Department of Health and Human Services (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Center for Substance Abuse Prevention (CSAP)

Drug Testing Advisory Board

December 3, 2024

Minutes – Open Session

SAMHSA's CASP Drug Testing Advisory Board (DTAB) convened on December 3, 2024, at 10:00 a.m.

In accordance with the provisions of Public Law 92-463, the virtual meeting was open to the public from 10:00 a.m. to 2:30 p.m.

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Board Members in Attendance
Ronald Flegel, MT(ASCP), M.S., Chairman
David Engelhart, Ph.D., D-ABFT-FD
Elizabeth Stuyt, M.D.
David K. Roberts, Ph.D., F-ABFT
E. Lindsey Everson, J.D.
Dawn Hahn, M.B.A., MT(ASCP), D-ABFT
Bryan Ruggery, M.F.S.
Michael Grommes, D-ABFT-FD
Samantha S. Tolliver, Ph.D.
Carl Christensen, M.D.
Bonnie A. Droter, B.B.A.

Ex Officio Members in Attendance
Joseph Kotarek, Ph.D. (U.S. Food and Drug Administration)
Bohdan Baczara, M.B.A. (Department of Transportation [DOT])
Brian Zaleski (U.S. Nuclear Regulatory Commission [NRC])
Lynn Wagner, Ph.D. (Department of Defense)

Designated Federal Officer
Lisa S. Davis, M.S., (SAMHSA)

Presenters
Bohdan Baczara, M.B.A. (DOT)
Brian Zaleski (NRC)
Ronald Flegel, MT(ASCP), M.S. (SAMHSA)
Eugene Hayes, Ph.D., M.B.A. (SAMHSA)
E. Dale Hart (National Laboratory Certification Program)

Call to Order and Approval of June 2024 DTAB Minutes

Lisa S. Davis, M.S., Designated Federal Officer (DFO), DTAB
CSAP, SAMHSA

DFO Ms. Lisa S. Davis called the meeting to order and welcomed participants. She announced that the virtual meeting was open to the public and thanked the board, *ex officio* members, and presenters for their service. Ms. Davis called the roll and confirmed that a quorum was present. She noted a correction to a presentation made at the June 4, 2024, meeting: Slide 15 of Dr. R. H. Barry Sample's presentation (a comparison of the various oral fluid assays currently available), has been corrected to show the appropriate color coding of the table displayed after a change to one cutoff. Board members were provided with the correction as part of their review, and the minutes of the June 4, 2024, meeting reflect the change. She invited questions or comments on the correction and hearing none, invited a motion to approve the minutes of the June 4, 2024, meeting. A motion to approve was made and seconded, and the minutes were unanimously approved. The December meeting summary and any public comments will be posted on the DTAB website. Ms. Davis reviewed the agenda for the meeting and invited Mr. Ron Flegel, DTAB Chairman, to offer opening remarks.

Welcome and Introductory Remarks

Ron R. Flegel, B.S., MT (ASCP), M.S., Chairman, DTAB
Director, Division of Workplace Programs (DWP), CSAP, SAMHSA

After thanking the board members and federal partners for their time and commitment, Mr. Flegel explained that SAMHSA continually strives to maintain and improve the quality of performance in the National Laboratory Certification Program (NLCP) and the Federal Drug-Free Workplace Program (DFWP). Program efforts include the expansion of HHS-certified laboratories for drug testing. For example, the Gap Analysis Program assists oral fluid and urine laboratories interested in applying for HHS certification. The NLCP also offers training opportunities for staff at HHS-certified laboratories.

DWP's standards for laboratory certification extend to nonregulated drug testing sectors. DWP standardized the cutoffs for urine and oral fluid drug testing. The program developed innovative ideas and collaborated with federal partners and industry leaders to improve the quality of testing and laboratory services. DWP is currently implementing various action plans in response to the Comprehensive Review. Mr. Flegel noted that he would discuss and present current and future challenges later in the meeting.

The DFWP serves as the gold standard for scientific and forensic integrity in workplace drug testing, as it has withstood many legal challenges. The DFWP is based on a trusted network of laboratories and robust partnerships. Although there have been challenges, the DFWP has built a solid reputation for valid and fair drug testing that serves as a deterrent to substance use. The program continues to consider suggestions for changes to the drug testing panel regarding removing MDMA and MDA. DWP will move forward with adding fentanyl. DWP reviewed the cutoff concentrations for most collection devices, as well as the sensitivity of current oral

fluid immunoassays. DWP recommends a cutoff concentration of 4 ng/mL for an initial oral fluid test for fentanyl, and the confirmation cutoff remains at 1 ng/mL. The screening and confirmation cutoffs for a urine test for fentanyl remain at 1 ng/mL.

The notice of Proposed Mandatory Guidelines for Hair (HMG) was published in the *Federal Register* on September 10, 2020, and the public comment period ended on November 9, 2020. DWP and DTAB reviewed all public comments and recommended revisions to the Proposed HMG, currently under review at the Office of Management and Budget (OMB). The most recent Mandatory Guidelines for Oral Fluid were published on October 12, 2023, with an effective date of October 10, 2023. The most recent Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on October 12, 2023, with an effective date of February 1, 2024. NLCP notices were sent that directed HHS-certified laboratories to implement the changes on February 1, 2024, for Federal agency specimens only. DWP is working with its federal partners to incorporate the latest revisions that were in the Urine Mandatory Guidelines. A comprehensive approach to federal drug testing is needed for the program to be effective. Such a program must include testing for adulteration and substitution, as well as use multiple matrices. Mr. Flegel emphasized that DWP will continue to work with both the U.S. Food and Drug Administration (FDA), device manufacturers and laboratories to advance the use of oral fluid drug testing as quickly as possible. DWP has asked that laboratories proposing to apply for certification proceed with validation of related devices, immunoassays, and their program applications.

Mr. Flegel elaborated on some topics discussed during the June 4, 2024, meeting. Regarding Ms. D. Faye Caldwell's presentation on the steps to take when considering oral fluid testing from the perspective of multiple stakeholders, he stressed that DWP is ready to offer assistance and guidance. Additionally, DWP is working with stakeholders and federal partners to expedite the availability of reagents to facilitate oral fluid testing. Mr. Flegel noted that his remarks offered a brief synopsis and that he would provide additional detail later in the meeting. He closed by thanking participants and presenters.

Department of Transportation (DOT) Update

Bohdan Baczara, MBA, Deputy Director, Office of Drug and Alcohol Policy and Compliance, DOT

Mr. Baczara reviewed DOT drug testing data (laboratory only) for marijuana, amphetamine, opioids, cocaine, and PCP covering the six-month period from January to June 2024. Approximately 3.4 million tests were completed during this timeframe. When compared to the previous six months (July to December 2023), the number of positive tests decreased from 2.3% to 2.23%. In fact, positive rates decreased for most drugs, although amphetamine was an exception (increasing from 0.77% to 0.79%). Rates of rejected (fatal and uncorrected flaws) and tampered-with tests also decreased during this period.

Regarding DOT's testing data from 2014 to 2024, Mr. Baczara noted that the rate of positive tests for opioids has been declining steadily since 2018, when DOT implemented testing for four semi-synthetic opioids (i.e., hydrocodone, oxycodone, hydromorphone, oxymorphone). The

number of samples that were rejected or tampered with also decreased during that same 10-year period. Marijuana was the most prevalent drug identified in positive tests, followed by amphetamines, opioids and opiates. Mr. Baczara said that although the rate of positive tests for marijuana had been increasing over several years, it has declined during the past 6 months. In addition, while the rate of tests positive for cocaine had been steady over several years, it had also decreased in the past six months. Rates for tests that were rejected, invalid, and substituted also have fallen recently. Historically, the percentage of adulterated tests has been low and remains so.

In his update on the Office of Drug and Alcohol Policy and Compliance's (ODAPC) rulemaking, Mr. Baczara reported that a Notice of Proposed Rulemaking (NPRM) was published on October 15, 2024. This NPRM proposes to amend DOT's regulations for conducting workplace drug and alcohol testing for the federally regulated transportation industry to allow electronic signatures, forms, and record storage. Mr. Baczara encouraged feedback on the NPRM. Public comments close on December 16, 2024.

A Technical Amendment to Part 40 was published in the *Federal Register* on June 21, 2024, to clarify certain provisions of the rule and address the clarifications and omissions that DOT became aware of since publication of the final rule. Two additional rules were also published on June 21, 2024. Both documents provide three things: 1) temporary qualification requirements for mock oral fluid collectors, 2) consistency with respect to who may be present during an oral fluid collection and 3) clarification on how collectors are to document that a sufficient volume of oral fluid has been collected. The final rule would have been effective August 1, 2024, unless adverse comments were received. Since adverse comments were received, DOT withdrew the direct final rule on August 1, 2024, addressed the issues, and published a revised final rule on November 5, 2024, with an effective date of December 5, 2024. This final rule clarified that a qualified urine specimen collector is not a qualified oral fluid collector and vice versa. It also clarified that a qualified oral fluid collector to observe the mock collections and have experience in oral fluid collections or training.

Regarding the temporary qualification requirements for mock oral fluid monitors, the monitor must: successfully complete an oral fluid train-the-trainer course; conduct oral fluid collector training. DOT is also waiving the requirement for those with at least one year of experience conducting such training. DOT emphasizes that when teaching oral fluid collector training, the person teaching must have a thorough understanding of Part 40 and maintain records to demonstrate that the training was conducted. Mr. Baczara explained that temporary relief will sunset one year after HHS certifies the first oral fluid drug testing laboratory. At that time, temporary relief will be out of effect.

Currently, individuals can complete oral fluid collection device training and oral fluid mock collections before HHS certifies oral fluid testing laboratories. However, training on an oral fluid collection device that has not been approved for use as part of an official HHS laboratory certification package comes with the risk that the device may not be ultimately included by a laboratory with its application package to HHS and/or approved for use by HHS. This risk is borne entirely by the trainer and prospective collector, as DOT does not have any role in determining which oral fluid collection device is submitted by a laboratory as part of its

application to HHS. Mr. Baczara noted that the DOT website offers a plain-language explanation of the revisions. He concluded the presentation by providing a list of ODAPC resources. There were no questions from DTAB members.

Department of Defense (DoD) Update

Capt. Erin Wilfong, Director, Office of Drug Demand Reduction, Office of Force Resiliency DOD

This presentation was withdrawn.

U.S. Nuclear Regulatory Commission (NRC) Update

Brian Zaleski, Fitness for Duty Specialist, 10 CFR Part 26 Drug and Alcohol Testing Program, NRC

Mr. Zaleski briefly reviewed data on NRC's 2023 invalid and substituted test results, updating the detailed information that he presented at the June 4, 2024, DTAB meeting. Typically, there are five to eight invalid test results annually with the required directly observed second specimen either drug-positive or the test is refused. Invalid test results are important events that are examined closely and if determined to be subversion or cheating, , invalid tests lead to permanent denial of unescorted access, meaning they cannot work at nuclear facility in the United States. However, recent years have seen a significant increase in the number of invalid tests—13 in 2022 and 22 in 2023. Many invalid tests occur during pre-employment (pre-access) testing, and it is good to catch these individuals before they attain a position. In 2023, 80% of invalids were on the pre-access testing. The general trend for workers caught cheating involve maintenance workers, mostly contractor vendors usually employed for short duration work during outages. On the observed follow up testing, half of the individuals tested positive for marijuana and half refused the second specimen collection. Mr. Zaleski reviewed four examples of invalid tests, which may be identified at various steps in the testing process. The examples show the potentially high level of sophistication that can occur with cheating events. Suspicious behavior, physical characteristics for specimens, unusual sounds may result in an observed specimen collection.

Prior to 2023, from one to three drug testing violations per year with the NRC were substituted urine specimens. In 2023, 13 substituted specimens were identified. Ten of these 13 specimens were pre-access testing.

Mr. Zaleski highlighted three 2024 HHS-Certified Laboratory Performance adverse events identified via blind performance test samples formulated to return specific test results (e.g., adulteration or positive for a particular drug).

Mr. Zaleski provided NRC updates for Part 26 rulemaking, published on November 22, 2022, with compliance required by November 22, 2023 revising laboratory testing contracts, updating blinds for different drugs with different cutoffs and training staff. Special analyses testing

involving dilute and observed specimens, is unique to NRC, and often the focus of questions from the field. Special analyses testing permits initial drug test at 40% of the cutoff level and confirmatory drug testing to the Limit of Quantitation for dilute specimens. The 2022 Part 26 Final Rule requires special analyses testing, which was previously optional, and also required directly observed specimens collected under four conditions. Those conditions are that the donor: (1) provides a urine specimen with a substituted, adulterated, or invalid result with no acceptable medical explanation; (2) provides a urine specimen that is outside the required temperature range at the collection; (3) displays conduct that indicates an attempt to subvert the testing process; or (4) requests a retest and either Bottle B is not available for testing.

Turning to NRC's rulemaking plan development related to technical issues, Mr. Zaleski noted that a key driver of this activity is the continuing prevalence of subversion attempts of the urine drug testing process. Subversion attempts represent about 30% of drug testing violations annually. Broadening the specimens collected to include oral fluid testing (once the technology is widely available) would address this situation, as all collections are observed. Drugs and Alcohol: Technical Issues and Editorial Changes discusses the effectiveness and efficiency of improvements in three topic areas: (1) the incorporation of more than 15 years of lessons learned from implementing Part 26, (2) alignment of updates to the HHS and DOT testing program requirements, and (3) resolution of three petitions for rulemaking accepted by the NRC. NRC convened a public meeting to discuss this plan on February 7, 2024, and delivered the Rulemaking Plan to the NRC Commission on July 9, 2024.

Anticipating the types of nuclear facilities in the future and focusing on the need for flexibility, NRC published a proposed rule—Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors—in the *Federal Register* on October 31, 2024. In the final rule, NRC proposes to create a risk-informed, performance-based, and technology-inclusive regulatory framework for the licensing and regulating of commercial nuclear plants under a new 10 CFR Part 53. There is a new proposed Subpart M to 10 CFR Part 26, applies various programmatic elements based on the level of risk of a facility. Mr. Zaleski ended his presentation, and DTAB members had no questions.

Regulatory Program Updates and Mandatory Guideline Updates

Ron Flegel, B.S., MT (ASCP), M.S., DWP
CSAP, SAMHSA

Mr. Flegel opened by reviewing the scope and impact of the DFWP, which covers more than 14 million employees. Through the program, SAMHSA is continually assessing the science and technology used in drug detection to advance national drug policy that is based on the latest scientific findings. Currently, one of the program's goals is the HHS-certification of oral fluid testing laboratories. Once HHS certifies the first oral fluid testing laboratory, federal agencies may begin testing, and DOT will be required to have two of laboratories before beginning testing.

Looking to DWP's future goals, Mr. Flegel highlighted the following aims: (1) addressing key policy and technical issues for implementation of the HMG and (2) identifying and enacting

enhancements to the Federal Drug Testing Program for urine, oral fluid, and hair. Per DWP's legislative authority, the main roles involve the forensic science, policy, and the emerging issues sections. Drug trends and the current landscape of drug use in the United States inform potential changes in DWP's drug testing panel. DWP follows an established process for changing its drug testing panel. Annually, DWP publishes a Drug Testing Panel, Then DTAB Meetings would provide information regarding potential changes. After comment periods and review of comments at subsequent DTAB Meetings, revisions would be published in the *Federal Register* with an implementation date.

Mr. Flegel briefly reviewed a graphic timeline showing the history and major milestones of the DFWP from its authority based on Executive Order (EO) 12564 in 1986 to the present. As of 2023, there are 21 HHS-certified laboratories for drug testing. In recent rulemaking, DWP released the OFMG and the Final UrMG. The proposed HMG remains under OMB Review. He noted the current Drug Enforcement Administration consideration of the rescheduling of marijuana to a Schedule III controlled substance.

The DFWP program is one of deterrence and is one of our largest prevention efforts. Workplace drug testing continues to be an effective tool and is essential for federal civilian employees in safety- and security-sensitive positions, and among federal partners DOT and NRC. Mr. Flegel explained that EO 12564 limits testing authority to Schedule I or II drugs under the Controlled Substances Act. It outlines the drug-free policy, agency responsibilities, drug testing programs, and personnel actions in response to positive tests. Per Public Law 100-71, each agency covered by EO 12564 shall develop a plan for achieving a drug-free workplace. Under this law, HHS responsibilities are to review and certify federal agency plans and to publish Mandatory Guidelines that establish scientific and technical guidelines. HHS also specifies the drugs for which federal civilian employees may be tested and administers the National Laboratory Certification Program (NLCP). The NLCP establishes comprehensive standards and procedures for certification, periodic review, and, when needed, the revocation of laboratory certification.

Mr. Flegel reviewed the Mandatory Guidelines routing process and provided an update on the HMG. SAMHSA reviewed more than 700 individual comments from 213 commenters. This information, along with the scientific studies referenced by commenters and the proposed HMG, were submitted for DTAB review and input in June 2021. SAMHSA also convened listening sessions with seven hair testing laboratories in March and April 2022. Topics discussed included proficiency testing requirements, quantitative agreement between laboratories, reporting criteria, and future technical working groups. SAMHSA also revised the HMG, which are currently under OMB review.

The NLCP conducts many applied studies including Johns Hopkins University (JHU) Cannabinoid Product Testing Survey, hair testing e-book, full spectrum hemp urine analysis, JHU delta-8-THC driving, and objective hair evaluation. Because the rate of federally mandated safety-sensitive post-accident tests positive for marijuana metabolite was mentioned at the June 4, 2024, DTAB meeting, Mr. Flegel showed data (provided by Quest Diagnostics) indicating an increase between 2012 and 2023. The federally mandated safety-sensitive post-accident positive rates for all drugs were relatively steady for the past five years, but marijuana is an exception and has increased dramatically during the past two years. This trend is not as strong in pre-

employment test results. Decisions about the analyte table were also discussed during the June 4, 2024, DTAB meeting. For oral fluid, the confirmation cutoff test for fentanyl remains unchanged (1 ng/mL) but the initial test cutoff was increased to 4 ng/mL due to the dilution factor in the collection device.

Ongoing challenges for DWP include ensuring that implementation of the OFMG meets HHS/DOT/FDA requirements and assuring that scientifically supported procedures will be used to distinguish drug use from external contamination of hair. Other challenges involve addressing emerging issues, such as the use of marijuana/hemp/CBD, opioids, synthetic drugs, and changing drug-related state legislation. A high-level review of the DFWP was conducted to assess current and future issues that affect the program, examine the state of the art and science, identify key policy and technical challenges, and highlight best practices for the future of DFWP. Based on the review, DWP developed a roadmap and action plan, and Mr. Flegel reported the status of several action items. Completed actions include the development of a pulse testing method to ascertain what other drugs may be present in specimens, separating the testing panel from the Mandatory Guidelines process, and removal of the requirement for clinical evaluation of opioid addiction. Ongoing action items include reducing the length of time from testing panel publication to implementation, aligning goals and timelines for DWP and regulated agency partners, and reviewing program specimen validity data and changing the criteria for dilute- or pH-invalid specimens. Mr. Flegel reported that the updated 2024 MRO Guidance Manual and Case Studies are now posted on the SAMHSA website.

HHS NLCP has received the first application for laboratory certification for oral fluid drug testing. Once a laboratory is certified, it can begin to test regulated specimens and will be added to the next monthly list of certified laboratories. When a laboratory is certified to test both urine and oral fluid, that facility's fee schedule will be reduced. DWP is considering how to alter the fees and coordinate the inspection process. Currently, SAMHSA covers all costs for laboratories applying to the oral fluid program until certification. SAMHSA will do as much as it can to continue to support those laboratories. Regarding the timing of the three proficiency testing rounds for initial certification, there is no wait time in between PT rounds. If proficiency testing results are acceptable, the NLCP will send the next set to the laboratory. Mr. Flegel noted that the oral fluid collection device validation has been revised and updated. Laboratories should refer to the latest notification when performing their validation studies. Laboratories with questions should reach out to the NLCP.

NLCP's mission is to ensure the accuracy, reliability, and consistency of federal workplace drug testing. New initiatives include the GAP Analysis Program, ECCF implementation and applied studies. NLCP continues the gold standard in the areas of inspection program administration, PT program management, non-negative specimen list maintenance and Mandatory Guideline revisions. Current challenges for the NLCP including overcoming barriers in certifying laboratories for oral fluid testing, addressing the diminished expertise among junior toxicologists, and ensuring consistent and up-to-date training for all inspectors, making drug testing panels more flexible and responsive to emerging drug trends, harmonizing rule-making efforts with federal partners, and decreasing the cost and burden for certified laboratories. NLCP's strategic focus areas include training and development, and the program has made operational improvements to facilitate the use of the Electronic Custody and Control Form.

NLCP also is focused on (1) applied studies on emerging drugs, testing methodologies (2) strengthening communication and collaboration within the program;(3) developing and implementing guidelines for the certification of international laboratories; and (4) optimizing processes.

The NLCP is working to improve the agility of drug testing panels, exploring alternative technologies for initial testing of oral fluid specimen, and expanding the number of certified laboratories with a focus on oral fluid testing and international facilities. Additionally, NLCP will continue to provide technical assistance and communicate with stakeholders. Mr. Flegel ended his presentation by providing a list of DFWP resources. He invited questions from board members.

Dr. Carl Christensen requested more details on the rationale underlying the increase in the oral fluid fentanyl cutoff to 4 ng/mL. Mr. Flegel explained that, after looking at the original cutoff of 1 ng/mL, it was increased to take into consideration the buffer in the collection devices.

Introduction to a Collaboration with the DOD

Eugene Hayes, Ph.D., M.B.A., Senior Project Officer, NLCP Contracting Officer's Representative
DWP, CSAP, SAMHSA

A relatively new activity for DWP is a SAMHSA-DoD Interagency Agreement (IAA) to leverage expertise and technology for drug use prevention, monitoring and intervention. With a total budget of $5 million over five years, the collaboration includes a subcontract with Kansas State University through the NLCP. Dr. Eugene Hayes noted that the landscape of drug use in the United States is rapidly evolving via synthetic drugs and the influence of social media. The current tools do not always enable a quick response, but this collaboration focuses on proactive intervention.

The collaboration will develop an Artificial Intelligence monitoring system to detect early signs of changing drug use patterns on social media and enable timely responses and harm reduction. This system will use predictive analytics to tailor public health campaigns and mitigate the impact of emerging drug trends. Key project tasks entail producing detailed study reports to inform future public health strategies. and implementing alternative drug testing technologies. In summary, the SAMHSA and DoD partnership will address emerging drug threats that impact both programs. With no questions from DTAB members, Dr. Hayes concluded his presentation.

Evaluation of the Cutoff for Invalid pH

E. Dale Hart, Research Forensic Scientist
NLCP, RTI International

Currently, all federally regulated specimens are subjected to pH testing. When a specimen's pH falls outside the acceptable range, a manual pH meter test is run on a new specimen aliquot. If that initial pH meter test is outside the acceptable range of 4.5 to 9, the laboratory does a second

pH meter test to determine if the sample is invalid. While there are both high and low cutoffs for reporting a specimen as invalid or adulterated for pH, this presentation will focus on the high pH specimens greater than or equal to nine. The invalid pH range goes greater than or equal to 9, but less than 11. If it's greater than or equal to 11, it's determined to be adulterated. High pH specimens require two pH meter tests, which takes a lot of time in the laboratory, but also often triggers recollections since invalid samples are often recollected with a direct observation.

Numerous specimens are reported as invalid based on high pH, but the concern is that urine pH can increase after collection based on time and the ambient temperature during transport to the laboratory due to bacterial action that converts urea to ammonia. In these situations, the pH of affected specimens reaches a plateau of about 9.1–9.3 and the number of invalid specimens in this pH range increases during warm months. A 2007 SAMHSA-funded study examined pH changes in human urine specimens at different temperatures, confirming that the pH rises to 9.1–9.3 when these samples are stored at elevated temperatures. Although the pH of specimens stored at about 20º C (or 77º F) are relatively stable, pH increases to greater than 9 when stored at room temperature or higher. However, time and temperature do not push the pH of specimens to 9.5.

A 2006 SAMHSA-funded study* evaluated the effect of elevated pH on drugs in urine specimens. In this study, the researchers added drug analytes at one and one-half to two times the federal cutoff for each, adjusted the pH by titration, and tested samples one to three days after preparing the specimens. Only benzoylecgonine (cocaine metabolite), phencyclidine (PCP), and 6-acetylmorphine (6-AM, heroin metabolite) were affected by pH levels 9.0–9.5. Mr. Hart reviewed the data for each drug analyte, noting that the study did not consider the time to transport specimens and that some drugs of current interest were not on the panel in 2006. Around pH 9.5, benzoylecgonine recovery was about After 87% recovery at day 1 and we got about 72% recovery at day 3. At a pH of 9.0–9.5, about 60% of PCP remains after one day and 50% after three days. Mr. Hart explained that PCP is an infrequently detected drug (4 specimens per 100,000). Specimens with PCP are usually not close to the cutoff. The least stable analyte was 6-AM as it starts to hydrolyze at a pH above 8.0. At a pH of 9.0–9.5, 42% of 6-AM remains at day one, with about 18% remaining at day three. This metabolite is infrequently detected, as heroin use has declined.

Tests in the invalid for high pH category peak in the summer and fall in the winter. Throughout the years, the number of specimens has been consistent for pH 9.0–9.5, but since 2022, more samples have been detected between pH 9.5 and 10.0 and since 2023, more samples have been detected with pH between 10 and 11. . This trend coincides with a spike in the rate of invalid samples in the NRC program. Samples with a pH of greater than 10 are likely to be a poorly formulated urine substitution product. Non-federally regulated samples tested at Clinical Reference Laboratory show a similar seasonal pattern of urine specimens with a pH greater than 9.0 during the summer and has also recently observed more samples with a pH greater than 9.5 since 2022. No natural process (e.g., elevated temperature or increased shipping time) would

* Francis M. Esposito, John M. Mitchell, Michael R. Baylor, and Donna M. Bush, Influence of Basic pH on Federal Regulated Drugs in Urine at Room Temperature. Poster presented at the Society for Forensic Toxicologists Annual meeting, 2006.

cause a sample to have a pH greater than 9.5, so there seems to be another unknown factor involved. Increasing the invalid pH cutoff from 9.0 to 9.5 would reduce the burden on donors, MROs, recollections, testing agencies, and laboratories without any negative impact on specimen reporting based on an evaluation of the prior year's inconsistent specimen result reported to NLCP. Mr. Hart concluded his presentation by acknowledging Dr. David Kuntz for providing data from the Clinical Reference Laboratory and Ms. Marquita Brogdon for analyzing NLCP data and providing the data charts.

Noting that the 2006 study did not include semi-synthetic opiates or opioids or MDMA on the test panel, Mr. Zaleski asked about the expected the effects of a pH greater than 9.0 on urine samples with those drugs. Mr. Hart responded that test results for those drugs would likely be similar to the results presented. THC, the most frequently detected drug, is more stable at a high pH level but is affected by a low pH level. Mr. Flegel asked about the concentrations used in the 2006 study. Mr. Hart replied that all the samples were one and one-half to two times the cutoff level. The current standard is to spike concentrations for study samples at two times the cutoff level.

Public Comment

After thanking presenters, Ms. Davis invited questions and comments from the public. There were no questions or comments from the public.

Adjournment of Open Meeting

Mr. Flegel thanked attendees and the meeting was adjourned at 1:52 p.m.