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

March 20, 2017

Minutes – Open Session

SAMHSA's CSAP Drug Testing Advisory Board (DTAB) convened on March 20, 2017

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on March 20, 2017 from 9:00 a.m. to 2:00 p.m.

Table of Contents

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 the remaining two meetings scheduled for 2017: June 12-13 and 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 the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for both urine and oral fluids; the status of the hair testing technical guidelines; an update on the federal Custody and Control Forms, including electronic versions (eCCF) and OMB extension; and an update on the Division of Workplace Programs initiatives. Executive Order 12564 and Public Law 100-71 mandates that the DWP develop and revise as necessary the Mandatory Guidelines, with the counsel of the DTAB, which was created to take advantage of the members' expertise in biochemistry, toxicology, laboratory operations, and in developing and testing of alternative matrices.

Mr. Flegel stated that the closed session would be mainly informational, allowing the members to hear about the current status of hair testing.

Federal Drug Testing Updates

Mandatory Guidelines for Federal Workplace Drug Testing Programs – Updates on Urine, Oral fluid and Hair

Mr. Flegel reported that Mandatory Guidelines for urine were published in the Federal Register on January 23, 2017, making the effective date of the guidelines October 1, 2017. Changes to the guidelines included the addition of oxycodone, oxymorphone, hydrocodone, and hydromorphone, all synthetic opioids covered under regulated drug testing for the first time. MDEA was removed from the panel because it rarely appeared in the program, and MDA was added as an initial testing analyte. The lower pH cutoff for adulterated specimens was raised from 3.0 to 4.0 because both synthetic and other specimens received by laboratories were generally in the 3.5 to 3.7 range, above the original cutoffs. The Department of Transportation Notice of Proposed Rulemaking on synthetic opiates, which mirror those in the Mandatory Guidelines, was published on January 23, 2017. Finally, THC and THCA are under review, specifically about route of administration (edible, smoked or vaporized marijuana). The proposed implementation date is early 2018.

Mr. Flegel stated that the DTAB's first draft on hair testing is under review by DWP, working with subject matter experts, Office of General Counsel and federal partners. Technical guidance on hair testing and proposed research is also being addressed. He presented a Gantt chart showing the 17 steps that will take place to ultimately reach publishing the final Mandatory Guidelines and implementation date in the Federal Register. The Guidelines will ??move their way from the DWP, through the SAMHSA administrator's office, the DHHS secretary's office, review by various DHHS OPDIVs, an thorough Office of Management and Budget review process, ending in a final Federal Register Notice, including announcement of an implementation date. Finally, Mr. Flegel added that the current federal Custody and Control Form (CCF) will expire on May 31, 2017, and revisions are being prepared.

Turning to the Drug-Free Workplace Program, Mr. Flegel noted that a Federal Register Notice has been filed for the Revised Mandatory Guidelines – Urine, with an implementation date of October 1, 2017. DWP continues to brief agency drug program coordinators, who oversee the individual federal programs in the various branches and agencies. A number of different mechanisms facilitate the information dissemination – a coordinating group chaired by the Office of National Drug Control Policy (ONDCP), a regularly scheduled conference call with ONDCP, contact with senior federal officials, and federal union briefings. Scientific and technical discussions are included when appropriate. DWP also provides training for Medical Review Officers (MROs), drug program coordinators/supervisors. On June 22, 2017, an all-day agency briefing will include coverage of the science of testing for synthetic opioids; the status of oral fluids testing, a look at studies and progress in the area of other testing matrices; electronic CCFs; and streamlining of the Annual Survey

Report. That report is a collection of information from various agencies about internal drug testing programs, with an eye toward building a real-time database to document positive results within federal agencies.

Turning to the National Laboratory Certification Program (NLCP), Mr. Flegel mentioned several documents which have been revised or are in the process of revision, to provide MROs with updated information about opioids and opioid testing (the NLPC manual, application, checklists, C-tables, and the revised MRO Guidance Manual). There was also a review of the HHS specimen collection handbook and preparation for a new oral fluids matrix. Beginning in May 2017, DWP is looking forward to implementing proficiency testing (PT) samples, practice PT materials (March 2017), three qualifying PTs (May 1, June 12 and July 24), and verification PTs on October 9. Finally, an NLCP inspector training program is being developed based on updated documents from 2008-2010, which have been edited to be more comprehensive. For the PT cycles, for urine, new analytes will be integrated and the revised pH numbers will be incorporated into quarterly PTs by January 2018. For oral fluids, three occasions, including new analytes, will begin in 2018. And development of an inventory of user hair specimens will continue. Upcoming research projects will include a look at cannabidiol in urine, including route of administration; and cannabidiol in oral fluids. Mr. Flegel commented that a survey of user hair for unique metabolites will be considered.

Mr. Flegel announced new initiatives within the DWP. First, the division is gathering information and data gained from the various projects undertaken during the past several years. The information, including technical analysis, will be organized and made available to anyone interested. There is also a publication entitled "News You Can Use," that will regularly publish items of interest related to the Division's activities and projects, with space for news from other agencies and groups involved in drug testing. Recently the web-based DWP Director's Report was established. It will relate concise, updatable descriptions of what DWP does and why. The report will include discussions of the organization of DWP, its people and programs, descriptions of product suites, plans to advance the science of drug testing, and updates on priorities and emerging issues. Mr. Flegel ended his presentation, expressing his appreciation for the opportunity to discuss the goals and aspirations of the DWP.

Federal eCCF Update and OMB Extension

Charles LoDico, M.S., F-ABFT, reported on the revised 2017 Custody and Control Forms (CCF); guidance for extending the OMB-approved CCF, and the process for transitioning from the current 2014 CCF to the revised 2017 form, including the changeover to the electronic CCF. The CCF has been modified since its last iteration in 2014, to make it shorter (from 7 legal-sized pages to 5 letter-sized pages), with some important changes: the addition of synthetics oxycodone, oxymorphone, hydrocodone and hydromorphone, and the deletion of methylenedioxy-N-ethylamphetamine (MDEA). Another important change is the deletion of the checkbox indicating DOT as the testing agency, because collectors would often fail to check the additional specific agency within DOT responsible for the collection. In essence, removal of the DOT checkbox forces collectors to provide more specific information.

OMB has set May 31, 2017 as the expiration date for the 2014 form. Mr. LoDico showed a PowerPoint of the 2017 form, which was developed with support from RTI. He mentioned that there were seven forms, which he listed, that had to be submitted to OMB to obtain extension approval. In addition, a 60-day Federal Register Notice (FRN) on burden hours to comply with the Government Paperwork Reduction Act (GPRA). That was done in February. Then a 30-day FRN was published for public comments on the CCF itself, followed by a supporting statement that detailed the purpose of the CCF, its users and uses, burden to laboratories, etc. Mr. LoDico reiterated the key dates – May 31, the current CCF expires; the following day, June 1, the OMB CCF is renewed, and from that day until October 1, the transition is completed to include all of the changes discussed. The DWP created a guidance document to help laboratories and the public understand the transition. It is available on the SAMHSA website.

Mr. LoDico observed that SAMHSA has certain criteria for granting approval of a lab to be considered electronic – eCCF. There are now 11 labs so designated and in 2016 they handled about 5 million samples. The total for all labs is about 6.6 million. The percentage of eCCF reports has steadily climbed from an initial 1.03% after the first month (one lab in September 2015), to 18% in February 2017. There are advantages to using the eCCF --- the process reduces entry time, minimizes human error (e.g., typos and illegible entries), reduces the need to maintain paper form inventories, and significantly reduces cost to the labs. Because of the new procedures, the guidance document has been revised and updated (including the addition of FAQs on the web site). The collection handbook, MRO manual and laboratory checklists have also been updated.

Hair Testing Analytes

Robert M. White, Sr., Ph.D., DABCC, F-ABFT discussed the metabolism of drugs that are tested under the various programs, and the metabolites that are formed during that process. In the urine program, DHHS allows testing for cannabinoids and their primary metabolite, tetrahydrocannabinol (THC), amphetamines that produce the metabolites of MDMA and MDA, codeine, morphine, and phencyclidine (PCP). Human urine is essentially filtered concentrated blood, "sieved" by the kidney, and the smaller particles (drugs and metabolites) become urine; the larger particles are flushed out of the body through the afferent arterioles. Urine is a good matrix for detecting a drug or a drug metabolite, which means that finding either in urine represents use.

Testing hair to ascertain use of a drug is challenging. Hair samples are taken from outside the body, hair emanating from the skin. Currently most hair testing focuses on the parent drug, not metabolites of the drug, except for (THC) and 9-tetrahudrocannabinol-9-carboxylic acid (THCA). The challenge in testing hair is the presence in the hair samples of significant external contamination from chemicals and other substances found in the samples. To rule out the effect of these external contaminants the test must show that a metabolite found in the sample is not a separately marketed drug; the result of a manufacturing impurity in the parent drug; the effect of a chemical decomposition product; or the product of an in vitro, external chemical reaction on the hair.

Dr. White briefly discussed a list of potential candidate metabolites to consider:

- Cocaine – usually contains numerous impurities, both pharmaceutical compounds and street cocaine. Numerous metabolites have been identified, but ortho, meta & para-hydroxycocaines appear to be promising indicators of drug use.
- Methamphetamine/amphetamine – a candidate metabolite to show use would be the hydroxyamphetamines.
- Phencyclidine (PCP) – transPCPdiol reveals the use of PCP.
- Codeine and morphine – a cytochrome, CYP3A4, produces norcodeine and normorphine, that indicate the use of those parent drugs.
- Hydrocodone, hydromorphone, oxycodone and oxymorphone – the glucuronides show use of these parent drugs; the normetabolite (CYP3A4) also show potential for identifying use.

Dr. White concluded his presentation with the summary that choices for metabolites to demonstrate that a drug or drug class was used by a donor currently exist. Drug metabolites exist in hair as the result of complex processes that probably include a combination of incorporation and metabolism in hair/hair bulb. Drug metabolism may be limited in a small number of cases because of polymorphism and other enzyme inactivation.

Hair as an Alternative to Urine Pre-Employment Testing

David Whiteside, senior director of compliance for J.B. Hunt Transport, discussed his company's establishment of hair testing as a permanent adjunct to the required DOT urine testing program. He described four drug-related accidents involving multiple fatalities. In most of the cases the drivers had successfully passed the pre-employment urine test, but failed the post-accident tests. Passing the initial test was the result of either substituting or adulterating samples, or the drivers could abstain from use long enough to clear the cocaine metabolite from their urine samples. Urine samples are self-collected, behind closed door, which provides an opportunity to compromise the test results. Since there was not enough time after the accident to abstain and clear the drug from their systems, it was reasonable to assume they were using drugs during employment.

Research into alternatives determined that hair collection was an observed process, and drug residues reside in the hair for longer periods of time, eliminating the possibility of delaying the test while the drug clears (an inch and a half of hair represents a three-month profile of potential drug use). Other schemes to obstruct the results were relatively easily overcome – applying the drug directly to hair was overcome by the washing requirements contained in the matrix; full body shaving to eliminate enough hair to sample was simply not allowed. The washing matrix also reduces the possibility of environmental contamination, such as in law enforcement officials who handle drugs, and attorneys who must be in close contact with suspected drug users. Truck drivers should not experience environmental exposure as a matter of routine, and it they do find themselves in a group of individuals using drugs they must extricate themselves or, as a matter of policy, a positive test will not be considered passive exposure.

Mr. Whiteside commented that, as the J.B. Hunt hair testing requirement became known to potential applicants, most of the drug users would choose not to apply. The rate of positive tests rapidly fell to the 4%-5% range. Although the requirement for the hair test was effective in that way, there were legitimate instances when refusal to surrender a hair sample created an inequity and an accommodation was necessary. One instance was refusal to allow cutting of hair based on religious beliefs, as in the case of the Sikh religion. The accommodation there was to allow submission of fingernail clippings, which could be tested with confidence.

With regard to the question of whether the hair test is legally defensible, Mr. Whiteside cited a number of legal decisions, some from state supreme courts (New York and Nevada), supporting the validity of hair testing. The National Transportation Safety Board published a recommendation that the Federal Motor Carrier Safety Administration encourage truck companies to use hair testing. One reason trucking companies don't comply is that the DOT test would still be required, and an additional test would create an added cost issue. Mr. Whiteside showed a bar chart that dramatically illustrated the impact of hair testing: as the number of previously hair-tested applicants rose to nearly 80% in 1980, the number of post-accident positive tests dropped to zero for nearly six years, rising only slightly in the last two years. Concomitantly, the drivers taking random tests show consistent negative results (in the 0.2% range, down from about 0.7% in 2007).

There is good evidence that hair and urine tests results are reliably similar. Of 103,377 tests analyzed in the decade preceding 2016, 94% were negative on both tests.

Mr. Whiteside addressed disparate impact, which occurs when one population is more likely to test positive than another because of environmental exposure or other external factors. Drug enforcement officers who handle drug evidence are more likely to test positive than truck drivers, who should rarely come in contact with environmental drugs. This disparity can be minimized by employing stringent hair washing procedures, including applying cocaine extended wash kinetics calculation. Disparate impact could also occur among diverse populations, such as truck drivers (different races, genders, etc.). Finally, Mr. Whiteside concluded that, for a one-year period (December 2011 through November 2012), using the EEOC 4/5ths Rule, J.B. Hunt's hair testing had no significant disparate impact. A university-based analysis of a larger set of company data strongly refutes disparate impact because it used a comparative analysis between hair and urine testing.

Marijuana Edible Study

Edward Cone, Ph.D., DABFT, commented that, fueled by the legalization of therapeutic marijuana in several states, the demand for all forms of marijuana has increased dramatically. Although most research has been focused on inhaling smoke from the combustion of cannabis, there are other routes of administration – vaped cannabis, when vapors are produced by heating marijuana without combustion; and edible marijuana, a market that offers thousands of products of widely varying potencies. About 40% of medical marijuana is distributed in edible form. The avoidance of combustion eliminates the smoke that may be as carcinogenic as that in cigarettes, and the effect of the drug lasts longer.

Dr. Cone described two SAMHSA studies of edible marijuana consumption. Study one involved the administration of THC and metabolites in three dose levels, 10, 25 and 50 milligrams, administered to six subjects in each dose group. The drug carrier was a "home-made" brownie baked in the lab. The subjects consumed a single dose, remained in clinical residence for 6 days for observation, returning on days 7,8 and 9 for outpatient observation. They had blood, urine, and oral fluid samples taken throughout the study, and their physiology, behavior and task performance abilities were observed. At the high dose, some paranoid psychosis developed (treated and resolved) and most were not able to perform computer tasks. Smokers feel high while they are smoking and return to normal in about 3-4 hours; edible cannabis users experience the high after about an hour, and it can last for 6-8 hours.

In summary, in Study 1, urine showed a long detection window of as much as 7 days. In oral fluids, THC concentrations were initially high and occurred reasonably soon after use (within 22 hours), but carboxy acid was unreliable, sometimes failing detection entirely. In blood, the low THC cutoff of less than 5 ng/mL would result in most participants not testing positive.

Study 2 is nearing completion. It is a crossover design that looks at both smoked and vaped cannabis consumption. It is known that about 20% of regular users have switched to vaped cannabis

Drug Testing Index

R.H. Barry Sample, Ph.D., reviewed statistics from Quest Diagnostics' Drug Testing Index, which are derived mainly from two sources, the federally-mandated, safety-sensitive workforce, and the general U.S. workforce. The former is predominately composed of FMCSA DOT-covered employees. Dr. Sample also included additional data from the National Survey of Drug Use and Health (NSDUH), a survey of about 67,500 civilians age 12 and older. That data on illicit drug use is self-reported. Key findings indicate that positive urine test results have increased over the last five years, and oral fluid positives have increased 47% over the last three years. Finally, hair test positives for the U.S. general workforce increased annually from 2013 to the present high of 10.3%.

Dr. Sample briefly covered specific drug test results:

- Marijuana, the most popular illicit drug in the U.S., since 2013, showed a slight upward trend in the Federally-Mandated, Safety-Sensitive Workforce, and a similar slightly steep increase in the General U.S. Workforce. The positive rate for oral fluids was nearly triple that for urine, but oral fluids is an observed collection process, which would make it less prone to manipulation by the donor.
- Cocaine barely changed from 2014 to 2015. Since 2010, cocaine positivity in urine and oral fluid tests has been below 0.5%, but in hair it has maintained a rate of about 2.5%.
- Methamphetamine positives began to decline in 2005, fell steadily through 2011, when the rate began to increase slightly from 2012 until the last survey. The upward trend was similar in hair.
- Amphetamines positives have increased every year since 2008, in part because of the ever-increasing use of the drug in the treatment of ADHD. Hair is not used to test for amphetamines.
- 6-acetylmorphine, a heroin-specific metabolite, has shown annual increases since 2010. Positives have more than doubled in that time period.
- Other drugs – prescription opiates positives may be on the decline since 2011. Looking at oxycodone, there has been a steady decline since 2012.

In the General U.S. Workforce, post-accident urine testing for drugs stayed below 6% positive results since 1999, breaking into a clear uptrend in 2014 when the rate exceeded 6%, then went to almost 7% in 2016. A less dramatic, but steady increase has also been occurring in the Federally-Mandated, Safety-Sensitive Workforce, where it was higher in 2016 than any year since 2006.

Dr. Sample summarized, following years of decline, the percentage of employees in the combined U.S. workforce testing positive for drugs has steadily increased over the last three years to a 10-year high of 4.0 percent. Positivity rates for post-accident urine drug testing are rising in both the general U.S. and federally-mandated, safety-sensitive workforces. The overall positivity rate for oral fluid testing increased 47 percent over the last three years in the general U.S. workforce. Overall positivity in the general U.S. workforce was highest in hair drug tests, at 10.3 percent in 2015, a seven percent increase over the prior year. Employers should be concerned that drug use by the American workforce is on the rise, and this trend extends to several different classes of drugs and categories of drug tests.

Public Comment

Abigail Potter, American Trucking Associations, stated that ATA represents more than 30,000 motor carriers in the U.S. ATA is an advocate for highway safety, on behalf of members, which is in part based on the premise that the highways are the drivers' workplace. ATA members have contributed many innovative and cost-effective solutions that improve highway safety, many of which are voluntarily adopted by the carriers, and many of which become part of the regulations governing motor carrier operations.

ATA commends DTAB for supporting the use of hair testing and moving toward developing hair testing standards. ATA agrees that hair testing in an effective method for screening employees. Ms. Potter stated that the Fixing America's Surface Transportation (FAST) Act requires the Department of Health and Human Services to publish scientific guidelines for hair testing as a method to detect the use of controlled substances. The guidelines could provide motor carriers with an option to use hair testing as an alternate to urine testing in meeting the federally-required testing requirements. ATA urges SAMHSA and DTAB to take timely action to complete the guidelines.

Lakshmi Anne, Ph.D., an employee of Thermo Fisher Scientific, stated that her company has two technologies for urine testing. One is CEDIA (cloned enzyme donor immunoassay), which uses two peptides that remain inactive until

combined. CEDIA includes an amphetamine panel and an opiate panel. The amphetamine panel detects amphetamine, methamphetamine, ecstasy (MDMA) and MDA. All four are covered by the one assay.

The second is VRA technology, using G63H enzyme, has two assays, one that detects amphetamine/methamphetamine; and an ecstasy assay (MDMA and MDA). There are separate assays for oxycodone and oxymorphone, and hydrocodone and hydromorphone.

Adjournment: Mr. Makela adjourned the DTAB open session.