

**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

September 25, 2019

Minutes Summary – Closed Sessions

SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened in closed session on September 25, 2019.

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ATTENDANCE

Board Members in Attendance

- Faye Caldwell
- Randal Clouette
- David Green
- Constantino Iannone
- Deborah Motika
- Barry Sample
- Jason Schaff
- Michael Schaffer
- Stephen Taylor

Ex Officios in Attendance

- Cathy Gautreaux - DOT
- Patrice Kelly - DOT
- Suzanne Lenhard - DOT
- James Mullally - FDA
- CAPT Eric Welsh - DoD
- Brian Zaleski - NRC

Subject Matter Experts in Attendance

- Edward Cone
- Mike Walsh
- Yale Caplan
- Denny Crouch
- Jim Bourland
- John Mitchell

Contractors in Attendance

Ruth Winecker
Susan Crumpton
Lisa Davis
John Bowers (transcriptionist)
Cameron Johnson (A/V operator)

SAMHSA Staff in Attendance

Matthew Aumen (DFO, CSAP OPAC)
Ron Flegel (DTAB Chair, DWP Director)
Hyden Shen (DWP)
Charles LoDico (DWP)
Eugene Hayes (DWP)
Deborah Galvin (DWP)
Anastasia Donovan (DWP)
Coleen Sanderson (DWP)
Jennifer Fan (DWP)
Mercedes Guzman (DWP)
Richard Carmi (CSAP Deputy Director)
Lindsey Gonzales (CBHSQ Special Assistant)

Others in Attendance

Ian Rucker
Christian Mahler

DAY 1, SEPTEMBER 25, 2019

Regulatory Program Discussion and Requirements of Mandatory Guidelines (Department of Transportation, Nuclear Regulatory Commission, Department of Defense and Department of Health and Human Services), Ron Flegel, Director, Division of Workplace Programs (DWP), CSAP, SAMHSA

HHS received authorization from Congress, pursuant to the SUPPORT for Patients and Communities Act, to develop Mandatory Guidelines for hair drug testing. Since then a draft of the guidelines was developed with input from DTAB, submitted to OMB, and sent to all interested federal agencies for review. The final draft of the Mandatory Guidelines for oral fluid will be submitted to OMB. Congress authorized a review of fentanyl and DTAB recommended the addition of fentanyl and methadone to the urine Mandatory Guidelines. The HHS Secretary has not yet made a decision. Approval would require inclusion of the drugs DOT tests. Agencies are independent and may or may not decide to add any analyte to their drug test panels. Finally, DTAB has recommended considering more expeditious processes to add or delete drugs within the HHS Mandatory Guidelines

Mr. LoDico discussed the regular three-year review/revision of the current urine-only federal custody and control form (CCF), which expires on August 20, 2020. Since a final Mandatory Guidelines for oral fluid is also pending, the best option is to design a combined Chain of Custody form to cover urine and oral fluid. A working group was established and developed a draft. Within eight months a Federal Register Notice will be published, and a study of burden hours required by the donor to complete the application process will be completed. If that application is not approved within eight months, an extension of the current CCF will be obtained pending approval.

Reports from ex officio members.

The DoD added fentanyl to its test panel. An initial test that is positive for both cocaine and any other opioid will require retesting with a fentanyl-specific screen. Some military service members unexpectedly tested positive because some dental extractions included sedation with fentanyl, recorded in lab notes, not medical records. About hemp products, the Army and the Air Force always banned use of any hemp products, as did the Navy, with the exception of topicals. Hemp products can trigger a positive test result. DOT reported that FMCSA collects data on positives, refusals to test, and alcohol violations for the motor carrier industry only. The FMCSA clearinghouse for that data becomes effective January 6, 2020. DOT's ODAPC has received many inquiries about allowable CBD use. Since a positive test could result, DOT's response was to issue a "buyer beware" notice. The NRC reported that its proposed rule was published as an FRN with a comment period ending on December 2, and a public hearing set for early November. NRC is proposing the alignment with HHS guidelines. Finally, FDA is working to expedite review of collection devices so that, when mandatory guidelines are published, there will be approved devices available to testing labs.

Latest Studies from Behavioral Pharmacology Research Unit (BPRU), Johns Hopkins, Ed Cone & Ryan Vandrey

BPRU began studies of CBD three years ago. The pilot study was completed, and subsequent studies are close to final results. CBD is widely available in thousands of products. Elixinol is sold in one-millimeter dose pens and, because it is derived from plants, may contain THC. Epidiolex, a Schedule V CBD oil, is FDA-approved for the treatment of pediatric febrile seizures and as an appetite stimulant. CBD products are big business, expected to reach \$2 billion by 2020. During the studies, the Agriculture Improvement Act of 2018 (Farm Bill) was enacted, legalizing hemp that could contain up to 0.3% THC. The current studies are looking at several aspects of CBD use: the exceptional similarity in the chemical structure of CBD and THC and the potential for conversion of CBD to THC; the route of administration of CBD; the role of contamination; and developing tests to differentiate users of marijuana versus CBD. The effects of CBD – humans recognize a drug effect that is not like THC. It is not euphoric, not like being high on THC.

Latest Studies from National Laboratory Certification Program, Ruth Winecker, RTI

Dr. Winecker briefly mentioned studies completed and new studies undertaken since the last DTAB meeting. The NLCP invited commercial labs to look at whether CBDA in urine screens positive for THCA, whether it is converted to THCA during confirmatory testing and, if so, at what concentrations and at what conversion percentage? And is there a synergistic effect of CBDA mixed with THCA? The result – with CBDA all specimens tested with four assays were negative; all labs reported no assays were reactive with any CBDA specimens. Ultimately the study concluded that the presence of CBD or CBDA alone, would not lead to positive THCA results in urine specimens. However, CBD products could contain THC.

A new study will look at the stability of CBD and CBDA in specific specimens, such as 7-carboxy CBD to convert to CBDA during storage. Another study will assess CBD stability in oral fluid when collected and stored at room temperature and refrigerated. Studies after that will look at CBD oral fluid PT and assess HHS-certified labs for risk of conversion of CBD to THC during analysis. And there will be a CBD pulse study. Finally, there will be a study of delta 8 THC in urine because it interferes with the delta 9 THC/THCA confirmation test. Delta 8 THC is of interest to drug users because it has a different kind of high, and possibly less undesirable side effects (less paranoia, a milder high). There is also a general perception that delta 8 THC can be used as an alternative to avoid delta 9 THC positives on federal drug tests.

Discussion of Hair Mandatory Guidelines.

Mr. Flegel stated that the Department has included a substantial explanation of scientific and legal issues that prevent using hair as a standalone drug test. An exception is that an employer or agency may authorize testing of a hair sample if another authorized sample (at this time, urine) is also collected. The two samples, which could be collected at the same time, or the second collected after analysis of the first sample, would be sent to different labs for analysis. As much as 95% of hair samples test negative, obviating the need for, but not the collection of the authorized sample. There is a nominal added cost to collect the authorized sample, but significant cost for the analysis. One consideration is contamination of samples, an issue that could be solved by identifying unique metabolites, an option not currently available for all drugs.

Results of testing hair, because it provides a profile of drug use over a longer period of time than other forms of testing, is a reflection of lifestyle. A negative test usually indicates a drug-free lifestyle, and there is little or no interest in pushback as a result of a negative test. The positive tests, only 5% of all hair tests, suggest a more chronic or more recent drug use and requires additional testing with an authorized sample. The department will solicit public comments about Hair Mandatory Guidelines and seek scientific information in other ways.

There was consensus that information gained from the public, including the scientific and legal communities, is important to mapping the road to a standalone hair test. When there is a positive test result there must be a robust system that guarantees there is no contamination and that the result is a true positive. Another important question for public comment is the issue of unique analytes and their related drugs. Unique analytes would obviate the problems presented by contamination.

Adjournment

Matthew Aumen adjourned the closed session DTAB meeting at 3:30 p.m.