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

March 7, 2023

Minutes – Open Session

SAMSHA'S CSAP Drug Testing Advisory Board (DTAB) convened on March 7, 2023 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 2:00 p.m.

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Board Members in Attendance

Ronald Flegel, Chairman
Jason Schaff, Ph.D.
Barry Sample, Ph.D.
Kristin Burke, Ph.D.
Deborah Motica, MBA
Alison Stockdale
Elizabeth Stuyt, MD
E. Lindsey Everson

Ex Officios

Joseph Kotarek, Ph.D. (FDA)

Bohdan Baczara, MBA (DOT)
Lynn Wagner, Ph.D. (DoD)

Designated Federal Officer

Lisa Davis, DFO, SAMHSA

Presenters

Bohdan Baczara, DOT
Brian Zaleski, NRC
Erin Wilfong (DoD)
Joseph Kotarek (FDA)
Ron Flegel, DWP, CSAP, SAMHSA
Svante Vikingsson, Ph.D.
Eugene D. Hayes, Ph.D., MBA

Call to Order

Ms. Lisa Davis, the Designated Federal Officer (DFO), called the meeting to order. She called the roll and confirmed that there was a quorum. She announced that the meeting as open to the public. Ms. Davis reviewed the agenda for the meeting and invited Mr. Ron Flegel to make opening remarks.

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

Mr. Flegel welcomed board members, ex officio members, federal partners, industry leaders, and members of the public. He mentioned two board members attending their last meeting, Drs. Barry R. H. Sample and Jason Schaff, thanking them for their significant contributions to DTAB during the past several years. Mr. Flegel stated that SAMHSA continues to work to improve the quality of services under the National Laboratory Certification Program (NLCP) and the Federal Drug Free Workplace Program (DWP) and for federally regulated testing and private sector testing. A Comprehensive Review of the program's strengths, challenges, opportunities, and threats was recently completed, the results of which will be discussed later in the meeting.

Mr. Flegel commented on the status of the DWP, stating that the Proposed Mandatory Guidelines for Hair were published in the Federal Register on September 10, 2020, inviting comment through November 9, 2020. Revised wording based on over 700 comments, some with scientific articles attached, was completed on June 8, 2021, HHS released a preliminary draft of the revisions of the proposed Hair Mandatory Guidelines to the Drug Testing Advisory Board, resulting in an additional 188 comments. The last DTAB review of the proposed Hair Mandatory Guidelines occurred in September 2022 after which it moved into the clearance process under HHS in October 2022. Revisions for urine and oral fluid were published in April 2022, prompting 57 public comments for urine and 204 comments for oral fluid. The Urine and Oral Fluid Mandatory Guidelines are under review at the Office of the Secretary of HHS. Mr. Flegel concluded his remarks.

Department of Transportation (DOT) Update, Bohdan Baczara, Deputy Director, Office of Drug and Alcohol Policy and Compliance

Mr. Baczara discussed two guidance documents related to COVID-19 which were released by

the Federal Rail Administration (FRA) and the Federal Aviation Administration (FAA). The documents described the process required if an individual cannot perform a test, which includes a fully documented history to ensure that all relevant facts are available if the employer is audited. There is also a guidance document that became effective on January 1, 2023, that allows authorized Substance Abuse Professionals to remotely conduct assessments and evaluations required under Part 40. This guidance document will be in effect until a Final Rule is issued.

The Federal Motor Carrier Safety Administration (FMCSA) Driver Clearinghouse became effective on January 6, 2020. It requires that employers, Medical Review Officers (MROs), and Substance Abuse Professionals, enter drug and alcohol violations into the database, and as of January 2023, there were 17,634,326 queries conducted (employers checking on driver's status). There were 182,745 drug violations reported and 4,203 alcohol violations reported. The top three drugs reported were marijuana, cocaine, and methamphetamine. The drivers in a prohibited status have either tested positive or refused to take a test and have not completed the return-to-duty process.

The DOT's Office of Drug & Alcohol Policy and Compliance (ODAPC) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register in February 2022 to authorize oral fluid as an addition to the DOT drug testing program. It elicited 417 comments and staff is working on a Final Rule. Finally, a proposed rule on electronic signatures was published on August 5, 2022. There were 77 comments received. When a final rule is reviewed and approved, DOT will publish those results in the Federal Register. There is a DOT web page to which employers are required to submit their aggregate drug and alcohol testing data for all employees. There is no personally identifiable information included. Mr. Baczara concluded his report.

Nuclear Regulatory Commission (NRC) Update, Brian Zaleski, Specialist – Fitness for Duty/Access Authorization

Mr. Zaleski stated that his remarks would pertain to three areas: rulemaking; fitness for duty program performance trends; and laboratory performance issues reported by licensees. Final rulemaking for 10 CFR Part 26 was published in the Federal Register on November 22, 2022, effective one month later, with compliance required by November 22, 2023. The rule aligns the NRC drug testing panel and the cutoffs with revisions that have been made to the DHHS Mandatory Guidelines. A significant change is an improvement in methods to identify subversion attempts. Another important change is that licensees now can collect and test oral fluid specimens using direct observation collection conditions. We added testing for hydrocodone, hydromorphone, oxycodone, oxymorphone, MDMA, and MDA, with cutoff levels that are established in the guidelines. Also added is initial drug testing for 6-acetylmorphine, and lowering initial and confirmatory cutoff levels for amphetamine, cocaine metabolite, and methamphetamine. Special analysis testing has been mandated for dilute specimens, lowering the cutoff concentration for those tests to 40 percent of the cutoff for screening and Limit of Quantitation (LOQ) testing for confirmation.

Mr. Zaleski presented data on subversion attempts, which are any willful act or attempted act by the donor to cheat on a required test by using something other than their own urine, including using synthetic urine or putting something in the urine to interfere with the testing process. About a third of all drug testing violations are subversion attempts, most during pre-access testing, often with contractor/vendors in situations that require relatively short-term employment of a large number of individuals, such as response to an outage. Mr. Zaleski described investigations of unsatisfactory performance that require reporting within 30 days. Two reports involved blind test samples where the marijuana metabolite was not within the target concentration range. Other 30-day event reports were due to the laboratory not reporting test

results within five days of receipt. This requirement ensures that an individual with a positive test is promptly removed from access. Other investigations related to procedural errors, like sending specimens to the wrong lab.

Department of Defense Drug Testing Update, CAPT Erin Wilfong, Director, Office of Drug Demand Reduction, Office of Force Resilience

CAPT Wilfong began her discussion by describing drugs that DoD includes in its panel that are not on the SAMHSA panel, beginning with delta-8-THC, added in the last quarter of FY 2021. Of samples that screen positive for cannabinoids, about 57% of samples confirm positive for delta-9-THCA, about 20% confirm positive for delta-8, and 16% confirm positive for both. Pulse testing for LSD was added in 2020, and if the current 10% pulse testing was extrapolated to 100%, LSD would be in the top five drugs in terms of prevalence. A 2020 report suggested that LSD use had increased nationally by more than 56% in three years. There is an indication that a number of states are considering decriminalizing it. Finally, fentanyl and its metabolite norfentanyl were added in FY 2019 with a 1 ng/mL cutoff. In FY 2021, the testing rate was increased to 100%. In terms of prevalence, fentanyl sits just above oxymorphone.
The DoD services are encouraged to test twice a year and are required to maintain frequent random drug collections. Significant data is collected, and DoD is looking at using that data to identify individuals, installations or geographic regions that might be at greater risk for overdoses, and further examine poly drug users.

CAPT Wilfong turned to synthetic cannabinoids, noting that a panel of seven synthetic cannabinoids established in 2013, showed a rapid decrease in positives during the following eight years, so a new panel of eight synthetic cannabinoids was implemented in October 2022 based on surveillance data, DEA trends, and data from the Armed Forces Medical Examiner System. Pulse testing at 10% yields a large percentage of positive results. The synthetic cannabinoids panel will likely need to be updated annually as the compounds change year to year.

Finally, CAPT Wilfong discussed the challenges presented by poppy seeds in foods, like muffins, which can trigger a positive drug test for codeine rather than morphine. An independent lab tested three commercial brands of poppy seeds (Great Value, Costco, and McCormick). The results showed that the cause of the positive codeine tests were codeine contamination in the poppy seeds. In one 2021 study of 17 participants who consumed one Costco muffin and provided a urine sample at 4-6 hours after ingestion and a second sample 21-25 hours after ingestion, three individuals tested over the 2,000 ng/mL cutoff for codeine. The possible testing of compounds such as thebaine or papaverine might be a useful chemical indicator of poppy seed exposure. CAPT Wilfong concluded her report.

Food and Drug Administration Update. Joseph Kotarek, Ph.D., Branch Chief, Toxicology

Dr. Kotarek discussed the FDA's in vitro diagnostic tests cleared for fentanyl. For Class II devices with moderate risk, FDA approval is required before they are marketed. Testing devices range from permanent central lab equipment requiring the sample to be brought to the site of the test equipment, to "near-patient" testing visually read test strips, some of which may be purchased at a retail site like Walgreens and used anywhere by the individual. Fentanyl testing is currently a more significant challenge because there is no FDA cleared visually read test strip for fentanyl. FDA has approved fentanyl test devices for urine and hair, but they require testing equipment only available in a lab environment. Recently, FDA approved the first urine-based fentanyl test for in vitro diagnostics for point of care use. It is a small instrument, not CLIA-waived, categorized as moderately complex, but it is a point of care instrument. Dr. Kotarek concluded his presentation.

Regulatory Program Updates and Mandatory Guidelines – Updates to Proposed Urine, Oral Fluid, and Hair Guidelines, Ron Flegel, B.S., MT (ASCP), M.S., DWP, CSAP, SAMHSA

Mr. Flegel began by sharing, with condolences, the passing of DWP team member Dr. Deborah Galvin. He noted that the past six months have been busy with many tasks including performing a Comprehensive Review of the Drug Free Workplace Program to identify key policy issues, technical issues, and existing challenges, conducting several studies, and revising all three Mandatory Guidelines. He stated that the overall goal of the DWP is to continually assess the science and technology used in drug detection to advance national drug policy based on the latest scientific findings. One specific HHS goal is to certify the first oral fluid testing lab, which will make possible another authorized specimen, other than urine, followed by the eventual addition of hair.

Mr. Flegel noted that the DWP impacts several federal agencies, including those in the Executive Branch, the Department of Transportation, the Nuclear Regulatory Commission, and civilian and federal employees of the Department of Defense. He added that the DWP incorporates both the science and the policy related to Federal Workplace testing, including national drug testing standards and the support for the current HHS-certified labs for urine, and the future HHS certified laboratories for oral fluid and hair and developing national MRO certification standards.

Mr. Flegel showed a flow chart for the progress in completing Mandatory Guidelines, which are close to being ready for HHS review. He added that public comment periods for hair ended in November 2020, for urine and oral fluid in June 2022, and all comments have been reviewed by HHS. The status of NLCP studies reveals ten have been completed, eight well on the way to completion, and one is in the early stage of study. Mr. Flegel stated that a timeline had been proposed for publishing the authorized drug testing panel and the biomarker testing panel (analytes and cutoffs) and explained the revised MRO verification process for positive morphine specimens. The presentation was concluded.

Presentation: Summary of Pulse Testing Studies of Fentanyl in Opioid Initial Test Positive and Delta-8-THC and THCA Initial Test Positive Specimens, Svante Vikingsson, Ph.D., Research Forensic Scientist, Center for Forensic Science, RTI International

Dr. Vikingsson discussed an opioid pulse testing study intended to assess the effects of proposed changes to the morphine cutoff and determine if fentanyl is a better marker for illicit heroin. He stated that between 2,000 and 15,000 ng/mL of morphine, a MRO will only report a positive if there is clinical evidence of drug abuse or if 6-acetylmorphine is positive. He noted how fentanyl may be used as a substitute for heroin in the U.S. drug supply. Hence, the fentanyl study investigated whether fentanyl may be a better marker for illicit heroin use than 6-acetylmorphine. The presence of drug positives in federally regulated drug testing is very low, requiring a relatively large number of samples to yield reliable results in a pulse study. Only specimens that screened positive for morphine were included in the study.

Raising the morphine cutoff from 2000 ng/mL to 4000 ng/mL appears to increase the overall positivity rate by approximately 65 percent as it removes the requirement of clinical evidence of abuse between 2000ng/mL and 15,000 ng/mL. Further utilizing fentanyl verses 6-acetylmorphine as a marker of heroin use increased the positivity rate by approximately 81 percent.

Dr. Vikingsson turned to the cannabinoids study. The main question is how common is delta-8-

THCA, and how do THC isomers contribute to cannabinoid testing? Delta-8-THC effects are similar to, though less potent than Delta-9-THC, the main psychoactive component of cannabis. Delta-8 is a concern for workplace safety and driving. Delta-8 is perceived as legal by most. Of the specimens tested in the pulse study that screened positive initially for marijuana metabolite, 9.7% of the specimens tested positive for delta-8-THCA only. Adding delta-8-THCA would increase the overall positivity by 11 percent. Dr. Vikingsson ended his presentation.

Update on Electronic Chain of Custody Form (ECCF), Eugene Hayes, Ph.D, MBA, Sr. Project Officer/Sr. Social Science Analyst

Dr. Hayes stated that the Mandatory Guidelines establish the custody and control form and procedures, and OMB established rules and guidelines for using the form. When published in the Federal Register the proposal had no changes. The goal is to have a final proposal by mid-July.

Regarding ECCF utilization, several labs have been approved: Quest Atlanta withdrew after initial approval, LabCorp South Haven increased usage in 2021, Fort Meade was approved in August 2022, LabCorp Houston was approved in July 2022 and LabCorp Raritan and LabCorp RTP were approved in 2023. There are issues with some laboratories gaining access to the available ECCF services on the market, so SAMHSA extended the deadline for federal workplace drug programs to switch from paper to electronic control forms (ECCF) from August 30, 2023, to August 30, 2026. The NLCP will support those having problems with access and a notice to that effect will be sent soon. Dr. Hayes ended his presentation.

Mr. Baczara added information to his presentation, that since the inception of the program there have been 25,552 drug test refusals entered into the FMCSA Driver Clearinghouse. And that number would include not only employer-decided refusals, such as at collection sites, but also MRO reported adulterated and substituted specimens.

Public Comment

Ms. Davis invited public comments.

Daniel Horvath, with the American Trucking Association, stated that his comments concerned the hair testing guidelines. The ATA has advocated for the use of hair testing as an approved alternative to urinalysis. The ATA is aware that data on positive results of drug tests cannot be reported to the Drug and Alcohol Clearinghouse, which is a safety issue. The 2020 guidelines are flawed in that they recommended a follow-up or secondary confirmation test in the event of a positive hair test, which does not change anything in the process in place today.

Jerry Lightfoot commented that delta-8-THCA is considered to be legal in the 2018 Farm Bill. He questioned the consequence of testing for it and what the positives would mean.

Dr. Michelle Alexander, director of medical affairs for Abbot Rapid Diagnostic eScreen, expressed concern about the effectiveness of virtual evaluations by Substance Abuse Professionals of individuals who test positive and then are cleared for return to work within a couple of days to weeks afterward. She stated that virtual evaluations cannot determine alcohol use or continued abuse. She expressed concern regarding opioid use among drivers that is verified as negative because they have authorized prescriptions for drugs like oxycodone or hydrocodone yet are taking up to 15 tablets per day.

Ms. Davis expressed appreciation for the comments, reminding the speakers that the DTAB is not permitted to respond to the questions asked during the public comment period.

Adjournment

Mr. Flegel expressed appreciation to all who participated and contributed. Ms. Davis noted there was no further business for the open session and adjourned the open session of the meeting.