SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened on June 21, 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 2:15 p.m.

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Board Members in Attendance

Ronald Flegel, Chairman
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.
Call to Order - Approval of March 9 DTAB Meeting Minutes, Lisa Davis, Designated Federal Officer, DTAB

Ms. Lisa Davis, 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 to the March 9, 2022 meeting and there were none. Ms. Davis invited approval of those minutes and, on motion duly made by Dr. Sample and seconded by Ms. Motika, the minutes of the March 9, 2022 meeting were unanimously approved. 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 expressed appreciation to DTAB members, ex officio members, industry representatives and members of the public for attending and participating in the meeting. He introduced two new members of DTAB, Ms. Lindsey Everson and Dr. David Roberts, and he expressed appreciation to Faye Caldwell, who recently ended her term as a board member, for her contributions to the board. He reiterated the mission of the board is to continue to improve the quality of the drug testing program for federally regulated and private drug testing programs by setting standards for certification of drug testing programs. The DWP has planned a comprehensive review of policies and practices.
The Notice of Proposed Mandatory Guidelines for federal workplace testing programs using hair was published in the Federal Register on September 10, 2020. The public comment period closed on November 9, 2020. The DWP is working on the final review of the draft final hair Mandatory Guidelines, which will go through HHS clearance and then final review by the Office of Management and Budget (OMB). The new guidelines for urine and oral fluid were published on April 4, 2022, and the public comment period ended on June 6, 2022. There were 47 comments, 18 for urine and 29 for oral fluid. The goal of the proposed revision is to facilitate modifications to authorized drugs and cutoffs as needed.

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

Mr. Baczara stated that three Covid-19 guidance documents published by the DOT agencies (FTA, FRA, FAA) continue in effect. They mandated continued testing, if possible, but if not, fully documented circumstances to provide information about the interruption when and if the DOT performs a review or audit. The DOT issued a COVID-19 Drug and Alcohol Testing Statement of Enforcement Discretion of Substance Abuse Professionals (SAPs) and Service Agents extending an option to conduct remote evaluations until December 31 but did not extend the provisions of that document to change the requalification timeline since there were no known situations related to obstacles for requalification.

Mr. Baczara commented that the Federal Motor Carrier Safety Administration (FMCSA) Driver Clearinghouse maintains information related to Part 382 violations (https://clearinghouse.fmcsa.dot.gov/ Resource/Index/monthly-report-April2022). Contributors include employers, medical review officers (MROs) and substance abuse professionals (SAPs). By May 1, 2022, there were 12 million queries conducted, mainly employers checking the status of an individual as to ability to perform safety-sensitive duties. There were about 132,152 drug violations reported and about 3,000 alcohol violations. Marijuana, cocaine, and methamphetamine were the most commonly reported drugs, and preemployment was the primary reason with the most violations. There are about 92,000 drivers prohibited by DOT employers from performing safety-sensitive duties until they complete the return to duty process.

The DOT published a Notice of Proposed Rulemaking (NPRM) in February 2022 to add oral fluid to the DOT drug testing program, with a public comment period until April 29. About 417 comments were received, which are currently under review and consideration. Mr. Baczara noted that DOT has a management information system for data reported by employers on its website that allows industry to submit negative and positive test results. There is no personally identifiable information permitted. Resources on the home page include a guidance as to whether an individual is covered by their regulations, a listserv, a page for Part 40, and an e-mail to ask questions.

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

Mr. Harris discussed the NRC’s Fitness for Duty program. As of May 25, 2022, there were 54 operating nuclear power plants in the U.S., which operate 92 nuclear reactors in 28 states. Fit for Duty describes an individual who is trustworthy and reliable, and not under the influence of any legal or illegal substance that might mentally or physically impair performance of duties. The program is based on “defense in depth” that includes rigid access authorization to enter
facilities; requires fatigue management; and behavioral observations composed of fitness and security perspectives. Mr. Harris presented data on drug testing that includes licensee employees and contractor/vendors. Licensees are effectively full- or part-time NRC employees. Pre-access (screening) testing has the highest positivity rate in which contract employees test positive at three times the rate of licensee employees. Under random testing protocols the contractor employees test positive at a rate four times higher than licensee employees. Finally, drug preference data shows that alcohol and marijuana continue to be the substances of choice, followed by cocaine and amphetamines. Twenty percent of contractor vendors fall into the refusal to test category.

The detection trends determine that marijuana continues to be a prevalently used drug. Cocaine has decreased over a number of years, whereas amphetamines have risen. Mr. Harris briefly discussed subversion attempts, efforts to alter drug test results or adulterate test samples, mainly on pre-testing (over 70%), mainly perpetrated by contractor/vendor employees (95%).

Mr. Harris commented on proposed rulemaking, specifically for Part 53 Fitness for Duty Framework which is a move towards risk-informed. The proposal is technology inclusive, which enables urine and oral fluid tests in all test conditions, use of hair for pre-access testing for Schedule 1 drugs; point of collection testing and assessment devices; and passive drug and alcohol screening devices.

Update on the Drug Free Workplace Program Comprehensive Review, Lisa Davis, M.S., DTAB, CSAP, SAMHSA

Ms. Davis stated that, since the program was established, there has not been a comprehensive review. To that end, three working groups were formed: WG 1 – Current legal, political and social issues; WG 2 – Scientific and laboratory issues; and WG 3 – Program management. The working groups met virtually in May 2022 to establish a baseline of understanding of the charge and agreed to meet again during the summer to develop a summary report of issues, assess strengths and weaknesses, identify science and policy challenges, and consider tasks to address the challenges.

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

Mr. Flegel showed a roster of the DWP staff, introducing new or returning members, Sean Belouin, Christie Lamb, and Joshua Hunt. He summarized the overall goal of the DWP, to continually assess science and technology of drug detection to support the national drug policy. A more immediate goal is to achieve HHS certification of an oral fluid laboratory and to publish Mandatory Guidelines for Hair in the Federal Register. Finally, conduct a high-level review of the Drug Free Workplace Program, which covers the federal executive branch agencies, the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense and it’s civilian employees, affecting about 14 million employees. The DWP oversees the Mandatory Guidelines for Drug Testing, the National Lab Certification Program (NCLP), the Drug Testing Advisory Board (DTAB) and the training of medical review officers (MROs). The DWP is also involved in providing technical assistance to federal agencies, certification of federal agency plans for policy and procedures, working with the Interagency Coordinating Group Executive Committee and evaluating the impact of policies and legislation.
Concerning development and approval of Mandatory Guidelines, the process is complex and lengthy. The Proposed Mandatory Guidelines for Urine and oral were published on April 7, 2022. The proposed Mandatory Guidelines for Hair were published on September 10, 2020, and the public comments are currently being reviewed. Mr. Flegel mentioned the major revisions under way, including revision of the timeline and process for publishing the drug testing panel, and establishing the same for an authorized biomarker testing panel; raising the morphine confirmatory cutoff from 2,000 ng/mL to 4,000; revising the MRO verification process for positive codeine and morphine specimens; and requiring MROs to submit semiannual reports on specimens reported positive by a lab and verified negative by the MRO. There were also changes to codeine and morphine certification that included removing the requirement for clinical evidence of illegal opioid use.

Mr. Flegel went over the timeline for publishing revised proposed Urine and Oral Fluid Mandatory Guidelines (April 7, 2022), a supplement to the proposed Hair Mandatory Guidelines, and ultimately the final Urine and Oral Fluid and Hair Mandatory Guidelines. Beginning in 2022 there will be a high-level review of the Drug Free Workplace Program to assess policy and technical issues and existing challenges. Regarding the Hair Mandatory Guidelines, public comments were gathered and reviewed, as well as recently published scientific papers, and DTAB held closed meetings in March and June of 2021 to discuss those public comments and to review the draft of the Hair Mandatory Guidelines. Finally, SAMHSA held listening sessions with seven commercial labs to consider performance testing programs, quantitative agreements among labs, and drug metabolite criteria for reporting drug positive results in hair. Also covered in the listening sessions were performance testing of samples (reference drug solution supplied with a blank matrix, reference samples produced from drug user hair, and contaminated hair), the need for consensus among labs for performance testing and methods used to liberate drug from hair matrix, and finally the need to establish working groups to work on related issues. Mr. Flegel indicated that a decision tree is needed to report positive test results for hydroxy cocaine for cocaine, amphetamine and methamphetamine. There are concerns by some labs that the proposed Hair Mandatory Guidelines do not require metabolites for reporting positive tests. Rules are needed for reporting morphine.

Mr. Flegel showed a listing of current National Laboratory Certification Program studies, some completed (hair lab results, delta-8 THCA cross reactivity, urine adulterants) and some in progress, related to acidic foods containing CBD, hair extract analyte formation, hair PT development, opioid glucuronide, and cannabinoid in hair, and Johns Hopkins University studies on chronic dosing of CBD, topical application of CBD and a Delta-8 dosing study. There are emerging issues in legislation (2015 FAST Act, 2018 Farm bill, and the 2018 Opioids Crisis Act). Ongoing challenges include new and novel drugs continue to emerge, the increased availability of marijuana as state laws are relaxed, and the increased demands on the DFWP related to the COVID-19 return to office challenges.

Ongoing challenges include finalizing Hair Mandatory Guidelines and implementing and funding new programs, addressing emerging issues already mentioned, and implementing the final Mandatory Guidelines for Urine, Oral Fluid and Hair, and conducting the high-level review of the DFWP described above. Mr. Flegel ended his presentation.
Updates on the Drug Free Workplace Program Supervisor Training, Website, FAQ’s, Hyden Shen, Policy and Regulatory Oversight Lead, DWP, CSAP, SAMHSA

Mr. Shen described three initiatives that have been implemented to improve the consistency, viability and stability of the Drug Free Workplace program. The first is an online training module to educate agency supervisors about programs and their responsibilities. This is meant to resolve the issue of outdated and/or inaccurate information and ensure government-wide standardization and consistency in agency policies and procedures. The module is free and available online to all agencies. Second, the DWP website has been completely updated and streamlined, and duplicate and outdated information has been eliminated. Third, the process of upgrading has provided the opportunity to create a frequently asked questions (FAQ) section to answer questions that have been asked most often in the past. Mr. Shen concluded his remarks.

Presentation: Workforce Drug Testing for Marijuana in 2021, Barry Sample, Ph.D.

Dr. Sample presented information on positive workforce testing results. Overall positivity for all drugs tested from 2020 to 2021 in the federally mandated safety sensitive federal workforce was 2.2%, about 5% higher than in 2017. In general workforce urine the positivity went up to 3.9%, the highest since 1996. The positivity rate for federally mandated marijuana testing increased over 9% between 2020 and 2021. Cocaine tests were up 5%. Dr. Sample provided data on marijuana in states with legal recreational use, states with medical only use, and states in which marijuana use is illegal across the board. In recreational use states there has been an increase in positivity rates of about 45% as compared with non-medical, non-recreational positivity states with a positivity increase of approximately 16%. Some employers now choose to remove marijuana from drug testing panels. Nationally, approximately 90 percent of urine tests now include marijuana.

Dr. Sample turned to specimen validity testing (SVT), noting that the invalid rates have increased significantly, up over 70 percent since 2017, indicating an increase in donor attempts to frustrate the testing, in part because the COVID pandemic resulted in less physical contact between the testers and the tested, negatively affecting observation. Looking at positivity by testing reason, post-accident testing has increased 83 percent, increasing significantly in 2018, perhaps due to the inclusion of prescription opiates. Concerning marijuana urine drug test results between 2012 and 2021, random testing and pre-employment testing positivity rates have not changed much, but post-accident testing positivity rate has increased steadily and significantly during that time, increasing 114 percent. During the same time, pre-employment cocaine positivity declined but post-accident cocaine positivity increased.

In summary, Dr. Sample pointed out that the difference in post-accident positivity verses pre-employment positivity increased in both the safety-sensitive and general workforces, in the case of marijuana, the increase was more than 25 times for the former and 2 times for the latter despite a significant decline in marijuana being included testing panels in recreational use states. Overall positivity in the combined U.S. workforce increased to 4.6% in 2021, up 31% in the last 10 years from a low of 3.5%. Dr. Sample ended his presentation.
Dr. Vikingsson explained that testing for cocaine in hair is challenging because cocaine can be incorporated from blood, sweat and externally from the environment. It is difficult to remove the externally contaminated cocaine due to differences in drug incorporation in hair complicated by damage from dying or bleaching and even brushing. In 2004 a proposed rule proposed the presence of the metabolites of cocaine, benzoylecgonine (BZE) at 5% of cocaine concentration or the presence of cocaethylene above a cutoff. Both of these criteria have been found to be problematic. Other alternative options are hydroxy cocaine metabolites. Dr. Vikingsson noted the importance of establishing cutoffs that exclude contamination to protect innocent donors from a determination of a positive result that is not from drug use. There are two approaches to evaluating hydroxy cocaine cutoffs. One is quantitating the metabolite levels above a cutoff value, but hydroxy cocaine contamination has a large quantitative range. Thus, utilizing a cutoff based on the ratio of each of the metabolites to the parent appears more useful.

Dr. Vikingsson summarized that cocaine is a difficult marker to use because it is difficult to decontaminate; that benzoylecgonine and cocaethylene are also not a good markers because they are either present in street cocaine or form in contaminated hair. Hydroxy cocaine ratios offer the possibility to establish a cutoff. Dr. Vikingsson ended his presentation.

Public Comment

Ms. Davis invited the first commenter, Andrea Steel, to speak. Ms. Steel, an attorney representing various interests in the cannabis industry supply chain, felt that testing for THC is problematic because there are numerous consumable hemp-derived products that are federally legal under the Farm Bill, which removed hemp from the Controlled Substance Act. The definition allows for a small amount of delta-9-THC and other forms of THC outside of delta-9 that could result in a positive test result. If testing cannot differentiate between different isomers of THC, then a positive test result for THC would not constitute evidence of illegal use of marijuana. There are also many CBD products that have higher levels of THC that still meet the Farm Bill definition. She recommended removing testing for THCA metabolites until there is a valid scientific test that can differentiate between legal and illegal cannabis-derived substances. There are 37 states that have approved medical marijuana laws and another 10 that have approved low THC for medical purposes, yet the rule states that a medical recommendation for a schedule 1 controlled substance is not a legitimate medical explanation for a positive test result, which undermines physician competency. She recommended a carve-out that would exempt a cannabis patient if evidence is provided of a state-licensed physician recommendation for cannabis in compliance with the state regulations. Finally, she recommended that if THC testing is required at all, that test should be based on an oral fluid analysis.

Daniel Horvath, with the American Trucking Associations, stated that ATA has long endorsed hair testing, but feels that requiring an alternate specimen in the event of a positive hair test result as recommended in the 2020 proposal is problematic and delegitimizes the hair testing program. Also, hair testing results today cannot be reported to DOT’s drug and alcohol clearinghouse. Hair testing is a safety issue that would result in removal of drivers from the nation’s highways who test positive and get them help before they return to duty.
Doug Voss, a professor of logistics and supply chain management at the University of Central Arkansas, commented on recent peer-reviewed research in urine and hair drug testing recently published in the Journal of Transportation Management. The research suggested that if all U.S. truck drivers submitted to a hair drug test, about 275,000 drivers would be disqualified from the workforce. Secondly, the study evaluated disparate impact of hair testing on ethnic minority groups utilizing the Four-Fifths rule, which provides that adverse impact is assumed if the selection rate for a specific group is less than 80% of that of the group with the highest selection rate. After testing eight ethnic groups, all exceeded the 80% criterion. Additionally, a chi-squared analysis was performed on the data. Both evaluation methods do not support the hypothesis that hair testing has disparate impact.

Greer Woodruff, with JB Hunt Transport, which has utilized preemployment and random hair testing since 2006 following two fatal accidents with failed post-accident drug tests that were positive for cocaine. JB Hunt began to seek a better way to ensure operators of JB Hunt trucks were drug free. JB Hunt previously shared comparative urine and hair drug test results from the same donor. They have presented data and research demonstrating that there is no racial or hair color bias based on specimen type. In the last 15 years, JB Hunt has had no legal challenges to the results of any hair test for any reason. As of March 2022, over 190,000 drivers have submitted to both a urinalysis and a hair test at JB Hunt. Their experience shows that hair tests are more reliable and accurate at identifying regular drug use than is urinalysis. Nine out of ten applicants who tested positive with the hair test passed the urine test. The proposed Federal Workplace drug testing Guidelines would compromise safety and prohibit JB Hunt from denying employment to those drivers provided they could pass a urine test. This creates a tremendous liability and a significant safety risk. Mr. Woodruff urged that the dual hair and urine positive drug test requirement be deleted from the future proposed rule.

Jo McGuire, executive director of the National Drug and Alcohol Screening Association, stated that the association is opposed to the proposal that changes to the drug panel may be made without the opportunity for public comment. She stated that public comment is necessary.

Michael Schaffer, a former member of DTAB, stated for the record that he did not agree with the guidelines published. Regarding hydroxy cocaine, with proper washing differentiation of drug users from non-drug users is reliable and accurate. Also, in a study similar to that of JB Hunt, it was determined that use of hydroxy cocaine removes any hair color bias. Finally, the Farm Bill introduces marijuana if the THC content is below a specified level (.3%). Dr. Schaffer contended that the level of THC can be lowered by adding extraneous plant parts to the mix (limbs and roots. Dr. Schaffer further noted that delta-8 products from CBD are one of the worst issues in a long time. He recommended taking a serious look at it.

Mr. Rector made an argument that drug testing doesn’t work. He stated that the database from the Federal Aviation Adminstration shows that in the last 30 years THC is only identifiable in 2.3% of post-accident drug tests. He suggested that pilots who pass post-accident drug tests would probably fail a fatigue or computerized impairment test.

Ms. Davis closed the public comment session.
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.