

**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

**May 20, 2016
Minutes – Open Session**

SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened on May 20, 2016.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on May 20, 2016, from 10:00 a.m. to 12:20 p.m.

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Board Members in Attendance

- Dr. Jennifer Collins
- Dr. Anthony Costantino
- Dr. James Ferguson
- Mr. Ron Flegel
- Dr. Greg Grinstead
- Mr. Costantino Iannone
- Dr. Courtney Lias (for Dr. Denise Johnson-Lyles)
- Ms. Patrice Kelly
- Ms. Susan Mills
- Ms. Madeline Montgomery
- Dr. Christine Moore
- Dr. Buddha Paul
- Dr. Jasbir Singh

Call to order

Matthew Aumen, the Acting Designated Federal Official of SAMHSA’s CSAP Drug Testing Advisory Board (DTAB), called the meeting to order at 10:00 a.m.

Mr. Aumen provided housekeeping announcements to both on-site and web conference attendees. He recognized the Board members, Division of Workplace Programs (DWP) staff, and federal partners. Mr. Aumen announced the dates for the remaining fiscal year (FY) 16 meeting.

Welcome and Introductions

Ron Flegel, B.S., MT(ASCAP), M.S., Director of DWP and DTAB Chair, thanked the Board, federal agencies, and the public for attending. He announced the formation of a scientific and technical (S&T) committee that met to answer the questions and concerns that have been expressed by the hair testing industry and the Board. Mr. Flegel outlined the purpose of the DTAB meeting, which was to provide federal program updates in open session and to review and discuss the final revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for both urine and oral fluids in closed session. He provided status updates on the proposed revisions to the MGs for oral fluid and urine, the updated Medical Review Officer (MRO) Manual, and implementation of the electronic federal Custody and Control Form (eCCF). He reviewed the research studies undertaken by DWP in conjunction with the National Laboratory Certification Program (NLCP), including studies involving prescription opioids and marijuana in various matrices, such as urine, oral fluid, and hair. Several marijuana exposure studies conducted in 2015 should be published in 2016. Mr. Flegel described several other DWP initiatives, including Prevention of Prescription Drugs in the Workplace, the Marijuana Toolkit, and the Marijuana Smartbook.

Federal Drug Testing Updates

Department of Transportation (DOT) Drug Testing Update

Patrice Kelly, J.D., Acting Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC) within the DOT, displayed a statement from the DOT Secretary as to the importance of their program. The function of ODAPC is to advise on program issues, demand reductions, supply reduction, and DOT agency and U.S. Coast Guard drug and alcohol program activities. Ms. Kelly described their ONE DOT approach in following 49 CFR Part 40. The services provided by ODAPC include developing plain language regulations and providing consultation and liaison to other executive agencies as well as foreign governments. The goal of their program is ensuring the safety and security of the travelling public by reducing the demand for drugs, reducing alcohol misuse in the transportation industry, and creating prevention and treatment opportunities. There is a deterrence program. The program is bound by the Omnibus Transportation Employee Testing Act to ensure fairness, integrity, privacy, and confidentiality. They issued two marijuana statements, one on medical marijuana in 2009 and another on recreational marijuana in 2012 to clarify to the MROs that marijuana use is never acceptable under the DOT program.

The 2015 drug testing data for DOT included about 6.3 million tests with 47,782 total positive drug results. The overall annual positive rates remained below 2 percent. The presented data are laboratory-reported results and are not MRO reviewed. Marijuana was the most frequently used, followed by amphetamines, cocaine, opiates, and phencyclidine (PCP). The detection of tetrahydrocannabinol (THC) did not increase radically and was at 0.75 percent in 2015. The positive rate for opiates has been increasing since 2011. Tampering has remained below 0.5 percent.

The horizon issues include the marijuana issues, testing for additional schedule II drugs, the alternative specimen testing methodologies of oral fluid and hair, the driver clearinghouse database, the eCCF implementation, and drug impairment studies. Funded research studies include determining marijuana impairment.

ODAPC's technical assistance includes education, outreach, and communication (emails, phone calls, Ask ODAPC web inquiries, listserv, and website).

U.S. Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program Update

Paul Harris, Senior Program Manager of the Fitness for Duty Program within the U.S NRC, stated that the NRC is responsible for the safe and secure operation and maintenance of our commercial nuclear industry, including fuel cycle facilities and many materials licensees. Employees are required to be fit for duty, not fatigued in their workplace, mentally and physically capable of safely and competently performing their assigned duties and responsibilities, and trustworthy and reliable. This is monitored through drug testing, criminal background checks, work hour controls for fatigue management, psychological reviews, and behavioral observations.

Brian Zaleski, NRC's Fitness for Duty (FFD) Program expert on drug and alcohol testing, continued with NRC's 2015 performance review that included pre-decisional, MRO-verified data. In 2015, NRC tested 163,000 people from 73 FFD programs or sites. Since the start of our program in 1990, the NRC noticed differences between the positivity rates and substances abused for licensee employees, who are generally fulltime employees, and contractor/vendors, who are typically short-term employees. Contractor/vendors test positive at rates generally 2 to 3 times higher than licensee employees. In 2015, the total number of positive results was 1,099, of which contractor/vendors numbered 1,068 and licensee employees 131. The overall positivity rate was 0.73 percent. For contractor/vendors, testing is mostly conducted at pre-access; licensee employees are primarily subjected to random testing. For contractor/vendors, 78,000 tests were conducted for pre-access versus 9,000 for licensee employees. About 70 percent of NRC's positive results each year come at pre-access. The remainder of the detections is either for random, for cause, post event, or follow-up testing. NRC utilizes a 50 percent random testing rate for both drugs and alcohol. The random positivity rate for the industry is 0.35 percent in aggregate, with a positivity rate of 0.14 percent for licensee employees and 0.62 percent for contractors. For licensee employees, alcohol is the most detected substance at 43 percent. In 2008, the cutoff levels for alcohol were decreased to below 0.04 based on time dependency. The time-dependent alcohol cutoff is 30 percent more effective. For the contractor/vendors, the most detected substance is marijuana. There are similar percentages of use for amphetamines, cocaine, and opiates between the two groups. Historically, the most detected substances for all employees are marijuana, alcohol, cocaine, and amphetamines. A notable trend observed from 2012 to 2015 was the increasing detection of amphetamines and methamphetamines. In 2011, NRC identified subversion attempts as becoming an issue. Between 14.7 to 19.3 percent of the total violations, which include alcohol, now are subversion attempts. Most occur at pre-access. In 2015, almost 25 percent of NRC's drug violations were because of subversion attempts. In 2015, there were 231 individuals among the 1,199 violations. Seventy-six percent of the subversion attempts occurred at pre-access testing because it is a predictable testing event. Ninety-five percent of the subversion attempts are by contractor and vendors. Between 2012 and 2015, between 34 and 61 individuals tested positive for more than one substance, and of which, 83 to 93 percent tested positive for amphetamines, methamphetamines, and/or cocaine. When the specimen temperature is out of range because of a suspected subversion attempt, and a second specimen is collected under direct observation. Marijuana is the most prevalent drug identified under direct observation. The percentage of multi-substance users identified in subversion attempts was 17.8 percent. Individuals that subvert are three times more likely to be using more than one substance. If an individual produces a dilute specimen, the licensee has the option to lower the initial cutoff level to 50 percent of the initial cutoff level with confirmatory testing performed at the limit of detection (LOD). In 2015, of the 755 individuals with dilute specimens, 17 individuals screened positive and 3 individuals confirmed positive on LOD testing. Our licensees are permitted, under our rule, to expand the testing panel. Several had as expanded their testing to include semisynthetic opioid testing on for cause, follow-up, and post event testing.

Punitive actions by NRC are graduated for individuals that test positive. The first time an individual tests positive for drugs and/or alcohol is a 14 day minimum suspension, a 5-year denial for a second positive, and a permanent denial for a third positive result. For a subversion attempt, the individual is permanently denied

In 2009, NRC converted to an electronic voluntary reporting system, which provided single event reports for each positive result. NRC has licensed inspectors working fulltime onsite at each of its nuclear power plants. NRC is drafting a proposed rule to lower its cutoff levels to make them in line with the current MG. Our testing standards for amphetamines, methamphetamines, and cocaine, and also how we test for 6-AM, the heroin metabolite, reflect what were in the MG prior to the 2008 update. All the information that the licensees presented to the NRC this year, including positive drug test results, single event reports, and the annual reports, are available on its public website for download.

The Department of Defense (DoD) Drug Testing Update

COL Tom Martin, Ph.D., Deputy Director of the Drug Testing and Program Policy within the Office of the Under Secretary of Defense for Personnel and Readiness, Operational Readiness and Safety, of DoD, presented the 2015 drug testing update. The majority of DoD's regulatory guidance comes from DoD instructions as well as an Executive Order. DoD's number one mission is to deter illicit drug use as well as prescription drug abuse in the military service members, as well

as its civilian personnel in testing designated positions (TDP) to ensure military readiness and safety. One driving factor for its program is the recruiting population of 18- to 25-year-old males, of which 20 percent abuse drugs. Secondly, DoD provides drug abuse prevention education and outreach services to military personnel, their families, and the military community. Thirdly, DoD identifies new drugs being abused within its population and develops testing procedures to detect their use. In 1987, DoD's program changed from a detection and treatment program to a punitive program. Individuals who test positive for drugs can be disciplined and discharged from the military.

The Drug Demand Reduction Program Office provides the policy, advice, and guidance, with the execution performed by the services. The Office advocates for program funding, assists in developing the procedures and standards for the laboratories, and maintains the certification and inspection programs for the laboratories. The Division of Forensic Toxicology under the Armed Forces Medical Examiner System provides the technical expertise for the program and provides external quality control and proficiency testing (PT) for the laboratories. The six drug testing laboratories perform specimen analysis. The Biochemical Testing Advisory Board (BTAB) evaluates new methodologies and new technologies for drug testing. The BTAB advises on external PT and quality assurance procedures. They oversee laboratory certification as well as decertification and recertification. The BTAB is extremely involved in evaluating the drug testing panel and whether to add or delete drugs on the panel. They recommend policy changes and drive prevalence testing to identify what DoD's service members may be abusing outside of the current testing panel.

DoD performs surveillance and prevalence testing to identify abused drugs to either add or delete quickly from its testing panel. In 2013, DoD implemented 100 percent testing for oxycodone, oxymorphone, hydrocodone, and hydromorphone as well as select benzodiazepines. In 2014 and 2015, specific synthetic cannabinoid testing was added. Recent deleted drugs include lysergic acid diethylamide (LSD), 3,4-methylenedioxy-N-ethyl-amphetamine (MDEA), as well as barbiturates. For any drug that is not on its current panel, the services can request that testing.

The presented data for FY15 are medically reviewed, unique, and derived from active duty service members. Marijuana is the number one positive drug, followed by cocaine, and then amphetamines. If opiates and semisynthetic opioids are combined, they are higher in prevalence than amphetamines and approaching cocaine levels. From 2013 to 2014, there was a 40 percent decrease in the number of synthetic opioid positives. In FY15, the positive rate for synthetic cannabinoids was 0.018 percent.

In 2015, the positivity rate was 0.84 percent overall for the entire military, which was its lowest rate in history. Military components including active duty, Reserve, Guard, and the applicant population. The Guard and Reserve members have a slightly higher positivity rate than the active duty force. The applicant rate is around 1 percent. The Army has the highest positivity rate at a little less than 1 percent. The Navy and the Air Force are close to having the lowest rates at 0.38 and 0.35 percent, respectively. The Reserve positivity rate is highest for the Army Reserve at about 1.6 percent. The Navy Reserve has the lowest rate at about 0.4 percent. For the Army and Air National Guard, the Army Guard positivity rate is a little less than 2 percent while the Air Guard is about a half a percent.

For civilians in DoD's random TDP testing pool, the positivity rate is about 0.35 percent overall. Its applicant rate is about 0.27 percent. The combined positivity rate is a little bit over 0.3 percent.

The automated MRO process involves linking laboratory data with its pharmacy prescription data to perform an automated electronic review. If a service member has an authorized prescription within a certain time period of the collection of his/her drug specimen, this is considered an MRO-negative result. In FY15, a little over 85 percent of those positive for oxycodone had a prescription. For benzodiazepines, 67 percent were considered MRO-negative results and for amphetamines, a little less than 50 percent had valid prescriptions.

Federal Workplace Drug Testing Programs Update

Eugene D. Hayes, Ph.D., MBA, Lieutenant Commander, United States Public Health Service of DWP, CSAP, SAMHSA presented data on the Federal Workplace Drug Testing Programs, specifically the NLCP results. As of May 1, 2016, there are 31 certified laboratories, with two category 0, ten category 1, six category 2 laboratories, three category 3, three

category 4, and seven category 5 laboratories. One laboratory is in the initial certification process. There are currently two approved laboratory eCCF applications and nine laboratories that are at some point in the review approval process.

In 2015, there were 6.65 million regulated specimens tested. The total number of specimens reported as drug positive, adulterated, invalid, or substituted non-negative was 132,000 in 2015. THC remains the most often identified drug in urine. The number of specimens containing amphetamines and/or methamphetamine has continued to increase over the last five years. The percent of reported specimens found to be invalid decreased. The specimens reported as invalid due to immunoassay interference has shown a declining trend since 2013. Overall, the number of specimens reported as invalid was 7,796 in 2015. In 2015, there was decrease in all the invalid categories except for invalid pH, which increased to 2,909 in 2015. The number of specimens invalid due to pH rises in the warm summer months and is lower in the cooler months of the year. The percentage of specimens reported as invalid due to pH remains higher than other invalid categories. Other invalid categories include abnormal physical characteristics; abnormal creatinine and specific gravity levels; gas chromatography, mass spectrometry, or immunoassay interference; and oxidant activity. The 2011-2012 increase in specimens reported invalid due to abnormally low pH was the result of a substitution product with a lower pH value than normally found in urine. This problem resolved in 2013 and 2014 when the percent of invalids due to pH was back to the 2010 levels. In 2015, the percent of invalids due to pH rose above the levels normally observed. The increase was primarily due to the number of specimens with high pH greater than or equal to 9 but less than 11. The number of specimens reported as invalid due to immunoassay interference decreased from 2013 to 2015. The combined positivity nonnegative rates have increased to 2.06 percent in 2015, primarily due to an increase in the combined drug positivity rate of 1.89 percent in 2015. In summary, the number of regulated specimens tested by HHS-certified laboratories increased by 12.5 percent from 2011 to 2015. The number of regulated specimens reported as positive, adulterated, invalid, or substituted also increased 20 percent for that same period.

The NLCP certifies our laboratories and investigates all anomalies that occur within our laboratories. The NLCP also works on special projects and programs with DWP, including the urine and oral fluid MGs.

Other Program initiatives include hair testing and the draft hair MG. Studies are on going in partnership with The Johns Hopkins University to investigate and improve our stance on both urine and oral fluid drug testing. DWP is drafting the Marijuana Smartbook.

Public Comments

There were no public comments.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/SIGNED/

Date

Ron R. Flegel, B.S., MT(ASCP), M.S.
Chair, DTAB