SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened in open session on December 7, 2021 at 10:00 a.m.

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Board Members in Attendance
- Mr. Ronald Flegel, Chairman
- Ms. Kristen Burke
- Ms. D. Faye Caldwell
- Dr. David Engelhart
- Ms. Deborah Motika
- Dr. Barry Sample
- Ms. Alison Stockdale
- Dr. Jason Schaff
- Dr. Elizabeth Stuyt

Acting Designated Federal Officer
- Anastasia Donovan
Call to Order, Ms. Anastasia Donovan, Acting Designated Federal Officer, DTAB

Ms. Anastasia Donovan, 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. Ms. Donovan expressed appreciation to CAPT Jennifer Fan for her outstanding service as DFO of the DTAB, noting that she had moved on to FDA. She also welcomed new board members Dr. David Engelhart and Dr. Elizabeth Stuyt. She briefly reviewed the agenda, which included the usual updates from the Department of Transportation (DOT), the Nuclear Regulatory Commission (NRC) and the Department of Defense (DoD) and noted that Dr. Ed Cone would make a presentation on tetrahydrocannabinol isomerism. Finally, she stated that the summary of this meeting would be posted in due course on the DTAB website. She invited Mr. Flegel to provide introductory remarks.

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

Mr. Flegel thanked Ms. Donovan for accepting the responsibility of Acting Designated Federal Officer and welcomed the board members and other participants. He stated that SAMHSA is dedicated to maintaining the quality and supporting the services of the federally regulated drug testing program, which includes setting standards for laboratory certification of the federal workplace drug testing program. Mr. Flegel commented that the Federal Register Notice of Proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair was published in the Federal Register for public comment on September 10, 2020. The public comment period closed on November 9, 2020. The proposal provided that Mandatory Guidelines would allow federal executive branch agencies to collect and test hair specimens as part of the workplace testing programs.

Hair testing would be limited to pre-employment for applicants applying for federal testing designated positions, and also for random testing. A federal agency choosing to test hair specimens would be required to collect and test at least one other specimen, either urine or oral fluid. The agency will also be required to provide procedures for collection of an alternate specimen (urine or oral fluid), in the event that the donor would be unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to insufficient amount of hair. SAMHSA is currently engaged in revising the proposed Mandatory Guidelines for hair based on public comments received and a review of current scientific literature. Once complete, the draft of the final hair Mandatory Guidelines will undergo HHS departmental clearance and ultimately OMB review, followed by a final Federal Register notice. The Mandatory Guidelines for federal workplace testing programs using urine and oral fluid are now in HHS departmental review and clearance. These proposed revisions would enable modification of the authorized drugs and the cutoffs as needed, which would also aid in the detection of donor attempts to subvert drug tests.

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

Mr. Baczara stated that guidance issued by the Office of Alcohol Policy and Compliance (ODAPC) and DOT agencies – the Federal Transit Administration (FTA), the Federal Railroad Administration (FRA), and the Federal Aviation Administration (FAA) – states that agencies are to continue testing as usual, and if testing cannot be done, the agency must fully document the event for any inspections or audits that might occur later, and this guidance remains in effect until June 2022. ODAPC published additional guidance stating remote evaluations by Substance Abuse Professionals (SAPS) is authorized if two-way audio-video is employed.
Service agents, collectors, BATs, STTs, MROs, and SAPs may continue in good standing if unable to obtain immediate requalification.

Mr. Baczara reported that the Federal Motor Carrier Safety Administration (FMCSA) Clearinghouse maintains statistics on driver safety reports. The reports showed that there were almost 9 million queries revealing 101,081 drug violations and 2,283 alcohol violations, and there were 75,337 placed on prohibited status. Most predominant drugs reported were marijuana, cocaine, methamphetamines, and the test reason with the most violations is preemployment testing. Those on prohibited status can regain qualification if they successfully complete the mandatory return to duty process. OMB temporarily approved the use of the 2017 custody and control form (CCF) effective November 23, 2021. This means that in the event collection sites do not have the new form, they may use the old form and do not need a memorandum for record for specimens collected after November 23, 2021. For specimens that were collected on the 2017 CCF from August 30, 2021, until November 22, 2021, collection sites will still need to complete a memorandum of record.

ODAPC published several rulemakings in the spring of 2021. First, the addition of oral fluid specimen testing for drugs in lieu of a urine specimen is in the proposed rule stage. Next, providing DOT-regulated employees an appeal process for employer-decided refusals to test. Lastly, allowing electronic signatures, electronic forms and to permit electronic records storage for drug and alcohol testing records.

The 2022 random testing rates for both the FTA and FAA will remain the same as before (FTA 50% for drugs and 10% for alcohol, FAA 25% for drugs and 10% for alcohol).

Finally, the Management Information Systems (MIS) aggregate data was published and submitted to Congress as required and the reports are available on the ODAPC website. This database shows drug and alcohol testing data reported by employers for each mode of transportation and is updated annually. ODAPC resources are also published on that website: a self-administered questionnaire “Am I Covered?”; the extensive Listserv notices; a discussion of Part 40; and a Guidance page that includes COVID-19 information.

**Nuclear Regulatory Commission Update (NRC), Paul Harris, Senior Program Manager, Fitness for duty Programs, Drugs and Alcohol**

Mr. Harris explained that his office provides regulatory oversight for the federal regulations concerned with the NRC’s Fitness for Duty programs. The insights provided by the DTAB significantly inform the NRC’s federally mandated drug testing framework, which includes the performance testing results collected for the commercial nuclear industry, all the nuclear power plants and the two Category 1 fuel fabrication facilities that provide nuclear fuel for the industry. Mr. Harris commented that the program objective is to ensure that personnel are fit for duty, trustworthy and reliable, which includes the requirement that they are not impaired by any substance to which they may be exposed on duty or off duty, in the plants or off NRC property. The program includes not only drug testing, but behavior observation on and off duty and regular character reviews.

All personnel are subject to 50% random testing on the job, mandatory pre-access testing, post-event testing, and for-cause testing. Concerning the results of the testing, typically about 67% of positive drug test results identified are from the pre-access part of the program, and 22% were identified on the random testing part. Also, of interest is that those full and part time
employees who are licensees test positive far less often than those who are outside contractors and vendors who test positive about four times more often. Mr. Harris added that if the DTAB successfully approves the addition of hair testing, it would substantially improve the evaluation of individuals applying for pre-access to nuclear facilities. He also noted that alcohol has the highest prevalence of use among the licensees, and for contractor/vendor personnel the top spot is taken by marijuana. Opiates are negligible by comparison. Individuals who attempt to bypass testing are defined as individuals who tried to subvert the testing and are usually identified in the pre-access testing.

The NRC has historically relied on DHHS to take the lead in developing Guidelines for specimen testing for drugs and for the rulemaking aspect of the process, in part because the DHHS has much more experience and the availability of staff to support the effort. Rulemaking is, however, conducted by the NRC and the NRC Commission, and the agency regularly reviews the program and any changes to the process. The proposed final rule Part 26 HHS Guidelines, which will align drug testing requirements with the 2008 and 2017 Mandatory Guidelines, is currently under review with the NRC Commission. Rulemaking takes time, and in an effort to reduce delays, there is a newly proposed reactor framework to enable licensees to make timely changes when that occurs such as changes to the drug testing panel.

Department of Defense Update, CAPT Erin Wilfong, Ph.D., USN, and Lynn Wagner, Ph.D., NRCC-TC, Office of Drug Demand Reduction, Office of the Executive Director, Force Resiliency, Office of the Under Secretary of Defense (Personnel and Readiness)

CAPT Wilfong described the DoD drug testing program that is supported by five drug testing labs and proficiency testing and quality assurance support from the Armed Forces Medical Examiner System lab in Dover, Delaware. In an effort to become more responsive, CAPT Wilfong explained that the DoD has adopted the assess-decide-implement-assure model in order to quickly expand testing capabilities. One of the outcomes of using this model focused on implementation of mass spectrometry screening at all five labs using the Agilent RapidFire platform to speed up and expand drug testing. Initially, three drug groups are involved in the program – LSD, synthetic cannabinoids and amphetamines (including designer drugs). The RapidFire platform incorporates solid phase extraction linked to mass spectrometry, using a Hamilton Microstar automated liquid handling sample prep system. DoD has already developed methods for three drug classes, some of which are already online, which dramatically speeds up the testing process and requires very small samples, all of which are urine in the DoD system. For example, the sample for LSD is three microliters and the test takes 19 seconds. The synthetic cannabinoid test requires 20 microliters and also takes 19 seconds on the automated rapid-fire instrument. The test for amphetamines needs one microliter of specimen to identify four compounds and the test takes 14.6 seconds. Since December 2020, the five labs have tested 200,000 samples by immunoassay for LSD. The rapid process has reduced the workload by 97% and the confirmation rate is 26.7%. CAPT Wilfong commented that the agility modeling resulted in a modification of the DoD drug testing panel when delta-8 THC was added to the panel in 2021, which occurred after the DoD labs and others began seeing delta-8 THC test results back in 2019.

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

Mr. Flegel mentioned two additions to the Division of Workplace Programs (DWP) personnel – Lisa Davis as senior toxicology policy advisor, and LCDR Joshua Hunt, a senior pharmacist.
DTAB has a new member in the clearance process, David Roberts. A goal is to continue to support the national drug policy and to assess the science and technology used in drug detection. A significant goal is to complete the proposed Mandatory Guidelines for hair for publication in the Federal Register. A more specific goal is to implement the first HHS-certified oral fluid lab, which will contribute to the program implementation of oral fluid as an alternative specimen. Mr. Flegel noted that a Summit meeting will take place which will involve a high-level review of the DFWP and will identify key policy and technical issues as well as existing challenges.

Mr. Flegel commented that the last revision of the Urine Mandatory Guidelines was implemented on October 1, 2017, and the Oral Fluid Mandatory Guidelines was implemented on January 1, 2020. The proposed Hair Mandatory Guidelines was published on September 10, 2020, and the final rule is going through review for clarification of technical issues. Under the proposed hair Guidelines, new standards and technical requirements for hair collection procedures and materials have been established, as have initial and confirmatory drug test analytes, cutoffs, and methods for hair testing. The Mandatory Guidelines using hair will include the same list of substances allowed to be tested in the Mandatory Guidelines using urine and oral fluid. Labs have been given requirements for decontamination procedures and identification of hair that has been damaged such that a drug test could be affected. Mr. Flegel mentioned that when the proposed hair Guidelines were first published in the Federal Register there were over 700 comments from 213 commenters, all of which were presented to DTAB in a closed session on March 21, followed by review and discussion of the draft hair Mandatory Guidelines in a closed session in June 2021. Finally, HHS will publish a final Federal Register Notice with supplemental revisions to the proposed Hair Mandatory Guidelines that will harmonize the Guidelines for all three test matrices – hair, oral fluid, and urine – and will authorize hair as a matrix that can be used in the federal drug testing program.

Mr. Flegel mentioned that the last year has seen a number of studies by the National Laboratory Certification Program (NLCP), which included a look at hair inventory, exploratory blind investigation, delta-8 THC cross-reactivity in HHS certified labs, CBD metabolites in urine, Q-TOF screening methods, urine adulterants, analysis of acidic foods containing CBD, hair extract analyze formation, chronic dosing of CBD, typical applications of CBD, THC and CBD pulse studies and others. And there are ongoing marijuana studies. The NLCP will also certify labs to conduct oral fluid testing as it did for urine.

Presentation: Tetrahydrocannabinol Isomerism, Edward Cone Ph.D., Johns Hopkins University

Dr. Cone explained that there is a hierarchy of names for different families of constitutional or structural isomers, and the more complex stereoisomers are divided into diastereomers and enantiomers or optical isomers, which are chiral molecules that have identical physical properties but cannot be superimposed on each other, like the right and left hand that are mirror images. Dr. Cone introduced the topic of THC isomers and their memory systems, and specifically the delta-9 isomer that has a double bond between carbon 9 and carbon 10. By manipulating the position of the double bond, one can create a total of 30 stereoisomers of THC. The first isomer of interest is the familiar delta-9 isomer, followed by delta-8 and delta-7. There are three more isomers of THC – the delta-6a(7), the delta-6a(10a), and the delta-10. The delta-9 is the most familiar in research settings. It produces a feeling of euphoria along with behavioral and physiological effects and its use can change perceptions, impair short-term memory, and high doses can induce paranoia, delusions and psychosis.
The next most familiar isomer is delta-8 which is now extensively available. It was tested in humans and produced effects similar to delta-9 but was only about 75% as potent. Because of the emergence of the delta-8 isomer, labs should develop protocols that ensure they can accurately distinguish between the two isomers. The delta 6a-10a isomers are not naturally occurring and produce psychic effects similar to delta-9 but was about one-third to one-sixth as potent. The delta-7 isomer has effects similar to delta-9 and is not naturally occurring. Delta-6a (7)-THC is also not naturally occurring and has not been tested in humans yet, but articles have reported methods of synthesis. The final two isomers, delta-10-THC and delta 9(11)-THC are anecdotally reported to be similar in psychoactive effect to delta-9-THC, but they have not been tested in humans.

Dr. Cone commented that he read the World Health Organization’s Expert Committee on Drug Dependence 2018 statement that, after reviewing the chemistry, pharmacology, and toxicology of the seven isomers of THC, the Expert Committee found no evidence that any of the isomers were being abused or likely to be abused, so as to constitute a public health problem. Dr. Cone suggested the statement may have been released prematurely considering the current widespread availability of delta-8-THC. A recent article in Chemical and Engineering News expressed concerns about currently available delta-8-THC products, which significantly increased after passage of the 2018 Farm Bill that legalized the production and sale of hemp and hemp products. The surplus depressed the market price for CBD and producers turned to delta-8-THC for consumers looking for relief of stress and anxiety. With no regulatory oversight and limited lab testing, most products sold as THC are not pure.

In another strange turn of events a company named Fusion Farms bought a large amount of cannabis biomass that had apparently been contaminated by a flame retardant, a byproduct of fighting the massive wildfires in the California area. Purification of the product by distillation resulted in a crystalline substance that was finally identified as delta-10-THC. It was anecdotally reported as half as potent as delta-9 but more stimulating and it had a cognitive enhancement effect and fewer side effects than delta-9.

Dr. Cone concluded his presentation with a discussion of CBD, which is a structural isomer of delta-9-THC, with the same molecular formula and same stereochemical configuration. CBD can convert to delta-9 and delta-8-THC and is very labile under acid conditions. Merrick et al reported rapid conversion of CBD to delta-8 and delta-9 in simulated gastric fluids, and under acid storage conditions CBD and hemp can be converted to THC. One study indicated that heat-treated CBD at e-cigarette temperatures of 250 to 400 degrees led to the formation of delta-8-THC and delta-9-THC, but a similar study at Johns Hopkins University using lower vaping temperature resulted in no evidence of blood or urine conversion.

**Federal eCCF Update and OMB Extension, Eugene Hayes, Ph.D. DWP**

Dr. Hayes explained that there are two Custody and Control Forms (CCFs) currently approved for use. Because there was a shortage of the more recent 2020 form that combined reporting urine and oral fluid on one form, the OMB approved an extension for the use of the 2017 form that had expired in August 2021. The approval was affective as of November 23rd. A review of that extension will be conducted some time in 2022. Dr. Hayes commented that the fully electronic version should be approved within that timeframe.
Public Comment

Ms. Donovan invited public comment. Samir Kapadia from the Vogel Group offered a comment as a representative of the Drug and Alcohol Testing Industry Association, composed of 1,500 member companies involved in the entire spectrum of the drug and alcohol service testing providers – collection sites, labs, third party administrators, MROs, testing equipment manufacturers and others. The Association is interested in participating in the evolving definition of safety sensitive positions.

Carl Selavka, a forensic toxicologist, stated that the DTAB appropriately focused on better understanding changes in interpretive assistance to be offered to employers for individuals who have medical marijuana cards or are legally using products that contain THC in states with recreational marijuana allowances. The compliance picture fundamentally changes when the drug moves from zero tolerance and elicit status to a legal status. He indicated the objective would be to understand how to support individual medical freedom while balancing employer expectations for unimpaired workers who have no preventable health concerns. He proposed that DTAB explore potential inclusion of ethanol biomarkers among the target analytes included in allowed test scopes going forward.

Adjournment

Ms. Donovan stated that there were no other public comments pending, no further business for the open session and adjourned the open session of the meeting.