support the arbitrary application of such a radically lowered half-life.

Jones gave varying testimony, first describing PEth half-life as approximately 4.5 days. (Jones, Tr. 128). Then, having "brushed up on" the published literature, he gave a PEth half-life range of 3 to 14 days. (Jones, Tr. 306). Dr. Tordella testified that both Dr. Jones and Dr. Javors advised him that PEth half-life was 4 to 10 days. (Tr. 383). Forensic Toxicologist Theodore Shults testified PEth half-life was 5 to 10 days. (Shults, Tr 854).

The treatise material was of limited utility. The Javors 2016 study involved the analysis of PEth half-life in 24 participants with a determination that the mean half-life was 4.6 days with a range of 1.0 to 13.1 days. (CX27 at 7). The Ulwelling review cited a series of previous studies finding PEth elimination half-lives of 3, 4.6, 6.1, and 4.5 to 10.1 days. (CX28 at 3). On the low

[35] The number is derived from halving the quantitative result of 98 ng/mL after 4.5 days to reach 49 ng/mL and halving it again after an additional 4.5 days to reach 24 ng/mL.

[36] The number is derived from halving the quantitative result of 69 ng/mL after 4.5 days to reach 34.5 ng/mL and halving it again after an additional 4.5 days to reach 17.25 ng/mL.

end, the study yielding the referenced 3-day half-life finding was based on a single dose of alcohol. (*Id*.). The Kummer research paper cites a PEth half-life of approximately 4 days, with chronic drinking producing a detection window of 28 days. (CX34 at 825-26).

Notwithstanding the above studies, Delta will ask the System Board to defer to the opinion of Dr. Taylor as the Company's PEth half-life expert. However, Taylor's opinion is born of a mixture of ignorance and sophistry that can be given no credence.

Dr. Taylor acknowledged that he has engaged in *no* studies related to the PEth bio-marker and that his laboratory does not conduct PEth testing. (Taylor, Tr. 1080-81). His knowledge of PEth half-life, therefore, could emanate only from what he had read, but he had read little and, what little he had read, he had not assimilated terribly well.

At the hearing, he was unable to identify any PEth half-life study other than the Javors' study. (Taylor, Tr. 1099). With respect to the Javors' study, he could not remember the level of participation (24 persons). (Taylor, Tr. 1100). He asserted that PEth half-life ranged from 1 to 13 days, with an average of 4.6 days, and that "the shorter half-lives are found in alcoholics," but could identify no other factor that would affect an individual's PEth half-life. (Taylor, 1033, 1076, 1101). Nevertheless, he peremptorily assigned Mr. Danford to the extreme low-end of the Javors' half-life spectrum, despite his admission on cross-examination that he had never determined Mr. Danford was an alcoholic or heavy drinker. (Taylor, Tr. 1101).

Indeed, there is nothing in the record that would support that Mr. Danford was an alcoholic or heavy drinker. He entered into the HIMS program as a volunteer after a single DUI incident. He had no health issues identified with alcohol. He had a string of negative tests so long, both before and after the May 9 PEth test, that Dr. Taylor could only speculate that Danford drank somewhere in the period of May 1 to May 15. (Taylor, Tr. 1034-35). But when

asked, in what proximity to testing would the heavy drinking have to occur in order to impact PEth half-life, he answered: "I – I --- I don't know the answer." (Taylor, Tr. 1101).

On cross-examination, Dr. Taylor denied that he had determined Mr. Danford's PEth half-life based on his supposed drinking. Instead, he stated that his half-life determination was "based on the data I had." (Taylor, Tr. 1102). The tautological nature of Dr. Taylor's "analysis" then seeped out:

> 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 data on which you based your determination of Mr. Danford's half-life.
>
> A: Correct.
>
> Q: So your determination of Mr. Danford's half-life was based on your assumption that the May 9th test was accurate, correct?
>
> A: Yes.

(Taylor, Tr. 1102-03). In other words, USDTL's test is accurate because it's accurate. Taylor's testimony would be laughable if not for the fact that a man's career and reputation hang in the balance. Here, again, we note that Captain Graham had no knowledge of PEth half-life or PEth's detection window at the time of the termination. (Graham, Tr. 479).

The Company provided no basis for ascribing to Mr. Danford a PEth half-life other than the average PEth half-life identified by USDTL and the treatise material in the evidentiary record. When considered together, the May 15 and May 16 PEth test results provide convincing evidence that the May 9 PEth test result may have been inaccurate. Under these facts, the grievance must be sustained.

B. Danford's Hair-Based EtG Results Further Confirm That the May 9 DBS PEth Test Was Erroneous

At the recommendation of the collection site personnel, Danford submitted, on May 15, and again on June 20, 2018, to EtG hair tests due to its six-month detection window. ExperTox Laboratory subsequently reported results consistent with total abstention from alcohol consumption over the prior six months. (Danford, Tr. 700-01; UX72, UX75). Dr. Jones concurred that nail and hair-based EtG provide good alternative testing methodologies in determining alcohol use. (Jones, Tr. 205). Thus, the hair-based EtG results confirmed the May 15 and May 16 negative DBS PEth test results. (Shults, Tr. 873; Skipper, Tr. 592).

Yet again, Delta relied on Dr. Taylor, who has engaged in no studies related to EtG testing, to challenge the results. With respect to the May 15 hair-based EtG test, Taylor dismissed the negative result as irrelevant because of a two-week delay in hair growth necessary to indicate recent alcohol consumption. According to Taylor, the May 15 hair-based EtG test only reflected abstinence prior to May 1. (Taylor, Tr. 1035). Thus, "if he drank a ton between May the 1st and May the 15th, you couldn't see it because it's below the skin." (*Id.*).

Taylor's testimony cannot be credited. He has no expertise in the area and made no reference to any relevant study, published or otherwise, in support of his two-week delay concept. His assertion, in this regard, not only conflicts with the conclusions of Shults and Skipper with respect to the probative value of the May 15 hair-based EtG test, but also with that of the federal agency SAMHSA, which has recently proposed the adoption of hair-based testing for pre-employment and random drug testing with the observation that the relevant metabolites may be detected in hair **"5 to 7 days after ingestion."** *Mandatory Guidelines for Federal Workplace Drug Testing Programs*, 85 Fed. Reg. 56108, 56115 (September 10, 2020). Thus, according to United States Department of Health and Human Services, there is good reason to

treat the May 15 hair-based EtG test as dispositive evidence demonstrating Mr. Danford's abstinence.

Even if the System Board were to credit the unsubstantiated two-week delay concept, Taylor concedes that the hair-based EtG test confirms Mr. Danford's abstinence at least until May 1. We are, thus, left with the improbable proposition that Mr. Danford's May 1 urine-based EtG test – the sole reason for subsequent May 9 DBS PEth test – was the result of alcohol consumption on the very day he was tested. Since Danford was subject to same-day testing notification at 6:00 a.m., the Jones' theory of alcohol consumption would appear to require the highly questionable assumption that Mr. Danford consumed alcohol *after* being notified of his May 1 EtG/EtS test. (Danford, Tr. 669).

With respect to the June 20 ExperTox hair-based EtG result, Taylor took the position that, while the hair now had sufficient time to grow to reflect the same time period covered by the May 9 PEth test, the 4.8 pg/mg result must be interpreted as a positive indicator of alcohol consumption because the word "positive" appears after the words Test Result on the ExperTox reporting form. (UX75).

If we have learned nothing else during the hearings in this matter, it is that testing laboratories have successfully divorced the term "positive" from any definitive meaning. Thus, USDTL designated Captain Perez' 10 ng/mL DBS PEth result as a "positive" even though Dr. Jones would not consider the result indicative of drinking alcohol. (UX33 at 5; Jones, Tr. 192, 195). Jones would, and did, allow Delta to set a "positive" cutoff level 8 ng/m, which Jones himself considered non-probative. (Jones, Tr. 194). Similarly, Quest allowed Delta to set a urine-based EtG quantitative result of 100 ng/mL as "positive" even though the low cutoff has been rejected by most laboratories, all other airlines, and the United States government. (*Supra.*

at 3-4). In short, a "positive" quantitative result means only that a metabolite is present; it says nothing, standing alone, as to what produced that metabolite.

ExperTox provides, under the title, "Suggested Cutoffs," that any quantitative result under 7 pg/mg indicates that the individual is a teetotaler. The laboratory deems a "Positive" indicating alcohol consumption to require a result higher than 7 pg/mg. (UX72; UX75). Again, Dr. Skipper, who has direct experience with EtG studies, testified that the "normal" positive cutoff standard for hair-based EtG testing is 20 pg/mg. (Skipper, Tr. 592). He characterized the 4.8 result as a negative. (Skipper, Tr. 592).

Significantly, Dr. Taylor concurred with Dr. Skipper. Taylor testified that 7 pg/mg is "typically used as a cutoff for hair testing". (Taylor, Tr. 1041-42). Nonetheless, Taylor proposed that a 2 pg/mg cutoff level could be used based on the Pirro study. (Taylor, Tr. 1042; CX33). The Pirro study was conducted seven years ago on 44 subjects almost half of whom were children of 1-12 years of age who were selected on the assumption that they had never had a drink. (CX33 at 2). Taylor concluded it is "possible" to drink and still get a 4.8 pg/mg hair-based EtG quantitative result. (Taylor, Tr. 1041).

Delta's position is ironic. Yes, anything is "possible" when applying newly developed testing methodologies, especially when they have been subjected to laboratory-specific modifications that have not been validated. Dr. Taylor's testimony confirms the necessity of evaluating such testing data in the context of a broader clinical review. In this case, the only person who conducted this clinical review – recommended by LabCorp, Quest, and even Taylor himself – was Dr. Skipper.[37]

[37] Delta has tried to suggest that Mr. Danford attempted to hide the June 20 ExperTox test. The facts do not support this conclusion. The June 20 test was provided to Dr. Skipper and incorporated into his expert report as evidence that Mr. Danford was a teetotaler. (UX57 at 4). Mr. Danford also provided the test result to forensic toxicologist Theodore Shults. (Shults, Tr. 892). There is a dispute as to whether Mr. Danford provided the June 20 result to Dr.

Applying the industry standard cutoff level – recognized by ExperTox, Dr. Skipper, and Dr. Taylor – to Mr. Danford's hair-based EtG tests provides an additional basis for sustaining the grievance.

VII.

THE REINSTATEMENT OF MR. DANFORD IS CONSISTENT WITH BOTH JUST CAUSE AND SAFETY

Delta may argue that Mr. Danford chose to be terminated. All he had to do was to enter re-treatment and, in the words of Chief Pilot Miller, he could "fight" his battle from there. Acquiescing to such a process would have been unfair and unsafe.

Unfair, because after a highly distressing experience at the Talbott Recovery Center, Mr. Danford faced yet another three to six-month internment during which he would be forced into false admissions that would compromise the integrity of the program. The just cause standard does not permit a veteran employee's termination to be based on such a Hobson's Choice.

Unsafe, because the reputation of the HIMS program is at stake. As Captain Graham recognized, the success of the HIMS program requires that it be managed in a "non-threatening manner" that cultivates the "ability for someone to come forward." (Graham, Tr. 439).

Going forward, every pilot inclined to voluntarily self-identify with a substance abuse problem will reconsider whether he is better off trying to address the problem on his own. The Board heard this in the deep frustration and even angry tones of Captains David Dodge and

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Tom Faulkner. (Danford, Tr. 745, 763; Faulkner, Tr. 922). To the extent it matters, the factual dispute should be resolved in favor of Mr. Danford's account. First, because he presented the data to his expert witnesses, one of whom incorporated it into his defense. Second, because Dr. Faulkner's testimony was inconsistent. Faulkner initially testified that Danford did not provide him with *any* post-May 9 tests. (Faulkner, Tr. 922). He also testified that his focus, with respect to his recommendation that Mr. Danford receive a first class medical, was based on the testing and evaluations performed beginning in late July, 2018. (Faulkner, Tr. 929). Finally, we note that a federal tribunal found Dr. Faulkner's testimony "less than credible" to the extent it concerned his "stated independence" from the Company in the context of Delta's weaponization of psychiatric analysis as a tool to suppress safety reports. *Petitt v. Delta Air Lines, Inc.*, 2018-AIR-00041 at 73 (December 21, 2020).

Michael Perez. Even among its adherents, the HIMS testing system is perceived as flawed and devoid of the necessary clinical review. (Dodge, Tr. 607). Indeed, HIMS Peer Mentor Dodge saluted Mr. Danford for his integrity in contesting the accusation of relapse. (Dodge, Tr.608-09).

There is nothing more certain to undermine aviation safety than the growing suspicion that the HIMS program does not comply with essential forensic protocols. It will lead directly to pilots with substance abuse problems continuing to fly without seeking assistance.

The FAA has provided Mr. Danford a first class medical, without the requirement of re-treatment, because it determined the May 9 DBS PEth test was not sufficiently probative of relapse. Mr. Danford is currently free to fly any aircraft for which he is rated and flies every week. As before, he is subject to the multifarious FAA-HIMS program elements that keep flying safe, including: psychiatric review, psychological review, AME evaluation, supporting group meeting, peer monitoring, and testing fourteen times per year. The flying in which he now engages should include the continuation of his unblemished and loyal service for Delta Air Lines.

CONCLUSION

In view of the foregoing, it is requested that the System Board sustain the grievance and reinstate Mr. Danford with full seniority and make whole relief.

Respectfully submitted,

/s/ Lee Seham
Lee Seham, Esq.
Seham, Seham, Meltz & Petersen, LLP
199 Main Street – Seventh Floor
White Plains, NY 10601
(914) 997-1346
lseham@ssmplaw.com