

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 13, 2017

Minutes – Open Session

SAMHSA’s CSAP Drug Testing Advisory Board (DTAB) convened on June 13, 2017

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on June 13, 2017 from 10:00 a.m. to 1:00 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
Mr. Tony Iannone
Dr. Courtney Lias.
Ms. Patrice Kelly
Ms. Madeline A. Montgomery
Dr. Christine M. Moore
Dr. Buddha D. Paul
Dr. Michael Schaffer

Call to Order

Brian Makela, the Designated Federal Official of SAMHSA's CSAP Drug Testing Advisory Board (DTAB) called the meeting to order at 10:00 a.m.

Mr. Makela welcomed the Board members, Division of Workplace Programs (DWP) staff, federal partners, contractors, invited guests, members of the public on site and those attending via the webcast. He especially welcomed four new Board members who were approved in December 2016, and who were attending their first DTAB meeting: Ms. Faye Caldwell, Mr. Randal Clouette, Dr. David Green, and Dr. Michael Schaffer. Mr. Makela announced that the last meeting for 2017 would be held on September 20.

Welcome and Introduction of New Members

Ron Flegel, B.S., MT(ASCAP), M.S., Director of DWP and DTAB Chair, added his welcome to DTAB members, ex officio members, industry representatives and members of the public, expressing his appreciation for their contribution of time and expertise. He noted that, during the day, the agenda would include updates on four federal drug testing programs – the Department of Transportation, the Nuclear Regulatory Commission, the Department of Defense, and the Federal Workplace National Laboratory Certification Program (NLCP). Mr. Flegel explained that the Drug Testing Advisory Board (DTAB) was established to provide advice and counsel to the DHHS Assistant Secretary for Mental Health and Substance Use, who is the administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA). The board is composed of experts in biochemistry, toxicology, laboratory operations, and drug testing. SAMHSA is responsible for the development and ongoing review and revision of the mandatory guidelines. The objective is to improve federal workplace drug testing, and to improve the quality and reliability of participating laboratories by developing standards for laboratory certification.

The mandatory guidelines for urine were published in the Federal Register on January 23, 2017, with an effective date of October 1, 2017. Several revisions were proposed: the addition to the testing panel of synthetic opioids (oxycodone, oxymorphone, hydrocodone and hydromorphone); deletion of MDEA; addition of MDA as an initial testing analyte; and an increase in the lower pH cutoff for determining adulterated specimens (from 3 to 4). The later was the result of NLCP data from samples submitted through that program. Related program documents are being revised to include these changes and others – The NLCP manual, the NLCP checklist for laboratory certification, and the C tables. Revisions should be completed by August 2017. As well, related publications have been revised, including the federal agency collection site assessment documents; the HHS medical review officer (MRO) guide; and the HHS specimen collection handbook.

Concerning proficiency tests (PTs), Mr. Flegel described three sets of PT samples sent to labs on May 1, June 2 and July 24. The first sample has been completed, results returned to CSAP, and there is confidence based on the results of the first PT sample that labs can perform the testing on synthetic opioids. Verification PTs will be completed by October. CSAP is working on drug program coordinator training and inspector training on the changes in the mandatory guidelines that should be completed by September. Finally, by January 2018, for urine, the new analytes and pH changes will be integrated into the quarterly PTs, and for oral fluids there will be three occasions including new analytes. Hair samples will continue to be added to a user hair specimen inventory.

Mr. Flegel noted that, within the Drugfree Workplace Program (DWP), agencies and unions are being briefed on the changes, particularly related to synthetics. The implementation of the revised mandatory guidelines is scheduled for October 1st, and a webinar is planned for September. The annual survey report for federal agencies is under review with an eye to simplification to try to publish data in a more timely manner, hopefully on a daily basis.

Finally, Mr. Flegel mentioned several ongoing and planned studies: A cannabidiol study that will begin in August; a study of the pharmacokinetics and pharmacodynamics of oral, smoked and vaporized cannabis; and a study of unique metabolites (opioid glucuronides) in the hair of opioid users.

Federal Drug Testing Updates

Department of Transportation Drug Testing Update

Ms. Patrice Kelly, acting director, Office of Drug and Alcohol Policy and Compliance (ODAPC), described the role of the program, which has a responsibility to advise the Secretary of the Department of Transportation (DOT), and the various DOT agency administrators, which includes the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, the Pipeline and Hazardous Materials Administration, the Federal Transit Administration, the Federal Aviation Administration, and the U.S. Coast Guard. The program consults with most federal agencies that have a drug testing component (Office of National Drug Control Policy-ONDCP), Homeland Security, Department of Defense, the Nuclear Regulatory Commission, and others. The program also maintains lines of communication with many foreign governments, which often request information about drug testing and 49 CFR Part 40, the primary federal guidelines for drug testing.

The industries regulated are exceptionally large, involving more than 5 million individuals who are tested annually. The mandate for testing involves five panels (categories), screening for tetrahydrocannabinol (THC), cocaine, amphetamines, opiates, and phencyclidine (PCP). In addition, 11 drugs are subject to confirmation, including six Schedule I drugs: marijuana, MDMA, MDA, MDEA, 6-AM (heroin) and PCP.

The DOT program collects data from labs, not individual employers, because of the large numbers involved. Collecting from individual employers would be cost prohibitive. Nor is the data reviewed by MROs. The positive test numbers are greatest for marijuana, followed by amphetamines, cocaine, opiates, and PCP respectively. The number of PCP positives is very low, but any positives in that drug is alarming because the drug is hallucinogenic and pain-suppressing. Ms. Kelly presented a bar graph showing the gradual increase in testing from 5.2 million in 2009 to 6.3 million in 2015. The number decreased significantly in 2016, to 5.4 million. Ms. Kelly showed a similar bar graph that indicated that the percent positive tests gradually increased from about 1.5% to 2% between 2009 and 2016. The percentage of tampered samples and rejected samples was very low, slightly less than 0.2% for each year.

Ms. Kelly noted that the National Highway Traffic Safety Administration (NHTSA) conducted tests to determine the level of impairment caused by marijuana, but the test was inconclusive because the product being grown was much less potent than the product being sold on the streets or in the states that have legalized therapeutic marijuana. The DOT is a member of a federal interagency working group dealing with the marijuana issue, and that group is monitoring related issues in foreign countries. Many of those countries are frustrated that, despite several treaties that include the U.S. agreement not to legalize certain drugs, the federal government is reluctant to impede several states that have relaxed or repealed marijuana use restrictions.

In conclusion, Ms. Kelly commented that her office was reaching out to experts, including CSAP and other SAMHSA offices, to get a better understanding of when oral fluids and hair sampling will be ready for inclusion in the mandatory guidelines. There has been an increase in interest from the public regarding the planned October 1 implementation of the of the oral fluids guidelines, which requires a final rule that has not been published. She added that ODAPC has received a record number (about 15,000 in the last year) of technical assistance inquiries, and now has 39,000 participants on the ODAPC list serve. The ODAPC's web site is the most viewed DOT site.

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

Mr. Paul Harris, Senior Program Manager, Fitness for Duty, US NRC, stated that the Nuclear Regulatory Commission (NRC) was established by the 1954 Atomic Energy Act to promote the peaceful use of nuclear energy. Originally part of the Department of Energy, the NRC became an independent agency in 1974, responsible for regulating the commercial nuclear industry. That responsibility includes protection of public health and safety, and includes regulation of special nuclear materials. The regulation is detailed in 10 CFR

Part 26, Fitness for Duty Programs. It identifies not only individuals who use drugs that impair, but what are called “insiders,” who have proven untrustworthy and unreliable in the performance of their duties. The NRC employs a broad approach that includes facility access authorization (background checks on criminal and other undesirable activities in the individual’s past, psychological assessments, and character and reputation reviews). There is fatigue management and behavioral observations, that requires the reporting by NRC employees and contractors of inappropriate behavior in others who have access to commercial nuclear facilities that generate about 20% of the nation’s energy, as well as fuel cycle facilities that create nuclear fuel.

Mr. Harris emphasized that drug and alcohol testing before granting access to nuclear facilities is the best policy to protect public health and safety. That is followed by post-access for cause behavioral observation and the Fitness for Duty (FFD) Program, which has several key elements: testing at lower cutoff levels; testing for additional drugs; testing for drugs in dilute specimens to the limit of detection; time-dependent alcohol limits; on-site and off-site behavior observations; sanctions for FFD violations; and integrating the FFD in employment screens. Sanctions escalate for repeat positive tests – first, denial of access to power plant for 14 days, then five years, then permanent exclusion.

Mr. Harris concluded his presentation by pointing out four observations.

- Positives in the nuclear industry are very low, and affected individuals have not contributed to any significant nuclear event.
- Pre-access testing clearly contributes to safety and security.
- Trained and vigilant collectors identify most subversive attempts.
- Behavioral observation contributes to safety and security.

Finally, for future policy consideration, Mr. Harris suggested reducing the burden of making changes to the mandatory guidelines (rulemaking is to agile revisions of process); establishing proactive assessment of prescription drug use; establishing portal monitors to exclude alcohol from nuclear facilities; enhancing detection of subversive attempts; and facilitating MRO access to state prescription databases to allow evaluation of an individual’s prescription drug profile.

Mr. Brian Zaleski, Fitness for Duty Program Specialist, presented 2016 test results for the NRC’s Fitness for Duty programs at NRC facilities across the country. The information is used to characterize the drug testing programs of the NRC, to allow individual utilities to look at their own performance in comparison to other utilities, and to inform the public. Also, inspectors who audit each program every three years, use the data for information and training. The Fitness for Duty program is more than a simple drug-testing program. It is about assessing the overall competence and performance of each participant involved in NRC activities. Although the industry is relatively small, there are 73 FFD programs operating at about a hundred NRC sites. The NRC tests about 150,000 people a year. In 2016, 1,163 individuals tested positive, 65% of whom were identified in the pre-access stage. That number has historically ranged from 65% to the low 70s. The NRC also conducts random tests for both drugs and alcohol in 50% of those subject to pre-access testing. Less than one percent of those tested are positive, a very low incidence. Finally, individuals identified with apparent impairment while on the job must undergo testing for cause. That population is smaller in number, but has a higher positive rate. A person in this group who tests negative will be referred to a physician for medical evaluation to confirm his or her capacity to work is not adversely affected by other causes.

Mr. Zaleski explained that there are two categories of employees – licensee employees, who are predominantly full time, and contractors and vendors, who are employed for certain projects, such as maintenance when a plant is shut down temporarily. The positive rate in licensee employees is very low, usually less than 0.1% (0.42% for randomly tested employees). The contractor/vendor population is much larger, and positives run three to four times higher than licensee employees.

Mr. Zaleski presented a timeline chart, beginning in 1990, of the positives identified in the NRC drug panel.

The substances included (with the approximate 2016 percentage of total positives in parentheses) are about marijuana (50%), alcohol (20%), cocaine (10%), amphetamines (10%), opiates (<10%) and PCP (negligible). The chart showed the recent trend of a significant increase in opiates and a decline in cocaine. Mr. Zaleski noted that about 20% of the drug-testing violations involve individuals suspected of attempting to subvert the tests, who may refuse to provide a sample, which results in a sanction. The number of sanctions exceed the number of positive test results.

Mr. Zaleski addressed the increase in subversion attempts, which is any willful act to cheat on the tests (refuse to provide a sample, adulterate a sample or submit a sample that did not originate in the donor's body). Between 2012 and 2016, subversion attempts have increased from 16% to 26%, nearly all identified in contractor/vendors. In 2016, 38% of subversion attempts were identified through testing specimens that were successfully collected. Inspectors assess samples based on visual examination (e.g., color) and sample temperature, which must be within a predictable range. If a sample is suspect, a second directly observed sample is required. In 2016, 62% of suspected subversion attempts were refusal to provide a sample, or the inspector stopped the testing procedure.

Finally, Mr. Zaleski briefly discussed testing errors that invalidate a sample analysis. These errors are mainly the result of human error in the HHS-certified labs. The number has slightly increased in the last several years.

Department of Defense Drug Testing Update

Col. Tom Martin, USA, Director, Drug Testing and Program Policy, explained that the mission of the Department of Defense (DoD) drug testing program is to deter illicit and prescription drug abuse by military personnel, and by civilians employed by the DoD in drug testing-designated positions. The program also provides drug abuse prevention services, education, outreach and counseling services to military personnel and their families. The Drug Demand Reduction Program (DDRP) tests for drugs through collection of samples from active duty personnel and potential recruits. A second function is outreach and prevention through an anti-drug awareness program. Although the individual programs are managed by the various services, the DDRP provides policy advice and program guidance for the entire Department of Defense.

There is a Biochemical Testing Advisory Board (BTAB) under the Assistant Secretary of Defense for Readiness, that is similar to DTAB in mission and function. The BTAB has two divisions – technical (drug testing) and personnel (sample collections). The BTAB is also involved in certification and decertification of testing labs through the Armed Forces Medical Examiner System (AFMES). BTAB also provides advice on adding and deleting drugs from the test panel. The decision-making process is streamlined to minimize paperwork impediments, and conforms to an established step-wise process.

One aspect of maintaining an appropriate drug panel is to assess the prevalence of drug use. In an example, Col. Martin described a prevalence study initiated when DoD leadership expressed concern that fentanyl might be an abuse problem. Labs tested 32,546 random samples, identified 127 positive results and 729 samples with possible positivity, performed confirmatory tests on all 856 samples and determined an illicit positive incidence rate of 0.006%. The results indicated no significant abuse and the DDRP recommended not adding fentanyl to the drug panel.

Col. Martin listed the current DoD Panel of Tested Drugs:

- Marijuana (THC)
- Cocaine (BZE)
- Amphetamine & Methamphetamine
- Designer Amphetamines / Ecstasy
- Heroin
- Oxycodone/Oxymorphone

- Hydrocodone/Hydromorphone
- Codeine/Morphine
- Benzodiazepines: nordiazepam, oxazepam, temazepam, lorazepam, and α -OH alprazolam
- Synthetic Cannabinoids (December 16, 2013)
- Special request for unusual or novel drug testing conducted at AFMES

He pointed out that the synthetic opioids, benzodiazepine and synthetic cannabinoids have been on the panel for some time. Col. Martin presented data from 2011 to 2016 on all positive drug tests whether or not they were included in the panel (26 specific drugs). He noted that marijuana and cocaine account for the highest number of positive tests. Misuse of prescription drugs has significantly decreased by about 70% among enlisted personnel, which can be attributed in part to improved oversight by medical providers and better prescription practices. The overall military positive rates declined sharply after 1990, when military policy changed from rehabilitation to a punitive policy. It has remained low since then. It was 0.85% in 2016.

Looking at the rates by component, Col. Martin reported that in 2016, all positive rates were below 2.0%. Active duty was lowest (0.6%), followed by recruits (1.15%), reserves (1.23%) and the National Guards (1.65%). By individual service, Air Force and Navy were 0.34% and 0.38% respectively, Marine Corps was 0.53% and Army was 0.95%. Col Martin divided all military personnel into high risk (18-25 years of age) and low risk (26 and older), noting that the high-risk group is 32% of the total population but accounts for 62% of the drug positives.

Finally, Col Martin discussed surveillance testing, a testing process aimed at characterizing the overall drug use by military and civilian DoD personnel, and at revealing novel and emerging issues that might be related to drug misuse. A random sample of urine samples are sent to the Division of Forensic Toxicology to complete a extensive screening of all of the drug-related substances that can be identified. Supported by AFMES, the specimens are subjected to several protocols to develop the detailed results required to create the surveillance report. One product of this effort is the development of the emerging drug compound panel.

Looking forward. Col. Martin commented that there is a continual updating of the “designer panel,” which includes newly revealed drug use patterns, and novel and emerging drugs. There is also continuing focus on the stimulants/hallucinogens panel and the benzodiazepine panel, including efforts to improve screening techniques.

Col. Martin stated the bottom line of the DDRP is to contribute to maintaining a mission-ready force that exists in a drug-free environment. He said that an individual must believe that the risk of using drugs is far greater than any benefit that might be imagined by using illicit drugs.

Federal Workplace Drug Testing Program

LCDR Eugene Hayes, Division of Workplace Programs, commented that there are now 29 certified NLCP labs, in six categories: two Cat 0, eight Cat 1, seven Cat 2, two Cat 3, five Cat 4, and seven Cat 5. The number of specimens tested in 2007 was about 8 million. That number declined to 5.47 million in 2009, a ten-year low. There was a gradual recovery through 2015 to about 6.6 million, then the number slipped back to 5.7 million in 2016.

The number of regulated specimens reported as Positive, Adulterated, Invalid and/or Substituted in 2012 through 2016 has increased from 112,000 to about 126,000, a 13% increase. The number of regulated specimens tested in 2012 through 2016 decreased by 6.1%. The yearly increases between 2012-2015 were outweighed by the significant 12.9% decrease in testing in 2016 as compared to the previous year. Specimens reported as invalid because of low pH, decreased from the levels seen in 2011-2012, and while slightly elevated in late 2014 and 2015, remained under 10% of reported Invalids throughout 2016. Specimens

reported as invalid due to high pH, increased significantly in 2016. Specimens reported as Invalid because of immunoassay interference continued to decrease from the highs of 2013. The positivity rates from 2012 to 2016 stayed close to 2.0% for the combined rate. In 2016, drugs were 2.03%. LCDR Hayes expressed the opinion that these levels were rates that should be maintained by the other programs in DOT, NRC, and Defense, because they testify that the program is working.

Reporting on program projects;

- Mr. Flegel already talked about urine and oral fluids mandatory guidelines.
- Concerning eCCF applications and approvals, 11 labs are approved to use the eCCF. One lab has been approved to use two different eCCF systems, and three more are currently pending approval.
- Oral fluid pilot proficiency testing has occurred, but because of budget restrictions, work in that area will be reduced.
- Laboratory investigations continue and discrepancies with checklists are being corrected.
- Mr. Flegel reviewed the marijuana smoked and vaporized study earlier.
- The Marijuana SmartBook was near publication, but because of some issues within the agency it will not be released and will be reserved as a resource for the CSAP director. The book includes a history of marijuana, and a discussion of the U.S. policy on marijuana.

One issue not yet discussed is the level of awareness among junior toxicologists about the federal programs. LCDR Hayes mentioned his attendance at SOFT, the Society of Forensic Toxicologists, and the marked ignorance among the junior members about the Federal Workplace Drug Testing Program. In response, the online training programs have been revitalized so that education is available to the junior toxicologists if they are interested.

A second issue identified in 2016 was the need for uniform inspector education, transfer of knowledge, and the application of inspection criteria. The solution is to change the format of the NLCP workshops from an update format to true training and education. The target audience is inspectors and lab directors.

Another serious obstacle is the lack of an agile drug testing panel, revisions of which can get delayed by the regulatory requirements of review and public comment. One solution is the National Forensic Laboratory Information System (NFLIS) report supported by the NLCP Drug Testing Matters Newsletter, which can publish information on which various groups may choose to act without being restricted by the regulatory rulemaking process.

Final comments and adjournment

Mr. Charles LoDico updated his presentation at the last DTAB meeting concerning federal custody and control form. A proposal has been submitted to OMB for review, that includes minor changes to the document. OMB has informed CSAP that the package, submitted in April 2017, has a 60-day window for approval. Since that has passed, there is a de factor continuation of the expired form. Mr. LoDico added that he regularly checks the status of the review and, to date, it has not been reviewed by OMB.

Mr. Makela stated that there had been no requests from the public to make comments.

There being no further business before the Board, Mr. Makela declared the meeting adjourned.