ILLINOIS FORENSIC SCIENCE COMMISSION
STATEMENT AND RECOMMENDATION IN RESPONSE TO "INVESTIGATIVE REPORT REGARDING THE UNIVERSITY OF ILLINOIS CHICAGO ANALYTICAL FORENSIC TESTING LABORATORY"

This Statement and Recommendation respond to the attached document titled "Investigative Report Regarding the University of Illinois Chicago Analytical Forensic Testing Laboratory" ("UIC Report") which was issued on May 28, 2025.[i]

On March 11, 2026, the Illinois Forensic Science Commission voted to issue this Statement and initial Recommendation.

Background

The University of Illinois Chicago ("UIC") retained the law firm of Taft Stettinius & Hollister LLP in November of 2024 to "conduct an independent investigation" into allegations related to Analytical Forensic Testing Laboratory's ("AFTL") tetrahydrocannabinol ("THC") testing methodologies and to advise the UIC "whether the allegations had merit."[ii] The UIC Report "is the product of that investigation" and is publicly available on the UIC's website.[iii]

The Quality Systems Subcommittee of the Illinois Forensic Science Commission conducted a page-by-page review of the UIC Report during public meetings on August 6, 2025, September 4, 2025, October 9, 2025, November 13, 2025, and January 7, 2026, and discussed numerous questions, observations, and concerns about information and conclusions contained within the UIC Report.[iv]

Because criminal justice stakeholders and the public may rely on the UIC Report, the Quality Systems Subcommittee recommended that the Illinois Forensic Science Commission issue this initial Statement to identify and summarize some of the key concerns that could directly affect end users of AFTL's forensic testing services. This Statement is not an exhaustive list of identified topics and concerns. Minutes from the Quality Systems Subcommittee's meetings are available on the Commission's website[v] and the Commission's examination of forensic testing, reporting, and testifying performed by AFTL continues.

Statement

The Illinois Forensic Science Commission finds the UIC Report insufficient to address the allegations related to the Analytical Forensic Testing Laboratory's ("AFTL") forensic testing of human blood and urine samples for the presence and quantity of Delta-9 THC for law enforcement agencies from 2016 through February of 2024.[vi]

The content of the attorney-authored UIC Report suggests a fundamental lack of understanding of forensic toxicology principles, forensic laboratory quality systems, and the duties and responsibilities of an accredited forensic testing laboratory to its end users. As such, the Illinois Forensic Science Commission does not consider the UIC Report to be an authoritative document for criminal justice stakeholders to evaluate the competency or accuracy of forensic testing, reporting, and testifying performed by AFTL.

At this time, the Illinois Forensic Science Commission specifically notes that the UIC Report contains insufficient factual or scientific support for the following conclusions related to the testing of human samples for the possible presence and quantity of Delta-9 THC:

I. "Prior to the commercial availability of consumable hemp-derived Delta-8 products in or after 2019, AFTL's THC testing methodologies were appropriate and met accepted scientific standards."[vii]
II. "[AFTL] [a]nalysts appropriately and necessarily utilized the process of hydrolysis in order to detect Delta-9 in urine."[viii]

Additionally, the Illinois Forensic Science Commission makes the following observations about information and assertions contained in the UIC Report:

1. AFTL's results on human blood and urine samples for the presence and quantity of Delta-9 THC were used in furtherance of criminal investigations and prosecutions in Illinois.

2. The UIC Report's finding that AFTL's THC testing methodologies were flawed and should have been modified because the laboratory did not use instrument methods that fully separated the Delta-8 and Delta-9 isomers of THC in blood and urine samples is consistent with AFTL's 2024 report of significant non-conformities to the Illinois Forensic Science Commission.[ix]

3. The UIC Report correctly observes that "it was incumbent upon AFTL to ensure that its methodologies could properly identify the presence of Delta-8 [THC] in a sample and properly separate the Delta-8 [THC] and Delta-9 [THC] isomers to reach a reliable Delta-9 [THC] quantitation result."[x] AFTL failed to do so.[xi]

4. Contrary to assertions in the UIC Report, the timing of a given lab result for the quantity of Delta-9 THC in a sample is not relevant to the assessment of whether AFTL's testing methodologies for the presence and quantity of Delta-9 THC were scientifically acceptable.[xii] Specifically, the commercial availability of Delta-8 THC and/or AFTL's awareness thereof are scientifically irrelevant to the question of whether AFTL's testing methodologies could properly identify the presence of Delta-8 in a sample and properly separate the Delta-8 and Delta-9 isomers to reach an accurate Delta-9 THC quantification result.[xiii] The methodologies used by AFTL to identify and quantify Delta-9 THC in samples admittedly were not fit for purpose in that they did not screen for or fully separate out the Delta-8 isomer, both before and after the alleged increase in commercially available Delta-8 THC products.[xiv]

5. As noted in the Illinois Forensic Science Commission's Report of Significant Non-Conformities for 2024, AFTL did not issue amended or supplementary reports as part of its corrective action related to AFTL's inability to fully separate the Delta-8 and Delta-9 isomers of THC in blood and

urine samples.[xv] As such, criminal justice stakeholders should not assume that a particular case(s) may not have been impacted by AFTL's flawed testing methodologies based solely on the fact that no amended or supplemental report was issued in a case(s).

6. The UIC Report recounts an ANSI National Accreditation Board ("ANAB") finding that "allegations related to inaccurate and unqualified testimony have merit."[xvi] The finding reportedly relates to the use of the term "scientifically under the influence" in communications and/or testimony.[xvii] As noted in the Illinois Forensic Science Commission's Report of Significant Non-Conformities for 2024, AFTL reported initiating a corrective action related to the use of the phrase "scientifically under the influence."[xviii] However, AFTL reported to the Commission that it was unable to identify which case(s) may have been impacted by the use of the phrase and that AFTL did not send notifications to State's Attorneys' Offices regarding testimony or communications using the phrase "scientifically under the influence."[xix] As such, criminal justice stakeholders should not assume that a particular case(s) may not have been impacted by the finding of "inaccurate and unqualified testimony" based solely on the fact that no notification was received.

7. As previously noted by the Commission, urine is not an appropriate matrix for detecting Delta-9 THC based on how Delta-9 THC is metabolized in the human body.[xx]

8. Unlike Section 11-501(a)(6) of the Illinois Vehicle Code, Section 11-501(a)(7) of the Illinois Vehicle Code does not specifically refer to "urine." [xxi] Section 11-501(a)(6) of the Illinois Vehicle Code refers to "any amount of a drug, substance, or compound in the person's breath, blood, other bodily substance, or urine resulting from the unlawful use or consumption of a controlled substance listed in the Illinois Controlled Substances Act, an intoxicating compound listed in the Use of Intoxicating Compounds Act, or methamphetamine as listed in the Methamphetamine Control and Community Protection Act."[xxii] Section 11-501(a)(7) of the Illinois Vehicle Code refers to "tetrahydrocannabinol concentration" only "in the person's whole blood or other bodily substance"[xxiii] with additional clarification in Section 11-501.2(a)(6) defining "tetrahydrocannabinol concentration" as only "[D]elta-9 tetrahydrocannabinol" in whole blood or other bodily substance.[xxiv] [xxv]

9. The UIC Report does not provide adequate information to draw any conclusions about the propriety of testimony about Delta-9 THC and conjugated Delta-9 THC in a particular case(s).[xxvi] The UIC Report states that ANAB found an allegation of "untruthful testimony" to be "without merit" and that the allegation "related to testimony regarding the chemical composition of Delta-9 in urine."[xxvii] The UIC Report does not outline or discuss the specific content of the testimony at issue, nor does the UIC Report identify the case(s) in which the complained-of testimony was given.[xxviii] The UIC Report states that ANAB determined the allegation to be without merit because "'[t]he law is silent on the form of [Delta-9], thereby treating conjugated and free [Delta-9] the same in urine.'"[xxix] The UIC Report does not provide a source document or reference for the quoted ANAB finding.[xxx]

10. The UIC Report is not the result of an audit of AFTL's lab operations conducted by subject matter experts. Rather, it is a summary of a retained law firm's assessment and opinions about allegations related to AFTL's forensic testing of human samples for the presence and quantity of Delta-9 THC. The "Investigative Team" responsible for reviewing materials, conducting interviews, and generating the UIC Report consisted solely of legal professionals.[xxxi] While a forensic toxicologist was consulted, the lack of specific references in the UIC Report made it unclear what, if any, portions of the UIC Report were informed by the retained consultant.[xxxii]

Recommendation

The Illinois Forensic Science Commission recommends that the University of Illinois Chicago ("UIC") initiate a comprehensive audit of the AFTL's forensic toxicology lab operations to be conducted posthaste and that a report of the findings be made publicly available upon completion of the audit. The audit should be conducted by an independent agency or vendor, and the audit team should be comprised of members with subject matter expertise in relevant aspects of forensic science services including, but not limited to, applicable forensic toxicology testing, ISO/IEC forensic laboratory accreditation, and forensic laboratory management.[xxxiii]

Approved: March 11, 2026

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[i] Available at https://aftl.lab.uic.edu/ (visited 2/23/26)

[ii] UIC Report 1-2

[iii] See https://aftl.lab.uic.edu/; https://uofi.app.box.com/s/yne9l5g2frd4sgvlu97aq7c1id0dm6zf (visited 2/27/26)

[iv] Available at https://isp.illinois.gov/Forensics/FSCMeetingYears

[v] Available at https://isp.illinois.gov/Forensics/FSCMeetingYears

[vi] UIC Report 1-2, 31-32

[vii] UIC Report 31

[viii] UIC Report 18

[ix] See *Annual Report to the Illinois Forensic Science Commission Significant Non-Conformities for 2024* (Available at https://isp.illinois.gov/StaticFiles/docs/ForensicServices/2025%20IFSC%20Report%20Sig%20NC%20for%202024.pdf)

[x] UIC Report 19

[xi] UIC Report 19-20

[xii] UIC Report 18

[xiii] UIC Report 18-19

[xiv] UIC Report 18-20

[xv] See *Annual Report to the Illinois Forensic Science Commission Significant Non-Conformities for 2024* at 14-15

[xvi] UIC Report 29

[xvii] UIC Report 29

[xviii] See *Annual Report to the Illinois Forensic Science Commission Significant Non-Conformities for 2024* at 13

[xix] See *Annual Report to the Illinois Forensic Science Commission Significant Non-Conformities for 2024* at 14-15

[xx] See *Statement of the Illinois Forensic Science Commission Regarding the 2-hour Sample Collection Time in 625 ILCS 5/11-501(a)(7)* at 3 (Available at https://isp.illinois.gov/StaticFiles/docs/ForensicServices/2%20hr%20Collection%20Stat%20Apprd.pdf)

[xxi] See 625 ILCS 5/11-501(a)(6), (a)(7)

[xxii] See 625 ILCS 5/11-501(a)(6)

[xxiii] See 625 ILCS 5/11-501(a)(7); see also 620 ILCS 5/11-501.2(b-5)

[xxiv] See 625 ILCS 5/11-501(a)(7); 625 ILCS 5/11-501.2(a)(6)

[xxv] The UIC Report asserts that "[t]he relevant Illinois statute specifically allows for the use of urine in testing for the concentration of Delta-9 in furtherance of criminal prosecutions for driving under the influence." (UIC Report 18, n. 8) The UIC Report fails to cite or acknowledge the contrary provisions of the Illinois Vehicle Code that apply specifically to DUI-Cannabis prosecutions under Section 11-501(a)(7).

[xxvi] UIC Report 29-30

[xxvii] UIC Report 29

[xxviii] UIC Report 29

[xxix] UIC Report 29

[xxx] UIC Report 29

[xxxi] UIC Report 4, n. 1

[xxxii] UIC Report 6

[xxxiii] See, i.e., Forward Resolutions, *Colorado Bureau of Investigations Forensic Services Audit and Assessment Report*, July 8, 2025 (available at https://cbi.colorado.gov/sites/cbi/files/CBI_ForensicServicesAuditandAssessmentFinalReport_20250708.pdf) (visited 2-27-26); see also https://cbi.colorado.gov/forensics/forward-resolutions-audit-assessment-of-cbi-forensic-services

INVESTIGATIVE REPORT REGARDING
THE UNIVERSITY OF ILLINOIS CHICAGO
ANALYTICAL FORENSIC TESTING LABORATORY

ISSUED MAY 28, 2025

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I. INTRODUCTION

From 2016 until February of 2024, the Analytical Forensic Testing Laboratory at the University of Illinois Chicago ("AFTL") conducted, among other things, forensic testing of human blood and urine samples for the presence and quantity of alcohol and drugs, as requested by its clients, various law enforcement agencies. The test results were used in furtherance of criminal investigations and prosecutions. The specific focus of this Report is AFTL's testing of human blood and urine samples for the presence and quantity of tetrahydrocannabinol ("THC"). AFTL tested for the presence and quantity of Delta-9-THC ("Delta-9") pursuant to Illinois statute, 625 ILCS 5/11-501, *et seq*. As relevant to this investigation, the statute prohibits driving a motor vehicle with a concentration of Delta-9 in one's blood or other bodily substances, including urine, above certain statutory levels.

In or around May and June 2024, the University became aware of questions raised regarding AFTL's THC testing methodologies. More specifically, the University learned of allegations made in various court pleadings that AFTL's methodologies were flawed because they failed to distinguish between Delta-9 and its closely related isomer, Delta-8-THC ("Delta-8"). It was alleged that, as a consequence of this failure, AFTL reported inaccurate and unreliable Delta-9 concentration results. Further, according to the allegations, AFTL and its analysts knew the lab's methodologies were flawed and the test results were unreliable, but nevertheless, continued to report unreliable results and in some instances, provided testimony in support of the inaccurate results in criminal cases. In doing so, according to the allegations, AFTL and its analysts knowingly concealed its purportedly flawed methodologies, inaccurate test results and false testimony, and failed to make appropriate disclosures of these deficiencies as required by law. University officials presented these allegations to University Counsel, and in November 2024, Taft

Stettinius & Hollister LLP was retained to conduct an independent investigation and to advise the University whether the allegations had merit. This Report is the product of that investigation.

II. EXECUTIVE SUMMARY OF KEY FINDINGS AND CONCLUSIONS

Based on our investigation, we have made the following Key Findings and Conclusions, each of which is discussed in greater detail in this Report:

- The methodologies AFTL used to test for the presence of Delta-9 in human blood and urine samples were at all times appropriate and met accepted scientific standards.

- The THC-testing methodologies AFTL used did not include testing for the presence of Delta-8, nor did they allow for the complete separation of the Delta-8 and Delta-9 isomers to baseline. Importantly, however, that does not mean that AFTL's Delta-9 quantitation results (i.e., the numeric value of the concentration of Delta-9 in a sample) are necessarily unreliable. The efficacy of the methodologies used by AFTL to quantitate the concentration of Delta-9 and the reliability of AFTL's Delta-9 quantitation results may be confirmed on a case-by-case basis with reference to the dates on which a particular sample was drawn and tested, as well as several other forensic data points.

- Prior to the commercial availability of consumable hemp-derived Delta-8 products, which came to market in or after 2019, AFTL's methodologies for Delta-9 quantitation were appropriate and met accepted scientific standards. That is because, prior to the passage of federal and state legislation in late 2018, Delta-8 products were not prevalent in the marketplace, and therefore, there was no need to identify or account for the presence of Delta-8 in human samples. After AFTL became aware or should have been aware that hemp-derived Delta-8 products were legal and commercially available, AFTL should have tested for the presence of Delta-8 and ensured the complete separation of the Delta-8 and Delta-9 isomers before quantitating Delta-9 in a sample.

We have evaluated the specific allegations made against AFTL and, based on our investigation, we have reached the following conclusions, each of which is discussed in greater detail in this Report:

- The allegation that AFTL used flawed methodologies in testing for the presence of Delta-9 in human blood and urine samples is unfounded.

- The allegation that AFTL used flawed methodologies in the quantitation of Delta-9 is unfounded in part and founded in part. This allegation is unfounded as to

methodologies used by AFTL before such time it was aware or should have been aware that hemp-derived Delta-8 products became legal and available on the commercial market. It is founded as to the methodologies used by AFTL after AFTL became aware or should have been aware of the commercial availability of hemp-derived Delta-8 products because Delta-8 then became a potentially relevant factor and AFTL's methodologies did not test for the presence of Delta-8 in test samples.

- The allegation that AFTL did not separate Delta-8 and Delta-9 isomers to baseline when analyzing human blood and urine samples is founded.

- The allegation that the methodologies AFTL used to quantitate Delta-9 artificially inflated the concentration of Delta-9 in test samples is unfounded as to AFTL's methodologies used before hemp-derived Delta-8 products became legal and available on the commercial market. Thereafter, whether AFTL's methodologies artificially inflated the concentration of Delta-9 can be evaluated on a case-by-case basis with reference to several forensic data points.

- The Investigative Team found no evidence that AFTL knew that it used flawed testing methodologies when it performed testing on human biological samples.

- The Investigative Team found no evidence that AFTL knew that it provided inaccurate laboratory results to law enforcement entities, which were subsequently used in criminal proceedings.

- The allegations that AFTL performed testing on human blood and urine samples without accreditation are unfounded.

- The Investigative Team found no evidence that AFTL analysts knowingly provided false testimony in criminal proceedings.

- The allegation that AFTL ceased testing on human blood and urine samples because of the allegations made against the laboratory is unfounded.

III. OVERVIEW OF EVIDENCE AND MATERIALS REVIEWED

The Investigative Team[1] reviewed numerous sources of evidence and materials in an iterative process as the investigation developed. As part of the investigation, the Investigative Team received and processed more than 416,000 documents to identify those that were potentially relevant. The Investigative Team subsequently reviewed voluminous documents and materials in connection with the investigation, including but not limited to the following categories of records:

- AFTL's Standard Operating Procedures ("SOPs");
- AFTL's Corrective and Preventive Action ("CAPA") forms from 2021 to the present;
- Documents related to accreditation and audits by ANSI National Accreditation Board ("ANAB");
- AFTL's contracts with various law enforcement agencies for human testing, billing documents, and invoices;
- Employment records of AFTL employees;
- Laboratory files, including laboratory reports issued by AFTL and underlying documentation from 2016 through 2024;
- Internal email communications between AFTL employees;[2]
- Email communications between AFTL employees and external attorneys, including prosecutors and defense counsel involved in criminal prosecutions on charges of driving while under the influence of drugs;
- Email communications between AFTL employees and employees of other forensic laboratories;
- Email communications between AFTL employees and representatives of ANAB;
- Pleadings, exhibits, and court transcripts from various criminal cases.

[1] The Investigative Team was comprised of Taft Stettinius & Hollister LLP attorneys Nancy DePodesta, John Kennedy, Elizabeth Babbitt, Paul Coogan, and Ioana Guset, and Taft Stettinius & Hollister LLP paralegal Hannah Farrell.

[2] With respect to email communications, the Investigative Team reviewed those email communications that were available pursuant to the University's records retention schedules.

In addition to reviewing the above materials and documents, members of the Investigative Team interviewed the following witnesses believed to possess information relevant to the investigation: Brendan Heffron (current AFTL Director of Laboratory Operations); Dr. Karl Larsen (former AFTL Director); Kristen Prieto (former AFTL Analytical Forensic Toxicology Specialist); Ashley Evers (former AFTL Analytical Forensic Toxicology Specialist); Jessica Ramirez (former AFTL Analytical Forensic Toxicology Specialist); Emilie Giacobbe (former AFTL Analytical Forensic Toxicology Specialist); and Nancy Freitag (Head, Department of Pharmaceutical Sciences, UIC Retzky College of Pharmacy).[3]

The Investigative Team also attempted, but was unable, to interview Jennifer Bash, the forensic analyst whose work and testimony has been the specific subject of certain allegations. The Investigative Team made numerous requests to interview Ms. Bash by contacting her attorney, Jennifer Bonjean, as well as Mark Ertler, an attorney and Ms. Bash's husband. Ms. Bash was the Senior Analytical Forensic Toxicology Specialist/Quality Manager at AFTL. Ms. Bash began her employment with AFTL in February 2015, and was the primary analyst overseeing and conducting testing of human samples until she resigned from AFTL, effective February 1, 2024.[4] Despite the Investigative Team's efforts, and intermittent indications that Ms. Bash would cooperate with the investigation, attorney Bonjean ultimately advised the Investigative Team on February 19, 2025, that Ms. Bash declined the Investigative Team's repeated requests for an interview.

[3] All interviewees were advised, consistent with *Upjohn Co. v. United States*, 449 U.S. 383 (1981), that the attorneys conducting the interview represented the University and were not their attorneys. Each of the interviewees acknowledged that they understood the disclosure and that any statements made during the course of the interview were not subject to the attorney-client privilege. Several current and former AFTL employees were represented by separate counsel during their interview.

[4] Ms. Bash was issued a notice of non-reappointment by the University on January 4, 2024, and subsequently resigned effective February 1, 2024.

The Investigative Team also attempted to contact Chikitsa Patel, who worked as a forensic analyst at AFTL from July 2020 to November 2021, to request an interview. The Investigative Team was unable to make contact with Ms. Patel.

As part of its investigation, the Investigative Team also consulted with Dr. Michael J. Coyer, Ph.D., a highly credentialed and experienced forensic toxicologist. Dr. Coyer earned his bachelor's degree in Chemistry from the University of Scranton, and earned his Ph.D. in Inorganic/Physical Chemistry from Rutgers University. From 2012 to the present, Dr. Coyer has served as the Laboratory Director of the New York State CLEP Laboratory. Dr. Coyer also currently serves as an Associate Director of Toxicology for the Occupational Testing Service at Labcorp, in Raritan, NJ; the Laboratory Research Director at Princeton Analytical, in Dunmore, PA; and the Laboratory Research Director at Northern Tier Research, in Dunmore, PA. Additionally, through his employment with Drugscan, Inc., in Horsham, PA, Dr. Coyer is retained by the City of Philadelphia as an expert in the area of forensic toxicology and pharmacology.

While not an exhaustive list, Dr. Coyer was provided and reviewed various AFTL SOPs, numerous lab reports containing underlying data, CAPA forms, accreditation materials, various court filings setting forth allegations against AFTL, and other related materials. Dr. Coyer also toured the laboratory, inspected the laboratory equipment, and met with Dr. Larsen and Mr. Heffron to discuss laboratory procedures and testing, including in some instances, specific lab results. The opinions, observations and information learned over the course of multiple meetings and discussions with Dr. Coyer informed the Investigative Team's findings and conclusions.

IV. OVERVIEW OF RELEVANT INSTRUMENTATION, KEY TERMINOLOGY, AND LABORATORY METHODOLOGIES

The allegations made against AFTL required the Investigative Team to gain a thorough understanding of the science and key terminology related to toxicology, as well as laboratory methodologies, procedures, and best practices. Dr. Michael Coyer, the forensic toxicology expert consultant engaged by the Investigative Team, provided context, experience, and analysis, which assisted the Investigative Team in understanding the subject matter and, ultimately, in reaching certain findings. This section of the Report provides an overview of the methodologies and associated terminology that are central to an understanding of the allegations, findings, and conclusions contained in the report.

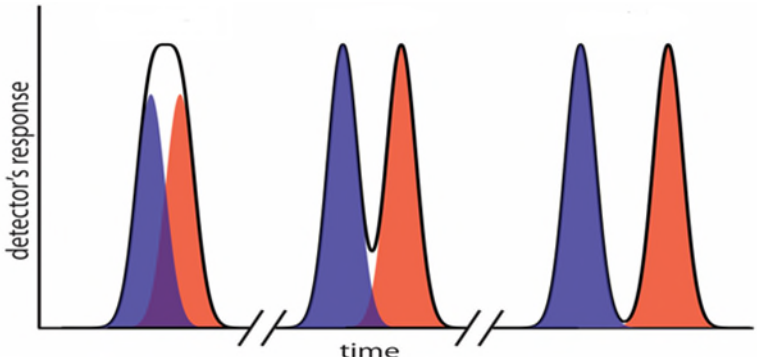
A. Liquid Chromatography Basics

By way of background, AFTL utilized liquid chromatography/tandem mass spectrometry (LC/MS/MS) analytical techniques for testing human blood and urine samples for THC. In general terms, LC/MS/MS analysis is used to identify and differentiate between various chemical compounds that may coexist in a given sample. This differentiation of chemical compounds via LC/MS/MS instrumentation is referred to throughout this Report as "separation."

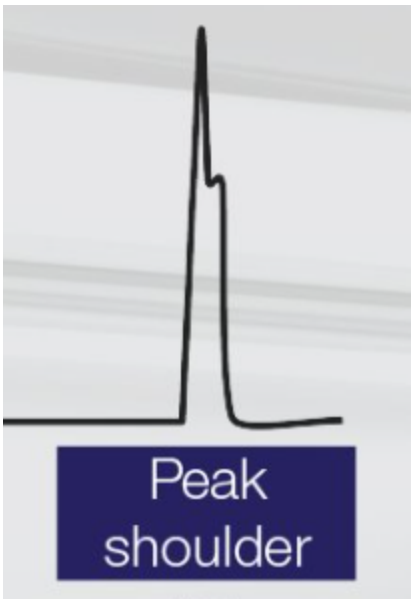
An LC/MS/MS instrument separates compounds in a sample by slowly moving the sample, containing multiple chemical components, through a chemically modified material, called a "stationary phase" or "column." The sample is passed through the column using a solvent (or mixture of solvents) known as the "mobile phase." Separation of constituents occurs because different compounds will be released from the column at different rates of speed based on the unique chemical characteristics of each particular compound. The amount of time it takes for a particular compound to pass through the column is referred to as the "retention time."

The rate at which a mobile phase solution is passed through the column is referred to as the "gradient time." The composition of the mobile phase and the gradient time, which are collectively referred to in this Report as "gradient," can affect the retention times of particular compounds. Thus, the gradient can be adjusted to improve the separation of particular compounds in a given test sample.

When a compound is identified in a sample, the LC/MS/MS instrument's output shows what is referred to as a "chromatographic peak." When two compounds are completely separated by the instrument, the individual compounds will show two distinct peaks that do not overlap. Such a scenario is referred to in this Report as "complete separation" or "separation to baseline." Complete separation occurs when the retention times of the individual compounds are sufficiently far apart to achieve fully resolved and distinct peaks. However, when the retention times for two compounds are too similar when using a particular gradient, complete separation does not occur. In that scenario, the LC/MS/MS output may show two overlapping peaks. The image below shows, from left to right, peaks with nominal separation, partial separation, and complete separation.



Where there is incomplete separation between compounds, the data may display what appears to be a single peak with an irregularity. This type of irregularity in a peak is often referred to as a "hump" or "shoulder." The image below shows how such a peak may appear.



In addition to qualitative identification of compounds, LC/MS/MS analysis can also be used to quantitate the amount of a particular compound that is present in a sample. Compounds that are completely separated (i.e., those that present distinct peaks) are generally more easily and reliably quantitated than compounds that are not completely separated (i.e., those that may present overlapping or irregular peaks).

B. AFTL's THC Methodologies

When testing for THC in human blood and urine, AFTL used two different LC/MS/MS systems, both of which were manufactured by Agilent Technologies. One system was used for screening/qualitative analysis (hereinafter "LC/MS #2"), and the other was used for confirmation/quantitative analysis (hereinafter "LC/MS #1").

Generally, after a blood or urine sample was received by the lab and prepared for testing, AFTL analysts utilized LC/MS #2 to "screen" or qualitatively determine the presence of any drugs or metabolites of interest in a human biological sample. This screening test identified whether Delta-9 and/or its metabolites were present in the sample. If Delta-9 was present, AFTL analysts would then run the sample on LC/MS #1 as a confirmation and to determine the quantity of Delta-

9 in the sample. A review of the instrument parameters employed by AFTL indicates that the LC/MS #2 had a longer and different gradient program than LC/MS #1. This longer gradient potentially allowed for better separation of compounds thereby giving more qualitative information about the compounds present in a particular sample.

AFTL utilized several quality controls in its testing methodologies to reach a reliable result. These included, but were not limited to, deuterated internal standards, calibration curves, and ion ratio monitoring. An internal standard refers to a known amount of a compound, with a known purity value, that mimics the characteristics (e.g., retention time) of a compound of interest, and can be used qualitatively to identify a compound of interest and quantitatively to confirm the concentration of the compound in a sample. For example, the retention time of a compound in an unknown sample can be compared to the retention time of the standards used in the calibration and quality control samples. The calibration curve is created utilizing the added internal standards by referencing their respective retention times and peak response. This calibration curve is used both qualitatively and quantitatively to identify a substance and the concentration of that compound. By comparing the analyte to the internal standard ratio responses of the unknown sample with the response ratios from the calibration and quality control standards, the analytical procedure can calculate the concentration of the substance in the unknown sample. Additionally, as part of the qualitative verification, ion ratios (i.e., comparisons of the relative abundances of ion characteristic of a compound) are used to confirm the identity of the compound of interest. These types of quality controls were regularly implemented in the qualitative and quantitative analysis of Delta-9 in blood and urine samples submitted to AFTL.

V. CHRONOLOGY AND SUMMARY OF RELEVANT EVENTS

This section provides a chronology and summary of events that are relevant to both the allegations made against AFTL, as well as the findings and conclusions reached by the Investigative Team and outlined in this Report.

A. AFTL began human blood and urine testing in 2016.

In 2016, AFTL[5] expanded its services to include the testing of human blood and urine samples for use in probationary matters and criminal cases involving charges of driving under the influence. At that time, Dr. Karl Larsen ("Dr. Larsen") was the Laboratory Director. Ms. Bash, a former Forensic Scientist at the Illinois State Police Crime Lab joined AFTL in February 2015 as the Senior Analytical Forensic Toxicology Specialist. AFTL hired Ms. Bash specifically for purposes of initiating and developing its human biological testing services. Around the time Ms. Bash was hired, AFTL was divided into two separate sections, one for human testing and the other for equine testing, with certain Analytical Forensic Toxicology Specialists (referred to herein as "analysts") assigned to a particular section.

With respect to human testing, AFTL contracted with law enforcement agencies to provide testing and analysis of human blood and urine samples for the presence of drugs and volatile substances. In 2016, AFTL began reporting quantitative levels of THC and its two main metabolites, Hydroxy-THC and Carboxy-THC. At various times between 2016 and 2024, the following individuals served as analysts on the human testing side of AFTL: Jennifer Bash, Ashley Evers, Emilie Giacobbe, Brendan Heffron, Chikitsa Patel, and Jessica Ramirez.

[5] AFTL is organized within the Department of Pharmaceutical Sciences in the University's Retzky College of Pharmacy. When the lab was originally created, it was engaged only in the forensic testing of equine samples for compliance with horse racing regulations. As such, AFTL was formerly known as the Animal Forensic Toxicology Laboratory.

B. The Farm Bill was passed in December 2018.

In December 2018, the federal Agriculture Improvement Act (Public Law No. 115-334) (the "Farm Bill") was signed into law. The Farm Bill authorized the production of hemp and removed hemp from the definition of marijuana, which is a Schedule 1 illegal substance under the federal Controlled Substances Act. The Farm Bill defined hemp as cannabis and derivatives of cannabis containing no more than 0.3 percent of Delta-9. Illinois also enacted legislation in 2018 that authorized the production of hemp (505 ILCS 89/1 *et seq*.). Under Illinois law, the legal hemp industry is regulated by the state, growers must register with the Department of Agriculture, and the hemp is tested to ensure compliance with the law.

Hemp contains low concentrations of both Delta-9 and Delta-8, but the Farm Bill and the Controlled Substances Act refer only to the concentration of Delta-9 for purposes of distinguishing between hemp and marijuana. As a result, the change in both federal and Illinois law left a "loophole" whereby products containing more significant concentrations of Delta-8 could be chemically derived from hemp (i.e., chemically converted cannabidiol).

C. Illinois State Police raise issue of separating Delta-8 and Delta-9 in 2021.

In or around March 2021, Dr. Larsen received a phone call from Shannon George, who worked at the Illinois State Police's forensic testing laboratory ("ISP"). Mr. George told Dr. Larsen that the ISP had recently begun testing for THC and, within a few months, ISP realized that it was not separating Delta-8 and Delta-9. Mr. George called to inquire as to whether AFTL was successfully separating Delta-8 and Delta-9 when testing blood and urine samples for Delta-9 and, if so, what methodology AFTL was using to do so.

On May 11, 2021, ISP issued a letter addressed to the attention of "State's Attorneys and Law Enforcement Agencies." The letter, which was signed by Mr. George, stated that through a "quality assurance review" of its THC quantitation methodology, ISP "determined that the

methodology may not have been consistently separating" Delta-8 from Delta-9, and "[a]s a result, the blood THC quantitative value reported may reflect a combined quantitative amount for both [Delta-8] and [Delta-9], if both isomers were present."

D. AFTL performs a limited test for separation in March 2021.

After receiving the phone call from ISP, Dr. Larsen instructed AFTL analysts to conduct a test to determine whether AFTL's methodology allowed for the separation of Delta-8 and Delta-9. On March 31, 2021, AFTL performed a limited test run ("March 2021 Test Run") to evaluate its methodologies. The results of the March 2021 Test Run indicated that the methodology used could not adequately separate the isomers in a sample that contained both Delta-8 and Delta-9. Notably, based on the materials reviewed and interviews conducted, it appears that the March 2021 Test Run was limited in that it was performed on only the LC-MS #1, and not the LC/MS #2. This is important because the LC/MS #2 would have been the more appropriate instrument, based on the existing gradient, for determining whether any separation of Delta-8 and Delta-9 could be achieved.

E. AFTL discussions regarding separation of Delta-8 and Delta-9 in 2021 and 2023.

On May 17, 2021, Kara Stefanson of the Cook County State's Attorney's Office emailed Ms. Bash to inquire whether AFTL's "testing allow[s] for the separation of [Delta-8 and Delta-9] in blood" and noted that "ISP has notified its user agencies that their methods in place for the past few years has not allowed for this separation and therefore the final quantitation may not be solely for the Delta-9 isomer." On May 17, 2021, Ms. Bash responded by stating, "We do have a difference in [retention time] for these compounds and we're always willing to do testing for agencies if it's needed." Dr. Larsen was carbon copied on Ms. Bash's response.

On May 20, 2021, Ms. Patel sent an email to Ms. Bash with the subject line: "delta-8 and delta-9 THC quantitation." The body of the email read: "As per this article, we can see two separate peaks for delta-8 and delta-9 in the mixture." The email also included a link to an article that was first published in December 2020, titled "Quantitation of [Delta-8-THC], [Delta-9-THC], Cannabidiol and 10 Other Cannabinoids and Metabolites in Oral Fluid by HPLC-MS-MS." That article presented a study demonstrating and validating a method for complete separation of Delta-8 and Delta-9 isomers on an LC/MS/MS instrument.

In March 2023, Ms. Bash and Dr. Larsen exchanged email communications in which they discussed the issue of separating Delta-8 and Delta-9. This discussion was prompted by a question from the Carol Stream Police Department to Ms. Bash as to whether AFTL had the capability to test products to determine whether they contained Delta-8 or Delta-10-THC.[6] On March 9, 2023, Ms. Bash told Dr. Larsen that, based on previous testing done "on the LC," they were unable to "see the difference when [Delta-8] was mixed" with Delta-9. Ms. Bash explained that if AFTL wanted to pursue the type of testing prompted by the Carol Stream Police Department, then AFTL "should get new standards and test out if it's possible to see them when it's in a mixture."

On September 18, 2023, Sabra Jones of the National Highway Traffic Safety Administration sent an email to Ms. Bash, along with representatives of other regional forensic laboratories, to gather information relating to what "labs are targeting for their cannabinoid method as well as any interferences that folks are aware of." Ms. Bash responded to this email the same day, stating: "In tox samples we screen for Delta-9, 11-OH, and carboxy. We only quantify Delta-9 and 11-OH. We have the capability to distinguish between Delta-9 and Delta-8 on the LCQQQ."

[6] Delta-10 is another THC isomer that naturally occurs in trace amounts in marijuana and hemp plants.

F. College of Pharmacy begins to analyze financial viability of AFTL.

Beginning in 2022, after AFTL had sustained a series of annual revenue shortfalls, the University's Retzky College of Pharmacy (the "College") began to evaluate the overall financial viability of AFTL moving forward. In 2022 and 2023, the College attempted to alleviate the financial burden of AFTL by implementing certain cost-cutting measures. By way of example, in or around April 2023, AFTL was relocated from an off-campus site to a building within the College in order to eliminate additional rent payments.

G. Ms. Bash resigns after AFTL announces it will cease human testing.

In late June 2023, discussions began internally at the College of Pharmacy regarding a potential reduction in staff on the human testing side of AFTL as a further cost-cutting measure. These discussions developed and culminated in the determination, in October 2023, not to renew human testing contracts and not to reappoint human testing staff. That decision was made before University or College officials were made aware of the allegations that are the subject of this Report. The College subsequently approved a deficit-reduction plan for AFTL in mid-October 2023. After Ms. Bash was notified that human testing would cease at AFTL, she resigned her position at AFTL, effective February 1, 2024. AFTL discontinued testing of human biological samples effective February 5, 2024.

H. CAPA relating to Delta-8 and Delta-9 separation is opened in March 2024.

In March 2024, Mr. Heffron opened a CAPA[7] ("March 2024 CAPA") in response to an inquiry from a criminal defense attorney "about validation data for [AFTL's] THC quantitation methods" and "specifically the laboratory's method's ability to distinguish Delta-8 and Delta-9."

[7] A CAPA is a form used by AFTL to identify and develop a plan for responding to an issue within the lab in need of correction or prevention. The form calls for an analysis of the "root cause" of the issue, a detailed "corrective/preventative action," and a plan for monitoring the corrective or preventative action prescribed.

The March 2024 CAPA stated that a search for "any validation data confirming that the analysis methods can separate the two isomers" was performed, but AFTL was "unable to locate it."

In furtherance of the March 2024 CAPA, a limited test run was performed in which Delta-8 and Delta-9 were run together on both LC/MS #1 and LC/MS #2. The test run showed "a lack of baseline separation between the two peaks," a difference in retention times of 0.2 minutes, and "approximately 40% peak overlap." Based on those results, the March 2024 CAPA stated: "In short, we are unable to distinguish between the two isomers using the current methods. It is unknown how many cases this may have affected as we used this method to report the Delta-9 THC isomer concentration since May 2018."

I. Dr. Larsen issues letter to law enforcement agencies in May 2024.

On May 16, 2024, Dr. Larsen published a letter addressed to the offices of the Illinois State's Attorney (the "May 2024 Letter"). In the May 2024 Letter, Dr. Larsen states, in relevant part:

> A recent quality assurance review of the instrumental methods used for the detection and quantitation of THC in 2024 has determined that the methodologies may not have been effectively separating the Delta-8-THC isomer from [the] Delta-9-THC isomer in some cases. As a result, the THC detection and quantitative value reported may reflect a combined amount of both Delta-8-THC and Delta-9-THC, if both isomers were present. This could be important if the person whose body fluid was analyzed has concurrently consumed a product with Delta-8-THC and a product containing Delta-9-THC.

VI. ASSESSMENT AND ANALYSIS OF THE ALLEGATIONS

The findings set forth below are based on the Investigative Team's extensive review of documents received from AFTL, the information derived from interviews of the witnesses identified above, and the opinions, observations, and information offered by Dr. Michael Coyer over the course of numerous meetings and discussions.

A. The allegation that AFTL used flawed methodologies in testing for the presence of Delta-9 in human bodily substances, specifically blood and urine, is unfounded.

It has been alleged that AFTL used flawed methodologies to detect the presence of Delta-9 in human blood and urine. This allegation is unfounded. AFTL used appropriate methodologies and laboratory equipment to detect the presence of Delta-9 in human blood and urine samples.

Based on expert review of AFTL's SOPs, as well as a subset of AFTL lab reports, AFTL's preparation of blood and urine samples to screen and test for the presence of Delta-9 was appropriate. This includes AFTL's extraction procedures, calibration and quality control sample preparation, and use of internal standards, retention times, and ion ratios. After preparing the samples, AFTL utilized scientifically acceptable toxicological testing methodologies to identify the presence of Delta-9 in urine and blood samples.

The testing protocol for urine was necessarily different than for blood because, unlike blood, urine is a human waste processed through the kidneys and liver and no longer in circulation in the body. This excretion process adds an element to the Delta-9 isomer in urine known as glucuronide. When testing for Delta-9 in urine, AFTL properly utilized a process known as hydrolysis to remove the glucuronide to reveal the presence of Delta-9. Hydrolysis does not alter the underlying Delta-9. Rather, it simply removes the glucuronide in order to detect the Delta-9. Stated more precisely, AFTL analysts appropriately used hydrolysis when testing urine samples where the major urinary metabolite excreted was the conjugated glucuronide-carboxy-THC based on the pharmacokinetics of THC in the body. The hydrolysis freed the glucuronide conjugate attached to the carboxy-THC, leaving the "free" carboxy-THC to be analyzed by the LC/MS instruments. Had AFTL not utilized hydrolysis in the testing of urine for the presence of THC metabolites, the analytical result would yield very low or possibly an immeasurable amount of

THC metabolites based on the pharmacokinetics of THC. Analysts appropriately and necessarily utilized the process of hydrolysis in order to detect Delta-9 in urine.[8]

With respect to blood samples, AFTL analysts examined Delta-9 and/or hydroxy-Delta-9 components as the "free" component. Blood samples to be tested for the presence of Delta-9 were processed in the LC/MS #2 instrument after applying the proper extraction techniques, sample preparation, and calibration standards, including the use of isotopically labelled internal standards, quality control samples, and ion ratios for Delta-9. This methodology, as implemented by AFTL analysts, was a scientifically accepted methodology for identifying the presence of Delta-9 in a human blood sample.

B. The allegation that AFTL used flawed methodologies when quantitating Delta-9 in human bodily substances is unfounded before hemp-derived Delta-8 products became available to the general public. The allegation is founded once AFTL was aware or should have been aware of the availability of such products.

The timing of a given lab result for the quantitation of Delta-9 is a critical consideration in assessing whether the methodologies used in the subject test were flawed. This is because in 2018, laws changed both federally and in Illinois allowing for hemp-derived Delta-8 consumer products, including edibles, oils, and vaping products, to become commercially available to the general public. Delta-8 is not naturally present in significant amounts in plant-based marijuana, and before these changes in the law, consumable products with significant amounts of Delta-8 were not widely available to the general public. Thus, prior to these changes in the law, AFTL's THC testing methodologies, which did not specifically test for the presence of Delta-8 in human samples, were scientifically acceptable.

[8] The relevant Illinois statute specifically allows for the use of urine in testing for the concentration of Delta-9 in furtherance of criminal prosecutions for driving while under the influence. 625 ILCS 5/11-501.2(a) (evidence of Delta-9 concentration, "as determined by analysis of the person's blood, urine, breath, or other bodily substance, shall be admissible").

However, as the availability and use of the these new hemp-derived Delta-8 products rose, AFTL should have altered its methodologies to detect the presence of Delta-8 and, where present, eliminate the potential interference of Delta-8 in the quantitation of Delta-9. AFTL did not do so. That said, AFTL's failure to properly screen for and completely separate Delta-8 does not render AFTL's Delta-9 quantitation results and reports unreliable per se. The reliability of AFTL's quantitations of Delta-9 may be confirmed on a case-by-case basis with reference to various forensic data points, which are discussed in greater detail below.

As explained above, the legalization of hemp under both federal and Illinois law in 2018 facilitated the rise of legal and commercially available products containing significant concentrations of Delta-8. Once these hemp-derived Delta-8 products became commercially available to the general public, it was incumbent upon AFTL to account for the potential presence of Delta-8 in the human samples it was asked to test because the presence or absence of Delta-8 became a potentially relevant data point. More specifically, once AFTL became aware or should have been aware that hemp-derived Delta-8 products were commercially available to the general public, it was incumbent upon AFTL to ensure that its methodologies could properly identify the presence of Delta-8 in a sample and properly separate the Delta-8 and Delta-9 isomers to reach a reliable Delta-9 quantitation result.

In response to an inquiry from ISP, AFTL performed the March 2021 Test Run, which indicated that the methodology AFTL used could not adequately separate the isomers in a sample that contained both Delta-8 and Delta-9. In the two years following the March 2021 Test Run, AFTL staff members engaged in multiple discussions, both internally and with individuals outside AFTL, regarding the lab's ability to separate Delta-8 and Delta-9. However, the Investigative Team found no evidence that AFTL ever considered implementing changes, nor did it find

evidence that AFTL analysts understood the limitations of the methodologies used by the lab in quantitating Delta-9.

It remains unclear why AFTL's leadership did not appreciate the significance of the issue and modify its methodologies either in March 2021 or thereafter. The necessary changes to the methodologies would not have required a major overhaul of the lab, the lab would not have needed to shut down for any significant period of time, and the analysts would not have required extensive training to implement the changes in methodologies. AFTL could have utilized Delta-8 controls to screen for the presence of Delta-8 in test samples, and it could have eliminated any potential interference by Delta-8 in the quantitation of Delta-9 by extending the gradient to allow for complete separation of the isomers to baseline. Based on the materials reviewed and the witnesses interviewed by the Investigative Team, AFTL did not make these corrections to its methodologies in March of 2021, or at any time thereafter. Its failure to do so is a flaw that could negatively affect the reliability of a given Delta-9 quantitation result.

Notwithstanding the flawed methodologies, AFTL's Delta-9 quantitation results cannot be considered unreliable per se. This is because the testing protocols utilized by AFTL to quantitate Delta-9 generated significant data that, on a case-by-case basis, may account for or eliminate any potential interference of Delta-8 in the quantitation of Delta-9 and confirm a scientifically reliable result. The relevant factors to be analyzed to determine the reliability of a given Delta-9 quantitation are discussed in detail in Section VI. D. below.

C. After the emergence of commercially available hemp-derived Delta-8 products, it is possible that AFTL's Delta-9 quantitation results were artificially inflated due to AFTL's failure to rule out the potential interference of Delta-8.

After the emergence of hemp-derived Delta-8 products on the commercial market, it is possible that AFTL's Delta-9 quantitation results could have been inflated if Delta-8 was present

in a given sample. In other words, by failing to rule out the presence of Delta-8 and/or properly separate Delta-8 from Delta-9 after the emergence of the Delta-8 market, it is possible that the quantitation results for Delta-9 reported by AFTL may have included (i.e., counted) Delta-8.

This does not mean, however, that all of AFTL's Delta-9 quantitation results are unreliable, even after the emergence of commercially available Delta-8 products. Instead, and as discussed in further detail below, the reliability of results may be confirmed on a case-by-case basis, with reference to the specific analytical findings and data points, as well as certain external and evidentiary factors.

D. AFTL results reporting quantitative values of Delta-9 may be scientifically reliable despite the flawed methodology, and reliability should be evaluated on a case-by-case basis.

Because AFTL did not use the proper gradient as part of its standard methodology for the quantitation of Delta-9, it did not, as a matter of course, separate Delta-8 and Delta-9 to baseline. It does not follow, however, that AFTL's Delta-9 quantitation results are necessarily unreliable. This is because, among other reasons, the methodologies used by AFTL allowed for some separation that, while not complete, may still provide qualitatively significant data. In other words, there may be data generated by AFTL's methodologies that, when reviewed on a case-by-case basis, may be determinative of whether Delta-8 could have been present in a given sample. For example, as discussed above, the LC/MS #2 instrument generates data, such as retention times and ion ratios, that can provide valuable information in furtherance of the reliability of a particular result. Relatedly, the shape of a Delta-9 peak and the appearance, or lack of, any "hump" or "shoulder" may provide valuable information regarding the presence and/or potential interference of Delta-8 in a given sample.

There is also certain external information and evidence that may be relevant in confirming, on a case-by-case basis, whether a Delta-9 quantitation result is reliable or whether there is the

potential for inflation by coexisting Delta-8. Such information includes the timing of a particular sample, as well as whether there is any evidence collected by law enforcement indicating that an individual smoked marijuana or consumed a synthetic Delta-8 product (such as edibles, oils, or vaping products). The timing of a particular sample is critical because, as discussed above in Section VI. B., a sample taken prior to the rise in commercially available Delta-8 products is highly unlikely to contain significant levels of Delta-8, and therefore, the quantitation of Delta-9 in such a sample is highly unlikely to be inflated by Delta-8.

Any evidence regarding an individual's THC consumption could also be critical in determining the effect of any potential Delta-8 interference. For example, if a criminal case file contained evidence that an individual only smoked marijuana (i.e., plant-based cannabis), the potential for any inflated Delta-9 quantitative result would be minimal and insignificant. This is due to the fact that the THC in plant-based cannabis contains anywhere from approximately 3-30 percent Delta-9, while it typically contains Delta-8 in a significantly lower range of 0.1-1.0 percent. So, in a case involving evidence of smoked marijuana, the potential prevalence of Delta-8 is likely to be so insignificant as to not affect the reliability of a Delta-9 quantitative test result. On the other hand, if there is evidence in a case file that an individual used a product that was or could have been fortified with Delta-8, there is a greater possibility that any quantitation of Delta-9 in that sample could be inflated by the presence of Delta-8.

In sum, while AFTL's failure to separate Delta-8 and Delta-9 to baseline was a flaw in its methodology, the Delta-9 quantitative results reported by AFTL cannot be summarily dismissed as inherently inaccurate or unreliable. The qualitative data and any additional external evidence must be reviewed to evaluate, on a case-by-case basis, the reliability of AFTL's reported THC testing results.

E. The March 2024 CAPA was insufficient for what it was designed to test, and its conclusions are overbroad, incomplete, and misleading.

The limited test run that was the subject of the March 2024 CAPA was hastily designed and performed. It failed to account for the manner in which Delta-8 and Delta-9 are present in real-world human samples and, as a result, it yielded results that do not accurately represent the data AFTL would have typically encountered when performing THC testing. Moreover, the conclusions in the March 2024 CAPA that AFTL is "unable to distinguish between [Delta-8 and Delta-9] using current methods" and that "[i]t is unknown how many cases this may have affected" were overbroad, incomplete, and misleading. Further analysis should have been conducted and a more in-depth explanation of the data derived from AFTL's methodologies should have been provided.

The March 2024 test run was flawed in that it only tested one sample that was prepared with equal concentrations of both Delta-8 and Delta-9 isomers (i.e., 50 percent Delta-8 and 50 percent Delta-9). Delta-8 and Delta-9 do not present in equal concentrations in marijuana plants, and, even when accounting for the range of THC products commercially available, it would not be typical for AFTL to test a human sample in which Delta-8 and Delta-9 would present in equal concentrations. Moreover, even if some useful information could be gathered from analyzing a 50/50 sample, the test should have been repeated with samples containing different concentrations so that additional analysis could be performed.

The March 2024 CAPA's conclusion that AFTL is "unable to distinguish between [Delta-8 and Delta-9] using current methods" is problematic in two significant respects. First, that statement is not an entirely accurate representation of what the subject test run showed. The test run that was performed on LC/MS #2 showed enough separation to demonstrate at least some difference between the two isomers. Moreover, when the CAPA acknowledges that there was a

difference in retention time of 0.2 minutes between Delta-8 and Delta-9, it necessarily acknowledges some differentiation of Delta-8 and Delta-9. It was therefore overbroad and inaccurate to conclude, based on that single run, that AFTL's methodologies could not distinguish between Delta-8 and Delta-9 *at all*.

Second, the March 2024 CAPA's conclusion is incomplete in that it should have explained the importance of the relative Delta-8 and Delta-9 concentrations in a given sample to determining whether separation to baseline is necessary for and/or significant to AFTL's ability to provide reliable Delta-9 quantitations. The test run should have been repeated using samples with different concentrations of the two isomers to demonstrate what data the LC/MS #2 could produce regarding separation and peak shape and size, with the particular gradient being utilized. As noted above, it would be unlikely for AFTL to encounter a real-world sample that contained equal concentrations of Delta-8 and Delta-9, and therefore, one test run of such a sample was insufficient to draw a firm conclusion about AFTL's ability to generate reliable results. Additional samples with relative Delta-8 and Delta-9 concentrations mimicking what AFTL would typically encounter in a real-world sample would have allowed for a more complete and useful analysis.

The March 2024 CAPA's statement that "[i]t is unknown how many cases this may have affected" could also be misconstrued. That statement, without any further context or explanation, could suggest that the results of the limited test run indicated that the reliability of AFTL's Delta-9 quantitative results could be called into question en masse. That is not accurate for all the reasons explained in the preceding sections of this Report. As previously described in detail, the reliability of any given test result may be determined on a case-by-case basis with reference to the numerous data points identified herein.

In sum, the March 2024 CAPA confirmed that the gradient AFTL used in its THC testing methodology was insufficient to separate Delta-8 and Delta-9 to baseline. However, there were deficiencies in the way the subject test run was performed, and as a result, the March 2024 CAPA's conclusions were not wholly accurate and, ultimately, could be misleading as they relate to the reliability of AFTL's Delta-9 quantitative results.

F. The Investigative Team found no evidence that AFTL was aware of inaccurate test results and failed to disclose this information to law enforcement and prosecuting authorities in violation of disclosure obligations.

The Investigative Team found no evidence, direct or indirect, to support the allegation that AFTL and its analysts knowingly provided inaccurate laboratory results to law enforcement entities to be used in criminal proceedings. Further, the Investigative Team did not find any evidence to indicate that AFTL and its analysts knew that its methodologies produced inaccurate results at any time, even after the market for Delta-8 products emerged.

The March 2021 Test Run is significant because it was performed in response to questions raised about AFTL's ability to differentiate Delta-8 from Delta-9 in THC testing. While those questions may, or even should, have illustrated that Delta-8 was becoming a relevant factor in the field, there is no evidence that AFTL knew that its methodologies were flawed in such a way that could have rendered its results unreliable, nor is there evidence that AFTL knowingly failed to disclose any flaw in its methodologies to law enforcement or prosecuting authorities.

The March 2021 Test Run was of limited value on its face because it was not a method validation study aimed at creating or modifying testing methodologies, nor was it intended to be. In addition, the Test Run was performed on only the LC/MS #1, when the LC/MS #2 should have been used if the purpose was to determine whether Delta-8 could be separated from Delta-9 for purposes of quantitation. Further, there is no evidence that AFTL actually analyzed the implications of the March 2021 Test Run or used the results of the Test Run to develop a method

validation study relating to the separation of Delta-8 and Delta-9. The lab analysts interviewed by the Investigative Team stated that they were not aware of the results of the March 2021 Test Run, and there is no evidence the significance or results of that Test Run were discussed internally by the leadership of AFTL (i.e., Dr. Larsen, Mr. Heffron, and Ms. Bash). The Investigative Team did not find any evidence that any analysts believed it was necessary to develop a new methodology to ensure separation of Delta-8 from Delta-9.

As described above, the Investigative Team reviewed email correspondence in which AFTL staff members reference the March 2021 Test Run and generally discuss the issue of separating Delta-8 from Delta-9. These emails may provide some insight into how AFTL viewed the March 2021 results and the efficacy of its methodologies, but there is limited context and the messages communicated in the emails are at times contradictory, or at the very least, open to interpretation. For example, in an email exchange in March of 2023, Dr. Larsen stated that he recalled the March 2021 data showed a lack of separation. In September of 2023, however, Ms. Bash responded in an email to a question regarding AFTL's methodologies by stating that AFTL had the ability to distinguish between Delta-8 and Delta-9, and that she was working on further developing related methodologies.[9] Unfortunately, Ms. Bash, who likely could have offered additional insight as to the results of the March 2021 testing and any analysis or other discussions that occurred as a result, declined numerous requests from the Investigative Team to be interviewed.

The lack of consensus as to what, if anything, AFTL learned from or did as a result of the March 2021 testing or the other discussions regarding separation of Delta-8 suggests that AFTL did not know that its methodologies were flawed. Greater analysis, review, and collaboration by

[9] The Investigative Team found no evidence of the work to which Ms. Bash referred.

AFTL leadership was warranted based on concerns raised by the ISP and others related to separation of the isomers. But, the lack of any corrective action taken in March 2021 or anytime thereafter suggests either that AFTL was satisfied that it was able to obtain separation, or that it did not appreciate the need to test for, and separate, Delta-8 from Delta-9 once the Delta-8 consumer market emerged. It is also possible that AFTL's leadership simply did not review the results of the March 2021 Test Run for the purpose of evaluating its THC testing methodologies.

To be clear, AFTL leadership missed the significance of the issue when legitimate concerns were first raised by the ISP in 2021, and thereafter as increased discussion was taking place in the scientific community regarding the need to separate Delta-8 and Delta-9. Greater attention to and clarification regarding this issue by AFTL leadership was warranted.

However, the fact that AFTL missed the significance of this issue does not support the allegations that AFTL knew its methodologies and/or test results were flawed and suppressed that knowledge from law enforcement or prosecuting authorities. The Investigative Team found no evidence of an intentional or deliberate attempt to mislead or report flawed test results. Rather, the Investigative Team found a fundamental lack of attention to the impact of the evolving Delta-8 consumer market to its THC testing methodologies.

G. Allegations that AFTL performed testing on human biological samples without being properly accredited are unfounded.

It has been alleged that the AFTL performed THC testing on human samples without accreditation. This allegation is unfounded. AFTL received its accreditation from ANAB, and at all relevant times, ANAB certified that the AFTL met the requirements of the applicable testing and competence standards.

As relevant here, ANAB's stated goal is to provide third-party assurance of the quality of forensic testing laboratories by evaluating laboratories' technical competence and methodologies

for compliance with ISO/IEC17025 ("ISO"), an internationally recognized standard of laboratory testing. Generally, the requirements of ISO relate to: (1) the laboratory's commitment to impartiality and confidentiality in its activities; (2) structural requirements related to the range of activities, management structure, roles and responsibilities of personnel, and documented procedures which ensure the consistent application of activities and the validity of results; (3) resource requirements related to lab personnel, including training, competency testing, and ongoing monitoring of personnel to ensure competence; (4) process requirements related to the handling of test and calibration actions in a manner to maintain the integrity of the work; and (5) management systems requirements related to policies and objectives appropriate for the scope of activities. ANAB evaluates laboratories for accreditation using subject matter experts with experience in the specific forensic discipline of the laboratory seeking accreditation.

On March 3, 2015, ANAB issued a certificate extending the scope of the accreditation that ANAB had previously issued to AFTL to include forensic testing on human samples. That certificate of accreditation was valid through March 10, 2018. Based on additional reviews and audits of AFTL, ANAB renewed its certification of AFTL's accreditation in 2018 and 2022, and each of those certifications were valid for a period of four years. In each instance, ANAB certified that it assessed AFTL and determined that AFTL met the requirements of the ISO "while demonstrating technical competence in the field of forensic science testing." In sum, AFTL was properly accredited by ANAB for forensic testing of human samples through February 5, 2024, when AFTL terminated its human testing services.

H. The Investigative Team found no evidence to suggest that AFTL analysts knowingly provided false testimony in criminal proceedings.

Ms. Bash was the primary lab analyst to provide testimony in criminal proceedings, and in particular, criminal proceedings involving AFTL's Delta-9 quantitation results. Ms. Patel, Ms.

Ramirez, and Mr. Heffron also testified in such criminal cases on a more limited basis. According to the interviews conducted, Ms. Giacobbe and Ms. Evers never testified in any matter stemming from their employment at AFTL. Based on its review of all of the material and its interviews with cooperating witnesses, the Investigative Team found no evidence to indicate that any AFTL analyst knowingly provided false testimony regarding AFTL's Delta-9 quantitation results in a criminal proceeding.

On one occasion, ANAB raised an allegation, through its audit process, that Ms. Bash gave "untruthful, inaccurate, and unqualified testimony." The allegation of "inaccurate and unqualified" testimony was based on "communications and testimony" in which Ms. Bash used the term "scientifically under the influence" when discussing test results. That was problematic in ANAB's view because that phrase could "reasonably be misunderstood as meaning 'impairment,'" and Ms. Bash and other analysts were not qualified to make a determination as to "impairment" because "the timeframe during which an individual consumed THC can vary based on frequency of use." Therefore, ANAB determined that "the allegations related to inaccurate and unqualified testimony have merit."

However, ANAB determined that the specific allegation of "untruthful testimony" was "without merit." That allegation related to testimony regarding the chemical composition of Delta-9 in urine. ANAB determined that Ms. Bash did not provide untruthful testimony because "[t]he law is silent on the form of [Delta-9], thereby treating conjugated and free [Delta-9] the same in urine."

None of the allegations raised by ANAB related in any way to the allegations regarding AFTL's THC testing methodologies and lab results. As previously stated, the Investigative Team's numerous efforts to interview Ms. Bash were unsuccessful. The Investigative Team continues to

believe that the investigation would be more complete if Ms. Bash cooperated with the investigation because she was the lead analyst during the relevant time period, she reported directly to Dr. Larsen, and she trained the analysts in the relevant methodologies. However, based upon the documents reviewed and the witnesses interviewed, there is no evidence to support the allegation that Ms. Bash knowingly provided false or inaccurate testimony in any criminal proceeding.

I. Allegations that AFTL ceased testing on human biological samples due to the laboratory's purported shortcomings are unfounded.

AFTL is a part of the College of Pharmacy. The decision to terminate the human testing side of AFTL was made by University officials within the College for two primary reasons: (1) the human testing side of AFTL no longer supported educational curriculum offered by the College; and (2) the human testing side of AFTL was not financially viable.

The decision to cease human testing was made jointly by Glen Schumock, the Dean of the College, Dale Rush, the Associate Dean for Administrative Affairs for the College, and Nancy Freitag, Head of the College's Department of Pharmaceutical Sciences. The decision-making process began in 2022, well before any allegations against AFTL were made known to the decision-makers.

For years, AFTL had sustained revenue shortfalls on the human testing side, which was supported by the College because that side of the lab provided some educational value for students enrolled in the University's Forensics Masters and PhD programs. In December 2022, the College decided to suspend its Masters of Science program, and over the course of 2022 and 2023, additional cost-cutting measures were implemented to ease the financial burden AFTL placed on College resources. For example, in or around April 2023, Department officials decided to relocate the laboratory from an off-campus site to a building within the College in order to eliminate

additional rent payments. Additionally, in late June 2023, discussions were held regarding a reduction in staff on the human side of AFTL as a further cost-cutting measure. These discussions culminated in the determination, made in October 2023, not to renew human testing contracts and not to reappoint human testing staff. The College subsequently approved a deficit-reduction plan for AFTL in mid-October 2023. After Ms. Bash was notified that human testing would cease at AFTL, she resigned her position at AFTL, effective February 1, 2024.

While concerns related to the separation of Delta-8 and Delta-9 for quantitative purposes became a greater focus within AFTL in or around March and April 2024, College officials were as yet unaware of any of the allegations made against AFTL. The decision to discontinue human testing at AFTL, effective on February 5, 2024, was the culmination of a process, which began in 2022, that weighed the financial burden of AFTL's human testing along with the decision to suspend the forensic science programs at the College. The allegations that AFTL closed human testing due to issues related to flawed methodologies are unfounded.

VII. CONCLUSION

In sum, while AFTL's testing methodologies did not allow for the complete separation of the Delta-8 and Delta-9 isomers, that does not mean that the Delta-9 quantitation results reported by AFTL can be summarily dismissed as inherently inaccurate or unreliable. Prior to the commercial availability of consumable hemp-derived Delta-8 products in or after 2019, AFTL's THC testing methodologies were appropriate and met accepted scientific standards. Once AFTL became aware or should have been aware that consumable hemp-derived Delta-8 products became available on the commercial market, AFTL should have modified its methodologies to allow for the complete separation of Delta-8 and Delta-9. Nonetheless, even after Delta-8 became a potentially relevant factor, AFTL's methodologies generated significant data that, when reviewed

on a case-by-case basis, may account for or eliminate any potential interference of Delta-8 in the quantitation of Delta-9 and confirm a scientifically reliable result.

AFTL leadership missed the significance of the issue despite legitimate concerns being raised and discussions occurring regarding this issue between 2021 and 2023. However, the Investigative Team found no evidence that AFTL knew its methodologies and/or test results were flawed and suppressed that knowledge from law enforcement or prosecuting authorities, nor did it find any evidence of an intentional or deliberate attempt to mislead or report flawed test results.