

**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  
June 11-12, 2019  
Minutes – Open Session**

SAMHSA's CSAP Drug Testing Advisory Board (DTAB) convened on June 11-12, 2019.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public from 9:30 a.m. to 4:30 p.m. A final presentation/discussion on Regulatory Program Requirements was scheduled for the open session on June 12, 2019 and is included herein.

**Table of Contents**

Board Members in Attendance .....	1
Call to Order .....	2
Welcome and Introductory Remarks.....	2
Department of Transportation (DOT) Update.....	3
Nuclear Regulatory Commission 10 CFR Part 26 Fitness for Duty Program Update, .....	5
Department of Defense Drug Testing Update .....	7
Program Updates by DWP (Urine, Oral Fluid, and Hair Mandatory Guidelines).....	8
Update on Emerging Marijuana Legalization .....	9
Drug Testing Index (DTI) Data: 2018 Update on Drug Use in the Workforce .....	10
Emerging Issues: Fentanyl and Fentanyl Analogs .....	12
2019 Update on Cannabidiol and Hemp Products .....	13
Regulatory Program Discussion and Requirements (DOT, NRC, DoD and HHS).....	15
Public Comment .....	16

**Board Members in Attendance**

- Ms. Kristen Burke
- Ms. D. Faye Caldwell
- Mr. Randal Clouette
- Dr. David Green
- Mr. Costantino Iannone (via teleconference)
- Ms. Deborah Motica
- Dr. Barry Sample
- Dr. Michael Schaffer
- Dr. Jason Schaff

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

**Call to Order**

Matthew Aumen, the Acting Designated Federal Officer of SAMHSA's CSAP Drug Testing Advisory Board (DTAB) announced that a quorum of the members was present, and called the meeting to order at 9:30a.m. He invited Ron Flegel, Director of the Division of Workplace Programs and chair of DTAB, to make opening remarks.

**Welcome and Introductory Remarks**

*Ron Flegel, B.S., MT(ASCAP), M.S., Director of the Division of Workplace Programs (DWP) and DTAB Chair*

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 noted that all the board members, except Mr. Steven Taylor, were present. He stated that the Interagency Coordinating Group Executive Committee (ICGEC) is an important part of the drug testing process, and he referred to Executive Order 12564 Federal Drug-Free Workplace Program, and Section 503 of Public Law 100-71. Both set out a series of discreet and collaborative roles for the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the Office of Personnel Management (OPM). HHS is responsible for the scientific and technical guidelines for the drug testing program and for the certification of agency plans and programs; DOJ provides legal advice on implementation; and OPM is responsible for appropriate benefits coverage, model employee assistance programs, and in cooperation with HHS, supervisor and employee education. In 1991, the Office of National Drug Control Policy (ONDCP) was named lead agency for the implementation of the Executive Order and has since chaired the ICGEC. Mr. Flegel introduced Dr. Roneet Lev, first Chief Medical Officer of the ONDCP, charged with providing medical leadership and coordinating drug policy across the federal government. She has extensive experience as an emergency physician. He invited her comments.

On behalf of the director of ONDCP, Dr. Lev expressed appreciation to the DTAB members for contributing their scientific knowledge and expertise in helping to develop drug testing standards for the federal workforce and associated groups. The ONDCP, in the Executive Office of the President, coordinates drug policy across 16 federal drug control program agencies. The president's budget proposal for FY 2020 includes \$34.6 billion to address every aspect of the addiction crisis, the highest funding ever for that purpose. Dr. Lev stated that part of her role as Chief Medical Officer is to strengthen coordination among public health agencies, law enforcement and community prevention programs in the U.S. It is estimated that over 20 million Americans over age 12 require treatment annually for substance abuse, a chronic relapsing disease. Dr. Lev added that an executive order issued in 1986 prohibits federal employees from using illegal substances on or off duty. She stated that ONDCP works with the Division of Workplace Programs and on the Federal Drug-Free Workplace Program to establish timely, evidence-based drug testing policy. Mr. Flegel expressed appreciation to Dr. Lev for her remarks.

Mr. Flegel announced changes in the Center for Substance Abuse Prevention (CSAP). Mr. Richard Carmi has been appointed Deputy Director, and Ms. Johnnetta Davis-Joyce, with a long career in public health, is the new CSAP Director. He invited Ms. Davis-Joyce to comment, and she stated that she was pleased to be at the DTAB meeting and expressed appreciation for the board's support of the CSAP mission. Mr. Flegel briefly outlined the day's agenda, discussed

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

the updates related to the DWP, which developed guidelines for the Federal Workplace Drug Testing Programs. SAMHSA continues to support improvements in the federal drug testing programs and programs in the private sector, which ultimately may positively affect policy. DTAB provides advice/recommendations to the Assistant Secretary for Mental Health and Substance Use, for which the board relies on the ongoing review of the agency's drug testing programs.

Mr. Flegel commented that the revised Mandatory Guidelines for urine had an effective date of October 1, 2017. The proposed oral fluid Mandatory Guidelines are in review at the Office of Management and Budget (OMB). Once approved, oral fluid will serve as a complementary specimen to urine. The oral fluid Mandatory Guidelines will support development of private sector testing protocols and promote standardization of collection devices and cutoff confirmation levels and help local jurisdictions (especially law enforcement for roadside testing) and other programs that use oral fluid as a testing matrix.

The hair Mandatory Guidelines have been submitted to OMB as a proposed rule, which will distribute the proposed draft to all relevant agencies for review and comment. DWP staff and the MRO Working Group have updated the MRO Guidance Manual to include the review of workplace prescription drug testing. The final version was posted on DWP's web site (with case studies about opioid testing). The MRO guidance manual for oral fluid is in development and will be posted after release of the final oral fluid mandatory guidelines.

The 2017 Federal Custody and Control form (CCF) which includes synthetic opioids, is not being used by most federal agencies. It expires on August 31 and DWP is forming a working group to look at the chain of custody forms for alternate matrices. DWP will help laboratories transition to these forms. Mr. Flegel mentioned the Fighting Opioid Abuse in the Transportation Act, which is included in the 2018 SUPPORT for Patients in Communities Act (SUPPORT - Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment). It includes a requirement that the HHS Secretary assess whether it is appropriate to revise mandatory testing to include testing for fentanyl or any other Schedule I drugs or substances.

Mr. Flegel discussed cannabidiol, CBD, which is being studied by RTI and the Behavioral Pharmacology Research Unit at Johns Hopkins University School of Medicine. The study is looking at ingested and vaporized CBD including oils, in all substance matrices. Mr. Flegel closed by recognizing contributions to this effort by Drs. Jennifer Collins, James Ferguson, and Christine Moore, all former DTAB members. Each will receive a certificate of appreciation from DTAB.

### **Department of Transportation (DOT) Update**

*Patrice Kelly, Director, DOT Office of Drug and Alcohol Policy Compliance (ODAPC)*

Ms. Kelly observed that the audience affected by the drug testing programs under the DOT numbers in the millions, and outreach is an important part of the DOT program. There were 6 million drug tests performed last year and the ODAPC technical assistance effort fielded over 16,000 e-mails, phone calls and other information-seeking contacts. The web site is one of the most viewed in the department, with nearly a million sessions during the year.

ODAPC is responsible for 49 CFR Part 40, which contains the procedures for workplace drug testing. Included in the DOT's purview are the Federal Motor Carrier Safety Administration

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

(FMCSA), Federal Railroad Administration (FRA), Pipeline and Hazardous Materials Safety Administration, Federal Transit Administration, Federal Aviation Administration, and the U.S. Coast Guard. DOT is dealing with a number of future issues including marijuana legalization; alternative specimen testing (oral fluid and hair, which may reduce the incidence of cheating on tests); implementation of the Fighting Opioids in Transportation (SUPPORT) Act; electronic reporting, including chain of custody forms; continuing development of the driver clearinghouse database that tracks individuals with positive drug tests; public interest exclusions, which can exclude a service agent who demonstrates serious regulatory noncompliance from working with a DOT-regulated employers for up to five years; and MRO onsite reviews to look at non-negative test results.

In response to the Fighting Opioids in Transportation Act, the FRA must designate rail mechanical employees as safety-sensitive employees subject to drug testing. On March 31<sup>st</sup>, ODAPC published a database of the drug and alcohol testing data reported by employers for each mode of transportation. If the Secretary of HHS expands the opiate category to include fentanyl, then DOT/ODAPC will publish a final rule to include it in its drug testing panel. Under the Act, the Secretary of HHS must submit a report every six months on the progress of attaining final hair testing Mandatory Guidelines, and insofar as practicable the hair Mandatory Guidelines must eliminate risks of positive tests caused by the drug use of others or use by the individual being tested, without compromising the objectives of testing. The same requirement was made for oral fluid testing, with a compliance deadline of December 21, 2018 (a deadline that was missed), although work continues to achieve the requirement.

Ms. Kelly explained that, under the Act, HHS must ensure that each certified laboratory that requests approval for the use of completely paperless electronic Federal Drug Testing CCFs from the National Laboratory Certification Program's Electronic Custody and Control Form systems receives approval for those completely paperless electronic forms instead of forms that include any combination of electronic traditional handwritten signatures executed on paper forms (deadline October 24, 2019). The DOT requires that 18 months after HHS approves the paperless electronic CCFs, DOT will issue a final rule revising Part 40 "to authorize, to the extent practicable, the use of electronic signatures or digital signatures executed to electronic forms instead of traditional handwritten signatures executed on paper forms." Ms. Kelly observed that compliance with this requirement is not practicable if drug testing forms are excluded, so additional cooperation with HHS is necessary to resolve the conflict.

Explaining the DOT-HHS relationship, Ms. Kelly stated that, in 1988, DOT agreed to proceed with drug testing, following what HHS established in the Mandatory Guidelines. The Omnibus Transportation Employees Testing Act of 1991 (OTETA) codified that agreement. DOT conforms to HHS standards for laboratory-controlled substances testing; minimum list of controlled substances; and standards for certifying and reviewing labs. However, there are several areas that may revise requirements to fit DOT needs, including the collection process, MRO verification of test results (which may vary in terms of an employee being medically unqualified under an applicable DOT agency regulation; reporting of significant safety risks to third parties, and the return-to-duty process. DOT cannot follow HHS when the Omnibus Act prohibits it (e.g., when the initial screening test and the confirmation test must be done at the same lab).

Referring to U.S.DOT regulated drug testing data, Ms. Kelly revealed that in the first few months of 2018 there was a significant increase in reports of opioid positives, going from 0.20% to 1.01%, declining slightly thereafter to the same level as marijuana. Ms. Kelly commented that

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

the FMCSA appears able to conform to the January 6, 2020 deadline to implement the final rule for the CD Drug and Alcohol Clearinghouse and to submit the progress reports to the House and Senate committees involved, as required by the Act. Registration opens in the fall of 2019 and the following must register:

- Drivers who hold CDLs or CLPs
- Employers of CDL drivers who operate CMVs
- Consortia/Third-Party Administrators (C/TPAs)
- Medical Review Officers (MROs)
- Substance Abuse Professionals (SAPs)
- State Drivers Licensing Agencies (SDLAs)

Ms. Kelly concluded her remarks.

**Nuclear Regulatory Commission 10 CFR Part 26 Fitness for Duty Program Update,**

*Mr. Paul Harris and Mr. Brian Zaleski, Nuclear Regulatory Commission*

Mr. Harris stated that he and his associate, Brian Zaleski, Fitness for Duty Specialist, would describe the fitness for duty program at NRC and discuss the FFD performance in the nation's commercial nuclear power industry. The challenges to the program are threefold:

1. Subversion of the drug testing process, which is encouraged by companies that make products designed to subvert the oral fluid tests. For years, there has been a goal to add hair testing to deter this violation.
2. Identifying the effect of drug use on the performance of duty by employees in safety-sensitive positions. It is unacceptable for these employees to be working under the influence of alcohol or legal or illegal drugs.
3. Testing for the correct drugs at the right time, preemployment screening, behavior observation, background checks, employee assistance programs, and training and empowering professional employees.

Mr. Harris stated that there must be protections from unlawful search and assurance that the procedures are efficient and not burdensome to individuals subject to drug testing. Testing must include marijuana and other appropriate compounds, such as benzodiazepine and other groups of impairing narcotics. Mr. Harris noted that the FFD program assures safety and security of NRC facilities through a defense-in-depth strategy. It focuses on the people by addressing their access requirements (e.g., background checks, fingerprinting, psychological testing), their physical /environmental protection (e.g., vehicle barriers, blast walls, blast resistant enclosures, etc.), the detection of threats (e.g., cameras, infra-red, motion, explosive vapors, x-ray), and the establishment of programs for insider mitigation to identify individuals who may present serious threats to safety, cyber protection, and information controls.

Mr. Harris identified several areas of ongoing interest including oral fluid testing and expanding the test panel; a focus on marijuana rescheduling, auditing of HHS-certified laboratories, blind performance testing, and a key element in current successes in proposed rulemaking to better align 10 CFR Part 26 with the HHS Mandatory Guidelines for urine testing. Mr. Harris invited Mr. Zaleski to discuss operating experience.

Mr. Zaleski stated that an important responsibility is to ensure that the public is aware of how

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

the NRC protects nuclear power plants. He gave an overall picture of drug testing, indicating that almost 146,000 individuals were tested in 2018, of which 1,185 tested positive (70% pre-access 22% randomly). The overall positivity rate for the industry pre-access was 0.8% and for random testing it was slightly less than 0.4%. Contractor/vendor personnel are generally three times as likely to test positive, and there are many more of them involved in NRC activities and their turnover is much greater. Licensee employees are more stable, more likely to be full-time and they have very low positivity rates.

Mr. Zaleski showed the drug detection trends since 1990, which have been fairly stable, with a couple of exceptions. Marijuana accounts for about half of all detections. Cocaine and alcohol shared most of the remaining detections, with alcohol surpassing cocaine in 2008 at about 25%, and cocaine declining significantly from 39% in 2006 to 10%-12% since 2010. Opiates and PCP detections were negligible during the period, with amphetamines slowly increasing beginning in 2002 and increasing more significantly after 2010 (to around 13% in 2018). Mr. Zaleski stated that the results are affected by subversions, perhaps at a rate as high as 20%-30%.

Pie charts revealed that among licensed employees over 70% of positive tests involve alcohol (42%) and marijuana (31%). About 8% refuse to be tested. Among contractor/vendors, marijuana accounts for 42%, and alcohol for 15%, and test refusals are 19%. Mr. Zaleski presented data that detailed the labor category of positive tests, and that data indicated that maintenance personnel are the most dominant users of marijuana. Finally, there was evidence that the cutoff levels affect results. In 2018, 42% of positives were below the 0.04% level, suggesting that more individuals are being identified as positive because of the more stringent cutoffs.

Concerning testing for additional substances, Mr. Zaleski stated that a licensee or other entity may expand the drug testing panel to account for local drug use trends that may affect the workforce (10 CFR26.31(d)(1)(i)) and/or test for any substance(s) that an individual is suspected of having abused, when performing follow-up, for-cause, and post-event tests (10CFR26.31(d)(1)(ii)). A forensic toxicologist must first review and validate the testing assays and cutoff levels used by the HHS-certified laboratory, unless already in use in the current HHS Mandatory Guidelines. In 2018, eight facilities conducted expanded panel testing in two ways: 1) tested all specimens collected for barbiturates, benzodiazepines, methadone, and propoxyphene (four facilities, one FFD program); 2) tested follow-up, for-cause, and post-event testing specimens for benzodiazepines (i.e., alprazolam, clonazepam, and lorazepam), and hydromorphone, hydrocodone, and oxycodone (four facilities, one FFD program).

Mr. Zaleski addressed subversion attempts, which is considered a trustworthy and reliability issue, and if proven, is cause for permanent denial of unescorted access. Each year between 20% and 33% of individuals that test positive on a drug test are shown to be attempting subversion, which is a significant number (298 of 1,100 testing positive). Pre-access testing accounted for 77% of subversion attempts, and 97% were committed by contractor/vendor individuals. Mr. Zaleski concluded with a brief discussion of blind performance testing related to laboratory testing errors, providing several examples. The NRC presentation was concluded.

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

**Department of Defense Drug Testing Update**

*CAPT Eric R. Welsh, US Navy*

CAPT Welsh reported that drug testing data for the DoD has been compiled and is in review. The report should be ready to present to the DTAB at the December meeting. The DoD drug panel is more extensive than the panels for most agencies. It includes marijuana, cocaine, and D-amphetamines, D-methamphetamines, MDEA and MDMA, and a more recent entry, opioids, which is testing positive in increasing numbers. Also included in the panel are codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, five benzodiazepines and six synthetic cannabinoids. There is now a process ongoing to add fentanyl and norfentanyl.

CAPT Welsh explained that the DoD has a Biochemical Testing Advisory Board (BTAB) with functions similarly to the SAMHSA DTAB. The BTAB completed two prevalence studies recently, which looked at 32,000 specimens and 24,000 randomized specimens respectively from specimens collected from the routine military drug testing population, and the results indicate a prevalence similar to that for heroin. The decision-making process on whether to add a drug to the panel (in this case fentanyl) asks two questions. First, is there justification to consider adding new drugs to the drug testing panel; and second, if the drug is added are the capabilities in place to conduct the tests?

The BTAB takes into consideration known science and anecdotal information about the risks of intentional and accidental exposure, the lethality of the drug, the likely potency of exposure to the drug, morbidity and mortality data, and whether the drug use is increasing. The BTAB agreed that fentanyl and norfentanyl should be added to the panel. Then there was the practical discussion of capability. Are the proper testing technologies available; is testing equipment available; and are there individuals with expertise available to perform the testing and analysis? The BTAB voted unanimously to add fentanyl and norfentanyl to the panel with a cutoff of one nanogram per milliliter. The Undersecretary of Defense endorsed the recommendation and issued a memorandum that initiated testing on June 3, 2019. The next step is to establish a contract that will cover the 5 million DoD tests annually. There are five DoD drug testing labs (Hawaii, Texas, Illinois, Jacksonville and Ft. Meade in suburban Maryland). Presumptive positive tests will be confirmed by the Armed Forces Medical Examiner System. Expansion of the testing program should begin by September.

During discussion, CAPT Welsh explained that, although there is not a screening test specifically for fentanyl in the DoD panel, the presumption of a positive test will rely on an individual being positive for fentanyl and another drug – for example, cocaine and fentanyl, or an opioid and fentanyl. It was decided that it was important to establish a deterrent for fentanyl while building an understanding of the testing for the drug. CAPT Welsh observed that a very large number of heroin samples had been obtained, but there has been no retrospective analysis for the presence of fentanyl, and none planned because heroin degrades such that the samples would not be considered reliable for testing purposes. CAPT Welsh concluded his update.

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

**Program Updates by DWP (Urine, Oral Fluid, and Hair Mandatory Guidelines)**

*Ron Flegel and DWP staff*

Mr. Flegel introduced three new DTAB members, Kristen Burke and Deborah Motika who were present, and Stephen Taylor, who was unable to attend. He mentioned a number of issues regarding regulation and policy, including emerging issues with the fentanyl, Medical Review Officer (MRO) Guidance Manual, new state laws regarding legalization of marijuana, and changes affecting MRO. An important DWP goal is to establish an implementation date for the Mandatory Guidelines for oral fluid. The Mandatory Guidelines for hair have been sent to the Office of Management and Budget for review, and final approval for the Mandatory Guidelines for oral fluid as an alternate specimen is imminent. Mr. Flegel mentioned that an important concern was noted by the NRC concerning the ongoing problems related to subversion of tests by those being tested. The direct observation of oral fluid specimens will alleviate that problem.

Mr. Flegel stated that the revised Mandatory Guidelines for urine were published in January 2017, so there has been 20 months of testing related to that. Those Mandatory Guidelines added oxycodone, oxymorphone, hydrocodone, hydromorphone, removed MDEA and added MDA as an initial testing analyte, raised the lower pH cutoff for adulterated specimens from 3 to 4, and added a number of wording changes to anticipate alternative specimens when authorized in the future. He reminded the board that the drug testing panel currently includes cocaine, amphetamines, marijuana, phencyclidine (PCP), and opioids (including those mentioned above). Adding the emerging drug fentanyl is under consideration. Agencies may test any Schedule I or Schedule II drug on a case-by-case basis and add other drugs to the agency's drug testing panel by obtaining written approval in advance from the Secretary, HHS. The Secretary's priority remains the opioid crisis.

During the meeting, the board will hear an update on the use of the current federal custody and control form (CCF), which will be in effect until June 1, 2020. A working group is developing the new oral fluid CCF. The marijuana studies are ongoing, and DWP is maintaining a space on its web site for technical and scientific peer-reviewed articles, which is updated regularly. Cannabidiol studies and available data for marijuana analytes are under review. A decision on the timing of a Federal Register Notice for oral fluid Mandatory Guidelines is under consideration. Inclusion of oral fluid as a new, additional matrix will improve the ability to prevent subversion and adulteration. An oral fluid specimen collection handbook is in the works that would include a site collection checklist, and laboratories will be able to use an alternate method (other than immunoassay) for initial testing in the transition from immunoassay to LC-MS-MS. Finally, testing for parent drug (e.g., THC as the psychoactive component of marijuana), is important for uses like conducting roadside tests to detect individuals driving under the influence of drugs (DUID).

Regarding hair Mandatory Guidelines, Mr. Flegel noted that DTAB recommended hair as an alternate matrix, developed Mandatory Guidelines that have been submitted to OMB for review, HHS operational divisions have submitted comments, and SAMHSA is accepting comments from other interested federal agencies and the public. The Secretary of HHS must report to Congress on the status of the final notice within 60 days of enactment and annually thereafter until the agency publishes the final Mandatory Guidelines. Mr. Flegel observed that there are significant advantages to using hair as a test matrix:

- Directly observed specimen collection.

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

- Non-invasive specimen collection.
- Difficult to adulterate or substitute.
- Readily available sample, depending on length of hair tested.
- Drug metabolites are present in hair as early as one week after most recent use.

Mr. Flegel presented a PowerPoint slide that showed the Mandatory Guideline routing process, which included 17 steps. He noted that the oral fluid Mandatory Guidelines have almost reached the last steps (final notice in the Federal Register), and hair Mandatory Guidelines are about halfway through the process (SAMHSA final review prior to OMB review). The MRO Guidance Manual for urine has been updated, and work continues on the MRO Guidance Manual for oral fluid.

Turning to the emerging issue of fentanyl, Mr. Flegel spoke about HHS's requirement to determine whether or not it might be justified to expand the opioid category in the list of authorized substance testing to include fentanyl. Mr. Flegel then spoke about the number of studies ongoing, including a pilot study looking at cannabidiol, which began in June 2018, and another looking at the pharmacokinetics and pharmacodynamics of oral, smoked and vaporized CBD, the latter of which is the most common method of ingestion. There are different characteristics of each form of use. Another FDA-approved cannabinoid product is Epidiolex, released in 2018 for the treatment of seizures, and specifically Dravet syndrome in young patients over two years old. It is a Schedule V drug (drugs with lower potential for abuse). Mr. Flegel concluded his remarks.

### **Update on Emerging Marijuana Legalization**

*Fay Caldwell, DTAB board member.*

Ms. Caldwell stated that on June 5, 2019, 33 states, the District of Columbia and three U.S. territories had enacted comprehensive medical marijuana legislation. Fourteen states have passed low THC/high CBD laws. Eleven states plus the District of Columbia and two U.S. territories have recreational marijuana laws. Only two states prohibit all cannabis for all purposes (Idaho and South Dakota).

Most of the states with medical marijuana laws allow some form of legal cannabis for different qualifying conditions, few of which are consistent with each other – different physician involvement requirements, different forms of reciprocity with other states, different amounts that are legal to possess, different potency limits, and so on. The same is true of recreational cannabis, very little consistency among the states. No state has moved in the other direction, to eliminate recreational marijuana after passing a law enabling possession. Potency limits vary widely, with Virginia and Georgia allowing the most potent product (0.5% by weight), and Texas the most stringent (0.5% by weight). After passing legislation, states must determine how marijuana may be distributed through dispensaries or through a registration process. Finally, it can take years to reach agreement before it becomes legally available.

Employment protections fall into three areas: states that have specific employment protections (15); states that have announced that no employment protections exist (7); and 11 states that have undefined protections. Ms. Caldwell commented that trends are beginning to emerge. There are some protections, such as states that agree that if the sole evidence of a metabolite in one's system is a drug test, that does not mean de facto there is impairment or indicate proof

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

that one was using drugs on the job. However, all states that have recreational marijuana laws include a provision that use of the drug can be prohibited when an individual is on the job, and one that allows employers to prohibit employees from working if under the influence of drugs. Antidiscrimination provisions exist in the Americans with Disabilities Act to prevent discrimination in the case of an individual who may be using marijuana for medical reasons.

There is a trend toward more reliance on physicians to provide a recommendation that an individual can use marijuana, some for specific diagnoses, and that authorization may be expanded to other health care specialists (e.g., nurse practitioner). It is also more common for medical marijuana to be consumed in nontraditional ways, not smoked, but taken orally in the form of tinctures or extractions. Although nearly all jurisdictions prohibit driving under the influence of drugs, there are very few guidelines, and virtually no agreement on acceptable limits of THC in the blood, and no agreement on what level of drug in the blood causes impairment. There are also employment protections emerging for off duty use of marijuana, but this trend is so new that it is very poorly defined. In two states it is an unlawful employment practice for an employer to refuse to hire an individual because he or she submitted to a screening test and failed it (except for some safety-sensitive positions). One state (Nevada) allows applicants who fail a drug test to take the test again within 30 days, which almost guarantees passing it. Ms. Caldwell commented that perhaps a more troubling law exists in New York, where employers cannot test preemployment for marijuana.

**Drug Testing Index (DTI) Data: 2018 Update on Drug Use in the Workforce**

*Barry Sample, Ph.D., Quest Diagnostics*

Dr. Sample presented an extensive analysis of laboratory positives taken prior to any Medical Review Officer review. He stated that Quest looks at two large populations, the combined U.S. workforce, and the federally mandated safety-sensitive (FMSS) workforce, the largest component of which is the DOT-regulated private sector transportation employees. The FMSS employees also include those who work in safety-sensitive positions at the NRC. He added that the data presented would include results of an annual survey conducted by HHS of a non-institutionalized civilian population age 12 and over that assesses drug, alcohol and tobacco usage in that group. The survey includes about 68,000 individuals.

He named the three primary matrices -- urine and oral fluid, which detects drug use in a relatively short three-day time period, and hair (usually head hair), which can reveal patterns of drug use for up to about 90 days after ingestion. The reason for conducting a test is usually a post-accident, followed by pre-employment screening and random testing. One recent development in testing is a significant increase in samples that are deemed invalid, an indication that individuals may be trying to subvert the test results. There is a three times higher positivity rate for oral fluid tests than for urine tests, probably because the sampling is observed, making subversion much more difficult. It is also higher than testing hair, which detects patterns of repetitive use.

Dr. Sample referred to the combined U.S. workforce, which had an overall positive rate of 13.6%, declining to a low of 4.5% in 2004. It declined slightly for the next decade and currently stands at 4.4%. Looking at the same timeframe, the federally mandated safety-sensitive workforce declined steadily from a high in 1996 of about 3.5% to about 1.5%, then reversing a new high in 2018 of 5.1%. Looking at the National Survey of Drug Use and Health (NSDUH), and at two populations within that survey, individuals subject to employer drug testing programs

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

and those not subject to employer programs (self-reported data), the data usually show a higher percentage, by 40% to 60%, of self-reported illicit drug use.

Dr. Sample stated that marijuana is the dominant drug in the U.S. From 2017 to 2018, in general workforce testing, it increased to its highest level since 2014. Use in the federally mandated safety-sensitive workforce is up 24% since 2014, and at its highest level since 2007. Dr. Sample showed marijuana positivity data for each recreational use state. Colorado and Washington, the first states permitting recreational use of marijuana, are comparable between 2012 and 2017. Marijuana became legal in 2014 with little impact on the positivity rate until 2016 when positive tests picked up and increased each year in 2016 through 2018. Nevada legalized the drug in 2016 and there were substantial increases in positives in 2017 and 2018. Since 2017 recreational drug states are at or above the national positivity average. Dr. Sample noted that the tests were all urine tests for simplicity of comparison.

Dr. Sample presented a parallel presentation of tests administered to the federally mandated safety-sensitive workforce. Compared to Colorado, the positivity pattern was similar but slightly lower; the District of Columbia showed year-to-year increases since 2014; Oregon's data was different in the federal employee category than in the general population; and California has been slightly lower each year. Of the remaining states, some were consistently higher than the national average, some consistently lower, and in some of the states that have legalized recreational use positive rates paradoxically remain lower than the national average.

In the general U.S. workforce, although 2015 and 2016 were similar, positives in 2017 and 2018 rose, and there was a higher positivity rate in recreational use states. In medical-only states, the rates are similar to non-recreational use states. A factor may be that smaller groups are qualified to be cardholders, and it could be that many of the cardholders are not in the workforce. There was also a small decline in the number of states that included marijuana in the drug test panel. Generally, there has been little change in employer testing, although there is significant variability in the continued inclusion of marijuana among the states.

Regarding cocaine, Dr. Sample stated that from 2017 to 2018, there was a 10% decline in positives among the federally mandated safety-sensitive data, but still at the highest level since 2014, at 12%. In the general U.S. workforce, the decline was 6.7% for those two years, but similarly the highest since 2014, 16.7%. In hair tests, which is particularly sensitive to cocaine, there have been yearly increases in positivity, standing at 3.4% in 2018, the highest level since 2008, up over 30% since 2014. In the federally mandatory safety-sensitive workforce, for 6-acetylmorphine, an active metabolite for heroin, there have been yearly declines in usage (31% between 2017 and 2018), as there have in the general U.S. workforce for heroin, down 16% since its peak in 2014-2015. Dr. Sample commented that amphetamines and/or methamphetamines remain the second most commonly detected group. After yearly increases since 2006, the level of amphetamine positives stabilized during the last three years at 1.2%. Although still at the highest level since 2016, methamphetamine positives have slightly declined to 0.17% (down 5.9% between 2017 and 2018). A difference in the screening tests for the two is that amphetamines have a higher cutoff.

Dr. Sample briefly presented data for other drugs that might be included in a non-regulated employer panel – barbiturates, benzodiazepines, methadone, and opiates. Positives for all but the opiates have slightly declined or remained stable for the last several years. For the opiates, most of the tests are for codeine and morphine. Generally, positive tests for the main prescription opiates (hydrocodone, hydromorphone and oxycodone) peaked around 2011 and

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

began to significantly decline beginning in 2015 and are now at their lowest levels since 2004. Dr. Sample compared testing by reason, noting that hydrocodone and hydromorphone positives were up to three times higher for post-accident tests versus preemployment tests (which does not prove that the prescription caused the accident).

Dr. Sample explained that there was a significant increase in 2018 in specimen validity testing resulting in a determination of invalid, which might be related to the introduction of synthetic urine. For the federally mandated safety-sensitive workforce, post-accident urine positives revealed a greater than 80% increase between 2014 and 2018. For the general U.S. workforce, the increase was 29% over the past five years. Increases in that category are a little faster than in the preemployment group. Dr. Sample explained an analysis of the impact of prescription opiates on post-accident positivity rates, concluding that preemployment and post-accident positivity rates remained about the same, random testing and reasonable cause testing declined slightly, and return-to-duty and periodic medical testing increased slightly.

**Emerging Issues: Fentanyl and Fentanyl Analogs**

*Dr. Ruth E. Winecker, RTI*

Dr. Winecker stated that the SUPPORT for Patients and Communities Act mandated the Secretary of HHS to determine whether there was justification to revise the Mandatory Guidelines to include fentanyl. In 2015, a determination was made that, because fentanyl was nearly always found in combination with heroin, fentanyl should not be included. In 2018, the DWP began gathering data to reconsider.

As background, Dr. Winecker explained that fentanyl and fentanyl analogs, classified as narcotic analgesics, can be associated with substances that began with synthetic cannabinoids. They were designed to mimic the effects of scheduled compounds that were hallucinogenic, anxiolytic, or narcotic analgesics. One of these compounds, fentanyl, is a Schedule I compound that appeared in 1960, approved by the FDA in 1968 for use as an adjunct to anesthesia (Sublimaze), and later, in 2005, as a chronic pain drug in the form of a transdermal patch (Duragesic). Illicit diversion of pharmaceutical grade fentanyl, which was made in several formulations, began to be illicitly manufactured and distributed usually as a component of other drugs – cocaine, methamphetamine, and heroin. It is distributed in the U.S. similarly to other illicit drugs. After February 2018, fentanyl analogs were designated Schedule I drugs.

Dr. Winecker commented that, over the years, there have been many concentrated fentanyl and fentanyl analog overdose deaths. She cataloged several of these “outbreaks,” which relied on product manufactured in Mexico with precursor compounds from China. From the sixties to the present fentanyl has been responsible for thousands of deaths, some in medical settings through diversion. Originally, fentanyl was almost always mixed with other drugs but beginning in 2016 it was more and more sold as fentanyl or a fentanyl analog, acetyl fentanyl. In 2004, fentanyl became one of the top five drugs related to drug overdose deaths, and around 2010 drug deaths exceeded deaths related to vehicular accidents.

Federal labs may request fentanyl and fentanyl analog testing, and there are two HHS-certified labs that provide that service. Those labs have fielded 50 requests, a negligible number compared to the total number of tests those labs complete. The HHS labs performing testing for non-regulated tests estimate positivity to be 0.2%. Dr. Winecker said that RTI performed some pulse studies at the direction of DWP. In 2017, 1,083 specimens were tested with an EIA

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

immunoassay and 1,056 were tested with ELISA. All were deidentified. Each resulted in three positives. Two tested with EIA and all three by ELISA were confirmed by LC/MS/MS. In 2019, 2,158 regulated urine specimen aliquots were deidentified, all tested by EIA, and there were eight positives, only two of which were confirmed by LC/MS/MS. No analogs were detected. The initial tests positivity rates were from .27% to .37%, and the low confirmation rates were 66% and 25% respectively.

Regarding the capabilities of the HHS-certified laboratories, 83% offer fentanyl and norfentanyl testing. The immunoassays in use target fentanyl and have cross-reactivity to analogs, and therefore are unreliable for detection of all analogs. They are also insensitive to norfentanyl. For fentanyl as an initial test analyte, the current immunoassays are compatible with a high-volume environment. The confirmation positivity rate is varied when compared to tests found in the literature and those from pulse testing studies. Confirmation testing is expensive. There is no immunoassay available for norfentanyl.

Dr. Winecker stated there is agreement that fentanyl deaths are increasing, and that fentanyl is readily accessible in the medical setting. Anyone using fentanyl is a problem in the safety-sensitive environment. There has also been a problem in the early perception that fentanyl offered a “legal high,” and that perception may have created a false impression that there was a limited legal risk to use.

### **2019 Update on Cannabidiol and Hemp Products**

*Mr. Charles LoDico, DWP*

Mr. LoDico explained that there are about 400 chemical compounds in hemp/cannabis, 110 known cannabidiols, including delta9-THC (a psychoactive) and cannabidiol (CBD, a non-psychoactive). There are about 200 terpenes, an odor, which adds mellowness and has what end users describe as an “entourage effect.” Finally, there are flavonoids. Over the years, hemp has been used in a number of ways:

- Industrial Fiber (rope, clothes)
- Seed oil (hemp oil)
- Food (ground hemp seed for flour)
- Recreation (to attain a “high,” a euphoric state)
- Religious customs (native cultures in rituals)
- Medicine (Marinol®, and Epidiolex® (CBD))

The scientific name is *Cannabis sativa* L. As a commercial hemp product, the *Cannabis sativa* L. is cultivated to have high levels of CBD and very little THC. However, *Cannabis sativa* L. can also be a plant that can contain a high level of THC and very little CBD. Structurally, hemp and marijuana are almost identical, but they have slightly different molecular masses – 314.469 for delta 9-THC and 314.464 for CBD.

Mr. LoDico introduced the term “new normal,” which refers to the changing THC potency over the years. In the eighties, marijuana typically contained 4% THC, with a Mexican strain containing 6%-11%. Currently the new normal is 13 -20% THC, with hashish/hashish oil at 20% to 40% THC, and with new concentrates containing 40% -80% THC. There are established negative effects on an individual who consumes marijuana: impairment of cognition, difficulty performing complex tasks, learning problems, anxiety, panic attacks, psychosis, paranoia, and

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

tendency toward high behavior. Users may also drive under the influence of the drug, experience cardiovascular and pulmonary effects, and expose themselves to contaminants in the drug that may cause infections and decreased blood coagulation effects. One other significant mortality risk is cannabinoid hyperemesis syndrome, which causes unremitting vomiting, which, in a few cases, has resulted in death.

Mr. LoDico commented that marijuana is most commonly consumed by smoking, which provides a rapid onset of the psychoactive effect, but relatively short duration. It can also be eaten or consumed in liquid form. Edibles have a slower onset of effect but often a longer duration. Labeling of these edibles may not be accurate or clearly understood, which can lead to an individual, disappointed in the initial effect, taking additional doses, which can result in overdose. Edibles can also be consumed naively, especially by children who only see a brownie or a cookie. A more dangerous possibility is the fact that dealers who want to increase the psychoactive effect may lace the product with fentanyl or synthetic cannabis. Finally, to increase the overall risk, marijuana has become more widely available because of legalization in some states, and the use of marijuana as a medical therapy.

Despite the legalization of marijuana in several states, and the increased availability in general, it is a Schedule I drug, a fact that was reinforced after an FDA-DEA evaluation in 2014 that determined that the drug should remain on the Schedule I list. There is still medical research ongoing and the NIH and several universities have submitted a petition to investigate the medical potential of cannabidiol therapeutic use as an anti-inflammatory, anti-psychotic, antioxidant and neuroprotective agent. The research will also look at THC to assess its analgesic, anti-spasmodic, anti-tremor, and inflammatory effects and efficacy as an appetite stimulant and antiemetic.

Mr. LoDico turned to the 2018 Farm Bill, HR 5485, which authorizes agricultural research pilot programs to grow industrial hemp, which includes *Cannabis sativa L* with a THC concentration not more than .3% by dry weight. At a presentation at the SAMHSA Prevention Day conference in May 2019, a DEA agent listed a number of concerns about the potential effects of the Farm Bill. Among them:

- High potency marijuana grown under the guise of “hemp”.
- Easier to sell mislabeled edible products made from hemp that contain THC.
- Impact on drug interdiction efforts and the security of our border by making it difficult to distinguish between marijuana and “hemp.”
- More difficult to detect and prevent citizens and workers in safety-sensitive positions who are under the influence of marijuana from operating planes, trains, trucks, etc.

Concerning legalization of marijuana, Mr. LoDico demonstrated that one effect is the change in the ratio of Starbucks and McDonald’s stores to legal marijuana dispensaries. In Washington State there are more marijuana dispensaries than either, and in Colorado there are more marijuana businesses than Starbucks and McDonald’s combined. Another indicator is the cost of marijuana per gram, which has dropped from a high of \$29/gram in August 2014 to a recent level of \$9-\$10 per gram. A headline just days before the DTAB meeting stated that supply in Oregon is double the demand, with an inventory equivalent to over a billion marijuana cigarettes for a state population of 4.2 million. There are also ads for CBD for pets, including dosage charts that show ranges from 75mg to 1,599 mg (for horses), although the efficacy and the dosage has not been validated. Looking at labels on one CBD product, the primary active

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

ingredients appear to include menthol (16%) and camphor (11%), the same ingredients in the commercial muscle pain relief product for humans, Bengay (10% and 4% respectively).

Mr. LoDico reported that, on June 27, 2018, the FDA approved Epidiolex as a Schedule V drug. It is for children two years of age and older to treat seizures caused by Lennox-Gastaut syndrome and Dravet syndrome. The drug is formulated in dehydrated ethanol, sesame oil, sucrose and strawberry flavoring, and it does not produce cannabinoid behavioral response like THC. But the package insert warns that those who consume Epidiolex could test positive in a cannabis drug screen. The cost of the drug is \$32,500 annually.

The evolution of policy related to marijuana: beginning in 2015, OPM issued a memo stating that under Schedule I of the Controlled Substance Act, knowing or intentional marijuana possession is illegal. On February 27, 2018, the Department of Defense released a memorandum to all four services and all civilian employees reiterating the same policy. And in 2017, SAMHSA issued a memo on marijuana oils and marijuana-infused commercial products with information that use of these products may result in a positive urine test for THCA. The DFWP and the Mandatory Guidelines will continue to operate in accordance with federal law, which identifies marijuana and CBD as Schedule I controlled substances. The last memo shared by Mr. LoDico was issued by Major League Baseball, affirming that marijuana, THC and CBD are banned under all MLB programs.

Mr. LoDico addressed truth in labeling, providing information on two Johns Hopkins University studies. The first by Vandrey et al (2015) revealed that only 17% were labeled correctly, the rest were either under-labeled (contained more drug than advertised – 23%), or over-labeled (contained less drug than advertised – 60%). In the second study by Bonn-Miller et al (2017), the numbers were 31%, 43% and 26% respectively.

June 12, 2019 – Open Session

**Regulatory Program Discussion and Requirements (DOT, NRC, DoD and HHS)**

*Charles LoDico, DWP*

Mr. LoDico commented on initiatives to standardize laboratory reporting. Historically the custody and control form has been a paper-based five-part form on which laboratories check whether the sample involved in the test is negative, a dilute, or positive, and includes a record of the concentration of the analyte. It was faxed as a PDF to the appropriate MRO. As new electronic reporting technology takes hold, it will be important to standardize the data elements that are included on the report. OMB has approved the current version of the electronic custody and control form (eCCF). Labs are not currently mandated to use the electronic form.

The eCCF review and approval process was presented to the board to illustrate the steps involved in reaching final release of a letter of approval from the Secretary of HHS. Individual labs are identified by codes in the left-hand column, it is populated with data showing the actions taken by the NLCP and the labs until the NLCP issues a final report, part of which includes results of an onsite inspection. Labs may respond to the report, after which a final report from NLCP is sent to SAMHSA, which issues a letter affirming the approval. It is a time-consuming process but important to ensure the integrity of the standardized process. There are 11 approved laboratories of various testing capabilities in terms of volume (designated 2 through 6, small to large). The category 6 labs may handle as many as 10,000 samples a day.

**Drug Testing Advisory Board (DTAB)**  
**Open Session Minutes**  
June 11-12, 2019

The share of total eCCFs the labs processed in 2018 ranged from about 9% to 42%, an increase for every lab over the previous year. However, the number of eCCFs processed by all of the labs was slightly less than 25%. In terms of numbers, of the total 5,529,893 tests for regulated specimens, the labs only handled 1,375,990 eCCFs. That means that 75% of all tests are still hand-written.

Mr. LoDico stated that when the eCCF was first approved in 2015 there was one lab that processed about 3,000 forms electronically. At the end of 2018, ten labs processed 1.2 million forms. The projection for the 12-month period is 1.6 million. The NLCP sent a notice to all reporting labs concerning standardization of variable reporting elements definitions and terminology. The next step is to develop minimum standard variables for the federal custody and control forms. The forms have information about the employer, the collector, the donor, the results and includes the MRO's signature. There are also specimen standard variables that include a record ID, employee category, reason, status, order date, schedule date, expiration date, electronic order ID and confirmation. Mr. LoDico noted that there could be additional standard variable categories added to the list, and work groups will be established to look at those.

- Employer – ID, organizational hierarchy, location and lab account
- Collection – Clinic ID and location, date and place of collection, observed collection or not, temperature in range, donor refusal.
- Laboratory—Lab name, location, specimen information such as relevant dates (received and reported), and specimen chemistry (dilute indicator, creatinine, specific gravity and pH).
- MRO -- Variables specific to the MRO including detailed specimen information
- Drug report – Drug/analyte description, addition of new analytes, screening, confirmation, lab disposition and MRO disposition, and the consistency of the custody and control forms, consistency of MRO terminology.

Mr. LoDico noted that much of this process is in the draft stage and additional discussion, including talks with the various work groups, will refine the list. One objective must be gaining a better understanding of the MROs, how many exist, including their training, the results of their reporting, and the consistency of their processes and procedures. An important part of the working group is its subgroup on standard variables, chaired by Dr. Sample.

Mr. LoDico concluded his remarks. During discussion there was a brief conversation about donor ID and reducing the opportunity for diversion, including by resorting to false IDs.

**Public Comment**

Mr. Aumen invited public comment from those present and on the phone. There were no requests to comment.