

**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 12, 2015
Minutes – Open Session**

The CSAP Drug Testing Advisory Board (DTAB) convened on June 11-12, 2015.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on June 12 from 10:00 a.m. to 2:30 p.m.

Table of Contents

Board Members in Attendance.....	1
Call to order	1
Welcome and Introductions	1
Opening Remarks and Status of the Previously Announced DTAB Recommendations.....	2
SAMHSA FRNs	2
DTAB’s Process for Evaluating the Scientific Supportability of Alternative Specimens for Federal Workplace Drug Testing Programs.....	2
HHS Approval of Entities that Certify Medical Review Officers (MRO).....	3
Federal Chain of Custody Form (CCF)	3
DOT Drug Testing Update	3
Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program.....	4
Department of Defense (DoD) Drug Testing Update.....	4
Federal Workplace Drug Testing Programs	5
Public Comments	5

Board Members in Attendance

- | | |
|------------------------|--------------------------|
| Dr. Jennifer Collins | Dr. Denise Johnson-Lyles |
| Dr. Janine Denis Cook | Ms. Patrice Kelly |
| Dr. Anthony Costantino | Ms. Susan Mills |
| Dr. James Ferguson | Ms. Madeline Montgomery |
| Mr. Ron Flegel | Dr. Christine Moore |
| Dr. Greg Grinstead | Dr. Buddha Paul |
| Dr. Marilyn Huestis | Dr. Jasbir Singh |

Call to order

Janine Denis Cook, the Designated Federal Official of the DTAB, called the meeting to order at 10:00 a.m.

Welcome and Introductions

Dr. Cook reviewed the items posted on the DTAB website. She provided housekeeping announcements to web conference attendees. She recognized the Board members, Division of Workplace Programs (DWP) staff, and federal partners. Dr. Cook announced the date for the remaining fiscal year 2015 DTAB meeting. The results of an informal poll of DTAB members on drug testing offerings in their workplaces, including reasons for testing and whether all employees are tested, were presented.

Opening Remarks and Status of the Previously Announced DTAB Recommendations

Ron Flegel, Director of DWP, welcomed all attendees. He announced that the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for oral fluid and urine were published in the Federal Register (FR) for public comment with a July 14 deadline. In addition, the Request for Information (RFI) on hair testing was also published in the FR for public comment. Requests have been received to extend the 30-day comment period of the RFI to 60 days; those requests are being taken under consideration. Public comments have been received on all three FR Notices (FRN), but additional comments were solicited. Ron reviewed the process for addressing all comments received to the MG FRNs.

Ron provided updates on the research studies supported by SAMHSA. These studies include a marijuana passive exposure study, an oral ingestion study for marijuana which focuses on marijuana edibles, and a number of synthetic opiate studies. Finally, Ron described a DWP initiative - Drugs in the 21st Century: Making the Science Actionable.

SAMHSA FRNs

Dr. Cook discussed the three previously mentioned FRNs. The two proposed MG FRNs were published on May 15, with public comments accepted until July 14, a 60-day comment period. For both the proposed MGs, public comments were solicited on specifically-targeted sections. The RFI for the hair specimen testing was published on May 29 with a 30-day public comment period ending June 29th. As mentioned earlier, an extension to July 29 for the RFI is being pursued. The number of comments received to date and a brief summary of categorized comments for each FRN was presented.

DTAB's Process for Evaluating the Scientific Supportability of Alternative Specimens for Federal Workplace Drug Testing Programs

As Dr. Cook did for the oral fluid alternate specimen initiative, she reviewed the Board's process of evaluating the scientific supportability of the hair specimen for Federal Workplace Drug Testing Programs. She began with providing background on the DTAB, including reviewing its mission as stated in its charter and its authority to provide recommendations to the SAMHSA Administrator. The history of the alternative specimens in the MGs was reviewed, beginning with the 2004 proposed MG in which the establishment of science and technical guidelines for testing of hair, sweat, and oral fluid specimen in addition to urine were proposed. In the final 2008 MG, only urine was included because of the significant scientific, legal, and public policy concerns about the use of alternative specimens. HHS did state that these alternate specimens aid in combating adulteration, substitution, and dilution. HHS established a staggered timeline for evaluating these alternate specimens.

To evaluate the scientific supportability of the hair specimen, in July 2013, the Board began its assessment of the current state of the science for hair as an alternative specimen. In addition, scientific experts were identified to assist in this process, an exhaustive literature search of peer-reviewed journals was performed, the RFI was published on topic areas that were specifically identified as requiring further research, and

interviews were conducted with those laboratories that are enrolled in the National Laboratory Certification Program's (NLCP) pilot PT hair program. At the August DTAB meeting, all the received public comments to the RFI will be reviewed. The final step, which is the recommendation process, was presented.

HHS Approval of Entities that Certify Medical Review Officers (MRO)

CDR Jennifer Fan of the DWP reviewed the requirements of the MRO and the MRO-certifying entities. The latest list of HHS-approved MRO-certifying entities was published in the FR on May 26, 2015. These entities are the American Association of Medical Review Officers and the Medical Review Officer Certification Council. In the past, those organizations that only provided training were also listed but were not listed this time. For the next annual review cycle, an MRO entity that seeks approval from the HHS Secretary must have its information submitted to SAMHSA by July 31, 2015.

Federal Chain of Custody Form (CCF)

Charles LoDico of the DWP provided an update to the electronic CCF (eCCF). The Office of Management and Budget (OMB)-approved CCF expires every three years; the current form expires May 31, 2017. To reduce burden per the Paperwork Reduction Act, OMB allowed the use of an eCCF. The CCF now exists as paper and electronic versions. The paper CCF can be all paper, as it has historically, or a combination whereby the collection information is entered electronically and then a paper copy is printed. For the electronic version, all aspects are electronic. The benefits to the eCCF include complete collection information, immediate distribution, and an audit trail.

On April 13, 2015, the Department of Transportation (DOT) published its final rule concerning the CCF in the FR (80 FR 19551). In that document are DOT's definition of the CCF, which will include both the paper and electronic form, and DOT's requirement that the laboratory eCCF must be reviewed, approved, and inspected by the NLCP before implementation. To support the laboratory's request for eCCF approval, DWP offers several eCCF documents, including an updated MRO Manual and Collection Handbook. To date, three applicant laboratories have submitted an eCCF application. The NLCP review process was reviewed in detail.

DOT Drug Testing Update

Patrice Kelly, the Acting Director of the Office of Drug and Alcohol Policy and Compliance (ODAPC) in the Department of Transportation, provided their 2015 program update. The ODAPC program advises the DOT Secretary and the DOT and U.S. Coast Guard agency administrators. Their program regulations are 49 CFR Part 40 and the Omnibus Transportation Employee Testing Act of 1991. In addition, the DOT agencies have their own individual regulations. The program's goal is to ensure the safety and security of the traveling public, reduce the demand for drugs by transportation workers, and reduce alcohol misuse in the transportation industry. DOT has the largest regulated testing program in the world with roughly eight million employees subject to testing.

Of the approximately 6.3 million tests performed last year, there were about 57,000 laboratory-confirmed positives, an overall positivity rate of 1.79 percent. Tetrahydrocannabinol (THC) is the most identified drug at 0.76 percent. The second most identified drug was the amphetamines, including methamphetamine, with positivity rate of 0.56 percent, the largest percentage ever. Cocaine was the third most frequently identified drug, with a decreasing positivity rate of 0.23 percent. Opiate positivity was 0.22 percent and phencyclidine (PCP) 0.02 percent. The positive rate for PCP continues to be higher than the Ecstasy drugs combined. The rate

of specimen results reported by laboratories for fatal flaws remains low. The rate of tampered specimens stayed the same for a second reporting period.

Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Program

Paul Harris, Senior Project Manager in the Fitness for Duty Program (FFD) in the NRC, stated that the mission of the FFD is to provide a direct contribution to public health and safety through effective regulatory oversight per 10 CFR Part 26 FFD Program. The FFD Program incorporates other elements beyond drug and alcohol testing, including reasonable assurance that persons are trustworthy and reliable, not under the influence of any legal or illegal substance or physically impaired from any cause, and not fatigued or in a state of diminished mental or physical capacity. The NRC utilizes time-dependent alcohol limits. In 2012, the NRC implemented an electronic drug and alcohol reporting system.

All presented data in this presentation are MRO-verified results. In 2014, 166,000 individuals were tested; of these, 1,132 were tested positive. The overall industry positive rate was 0.68 percent, with a licensee employee rate of 0.23 percent and a contractor/vendor rate of 0.88 percent. The positive rates for contractor/vendors are about three times the rates for licensee employees. Sixty-seven percent of all positive, adulterated, and substituted test results occur on pre-access testing. Twenty percent of all testing violations occur on random testing. The random positive rate was 0.14 percent for licensee employees, which was three to five times lower than the contractor/vendor rate. For licensee employees, there was one positive post-event test result compared to 12 positives for contractors/vendors.

Alcohol and THC are the most prevalent drugs detected. For licensee employees, alcohol is number one, followed by THC. For the contractor/vendors, THC is number one, followed by alcohol, cocaine, and the amphetamines. An increase in amphetamine use was seen in 2014. From 2012 to 2014, the subversion rate was about 15 percent annually. In 2014, 72 percent of all subversion attempts were at pre-access. Ninety-six percent of those subversion attempts were by contractor/vendors.

Department of Defense (DoD) Drug Testing Update

Colonel Tom Martin, Deputy Director of the Drug Testing Program Policy within DoD, explained that the mission of the DoD Drug Demand Reduction Program (DDRP) is to deter illicit and prescription drug abuse, detect use, and hold those individuals accountable for the choice to use or abuse drugs in both military service members as well as DoD civilian agencies.

Marijuana was the number one drug in the military population, followed by cocaine. The third most prevalent was d-amphetamine followed by oxycodone. There was an increase in synthetic or semi-synthetic opiate results, especially those outside that 18-25 year old group. The highest drug positive rate is with 18-25 year old male recruits. In 2014, overall positivity was 0.88 percent. Differences in the positivity rates are evident by component – active duty, reserve, National Guard, and military applicants. The National Guard and reserve members have higher rates than active duty personnel. Since 2009, a very significant decline in positivity rates for military applicants was seen. In 2014, the random positive rate for synthetic cannabinoids or Spice was the same as that of 3,4-methylenedioxy-methamphetamine (MDMA).

On the military side, DoD can rapidly change our testing panel to respond to a threat identified through prevalence testing. For military members who use Tricare insurance, DoD uses an automated MRO review process, whereby laboratory results are matched to prescriptions. About 25 percent of laboratory-reported positives are considered unauthorized use for all the reported drugs. By drug, the majority of the

methamphetamine positives are unauthorized use. The majority of amphetamine and codeine positives are authorized use.

Federal Workplace Drug Testing Programs

Charlie LoDico presented an overview and 2014 data from the federal drug testing program. First, the distribution of 31 NLCP laboratories by size category 0 through 5 was shown. Laboratory fees and inspection review criteria are based on laboratory size. In 2014, about 6.5 million total specimens were in analyzed HHS-certified laboratories, an increase of 15.2 percent from 2010.

As the volume of total specimens tested increased, the number of positive specimens increased. For the regulated specimens that are positive, adulterated, invalid, or substituted, there is a slight increase from 1.7 percent in 2010 to 2.0 percent in 2014. Between 2010 and 2014, the drug positivity rate increased from 1.54 to 1.80. THC yielded the most positive test results annually, followed by amphetamines. Invalid pH results increased between 2010 and 2014. Invalid high pH results increased in the summer months because specimens were not properly stored during transport to the laboratory; the resulting increase in bacterial growth caused the increase in pH. Urine specimen invalid results were related to abnormal physical characteristics, abnormal clinical criteria, abnormal confirmation test findings, immunoassay interferences, and oxidant activity. For immunoassay interference, the most invalid results were found with the 6-acetylmorphine kit.

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/

Janine Denis Cook, Ph.D., DABCC, FACB
Designated Federal Official, DTAB