SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened on March 9, 2022 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 1:00 p.m.

Table of Contents
Call to Order - Approval of December 2021 Meeting Minutes........................................... 2
Welcome and Introductory Remarks ................................................................................. 2
Department of Transportation (DOT) Update .................................................................... 3
Nuclear Regulatory Commission (NRC) Update............................................................... 4
Food and Drug Administration (FDA) Update ................................................................. 4
Drug Free Workplace Program Summit Meeting May 2022.............................................. 5
NLCP Drug Testing Results .............................................................................................. 5
Regulatory Program Updates and Mandatory Guidelines.............................................. 6
NLCP Updates – Synthetic Urines and Adulterants......................................................... 7
Public Comment ................................................................................................................ 7
Adjournment ...................................................................................................................... 8

Board Members in Attendance

Ronald Flegel, Chairman
D. Faye Caldwell, J.D.
Jason E. Schaff, Ph.D.
Barry R.H. Sample, Ph.D.
Kristen Burke, Ph.D.
Deborah Motika, MBA
Stephen Mark Taylor, M.D.
Alison Stockdale
David Engelhart, Ph.D.
Elizabeth Stuyt, MD
Call to Order - Approval of December 2021 Meeting Minutes, Lisa Davis, Designated Federal Officer, DTAB

Ms. Lisa Davis, the Designated Federal Officer (DFO), called the meeting to order. She called the roll and confirmed that there was a quorum present. She announced that the meeting was open to the public. She invited DTAB member comments concerning additions or amendments to the December 7, 2021 meeting and there were none. Ms. Davis invited approval of those minutes and, on motion duly made by Dr. Sample and seconded by Ms. Caldwell, the minutes of the last meeting were unanimously approved. She briefly described the agenda and invited Mr. Ron Flegel to make introductory remarks.

Welcome and Introductory Remarks, Mr. Ron Flegel, Chairman, DTAB

Mr. Flegel expressed appreciation to Ms. Davis for accepting the responsibility of DFO and to Ms. Anastasia Donovan for filling in during the last meeting. He thanked all of those present for attending the meeting and taking part. He noted that SAMHSA is committed to maintaining the excellence of workplace drug testing by assessing the science and technology used in drug testing, and improving the quality of related laboratory services, and by setting standards, which extends to regulated and non-regulated testing programs. The Federal Register Notice regarding the revised Mandatory Guidelines for Hair was published for public comment on September 10, 2020. Public comment closed on November 9th. It included the requirement that agencies must authorize collection of one other specimen type, either urine or oral fluid as authorized under the Mandatory Guidelines for Federal Workplace Programs. When the guideline for hair is complete it will be reviewed at the DHHS level and by the OMB.

The guidelines for urine and oral fluid are currently under OMB review and clearance, and the goals are to facilitate revisions to authorized test drugs and cutoffs as needed and, in part, to reduce opportunities for donors to subvert drug tests. The Division of Workplace Programs
Department of Transportation Update (DOT), Bohdan Baczara. Deputy Director, Office of Drug and Alcohol Policy and Compliance

Mr. Baczara discussed the COVID-19 guidance previously released by three DOT agencies, including the Office of Drug and Alcohol Policy and Compliance (ODAPC), which confirms the importance of continued testing. Inability to conduct testing requires documentation as to the reasons. ODAPC guidance includes a statement of enforcement discretion for substance abuse professionals updated in November 2021, extending the policy through June 30, 2022. It provides an automatic extension of qualification of anyone who is involved in assessment and collections who have not had the opportunity to get requalified. Substance Abuse Professionals may also conduct assessments via a remote two-way audio/video interview.

Mr. Baczara discussed the latest data from the Federal Motor Carrier Safety Administration (FMCSA) Driver Clearinghouse, which houses information input by employers, Medical Review Officers (MROs) and Substance Abuse Professionals (SAPs). Over 11 million employer queries to identify driver drug or alcohol violations have been conducted since the beginning of the program in January 2020. In summary, the numbers are:

- Number of drug violations reported: 115,367
- Number of alcohol violations reported: 2,639
- Top 3 drug violations reported: Marijuana, Cocaine, Methamphetamine
- Test reason with most reported violations: Pre-employment
- Number of drivers in prohibited status: 83,283

Mr. Baczara announced that a Notice of Proposed Rulemaking for oral fluids was published in the Federal Register on February 28th inviting comments submitted by March 30, 2022. The NPRM offers an opportunity to comment on the use of oral fluids as an alternative drug test using the same collection procedures as DHHS; and the allowance of direct observation urine collection by a licensed or certified medical professional legally authorized to take part in a medical examination in the jurisdiction where the collection takes place. There is also a proposal to allow the MRO to contact pharmacies to verify prescriptions; whether to allow an MRO to “uncancel” a test once a test has been cancelled; to allow the optional use of identification numbers issued by state and/or local authorities instead of Social Security numbers; to propose that labs submit DOT biannual data by test reason and specimen type; to require labs withdrawing from the NLCP program to provide data for the period of withdrawal; to require labs to maintain non-negative specimens for only 90 days.

Finally, the collector phone number on the Federal Chain of Custody form would be a number that would go directly to the collector and not to a general call center or a supervisor. Mr. Baczara invited comments on all aspects of his presentation. He mentioned several ODAPC resources available on the ODAPC web site: a guide to who is covered by DOT regulations, a discussion of Part 40, a listserv to obtain information about what is going on in the DOT program, and a guidance page.
Nuclear Regulatory Commission Update (NRC), Brian Zaleski, Fitness for Duty Specialist, 10 CFR Part 26 Drug and Alcohol Testing Program

Mr. Zaleski noted that his discussion would include an overview of the Part 26 Fitness for Duty (FFD) program, a description of current rulemaking, and trends in the FFD program regarding subversion, and a look at laboratory performance issues, some related to the COVID pandemic. The FFD program requires that a licensee must provide reasonable assurance that those involved are trustworthy and reliable and not under the influence of any substance or other issue that might impair mental or physical abilities to perform assigned duties. It is clearly more than just drugs. The framework that determines an individual’s access to NRC facilities involves a formal process (fingerprinting, background investigation, psychological evaluations, drug and alcohol testing, behavior observation, etc.).

The NRC has a rulemaking process ongoing based on a Federal Register Notice that includes a proposal to align the urine testing panel and cutoffs with 2017 HHS Mandatory Guidelines, to allow collection and testing of oral fluid specimens under direct observation, and to strengthen subversion detection by mandating special analysis of specimens collected under direct observation when a suspected subversion attempt exists. Mr. Zaleski commented that there were several laboratory issues in 2021, including specimen shipment interruptions caused by severe weather, shipments of specimens lost in transit, some specimen testing delays for various reasons that caused a failure to meet the requirements to complete the tests within a 5-business-day window, and finally one lab ceased operations and had to obtain authorization to refer the tests to another lab.

The number of subversion attempts has been significant since 2014 involving 2,195 individuals, which is a higher level than alcohol violations. They are identified by the collectors noticing irregularities in the specimens or specimen collection – temperature and physical appearance anomalies, significant differences in the characteristics of two separate specimens collected at about the same time and attempts to substitute synthetic urine. Additional research will be conducted to refine the collector’s ability to make these observations, particularly direct observation of collection. Mr. Zaleski added that the violations predominantly involve contractor/vendor personnel.

Food and Drug Administration (FDA) Update, Joseph Koterek, Branch Chief (Acting), Toxicology, Food and Drug Administration, Office of In Vitro Diagnostics and Radiological Health, Division of Chemistry and Toxicology Devices

Dr. Kotarek discussed the FDA’s Drugs of Abuse (DoA) Regulation updates, the proposal for oral fluid mandatory guidelines, and point of care considerations for DoA devices. Regarding regulation, most DoA tests are covered under moderate risk (Class II) regulation and require 510(k) clearance before going to market. The tests involve the full range of complexity from central lab tests to point of care use involving a single patient, who may obtain an over-the-counter test for self-administration. On December 30, 2019, a final Federal Register Notice was published that exempted many DoA tests from having to submit a 510(k) prior to marketing for tests intended only for employment and insurance testing. All other devices would require the normal submission of a 510(k) registration application. After review and approval, the full details of the DoA device is published on the FDA web site, and the list of devices is extensive. There are also reasonably concise summaries of the approvals for every device.
Dr. Kotarek briefly focused on oral fluid tests, noting that an advantage is ease of collection and observation of collection, adding that there are concerns about safety, performance and reliability of the test, and the clinical validity of the test and the assurance that an individual who self-administers a test can properly perform the procedure and that the device involved does not adversely affect the sample, and that environmental conditions (such as the presence of food, tobacco, caffeine, etc.) do not compromise the results. Finally, there should be assurance that the cutoffs established are valid and useful.

Drug Free Workplace Program Summit Meeting, Hyden Shen, Policy and Regulatory Oversight Lead, DWP, CSAP, SAMHSA

Mr. Shen reported on the Drug Free Workplace Program Summit meeting to be held in May 2022, stating that a high-level review will be conducted to identify and assess critical issues and implement proper programmatic policies ensure the national security, public health and public safety of our country. This year a number of workgroups composed of subject matter experts from the scientific, workplace and drug testing fields will convene to provide the insight for preparing for the future of the program.

NLCP Drug Testing Results, Eugene Hayes, Ph.D., MBA, DWP, CSAP, SAMHSA

Dr. Hayes reported that, as of February 1, 2022, there were 21 active certified labs – six each Category 1 and 2, one category 3, three category 4, two category 5, one category 6 and two category 7 laboratories. During the past five years ten labs have withdrawn for various reasons – operational/organizational changes, mergers, inappropriate conduct in forensic drug testing, etc. On the positive side, there was one new lab certified and two in the process of certification. The number of specimens collected has ranged from a low of 5.79 million in 2016 to a high of 6.65 million in 2015. In 2020, there was a significant reduction in testing in March and April because of the pandemic, however testing volume recovered to 6.1 million samples tested, and in 2021, 6.9 million specimens were tested. The number of specimens reported as drug positive, adulterated, invalid, or substituted, increased from 136,000 in 2017 to 196,000 in 2018. Specimens invalid because of pH increases during the warmer months and decreases in the cooler months, and the percentage of invalids caused by pH remains higher than other invalid categories. In 2021, as a percent of the total tested specimens, those reported invalid due to inconsistent creatinine and specific gravity concentration increased by more than 90 percent as compared to 2020, while those reported invalid due to possible oxidant activity decreased by about 33 percent. There has been an increase in those specimens reported invalid due to pH greater than or equal to 9.5, and invalid due to inconsistent creatinine concentrations and specific gravity results, creatinine less than 2. This increase began mid-2020 and has since continued. This could be a signal to indicate the presence of new synthetic urine or adulterant products in the market resulting in an increase in the type of invalid reporting.

Specimens reported invalid because of immunoassay interference increased significantly in late 2017 and 2018, more than tripling those seen in 2016. In February 2018, two large labs reported to NLCP of the increase in invalids, most of which showed depressed immunoassay results with 6-acetylmorphine and amphetamine using CDIA reagent. A substitution product was suspected, but the reports have decreased in the past three years. In 2021, most of the invalids due to immunoassay interference resulted from the hydrocodone/hydromorphone assay. At any given time, the NLCP has about 40-50 projects in progress as well as a series of
studies, 28 at the present time. The NLCP publishes a continuing education newsletter on topics of interest to the drug testing industry.

In summary, Dr. Hayes stated that the number of regulated specimens tested by HHS-certified labs increased 15.4% in 2021 compared to 2017. The number of regulated specimens reported as positive, adulterated, invalid or substituted increased almost 33% during the same period. Specimens reported as invalid due to low pH decreased, and specimens reported as invalid due to high pH continued to increase in 2021, and specimens reported as invalid due to low immunoassay interference continued to decrease from the high levels in 2017 and 2018.

Regulatory Program Updates and Mandatory Guidelines, Ron Flegel, B.S., MT (ASCP), M.S., DWP, CSAP, SAMHSA

Mr. Flegel noted that the Drug Testing Advisory Board added a newly nominated member, Dr. David Roberts, who is in the clearance process and should be a member and present at the next regular meeting, which we hope will be an in-person meeting for the first time in a couple of years. The overall goal of the DWP is to continually assess the science and technology employed in the Drug Free Workplace Program. A critical goal is implementation of oral fluid as an alternative test matrix, and the certification of the first HHS-certified oral fluid testing laboratory so that agencies will have the ability to test a second specimen, and publication in the Federal Register of the proposed Mandatory Guidelines for hair. An important activity will be a high-level review of the Drug Free Workplace Program (DWP). Emerging issues include the Farm bill and evolving drug environment.

Mr. Flegel briefly discussed the process to develop the latest updated mandatory guidelines – for urine updated October 1, 2017; for oral fluid updated January 1, 2020; and for hair effective September 10, 2020. The latter included the establishment of new hair collection procedures, a list of substances allowed to be tested in urine and oral fluid, initial and confirmatory cutoffs, required decontamination procedures, revision of the requalification requirements for Medical Review Officers (MROs), and specifications for use of an alternative specimen. The proposed new matrix for testing hair was published for public comment in a Federal Register Notice (FRN) in September 2020, and a subsequent FRN will be published to announce the harmonized hair, oral fluid, and urine mandatory guidelines, which will be finalized after OMB review. There were over 700 individual comments from 213 commenters in response to the call for public comment, all of which have been reviewed by DTAB in closed sessions in March and June of 2021, and SAMHSA will be inviting specific hair testing labs to provide additional comments in the future. Urine and Oral Fluid Mandatory Guidelines have also been reviewed and revisions were made to facilitate and streamline revisions to the list of drugs and their cutoffs. Those revisions are currently under OMB review. Finally, Mr. Flegel mentioned over a dozen studies completed and ongoing, including a recently added THC/CBD pulse study and a study looking at fentanyl in opiate-positive specimens being tested.

Emerging issues include the need to respond to the 2015 FAST Act requirements involving Mandatory Guidelines for hair in face of continuing issues of hair color impact and external contamination, and the changes posed by the Farm Bill that make it very difficult to discern between legal and illegal sources of THC. And there is the 2018 Opioids Crisis Response Act and its relation to synthetic opioids. Mr. Flegel noted that the opioid landscape is evolving with new synthetic drugs and the increasing acceptability and availability of marijuana and CBD
products, which has an effect on workplace safety and security. Finally, there will be challenges associated with the COVID return-to-work process.

**NLCP Updates – Synthetic Urines and Adulterants, Svante Vikingsson, Ph.D. Research Forensic Scientist, Center for Forensic Science, RTI International**

Dr. Vikingsson defined a synthetic urine as a product that the donor submits as a substitute for his or her own urine specimen, while an adulterant is a product that is added to the donor’s urine sample in an effort to confound the test results. He identified 32 synthetic urines on the market and three adulterants. Of that group, 10 synthetic urines and the three adulterants were sent to five HHS-certified labs. Results were returned by all labs. In addition to the usual analysis, the labs provided information on specimens that additionally contained uric acid and magnesium, a separate biomarker panel and dipsticks. The three adulterants were the Spike additive that had no apparent effect, Urine Luck, a two-component additive that appeared to contain iodate, and the Klear Additive believed to be potassium nitrate. Dr. Vikingsson showed packaging for about 16 synthetic urines, most of which were premixed solutions, concentrates and powdered urine to dissolve in water. They are available without prescription at various retail establishments suggesting there is a commercial market for them. Most have a temperature strip to aid in creating a sample within the normal temperature range.

Looking at adulterants, the NLCP formulated samples that were about double the NLCP cutoffs and the initial immunoassay screen results mostly returned a positive result with some interference for 6-acetylmorphine and methamphetamine in a few labs, mainly in the CEDIA assays. With the confirmation results, there was no real effect for codeine and hydrocodone, but small reductions for oxycodone, morphine, hydromorphone and oxymorphone, all opioids, no effect for 6-acetylermotphine, but a significant reduction in THC carboxy (THCA) concentrations. There was some immunoassay interference with the A2 sample and some interference with the confirmation assays for sample A3. There was one lab that tested for iodate and showed a positive reading, and some labs identified oxidant activity.

Dr. Vikingsson focused on synthetic urines SVT testing because it is a more prevalent way to subvert drug testing. A synthetic urine dipstick was not clearly definitive to the eye for decision purposes. The uric acid / magnesium tests revealed that almost all synthetic urines contain uric acid at lower concentrations than those expected in human urines. A biomarker panel tested for seven biomarkers and tested positive for all in the control urine but synthetic urines contained three at most.

In summary, Dr. Vikingsson explained that three adulterants were analyzed and showed small effects and and were identifiable by oxidant screen and by immunoassay interference. The synthetic urines were not detectable by typical SVT assays and the uric acid acid tests were of limited value.

**Public Comment**

Ms. Davis invited public comment. Carl Shadwire asked about inquiries from manufacturers when developing and validating new immunoassays. One challenge with some drugs is finding authentic patient samples that fall within the range of plus/minus 50 percent of the cutoff to effectively challenge the cutoff, so when it is not practical to obtain those samples, would it be possible to dilute positive patient samples with drug-free urine or matrix to create those
concentrations to evaluate the cutoff? Ms. Davis reminded Dr. Kotarek (FDA) to whom the question was directed that questions are not answered during the public comment period.

Dr. Kotarek stated that he could follow up with a response offline after the session. Ms. Davis stated that another question involved whether any studies have been conducted on other than marijuana second-hand smoke? Mr. Flegel said that the question would be extracted from the transcript and a reply developed offline. Ms. Davis stated that there were no other public comments pending, which ends the public comment session.

Adjournment

Ms. Davis noted that there was no further business for the open session and adjourned the open session of the meeting.