

**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

**December 4, 2018
Minutes Summary – Open Session**

SAMHSA's CSAP Drug Testing Advisory Board (DTAB) convened in open session on December 4, 2018 at 9:00 a.m.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public from 9:00 a.m. to 4:00 p.m.

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Board Members in Attendance

Ms. D. Faye Caldwell
Mr. Randal Clouette
Dr. Jennifer A. Collins
Dr. James L. Ferguson
Mr. Ronald R. Flegel
Dr. David Green.
Mr. Paul Harris
Ms. Patrice Kelly
Dr. Christine M. Moore
Dr. Michael Schaffer
CAPT Eric Welsh, USN

Call to Order

CAPT Sean J. Belouin (DFO) DTAB, SAMHSA

CAPT Belouin called the open session to order and welcomed the Division of Workplace Programs (DWP) staff, federal partners, contractors, invited guests, members of the public and members of the board. He announced that during the open session the agenda would include a discussion of the proposed Mandatory Guidelines for federal workplace drug testing programs, and updates from the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense. There would also be presentations from the DWP staff on urine, oral fluid, and hair Mandatory Guidelines, electronic chain of custody and standard variables, and a presentation on emerging issues related to marijuana legislation. A public comment period was scheduled at the end of the day's sessions.

CAPT Belouin noted that the meeting information would be posted on the Drug Testing Advisory Board (DTAB) web site, including the open session summary, presentations, including PowerPoints, and the public comments, if any approximately six to eight weeks following the meeting. After a roll call of board members, CAPT Belouin invited Mr. Flegel to guide the meeting.

Welcome and Introductory Remarks, Ron R. Flegel, Chairman, Drug Testing Advisory Board

Mr. Flegel added his welcome and appreciation to all in attendance. He explained that under Executive Order 12564 in Section 503 of Public Law 100-71, the DWP develops and revises Mandatory Guidelines for federal workplace drug testing programs. The DTAB was established to enlist the support of experts in all fields of drug testing, including biochemistry, toxicology, laboratory operations and alternative specimen testing such as oral fluid and hair. DTAB advises the Assistant Secretary for Mental Health and Substance Use on the development and revisions of the Mandatory Guidelines for federal workplace work testing. SAMHSA's mission includes improvement of the quality of services for forensic workplace drug testing and the regulated and private sectors by assessing the science and technology relied on in drug analysis, by improving the quality of related laboratory services and the systems for drug testing, and by setting standards for laboratory certifications of the federal workplace testing programs.

The revised Mandatory Guidelines for federal workplace programs (FWP) urine drug testing had an effective date for implementation of October 1, 2017. Testing has been conducted for about 13 months. The major change to the Mandatory Guidelines was inclusion of the semisynthetic opioids and an increase in the lower pH cutoff range for indicating adulteration. DWP continues to streamline the annual survey report for federal agencies and deferred the reporting period to mid-2018 to accommodate changes, mainly for collection of synthetic opioid data.

Mr. Flegel noted that the proposed final oral fluid Guidelines have been referred to the Office of Management and Budget (OMB) for review and, when finalized, will enhance the federal program's ability to use an alternate specimen to urine. The Guidelines will also support standardization of oral fluid collection devices, cutoffs, confirmation levels, and collection processes for laboratory private employer testing in states and public sectors.

An internal draft of hair Mandatory Guidelines is in the final stage of review at the Department of Health and Human Services (DHHS) prior to review by the OMB. The draft will be distributed to all federal agencies for comment. The draft recommendations will address decontamination of hair specimens and hair color impact, including type of testing, the collection process, collection containers, etc. CAPT Sean Belouin, with assistance from the MRO advisory group, drafted, edited, cleared, and published the MRO Guidance Manual to include the review of workplace prescription drug testing, which was posted on the DWP website on November 2017, with the final version in March of 2018. Additionally, the MRO Guidance Manual for oral fluid is in development and should be published prior to the implementation date for the oral fluid Mandatory

Guidelines. DWP has continued to work with HHS-certified laboratories to implement the current 2017 federal chain of custody form (CCF) in the electronic and paper versions. The 2014 CCF expired on June 1, 2018 and is no longer used. The newly approved CCF, which includes synthetic opioids, is now in use by federal agencies and federally-regulated drug testing sectors, and DWP continues to help labs to convert to electronic CCFs. Concluding this part of his remarks, Mr. Flegel referred to the Fighting Opioid Abuse in the Transportation Act, including support for the Patients and Communities Act (PL 115-271), which directs the Secretary regarding the Mandatory Guidelines for drug testing Sections 8105 and 8108. Copies of the act will be sent to board members for review after the DTAB meeting.

Mr. Flegel discussed Epidiolex (cannabidiol), an FDA-approved product to treat patients as young as two years of age for seizures associated with epileptic Lennox-Gastaut and Dravet syndromes. It is an oral solution for ingestion, the first approved drug that contains purified marijuana (CBD). CBD is a Schedule I drug, but because Epidiolex is the first promising treatment of Dravet syndrome, it has been moved to Schedule V. It should not be confused with other CBD product such as oils and extracts.

In closing, Mr. Flegel expressed appreciation to Dr. John Mitchell for his contributions to DTAB, and announced that Dr. Barry Sample, senior director of science and technology at Quest Diagnostics, and Dr. Jason Schaff, a forensic examiner for the FBI, would be new members of DTAB.

Presentation: Department of Transportation (DOT) Update, Ms. Patrice Kelly

Ms. Kelly explained that the DOT operates under 49 CFR Part 40, which prescribes procedures for drug testing and the responsibilities of the testing lab, the role of the collector, the medical review officer (MRO), and others. The designation of employers and employees who fall under the safety-sensitive categories are determined for each of the model regulations – Federal Motor Carriers Safety Administration (FMCSA), Federal Railroad Administration, the Federal Transit Administration, Federal Aviation Administration, the Pipeline and Hazardous Materials Administration, and the U.S. Coast Guard.

Ms. Kelly noted that one issue pending clarification is marijuana, which is a Schedule I drug and use is absolutely prohibited by anyone regulated under DOT. A ramification is that, regardless of state medical marijuana or recreational marijuana laws, testing positive would not be an acceptable medical explanation for a positive DOT-regulated test. A high priority for DOT is to create transparency for the federal management information system (MIS), which is data submitted by transportation employers. Accomplishment of that goal is scheduled for March 2019. The driver clearinghouse database, an FMCSA initiative, should be operational by January 2020. Regarding electronic reporting records, addressed in the Opioids Act, DOT is anticipating a fully electronic chain of custody form to enable modification of Part 40 so that all records can be applied to all DOT records, drug and alcohol. Ms. Kelly explained that public interest exclusions (PIEs) are decisions by DOT, written by the Office of Drug and Alcohol Policy and Compliance (ODAPC). The decisions relate to serious noncompliance that has strong safety implications. Finally, alternative specimen testing of oral fluids and hair are also on the agenda for future modification. Ms. Kelly added that the random drug testing rates for 2019 have changed. The FTA increased the testing rate from 25% to 50%; PHMSA rose last year to 50%; other modes have not announced changes.

Ms. Kelly made some observations about outreach. As a gauge of interest in drug testing, ODAPC fielded 15,662 inquiries by DOT program managers and the regulated public; hosted almost 65,000 list serve subscribers; and the ODAPC web site recorded almost 786,000 sessions on its web site. Ms. Kelly commented that the ODAPC list serve, the largest list serve in the world, is an effective way to inform regulators, labs, MROs and others of the latest information on drug testing. She added that last year representatives of ODAPC spoke about opioids to more than 2,000 individuals at events sponsored by industry and labor organizations. Finally, in an employee notice disseminated by a list serve on December 11, 2017, ODAPC provided an educational discussion about potential opioid addiction; reiterated the importance of a continuing dialog with treating physicians about using opioids before performing DOT safety-sensitive functions; and reminded

employees that an MRO may report that an individual is likely to pose a significant risk, even if a drug test result is negative.

Turning to the Fighting Opioids in Transportation Act (PL 115-271), Ms. Kelly announced that the FRA will be required to identify rail mechanical employees as responsible for safety-sensitive functions, adding a whole new class of employee. DOT will be required to add to its web site a database of alcohol and drug testing data reported by MROs for each mode of transportation. The data covering all modes will be identified and will include total number of tests by substance, results, reason for test (e.g., pre-employment, random test, etc.) and number of individuals who refused testing. Ms. Kelly noted that the Comptroller General will review the DOT Drug and Alcohol Testing Management Information System for the appropriate Senate committee, but the report also will be useful to the DOT in assessing the MIS.

Ms. Kelly commented that, by Congressional mandate, DHHS is responsible for assessing fentanyl and developing a recommendation whether to include revision of the Mandatory Guidelines to include fentanyl. If fentanyl is added, then DOT must add it to the testing panel. Regarding hair testing, DHHS must submit a report to Congress every six months on the status of hair testing. Secondly, the final notice of scientific and technical Guidelines must include provisions that eliminate the risk of a positive test caused by drug use by others, and not by drug use of the individual being tested.

Ms. Kelly discussed the requirement that, when requested by any certified lab, DHHS approve the use of any CCF that is completely electronic, and that DOT issue a final rule revising Part 40 that authorizes (to the extent practicable) use of electronic/digital signatures applied to electronic forms in lieu of handwritten signatures. Implementation of these changes will result in the eventual elimination of the logistics required to store huge amounts of paper. Finally, Ms. Kelly stated that the FMCSA CDL Drug and Alcohol Clearinghouse is on track to go into effect in January 2020. ODAPC and the FMCSA are prepared to provide briefings on this process.

The Omnibus Transportation Employee Testing Act (OTETA) requires that DOT follow the lead of DHHS in developing comprehensive standards for laboratory-controlled substances testing; in developing a minimum list of controlled substances for which individuals may be tested; and establishing appropriate standards for certifying and reviewing labs. Regardless of that mandate, there are instances when DOT cannot follow DHHS if the Omnibus Act prohibits that. An example is the IITF (instrument initial test facility) – the Omnibus Act requires that initial test and confirmation be performed at the same lab, which also makes on-site testing impracticable.

Presentation: Nuclear Regulatory Commission (NRC) Update, Mr. Paul Harris

Mr. Harris indicated that he would discuss the NRC's Fitness for Duty (FFD) program, individuals covered by the program and program elements, as well as the defense-in-depth strategy. The program objective is to provide assurance that nuclear power plant personnel are trustworthy and reliable, and are not under the influence of any legal or illegal substance, and are not mentally or physically impaired from any cause that in any way adversely affects their ability to safely and competently perform assigned duties or be afforded unescorted access to the protected areas of nuclear power plants, sensitive information, or strategic special nuclear material. The FFD program's primary mission is to create an environment which is free of drugs and alcohol, and the effects of such substances. It applies to security officers, control room operators, maintenance and surveillance (craft & supervisors), health physics, chemistry, and emergency response personnel, those who construct or direct the construction of reactor plants, and all other persons who have unescorted access.

There is a requirement that the NRC be informed of any issues related to the fitness for duty of all personnel mentioned, which extends beyond basic drug testing to include managerial or procedural issues. The NRC is also informed within 30 days if a medical review officer makes an error in assessing an individual

such that the original report must be changed. That would include drug tests, behavioral observations, fatigue management, and questions that may arise in terms of qualifications. There are stringent access controls and facility risk reduction features, such as background checks, psychological testing, and physical features to protect individuals from injury and harm (blast walls, bullet resistant enclosures). Insider mitigation involves an increased level of scrutiny for those who have unescorted access to the power plant.

Mr. Harris described overall industry performance during 2017 that included 148,357 individuals tested for drug & alcohol; and 1,143 individuals who tested positive for a drug, alcohol, or refused a test (2/3 identified prior to entering the facility and 1/3 identified inside the facility, primarily by random testing). The overall random positive testing rate is 0.44%, and the overall positive rate for the industry is 0.77%. Contractor vendors test positive 3 to 4 times more often than licensee employees. Subversion attempts continue to be identified in the industry and probably in society. The FFD personnel – collectors, MROs, managers, and substance review officers – are the first line of defense in assessing the individual when they appear for a test.

Mr. Harris displayed a chart with details of the breakdown of test results for licensee and contractor personnel, and for the type of test administered. He pointed out that the difference in licensee employee positive tests was nominal – 32% pre-access and 43% random. The reasons might be related to an individual's knowledge that there is a predictable pre-access test for which the employee may temporarily abstain to reduce the chance of discovery, and the test is based on urine analysis for which there are many open source products available to subvert the test. Mr. Harris described the trends in positive tests results over time (1990 through 2017). Marijuana positives are about half of the tests, alcohol about 20%-25%, opiates and PCP a minimal 2%-3%. There has been a significant decline in cocaine positives beginning in 2006 (when it was about 23%) and dropping to about 12% in 2017. The share of positives for licensee employees is split 1/3 alcohol and 1/3 marijuana. For contractors and vendors, the proportion is about 16% alcohol positives and 40% marijuana. Tests have revealed that, for drugs not on the standard drug panel, the greatest number of positive tests result from for-cause testing.

Mr. Harris explained that subversion is any attempt to cheat on a required test. The sanction for subverting or attempting to subvert a test (including refusal to undergo testing) is permanent denial of access. Subversion attempts from 2012 to 2014 were about 15%, increasing to 26% in 2016-2017. Contractors and vendors are involved in 98% of subversion attempts.

Finally, Mr. Harris noted several industry activities and initiatives. NRC is interested in oral fluid testing and expanding the panel of drugs tested. There is also an interest in establishing a program to revise the way the nuclear industry audits HHS-certified labs and improving background checks and true identity determinations to make the pre-access process more effective.

Mr. Flegel expressed appreciation for the three presentations, adding a comment about the importance of having alternate matrices, with oral fluid and hair being possible additions.

Presentation – Department of Defense (DoD) Update, CAPT Eric Welsh

CAPT Welsh stated that the mission of the DoD Office of Drug Demand Reduction (ODDR) is to maintain a safe and ready force, which includes the ability of the armed forces to prosecute war. Use of drugs undermines safety and discipline, and the ability to respond when called. The total force includes those in uniform in the four services, and those civilians (including contractors) who support those in uniform. The ODDR relies on drug demand reduction achieved through a robust drug testing program. There are also prevention, education and outreach efforts, collection programs, and the development of new testing procedures and conducting surveillance.

The scope involves all DoD components, Army, Navy, Air Force and Marines, and the active support personnel, including reservists, who work one weekend a month and are subject to active duty recall, and

finally the National Guard. Policy is promulgated through three Department of Defense Instructions – general overarching guidance for the drug abuse testing program; instructions specific to federal civilian employees subject to the Drug-Free Workplace Program; and technical procedures for the military personnel drug abuse testing program (MPDATP).

The main focus areas and the principal means to deter drug use is through testing (with punitive consequences if applicable) and collections; followed by prevention education and outreach; and a joint service centralized procurement system that purchases all requirements of the drug testing program (equipment, reagents and compounds). The ODDR also partners with the Armed Forces Medical Examiner System (ASMES), which is the forensic toxicology lab supporting the program. CAPT Welsh described the organization of DoD leadership involved with drug demand reduction, showing chain of command from ODDR (in the Office of Force Resiliency), through the Undersecretary for Personnel and Readiness, to the Secretary of Defense. The technical side of the organization includes the Biochemical Testing Advisory Board (BTAB), which is similar in function to the DTAB for the FWP. The technical program managers of the various services and the ASMES are the primary members of the BTAB, which provides advice to the director of ODDR on technical and policy issues. BTAB focuses on new technologies for drug testing, proficiency testing, quality assurance, regular lab inspections, recommendations related to lab certification, revisions to the drug testing panel, policy changes, recommending research and monitoring prevalence testing. BTAB strives to develop data-driven recommendations, obtaining data from surveillance and evidence seized in criminal investigations, literature reviews, monitoring news media, and responding to Congressional inquiries. Data is evaluated in terms of capability, capacity and cost and a final policy (revision of the drug testing panel) is approved by the Undersecretary for Personnel and Readiness. Finally, there is a quality assurance feedback mechanism to ensure the policy change was the correct decision.

CAPT Welsh described several outcomes of the process based on the data analysis process described. Ecstasy, oxycodone and oxymorphone were added to the panel a number of years ago; hydrocodone and hydromorphone were added in 2012; five benzodiazepines in 2013; and synthetic cannabinoids in 2014. There were also deletions recommended – LSD, MDEA, and barbiturates – because of decreased prevalence.

Addressing the initiation of punitive drug testing, CAPT Welsh described the early data related to drug use during the Vietnam War (42% of service members voluntarily admitted drug use during that conflict). During the seventies, treatment for addiction was provided and clinical testing without prejudice was instigated. In 1980, a similar survey revealed that those admitting use of drugs dropped to 38%. There was still no consequence for drug use until May 25, 1981 when there was a night landing mishap on the aircraft carrier USS Nimitz that killed 14, injured 48 and destroyed seven aircraft. Six of the deceased tested positive for marijuana. In December of 1981, urine drug tests were authorized and those testing positive could be subject to courts martial or military separation. However, there was poor chain of custody that tainted the legal process such that many of the service members separated from service were restored and their records of drug use expunged. After correcting for that failure, the process was corrected and in 1987 positive test rates dropped significantly from about 3.5% to 0.88% in 2017. CAPT Welsh stated that DoD has five drug testing laboratories (two Navy, two Army, two Air Force) that handle 4.6 million samples a year, most of which are from military personnel.

The data reveals that National Guard and Reserve personnel (who are essentially in the civilian population) have the highest positive test rate, followed by military applicants (over 1%), and active duty personnel the lowest rate (less than 1%). Generally, by service, Army personnel have the highest positive rate (about 1%), Marine Corps and Navy next (about 0.5%); and Air Force personnel the lowest (about 0.35%). CAPT Welsh described the current situation with regard to positive drug tests, noting that although the panel has remained the same since 2012, an increased percentage (100%) of specimens are now tested. There has been a 76% decrease in positive opioid tests since 2013, and a 54% decrease in heroin. But during the same period, there has been a 58% increase in cocaine positive tests and a 72% increase in ecstasy positives.

Marijuana and cocaine represent 78% of all positive results. Unlike the federal workplace program, the military has access to prescription information for each employee, which allows an adjustment to the data when an individual has a prescription and has picked up the prescription during the observation period. For oxycodone, for example, over 80% of those positive tests are washed out of the data. Another confounding factor is that there is no time limit on when a prescription may be used, and a policy is being considered to allow a limited time (180 days) to use a prescription drug. CAPT Welsh stated that there are seven synthetic cannabinoids on the drug test panel and there has been a 67% decrease in positive benzodiazepine tests since testing began for these drugs in 2013.

The high-risk population in the DoD has been 18-25-year-old enlisted males, who represent only 37% of the individuals tested and account for two-thirds of all drug positive results. The result has been relatively stable for the past several years. The legalization of marijuana is a cause for concern because members of the service often believe that if they are stationed in an area where prescription or recreational marijuana is legal, the same would apply to them – which is not the case since the drug is a Schedule I substance. Marijuana accounts for 73% of all drug positive service members, which is a slight increase in the past several years. The conclusion might be that, to increase the effectiveness of screening, testing should focus on younger men and women and focus only on marijuana. Marijuana accounted for 96% of all applicant positives. Among civilians, the positive rates for those already employed and for those applying for employment are similar, 0.33 and 0.32 respectively.

CAPT Welsh commented that surveillance testing is done in groups of 2,000 specimens evaluated each reporting period. There are 202 drugs in the test panel – stimulants and hallucinogens (45), designer drugs (75), synthetic cannabinoids (46), and benzodiazepines (36). Thirteen of the stimulants/hallucinogens have been detected during testing, and 16 of 75 designer drugs were detected. For benzodiazepines, an increase was noted for midazolam and oxazepam/temazepam/nordiazepam, likely for legitimate prescriptions, since the last round. There are also other stimulants that are of interest – dimethylamine, kratom and phentermine, which are present in some over-the-counter supplements. The latter, phentermine, an anorexiant that suppresses appetite, requires a prescription not available in the military medical system. Military personnel who are trying to maintain weight standards may resort to outside commercial sources to purchase the drug.

Current military initiatives include increasing test coverage to 100 percent of all personnel for synthetic cannabinoids, opiates and benzodiazepines, and others on the panel that now include 25 drugs; and testing applicants for the full drug panel (previously only four drugs were tested). A high priority goal is developing a program for testing emerging drugs in real time and funneling all confirming tests to the AFMES, which is the only lab required to be certified. CAPT Welsh noted that the Navy lab at San Diego was closed for cost reduction; that there is an ongoing investment in robotic technology to speed up the testing process; about every three years prevalence testing is conducted on drugs that have been removed from the panel (like PCP and LSD); and civilian testing rates will be increased from 50% to 75% in response to the abuse of opioids and legalization of marijuana.

Finally, CAPT Welsh mentioned future challenges that include monitoring the high risk enlisted segment of 18-25 years old; deterring prescription drug abuse (especially using old prescriptions); addressing the higher drug positive rates among National Guard and Reservists; and improving agility in responding to emerging drugs threats, such as synthetic cannabinoids. Finally, hiring and retaining qualified personnel in the testing programs is challenging, especially when the testing program is expanded.

CAPT Welsh reiterated that the overall goal of the ODDR is to maintain a ready and safe force in DoD, such that the consequences of drugs do not affect the mission, and to ensure a drug-free work environment. The frequent random drug testing program is the principal way to do that. The last important objective is to integrate drug violation reports into the Defense Information System for Security that ensures that anyone who has a drug violation can be identified by any other agency in the Federal Establishment interested in screening employees for drug use. During discussion, responding to a question about alcohol screening, CAPT Welsh

explained that alcohol is covered under a wellness program under the Defense Health Agency, which has a method for dealing with fitness for duty. Asked about hair and oral fluid testing, CAPT Welsh agreed that, because there is added expense to collection when a visual confirmation of a urinalysis is done (to pay the observer), being able to rely on hair or oral fluid would be a welcome change to collections in the military.

Update by DWP Staff – Urine, Oral Fluid, and Hair Mandatory Guidelines

Mr. Flegel introduced his presentation by describing the regulation and policy hierarchy that places the donor drug test result at the top of the pyramid. The entities that produce this result include the MROs, trained collectors, affiliates of HHS-certified laboratories, the support provided by the National Laboratory Certification Program (NLCP), the federal agency plan and TDP list, and finally the Mandatory Guidelines. Decisions related to regulation and policy come from recommendations developed by the DTAB, the Interagency Coordinating Group Executive Committee, the DWP, and the Office of National Drug Control Policy, all guided by Executive Order 12564 and Public Law 100-71.

Mr. Flegel commented that DWP goals include establishment of an implementation date for the Mandatory Guidelines for oral fluid, and development of final Mandatory Guidelines for submission to OMB for review and subsequent distribution to all interested federal agencies for comment. Currently, DWP is working on obtaining final approval of Mandatory Guidelines for oral fluid as an alternative specimen to enhance the Federal Workplace Drug Testing Program.

Detailing the revised urine Mandatory Guidelines, Mr. Flegel mentioned that the Federal Register Notice was on January 23, 2017, implementation on October 1, 2017, and the most significant changes were:

- Adding oxycodone, oxymorphone, hydrocodone, hydromorphone;
- Removing MDEA;
- Adding MDA as an initial testing analyte;
- Raising lower pH cutoff level for adulterated specs [3 → 4];
- Revising some wording to address alternative specimens when authorized.

Mr. Flegel listed the drug testing panel currently in effect that includes cocaine, amphetamines, marijuana, phencyclidine, opioids and emerging drugs. Under the Patients and Communities Act (PL 115-271), by December 31, 2018, the Secretary of DHHS must publish a Federal Register Notice for a final notice of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid. A significant objective of the law is to eliminate for the individual being tested, the risk of positive test results that could be attributed by drugs used by other individuals.

Marijuana studies were undertaken that considered published peer-reviewed articles related to oral fluid Mandatory Guidelines. Mr. Flegel thanked Drs. Ed Cone and Ryan Vandrey, who guided the studies. Regarding oral fluid, a Federal Register Notice for marijuana testing is contemplated for 2018 or 2019; and development of the MRO Guidance Manual and collection manuals are in progress. DWP encourages the development of alternate testing methods, other than immunoassay, and testing for THC is important, especially issues related to driving under the influence of drugs. Finalizing an implementation date for certification of HHS certification for labs is on the agenda.

With regard to hair Mandatory Guidelines, a draft of the Guidelines has been developed; unique metabolites are being studied, as are the effectiveness of the decontamination procedures; comments and recommendations have been received from HHS divisions; scientific and technical issues are being studied; and public comment will be invited for other issues. As recommended by DTAB, hair testing as an alternative matrix will include hair decontamination and hair color impact, and the proposed Mandatory Guidelines currently under review is based on those and other recommendations received. Mr. Flegel listed the advantages of hair samples: directly observed specimen collection; non-invasive specimen collection; resistant

to adulteration or substitution; readily available sample, if hair is long enough; and drug metabolites are available as early as one week after most recent use.

The Secretary will announce within 180 days if fentanyl will be included in the federal drug testing program. There are a number of ongoing studies on cannabidiol; pharmacokinetics and pharmacodynamics of oral, smoked and vaporized CBD; and data continues to be collected on opioids in terms of pH changes, invalid results, and substitution/adulteration. Mr. Flegel concluded with a list of emerging issues including synthetic marijuana, enactment of marijuana, making conclusions about the various CBD studies that have been conducted, and issues related to synthetic drugs.

Presentation – Electronic Chain of Custody Forms (ECCF) and Standard Variables, Mr. Charles LoDico

Mr. LoDico commented that the ECCF was approved by OMB in the summer of 2014. Although there are 26 certified labs, only 12 are approved by NLCP to provide ECCF services. There are three types of services (software) – FormFox, eScreen and LabCorp -- and a lab may offer more than one service. The 12 labs, which handle 83% of the total market, process 5.2 million samples annually, of which 991,000 are translated into ECCFs (only 17% of the total). A challenge occurs if the labs do not maintain currency with applicable technology because they would be unable to complete the task mandated by congress. OMB-approved ECCFs expire after three years (next expiration date is 2020) at which time an evaluation must determine if the system is capturing the data in the electronic format.

The specifications for use of the ECCF are in the NLCP manual, and there is a requirement that personally identifiable information provided by the donor be protected and that the security element is not compromised. On February 6, 2018 an alert was sent to federal labs regarding standard variables focusing on one issue, that the electronic reporting could not differentiate between a scientific technician versus a certifying scientist. The alert emphasized that the lab must have standard terminology that reflects the action of a particular individual. In August 2018 there was a decision to standardize variables (information that would be in an electronic report). Dr. Barry Sample agreed to chair a working group to create standard variables that would be adopted by all labs. The work group will look at the definition for standard variables, how they cross between matrices, what variables should be captured on the ECCF, and define the benefit to the HHS-certified labs. One benefit would be the annual survey report (ASR) and the clearinghouse database that will be required by DOT. Lastly, what is the benefit to the regulatory industry in reporting standard information? Mr. LoDico noted that Quest Laboratories provided a list of potential standard variables focused on the specimen, employer, collection site, laboratories, the MRO, reporting analyte and specimen ID. He also presented a chart of analytes that apply to urine, oral fluid and hair. The purpose is to develop an understanding by all labs of the uniform designations.

Mr. LoDico commented that the presentation was meant to explain the way the NLCP, DWP and RTI are moving forward to capture information in a consistent way reflecting the usage of the ECCF among all labs. During discussions, Ms. Kelly stated that DOT supports the concept of a fully electronic custody form. DOT would accept some paper forms because there are some collection sites where there is no Internet (e.g., submitting a form from a site like an oil platform in the Gulf of Mexico).

Update – Opioids and pH, Marquita Brogdon, RTI

Ms. Brogdon was not connected to the teleconference call at the beginning of the opioid discussion. Mr. Flegel stated that he would provide a brief overview. The effective date was October 1, 2017 and there has been a 13-month test to date. The most significant changes related to synthetic opioids and the change in the pH level from 3 to 4 for identifying adulterated specimens. Revised pH levels for federal agency and DOT-regulated specimens were identified. Federal agencies discontinued testing for MDEA, although DOT

continued testing. Testing of federal agency specimens was delayed until the effective date and DOT began testing the four additional opioids on January 1, 2018.

Ms. Brogdon joined the meeting and continued the presentation, noting that some federal agencies were not prepared to add those opioids on the October 1 effective date. SAMHSA asked those labs to advise service providers of the date when testing would begin. Even a year later, some agencies may not have begun testing. Regarding non-negative results (specimens reported drug positive, adulterated, substituted or invalid), the incidence over the year was relatively stable. However, in the last quarter of 2017, the incidence slightly increased mainly because of the introduction of synthetic opioids. The new opioids also resulted in a significant gap (increase in incidence) beginning with January 2018. That gap may have been related to DOT's initiation of testing the new opioids. DOT conducts the majority of federally-regulated drug testing. About 5.3 million tests have been conducted in 2018. Slightly more hydrocodone/hydromorphone specimens tested positive than oxycodone/oxymorphone. The incidence is moderately positively correlated.

Ms. Brogdon discussed the impact of the revised pH cutoffs (to a minimum of 4) as reported in MRO reports of adulterated specimens. Changing the cutoff has reduced the number of specimens reported as adulterated (from 106/119 to 82/96). There has also been a significant decrease in the number of specimens being reported as adulterated overall because DOT revised Part 40 (effective January 1, 2018) such that employers and/or third-party administrators are no longer required to submit blind specimens to labs. In effect, specimens with a pH greater than 3 but less than 4 are reported as adulterated rather than invalid. The result of raising the pH cutoff is that adulterated specimen reports have doubled.

There is an indication that, since the revisions that added opioids, increased the pH cutoff, removed MDEA, and revised MRO requalification requirements, detection of donors trying to subvert the drug testing process has increased and there is a probability that the additional opioids have increased the drug positive detection rate about 1%, which is a 50% increase over the previous rate. These results are lab reported and not MRO verified, and such verification would reduce the number because of confirmation of a donor's valid prescription. Ms. Brogdon noted that the data presented were from RTI, which also provides recommendations that are subject to SAMHSA approval.

Presentation: Emerging Issues with Marijuana Legalization, Ms. Faye Caldwell

Ms. Caldwell explained that federal law classifies marijuana as a Schedule I drug, which makes possession a federal crime. States may also enact laws that are in consonance or in conflict with the federal law. The details may vary (different penalties or different amounts in possession, for example). Currently, 33 states, the District of Columbia, and two U.S. territories have enacted comprehensive medical marijuana laws, which may vary widely from each other. Thirteen other states have enacted "low THC/high CBD" laws. Ten states, the District of Columbia and one U.S. territory have "recreational marijuana" laws, which means marijuana is decriminalized for all purposes. Therefore, there are only four states that prohibit marijuana in all forms. Neighboring countries also have marijuana laws – Mexico permits medical marijuana, Canada permits both medical and recreational marijuana possession. Ms. Caldwell reiterated that almost every law is different from the others in some aspect – for example, different amounts that can be in a person's possession, potency (percentage of THC content), method of ingestion, workplace and other civil protections, taxation.

Ms. Caldwell repeated the admonition that under federal law, marijuana is illegal in every state and territory, and the DOT does not consider medical marijuana as an exemption from penalties associated with a positive marijuana test. Regardless of the authority granted to federal enforcement agents, they will not charge an individual for possession of marijuana when he or she possesses a state-issued medical marijuana exemption. In part that is because the Rohrabacher–Farr amendment (also known as the Rohrabacher–Blumenauer amendment) is legislation prohibiting the Justice Department from spending funds to interfere with the implementation of state medical cannabis laws. The prohibition, which stymies criminal prosecution, depends on each successive budget authorization which must specify the continuance of the exemption.

States are increasingly developing employment protections as well as protections that affect housing, custody, and access to medical care. There is also state action to ameliorate laws that impose onerous restrictions on a person's options in various areas. The trend on legalized recreational marijuana is to provide no employment protection. Interpretation of the laws is not sufficient to develop a complete understanding of the impact of the laws. A body of case law is being developed as issues are brought to court and judges pass down rulings.

Since drug testing predominantly affects employment, there are three categories of protection: states with explicit statutory protections (available in 13 states); no employment protection statutes (7 states); and jurisdictions that have undefined protections, laws that are vague or nonspecific (13 states and DC). In the first category, explicit protections, states have specific drug positive drug test language. The usual test matrices – urine, oral fluid and hair – do not gauge definitive impairment. Therefore, an employer cannot discriminate based on a positive drug test. Some states view drug use as a disability and two states have limits or restrictions on activity related to safety-sensitive tasks defined by a blood test. Blood tests are not a typical workplace matrix. There are exceptions in most laws. In none of the states does an employer have to allow the use of marijuana in the workplace or require or allow employees to work while impaired.

There is a no-protection category in seven states where there is no duty to accommodate off-duty marijuana use. 13 states either do not address employment or have nonspecific protections that may be covered under other state laws, or they have not affirmatively addressed employment. Some states have guidance documents or are dealing with pending lawsuits. In any case, final resolution takes a long time. However, the trend is to add employment protections, which means absent signs and symptoms of impairment, employers will have an increasingly difficult time sanctioning an employee.

The year 2017 was a pivotal time with regard to drug test legislation. Prior to that year, decisions were based on state laws that did not contain explicit protections; after that year, decisions began to come down that contained explicit protections, implied rights of action, and a rejection of preemption. There have also been inconsistencies, where different courts come to opposite outcomes in rulings, most of which will be resolved as the decisions are published and become final, and pending lawsuits are resolved. With regard to medical marijuana, the qualification to use marijuana typically has been based on physician recommendations, although increasingly the list of qualifying conditions had been subject to legislative limitations. The qualifying conditions include chronic intractable pain, autism spectrum disorder, Tourette's syndrome, PTSD, arthritis, sleep apnea, anxiety and lupus.

An important new issue in the area of drug testing is the introduction into more common use of opioids. Opioid abuse disorder was not considered a qualifying condition until recently, literally within the last 4-5 months. The current take on the disorder is to rely on the medical diagnosis of opioid use disorder to convert an individual to a medical marijuana patient. The rationale is that in states that have the option of medical marijuana treatment, opioid deaths and prescription rates have declined. Medical marijuana is experiencing an expansion in access, which is seeing a move away from the focus on physician recommendations and adding nurses, physician assistants and nurse practitioners to those who may recommend and/or administer medical marijuana treatment. There has also been a relaxation of qualifications to be able to obtain marijuana, now including caregivers, lengthening the certification period and allowing those involved in telehealth to prescribe. There are also protections in many places to ensure that those non-physician individuals who are authorized to manage a patient's marijuana treatment (mainly transport marijuana) are not subject to sanctions if they test positive for marijuana.

Finally, Ms. Caldwell discussed impairment laws, usually intended to apply in cases of criminal violations such as DUI (which often involves a blood test). Some states have established per se limits of 1 to 5 nanograms per milliliter in blood, but there is little activity in legislating those limits.

CAPT Belouin confirmed with the teleconference operator that there were no requests from the public or others to make a comment during the scheduled public comment period. Mr. Flegel announced that the following day's closed session would not occur. The second day of the DTAB meeting was cancelled.

Adjournment

CAPT Belouin adjourned the open session of the DTAB.

(The meeting was adjourned.)