**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 10-11, 2014**
**Minutes – Open Session**

The CSAP Drug Testing Advisory Board (DTAB) convened via web conference on June 10-11, 2014.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on June 10, 2014 from 10:00 a.m. to 4:10 p.m. and on June 11, 2014 from 10:00 a.m. to 10:45 a.m. The meeting was closed to the public on June 11, 2014 from 11:00 a.m. to 2:00 p.m.

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**Board Members in Attendance**

Dr. Janine Denis Cook
Mr. Robert Bonds
Dr. Lawrence Brown
Ms. Phyllis Chandler
Dr. Anthony Costantino
Ms. Laurel Farrell
Dr. Greg Grinstead
Dr. Marilyn Huestis
Dr. Denise Johnson-Lyles
Ms. Patrice Kelly
Ms. Susan Mills
Dr. Jasbir Singh
Dr. Donna Smith
Dr. Steve Wong

**Call to order**

Dr. Janine Denis Cook, the Designated Federal Official of the DTAB, called the meeting to order at 10:00 a.m. Dr. Cook provided announcements to the web conference attendees. She welcomed the two new ex officio Board members.

**Welcome, Introductions, and Opening Remarks**

Dr. Cook, Acting Chair of the DTAB, introduced the members of DTAB and the staff of the Division of Workplace Programs (DWP) and welcomed federal partners and the public. She announced that the remaining meeting dates for fiscal year 2014 are September 3-4, 2014.

Ron Flegel, Director of DWP, welcomed all attendees. He apologized for cancelling the March 17, 2014 DTAB meeting because of inclement weather. He thanked the DWP staff for the work it does in support of the Federal Drug-Free Workplace Programs. Today's presentations will demonstrate how DWP supports SAMHSA's mission of reducing the effects of substance abuse in America through its workplace drug testing programs. Mr. Flegel provided a status update on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug-Testing Programs (MG), which are currently under review at the Office of Management and Budget (OMB). He illustrated the routing and approval process for the MG. Finally, Mr. Flegel provided status updates for the various initiatives underway at DWP, including the revision of the Medical Review Officer (MRO) Manual to include the interpretation of workplace prescription drug results, the electronic chain of custody form (eCCF), various research projects, and the Prevention of Prescription Drugs in the Workplace initiative.

Mirtha Beadle, Deputy Director of CSAP, welcomed the public, DTAB members, DWP staff, and our federal partners on behalf of Fran Harding. She explained the role of the DTAB and its relationship to SAMHSA's mission and the Federal Drug-Free Workplace Programs. Since this program's creation in 1988, historical data show a continuing decline in illicit drug use among the targeted populations. In addition, evidence demonstrates that the universal protection derived from workplace drug testing programs effectively decreases injury and death among the general population.

**Medical Review Officer (MRO)**

CDR Jennifer E. Fan, Pharm.D., J.D., reviewed the qualifications of a MRO and MRO-certifiying entities and subspecialty boards as stated in the MG. The current list of MRO entities was published in the Federal Register on March 11, 2014. Those entities seeking HHS approval must submit the required information to SAMHSA by July 21, 2014. She described the mission of the MRO workgroup and its progress in revising the MRO Manual.

**Custody and Control Form (CCF)**

Charles LoDico, M.S., D-ABFT, related how OMB set the terms of clearance for the extension of the CCF, which will include a progress update on the adoption of electronic forms to reduce the paperwork burden associated with this form. To do this, SAMHSA convened a workgroup to establish standards related to the various aspects related to the use of electronic forms. On May 28, 2014, OMB extended the expiration date of the CCF to 5.31.2017. Other documents that must be updated in response to the eCCF are the MRO Manual, Collection Handbook, the Laboratory Checklist, and Guidance for using the 2014 Federal CCF.

**Introduction to the Federal Drug-Free Workplace Programs**

Hyden Shen, J.D., provided the governing authorities, including Executive Order 12564, Public Law 100-71, and the MG, for the Federal Drug-Free Workplace Programs. The guidance documents are the Model Plan for Comprehensive Drug-Free Workplace Programs and the 2013 Guidance for Selection of Testing Designated Positions. Each agency has a Drug Program Coordinator who is responsible for implementing, directing, administering, and managing the drug program within his/her agency. He clarified that under the Controlled Substances Act, marijuana is a Schedule I drug and thus will continue to be tested under the Federal Workplace Drug-Free Workplace Programs.

**Introduction to the National Laboratory Certification Program (NLCP)**

Charles LoDico, M.S., D-ABFT, announced that a new NLCP contract was awarded to RTI in September 2013. He described the duties of the NLCP, which include ensuring that the HHS-certified laboratories adhere to the MG. Special studies conducted in 2013 under the NLCP contract included a synthetic opioid single dosing study, a passive cannabis

exposure study, oral fluid specimen stability study, oral fluid poppy seed ingestion study, and oral fluid Vicks inhaler study. Also under the NLCP, notices and newsletters are issued to the certified laboratories.

**Research Studies**

1. Opioid Abuse - Profiling Hydrocodone and Metabolites in Urine

Charles LoDico, M.S., D-ABFT, described the hydrocodone single dose dosing study that was presented as a poster at the 2013 Society of Forensic Toxicology meeting and published in the October issue of the Journal of Analytical Toxicology. Urine specimens were collected at specified time intervals from 12 healthy adult volunteers before and after the administration of a 20 mg dose of hydrocodone bitartrate. Free and total analytes were quantified by LC/MS-MS. Hydrocodone, norhydrocodone, and dihydrocodone were excreted unconjugated while hydromorphone was excreted conjugated. Detection of hydrocodone in urine was 28 hours using a 50 ng/mL cutoff.

2. Prescription Opioid Abuse - Profiling Hydrocodone and Metabolites in Urine
3. Oxycodone and Hydrocodone: Kinetic Relationships of Whole Blood to Oral Fluid
4. Disposition of Oxycodone and Hydrocodone in Oral Fluid

Ron Flegel, B.S., MT(ASCP), M.S., described the study goals and designs for the above listed three single dose dosing studies and the results for the oxycodone and hydrocodone pharmacokinetics in urine and oral fluid. Each study enrolled 12 subjects and oral fluid, whole blood, and urine specimens were collected at specified intervals before and after drug administration. Twelve opioid analytes were measured by LC/MS-MS. Adverse events were delineated for each administered drug. For oxycodone and hydrocodone and noroxycodone and norhydrocodone, the oral fluid and blood results by time were graphically compared. The correlations for oral fluid and blood for oxycodone and hydrocodone showed great inter-subject variability. The pharmacokinetic parameters for oxycodone and hydrocodone metabolites in oral fluid and blood were presented. The mean excretion data for hydrolyzed oxycodone and hydrocodone and their metabolites in urine were presented and showed great inter-subject variability. The mean detection times for oxycodone, hydrocodone, and their metabolites in urine were displayed by cutoff, with greater detection times found at lower cutoffs. The combination of oxycodone, oxymorphone, and/or noroxycodone or noroxycodone alone identified the greatest number of oxycodone positive specimens. Norhydrocodone alone identified the greatest number of hydrocodone positive specimens.

**25 Years of Workplace Drug Testing in America**

R. H. Barry Sample, Ph.D., Director of Science and Technology**,** Employer Solutions at Quest Diagnostics, began by describing the data that are incorporated into the Drug Testing Index® (DTI). He put the DTI into perspective by citing statistics from the National Survey of Drug Use and Health. Barry displayed a timeline of significant events that shaped the federal drug testing program. In the last 25 years (1988-2012), the workplace drug positivity rates declined 74% to 3.5% in 2012. Federally-mandated testing showed a 38% decline during this time period compared to a 60% decline in the U.S. general workforce. Urine and oral fluid show similar positivity rates in the general workforce while positivity rates for hair are somewhat higher. Positivity rates in urine for the general workforce were greater in the pre-employment category compared to random. Pre-employment positives were higher for the general workforce than for the federally-mandated workforce. Amphetamines positives in the general workforce increased 196% from 1997-2012, which may be related to the 100+% increase in amphetamine prescriptions such as Adderall®. Methamphetamine positivity is declining and coincides with the law enforcement meth lab crackdown. Positivity rates for amphetamines in hair are greater than those in urine or oral fluid. Conversely, positivity rates in methamphetamine are greater in urine than oral fluid. Cocaine positivity rates are declining, with greater detection in hair when compared to urine or oral fluid. Overall positivity rates for marijuana are declining also, with comparable positivity rates in hair, urine, and oral fluid. The positivity rates for expanded opiates are increasing over time; from 2005-2012, hydromorphone increased 423%, hydrocodone 172%, oxycodone 71%, and morphine 34%. By testing reason, the highest positivity rates for hydrocodone, hydromorphone, and oxycodone are found in post-accident as compared to random and pre-employment. The overall positivity rates for 6-acetylmorphine (6-AM) are increasing for both workforces while that for MDMA decreased. Abnormal pH is found most often in both workforces' specimen validity testing. The percentage of dilute specimens is decreasing over time in both workforces.

**Department of Defense Drug Demand Reduction Program (DDRP)**
LTC Tom Martin, Ph.D. (USA), Deputy Director, Drug Testing and Program Policy in the Office of the Under Secretary of Defense for Personnel and Readiness Operational Readiness and Safety, described the mission of the DDRP. He explained the importance for readiness and safety among the military ranks. He reviewed the history of the DDRP, which began in 1971 when President Nixon directed the military urine drug testing program. LTC Martin described the military's Health-Related Behaviors Study, which began in 1980 and is administered every three years. This survey queries service members on their self-reported use of illicit and prescription drugs. In the 2011 survey, 5.7% self-reported abusing drugs, which compares to the 0.7% detected for illicit drug use in the six military laboratories. He presented the current panel of drugs tested in his program along with their screening and confirmation cutoffs. LTC Martin provided data from the last five years on the number of active duty service members testing positive for specific drugs. He described the systems approach associated with the DDRP, including readiness and information sharing. He explained the military's automated MRO review process as well as how the military can adjust its testing panel rapidly in response to emerging drug threats, such as prescription drugs, "spice", and "bath salts".

**Department of Transportation (DOT) Program Overview**
Patrice Kelly, J.D., Acting Director in the Office of Drug and Alcohol Policy and Compliance (ODAPC), shared the leadership and responsibilities statement of the DOT's Office of the Secretary and as well as a letter from Secretary Anthony Foxx on the importance of ODAPC. She described the mission of ODAPC and its key services. Patrice outlined the history of DOT's drug testing program, beginning in 1988 with the publication of Part 40. The Omnibus Transportation Employees Testing Act of 1991 contains eight subparts and outlines the testing program in detail. The goals of the DOT program are primarily to ensure the safety and security of the traveling public and to ensure fairness and integrity of the testing process. DOT's drug and alcohol testing program pertains to FMCSA, FAA, FRA, FTA, PHMSA, and USCG. The drugs currently tested in the DOT program were listed. In 2013, 6.1 million specimens were tested under the DOT regulations, with 1.76% testing positive, 0.25% detected as tampered, and 0.17% rejected for testing. THC continues as the most abused drug in 2013 with a percent positive of 0.74% (44,814 positive results). Future issues for ODAPC include the eCCF, the oral fluid alternative specimen, marijuana legalization, international issues, and testing for additional Schedule II drugs. The DOT program managers, ODAPC staff, and the ODAPC website were listed. ODAPC is proud of its outreach services, including its documents-on-demand.

**U.S. Nuclear Regulatory Commission (NRC) 10 CFR Part 26 Fitness for Duty Programs (FFD)**
Paul Harris, Senior Program Manager, Fitness for Duty, described the missions of the NRC and its FFD Programs, which includes safety and security. The vision of the FFD Programs is to provide a regulatory framework consistent with 10 CFR 26.23. The FFD strategy strives for fit, reliable, trustworthy workers through authorization requirements, drug and alcohol testing, behavioral observation, and fatigue management. He described what it means to be fit for duty. Paul outlined the sanctions that the NRC can impose based on drug and alcohol results. The NRC in 2008 implemented the use of time-dependent alcohol limits to determine fitness for duty. The NRC's drug and alcohol 2013 test results were displayed by test and employment categories and in trending relationships back to 1993. The NRC can further divide its data by nuclear site and by testing category to ascertain geographical drug prevalence. Important issues for the NRC include test subversions, specimen adulterations, and specimen validity. Paul outlined those topics for which he would like to see additional research and information. He shared temperature-profiling software that he hopes will serve as a training aid.

**Federal Workplace Drug Testing Programs**
Ron R. Flegel, B.S., MT(ASCP), M.S., Director of the DWP, described the categorization of the HHS-certified laboratories. The number of regulated specimens from 2004-2013 were displayed, showing an increasing trend since 2009. The total regulated specimens tested from 2009-2013 were also displayed by month. The number of regulated specimens reported as positive, adulterated, invalid, or substituted from 2009 to 2013 were shown by year, by month, and by drug class. Non-negative results reached about 122,000 in 2013. THC continues to be the most reported drug, followed by amphetamines and benzoylecgonine. Invalid results outnumber substituted and adulterated results. Specimens reported invalid for pH, whether high or low, depicted a summer seasonal pattern in 2009-2010. In 2011-2012, the pattern for low pH-related invalids shifted to an increased winter pattern. The invalid reported category for 2013 was subdivided by physical characteristics, creatinine and/or specific gravity, immunoassay interference, oxidants, pH, and other.

Immunoassay interference produced the greatest percentage of invalid specimens, with the 6-AM immunoassay producing the most. Immunoassay interference varies by laboratory and is related to the specific immunoassays used by the laboratories.

**Public Comments**
Sarah Ashby, Vice President and General Counsel at Psychemedics Corporation, expressed her concern on a lack of balance in information presented on hair testing science, specifically, legal precedent and decontamination studies. She provided a list of decontamination studies for the Board's review. In particular, the 2011 Department of Justice report stated that the "most significant impact of this research will be the need for hair drug testing guidelines to require the use of extended decontamination wash procedures and mathematical calculations, in addition to currently used cut-off concentrations and the BE/COC ratio". The listed 2004 study contains a recipe for an effective wash procedure. Hair testing has been used in the workplace for at least 25 years and is a proven success in deterring drug use and increasing safety. It has a longer window of detection and provides a powerful, upfront deterrent to drug use.

**The Science of Hair Testing – Summary of Literature Review**
Brian Makela explained that 41 articles on hair contamination published over the last 10 years were reviewed and grouped into the following categories: general review, collection, passive exposure in children, proficiency testing (PT), decontamination procedures, drug specific studies, and methodologies. From the general review, the following information was abstracted: hair grows about 1.5 cm/month; the scalp posterior vertex is the preferred collection site; drugs are deposited in hair by blood, sweat and sebum, and the external environment; and wash steps are critical. Hair collection varies from person to person and individual growth rates affect the amount collected, which is an important factor in segmented analysis. Children in drug user environments can test positive for drugs in hair from external contamination and absorption through passive exposure. Decontamination procedures involve organic and/or aqueous washes that do not remove all external contamination. Finally, Brian covered several drug-specific hair studies as well as hair testing methodologies.

**Hair Contamination Questions**
Janine Denis Cook, Ph.D., DABCC, described the process whereby the hair contamination literature was reviewed and a summary provided to the Board members, who were asked to develop questions based on the literature review. Seven questions were submitted in the following categories: PT, wash procedures, standardization, quality control, metabolite criteria, spiking, and contamination studies.

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 and Acting Chair, DTAB