Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention

Drug Testing Advisory Board

May 3-4, 2011

The Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) meeting was convened at 10:00 a.m. EDT on May 3, 2011 in the SAMHSA Building (Sugarloaf Conference Room), 1 Choke Cherry Road, Rockville, Maryland 20857.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on May 3, 2011 from 10:00 a.m. to 4:30 p.m. EDT. The meeting was closed to the public on May 4, 2011.

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Attendees

Board members present:

Dr. Janine Denis Cook, DFO and Chair
Mr. Robert Bonds
Dr. James Bourland
Dr. Larry Bowers
Dr. Lawrence Brown
Ms. Phyllis Chandler
Ms. Laurel Farrell
Dr. Courtney Harper
Ms. Barbara Rowland
Dr. Donna Smith
Mr. Jim Swart
Dr. Steve Wong

Others present for the meeting:

First name	Last name	Affiliation
Kelley	AbdelQader	Affiliated Healthcare Systems
Ann	Adcook	Roche Diagnostics
Rodney	Ahmann	Department of the Navy
Suzanne	Allison	Clinical Reference Laboratory
Frank	Amanat	Office of Legal Policy, U.S. Department of Justice

First name	Last name	Affiliation
Aimee	Arnold	Drug Screens Plus
Dan	Augenstene	ONDCP
Bohdan	Baczara	DOT/OST - ODAPC
Sherry	Bender	Affiniton
Vanessa	Berry	USDOJ
Isaac	Betts	Defense Intelligence Agency
Kimberly	Blake	Siemens Healthcare Diagnostics
Mary	Brown-Ybos	DISA
Donna	Bush	FDA/CDRH/OIVD/DCTD
Lindsay	Cammel	Omega Laboratories, Inc.
Yale	Caplan	National Scientific Services
Pamela	Carter-Coleman	Internal Revenue Service
Kimberly	Castillo	Clinical Laboratories of Hawaii, LLP
Paula	Childs	Childs International
Jennifer	Collins	MEDTOX Laboratories, Inc
Ed	Cone	The Johns Hopkins University
Charles	Cook JR.	ICE/DHS
Jared	Cooper	RTI
Bill	Corl	Omega Laboratories, Inc.
Dennis	Crouch	Aegis Sciences Corp
Larisa	Cummings	Swedish Health Services/Business Health Link
Lori	Dekker	Keys Consortium
Ken	Edgell	Pipeline Testing
Francis	Esposito	RTI International
Jennifer	Fan	SAMHSA
Laurel	Farrell	DTAB
Jim	Ferguson	FirstLab
Ronald	Flegel	SAMHSA
Neil	Fortner	HQ Air Force Drug Testing Laboratory
Dean	Fritch	OraSure technologies, Inc.
David	Green	Alere Toxicology Services, Inc.
Jennifer	Greer	NASA Shared Services Center
Rina	Hakimian	OGC
Terry	Hall	Toxicology Testing Service Inc
Erica	Harbison	RTI
Paul	Harris	U.S. NRC
Nick	Hartman	TalentWise Solutions
Marilyn	Hayes	C.H.A.S.E., LLC
Eugene	Hayes	SAMHSA/CSAP/DWP
Marilyn	Huestis	NIDA, NIH
Cindy	Ingrao	DOT/OST/ODAPC
Richard	Jenny	NYS Dept of Health
Ted	Johnson	Quest Diagnostics
Jackie	Justice	Dept. of Justice/ Bureau of Prisons
Keith	Kardos	OraSure Technologies, Inc.
Patrice	Kelly	US Department of Transportation, ODAPC

First name	Last name	Affiliation
Josephine	Kenney	First Advantage
B	Kirby	Federal Aviation Administration
Kevin	Klette	Department of Defense
Cynthia	Kunz	The CDM Group, Inc.
Barry	Kurtzer	DriverCheck / CANADA
Gail	Laber	WHS
Yuk-Ting	Lewis	Siemens Healthcare Diagnostics Inc.
Marie	Lin	Lin-Zhi International
Charles	LoDico	DWP/CSAP/SAMHSA
David	Martin	Drug and Alcohol Testing Industry Association
LK	Matthews	Advantage Testing & Professional Services
Patricia	McMinn	Defense Logistics Agency
John	Mitchell	RTI International
Christine	Moore	Immunalysis Corporation
Kristina	Morales	Basic Energy Services
Reed	Morrison	ASAP, Inc.
Jamie	Perez-Carter	Mission Support Alliance, LLC
Kathryn	Petrick	American Solutions for Business/American Diversity Business Solutions
Jackie	Pirone	OraSure Technologies
Abigail	Potter	American Trucking Associations
Claus	Pruemper	Siemens
Eric	Quilter	Compliance Information Systems
Matthew	Respicio	Clinical Laboratories of Hawaii, LLP
Carol	Rest-Mincberg	SAMHSA
Cynthia	Robinson	Department of Defense
Alex	Rose	Foley Carrier Services
Barry	Sample	Quest Diagnostics
Robert	Schoening	U.S. Coast Guard
Nancy	Schultz	BAT
Christine	Secor	U.S. Nuclear Regulatory Commission
Laura	Shelton	DATIA
Hyden	Shen	SAMHSA/DWP
Theodore	Shults	American Association of Medical Review Officers
Gerald	Siefring	Siemens Healthcare Diagnostics
Cathy	Skinner	Defense Contract Audit Agency
Mark	Snider	U.S. DOT
Bill	Sowers	SAMHSA
Paul	Speidel	Psychemedics Corporation
Ernest	Street	EWJ-Street Consulting
Jack	Stein	ONDCP
Alison	Stockdale	NBC
Jim	Swart	DOT Office of Drug and Alcohol Policy and Compliance
Jean	Teetsell	U.S. Department of Labor
Sandra	Vanderploeg	Interactive Medical Connections, Inc.
Josh	Vickers	

First name	Last name	Affiliation
Toian	Vaughn	SAMHSA
First name	**Last name**	**Affiliation**
Terri	Walker	DriverCheck
J Michael	Walsh	The Walsh Group
John	Ward	
Lynn	Ward	University Services
Mary	Warren	Bureau of Engraving and Printing
Lottie	Winters-Adona	District Government Department of Public Works
Melanie	Womble	Professional Drug Screening.com
Richard	Wrobel	Forensic Drug & Alcohol Testing, LLC
Mark	Wuest	Quest Diagnostics

Call to order

Dr. Janine Cook, the Designated Federal Official (DFO) of the DTAB, called the meeting to order at 10:00 a.m. EDT. Dr. Cook explained the public comment process, provided housekeeping announcements for the onsite attendees, and gave instructions regarding Adobe Connect for those attendees participating remotely.

Welcome and Opening Remarks

Dr. Cook, as Acting Chair of DTAB, welcomed everyone. She introduced each member of the DTAB and the Division in Workplace Programs (DWP). Dr. Cook provided the DTAB meeting schedule for the remainder of the fiscal year: July 12-13 and September 12-13, 2011.

CAPT Carol Rest-Mincberg, the Acting Director of the DWP explained how, under a delegation of authority from the Secretary of HHS, SAMHSA's Division of Workplace Programs carries out the HHS role in the Federal Drug Workplace Testing Program. Workplace drug testing is one of the largest public health prevention programs in the United States. Empirical evidence demonstrates a continuing decline in illicit drug use since the creation of this program. There are over 60 million Americans from the federal, regulated, and non-regulated sectors that are drug tested as a condition of their employment, which deters people from using illicit drugs.

Mr. Hyden Shen, the policy oversight lead within DWP for the Federal Drug-Free Workplace Programs, provided a broad overview of our direction on alternative specimens within the Federal Drug-Free Workplace Program. In 2004, the proposed revisions to the Mandatory Guidelines included alternate testing matrices. The 2008 decision to continue with only urine specimen testing was based on three specific issues raised through public comments and federal agency concerns, which expressed scientific, legal, and public policy issues regarding the use of alternative specimens. HHS stated that further research was needed to investigate the state of the science and the legal defensibility of alternative specimens. However, HHS' position was that the use of additional testing matrices would compliment and strengthen the current drug-free workplace program. The next step is to determine whether the research on oral fluids is scientifically sound and legally defensible for inclusion in the federal drug-testing program. This decision to begin with oral fluids was made and supported by over 620 peer-reviewed publications and by the current science. Based on the scientific research and studies, the DTAB will or will not recommend proposed revisions to include oral fluids in the Mandatory Guidelines for publication in the Federal Register, with the opportunity for public comment. Our overall goal within HHS is to continue pursuing ways to further strengthen the drug-free workplace program.

Federal Drug Testing Updates – 2010 Lab Results

DOT Drug Testing Update

Mr. Jim Swart, of the Department of Transportation's (DOT) Office of Drug and Alcohol Policy and Compliance, brought greetings from Mr. Ray LaHood, the Secretary of Transportation, who is very interested in the drug testing matters that are currently before the Board. DOT is the world's largest regulated drug testing program, annually testing over 5 million safety-sensitive transportation employees in the trucking, aviation, railroad, transit, pipeline, and the maritime industries. Mr. Swart acknowledged the Program Managers within the transportation industries, including FMCSA, FTA, FAA, FRA, PHMSA, and Coast Guard; the DOT internal program; and his staff.

In 2010, DOT testing volume increased over 2009. The positive drug testing percentage rate, which had been in decline, rose slightly in 2010 by 0.03 percent. The amphetamine positivity rate continued to be greater than that for cocaine for the fourth consecutive six-month reporting period. Marijuana continued to be the most prevalent drug identified. There were fewer invalid tests but more substituted and adulterated tests identified than in 2009. The new rules that went into effect October 1, 2010 included new cutoffs for amphetamine, methamphetamine, and cocaine; new rules for 6-AM testing; and testing for ecstasy (MDMA), MDA, and MDEA. Comparison between the third and fourth quarter data which straddled this change showed there were fewer tests performed in the fourth quarter than in the third quarter. However, there were more amphetamine and methamphetamine positives than in the previous quarter. Cocaine, with a lower cutoff, had more positives in the fourth quarter despite having fewer tests performed. There was a trend towards more 6-AM positives being identified beginning in 2008 that continued under the new rules.

DoD Drug Testing Update

Captain Kevin Klette is the Director of Drug Testing and Program Policy, the Office of the Assistant Secretary of Defense for Health Affairs in the Department of Defense (DoD). The current DoD panel of drugs that is screened for at a one hundred percent specimen testing rate includes marijuana, cocaine, amphetamine, methamphetamine, heroin, and the designer amphetamines, such as ecstasy (MDMA) and MDA. Pulse testing, with a test frequency of 20 percent, is performed for oxycodone, oxymorphone, codeine, morphine, and PCP. Special request testing for barbiturates, benzodiazepines, synthetic opiates, ketamines, etc. is also conducted.

From 2006 through 2010, the DoD overall positivity rate was just above one percent, compared to the illicit drug positivity rate goal of two percent or less. The positivity rates for Army, Marine Corps, and Navy show a decreasing trend, while the Air Force rate has remained steady through this period. The mean active duty testing rates by service are three times per person per year for the Navy and Marine Corps, twice a year for the Army, and once a year for the Air Force. In 2010, the overall active duty high risk population positivity rates for males between the ages of 18 and 25 were 2.5 percent for the Army and less than 1.5 percent for the Marine Corps. The positivity rates for non-active duty reserve components were less than 2 percent for the Air Force, Navy, and Marine Corps and 2.28 percent for the Army reserve. The positivity rates for high risk population non-active duty reserve components were 4.5 percent for Army and 2.3 percent for the Marine Corps. For the non-active duty National Guard members, the Army National Guard positivity rate was over 2.5 percent. DoD annually queries its DMDC database to determine if specific units or locations have pockets of high drug use, and then this information is relayed to the services for potential remediation.

The DoD laboratory drug positive results by drug were marijuana at 67.4 percent, cocaine at 13.2 percent, D-amphetamine at 5.6 percent, D-methamphetamine at 3.1 percent, and ecstasy (MDMA) and MDA at 2.8 percent. PCP use is almost nonexistent in this population. Codeine, morphine, oxycodone, and oxymorphone are at low positivity rates.

Since 1998, illicit drug use has decreased dramatically in the military, confirming the deterrent effect of this program. Similarly, self-reported illicit drug use over the past 30 days from all military services from 1980 to 2002 has also decreased to less than 5 percent. In 2008, though, 12 percent of the members admitted to the illicit use of prescription medications. From 2005 to 2009, in the high risk category, psychiatric medication prescriptions rose by 42 percent. Prevalence testing in 2009 indicated that prescription drug abuse exceeded

illegal drug abuse. In 2012, hydrocodone, hydromorphone, and benzodiazepine testing will be added to the DoD drug panel.

There are 15 agencies in DoD that are under the HHS program. Overall, the DoD agency positivity rate was 0.3 percent.

NRC 10 CFR Part 26 Fitness for Duty Program

Mr. Paul Harris, the Senior Program Manager for the Fitness for Duty Program at the U.S. Nuclear Regulatory Commission (NRC), provides the technical oversight of security at NRC-licensed facilities, including 104 nuclear power reactors, 6 fuel cycle facilities, and a number of material users of radioactive materials that fall under the regulatory auspices of the NRC.

NRC's regulation is 10 CFR Part 26, Fitness for Duty Programs, which parallels the HHS Guidelines, though NRC has yet to implement rulemaking to institute the November 25, 2008 HHS Guidelines. NRC's Fitness for Duty Program strategy involves drug and alcohol testing at a 50 percent random testing rate; fatigue management; behavioral observations; and access authorization, including initial drug testing, criminal history, psychological tests, criminal background checks, financial history checks, etc. The NRC has a zero tolerance drug and alcohol policy with imposed sanctions. For the first offense, the worker is banned for 14 days. For the second offense, the worker is banned for 3 years from working in the nuclear industry. For third offense, the worker is banned forever from NRC licensed activities.

The overall percent positivity rate for both employees and contractors is about 0.6 percent in 2010. Marijuana is the most prevalent drug, with positive results also obtained alcohol, cocaine, and refusal to test. The majority of the positive results are in the random, for-cause, post-events, and follow-up categories. About one-third of all the NRC licensees have lowered the blood alcohol concentration levels. Almost all of the NRC licensees have lowered their cutoffs for marijuana. Many of the licensees have lowered their opiate levels voluntarily. Four licensees are testing for barbiturates, methadone, methaqualone, propoxyphene, and benzodiazepines.

Federal Workplace Drug Testing Programs

Mr. Ron Flegel, a forensic toxicologist within DWP, provided an update on the 2010 lab results for the Federal Workplace Drug Testing Programs. In 2010, the specimens tested numbered around 5.7 million, compared to 5.5 million in 2009. The number of specimens reported as drug positive, adulterated, invalid, and substituted increased from 88,500 in 2009 to 95,400 in 2010. The percentages of drugs reported positive in 2010 and 2009 were very similar, with the notable exception of amphetamines. The number of specimens tested in the quarter after implementation of the revised Guidelines was 1.4 million, compared to the 1.49 million tested in the preceding quarter. The number of specimens reported as drug positive, adulterated, invalid, and/or substituted increased to 1.76 percent in the quarter after implementation compared to 1.65 percent in the prior quarter. Compared to the third quarter, fourth quarter percent positive results for marijuana decreased while results for amphetamine, methamphetamine, cocaine, opiates, and 6-AM increased. The number and percentages of adulterated, substituted, and PCP positive results were very similar for both quarters, with invalid results being slightly higher in the third quarter. Specimens were also being reported as positive for the designer drugs, specifically ecstasy and MDMA; however, these drugs do not account for much of an increase in the overall positivity rate. In summary, after the implementation of the revised Guidelines on October 1, 2010, there was about a 4 percent reduction in the number of specimens tested, but overall there was an increase in the percent of specimens reported as drug positive. Secondly, the major drugs responsible for the increase in the percent of specimens reported positive were those for which the cutoffs were lowered on October 1st, specifically, cocaine, amphetamine, methamphetamine, and MDMA. Finally, there were smaller increases observed with the 6-acetylmorphine and codeine.

Medical Review Officer (MRO) Certification

Commander Jennifer Fan, of the United States Public Health Service and a member of DWP, updated the Board on the Medical Review Officers' Certification process. An MRO (Medical Review Officer) must be a physician that has either an MD or a DO, has knowledge regarding the pharmacology and toxicology of illicit drugs, has completed training necessary to serve as an MRO, and has satisfactorily passed an examination administered by a nationally-recognized entity, which has been approved by the Secretary, that certifies MROs or a subspecialty board for physicians performing reviews of Federal employee drug tests. An MRO-certifying entity must be nationally-recognized and must submit their qualifications and sample examination to SAMHSA. That information will be subjected to an objective annual review and found acceptable before approval by the HHS secretary. The currently approved MRO entities that are certified for training and certification of MROs are the American Association of Medical Review Officers (AAMRO) and the Medical Review Officers Certification Council (AAMROC). The organizations that are approved for MRO training are the American College of Occupational and Environmental Medicine (ACOEM) and the American Society of Addiction Medicine (AASAM). The 2011 MRO entity approval timeline will be based on last year's timeline. MRO entities that are interested in seeking approval from the HHS Secretary must submit the information to DWP by August 2011. Once the Secretary approves the MRO entities, the list will be published by September 2011 in the Federal Register.

Emails and notifications from the National Laboratory Certification Program that impact MROs are sent to the four certified entities for dissemination to their membership. MRO entity guidance in a FAQ format is currently under development and will be posted on the DWP website in the next coming months,

Electronic Custody and Control Form (CCF)

Electronic Documents

Mr. Neil Fortner, Chief of Quality Assurance for the Air Force Drug Testing Lab, described the current CCF process. The life of the current five-part CCF form begins with the collection process and ends with its distribution to the laboratory, donor, MRO, and employer. In 2010, DOT conducted 5.4 million drug tests using the CCF, which equates to 26 million pieces of paper. Problems with the current CCF include the quality of the printed form, difficulty in reading back copies; faxing, mailing, and turnaround issues; and labor and cost in tracking errors.

Federal documents that are relevant to the electronic CCF include the Government Paperwork Elimination Act, which defines an electronic signature as something that identifies and authenticates a particular person as the source of that electronic communication and states that the process shall not be denied as a legal document in terms of the intent of that person in signing that document.

An MRO group provided information on the 5800 DOT CCFs that it processed in a one week time period. Of those, 400 had illegible donor signatures and 1300 had missing information; this equates to 29 percent with errors. Not included in these numbers were missing CCFs and CCFs that could not be matched to a drug testing result. Other CCF issues include unchecked temperature boxes and illegible collector names. A smaller MRO organization provided CCF data on 10,000 DOT-reviewed results; 5 percent had CCF errors, including unchecked temperature boxes, missing signatures, missing dates, and missing donor or employer information. Regardless of the reason, these problems cost time and money and delay the reporting of results.
One MRO group's cost analysis of problem CCFs concluded that an additional four dollars of direct costs per specimen over the routine cost was incurred.

The non-regulated drug testing industry groups that provide electronic CCFs include Medtox, eScreen, FormFox, Quest, and LabCorp. Each of the programs has different approaches. LabCorp uses print-on-demand, where the information is downloaded electronically, hard copies are printed, and the donor provides a wet signature. For MedTox, the process is entirely electronic; the information is downloaded, bar codes are assigned to the specimen bottles, no chain of custody is printed, and a digital signature capture pad is used to capture the collector's and donor's signatures. Quest uses an in-between process. Advantages include no printing and mailing/faxing of the other form parts, no CCF inventory in the field, software-controlled data entry,

web-based, ability to keep MRO/collector/employer information current, electronic submission of data, directed accessioning, encrypted data transmissions, and fewer errors. One of the organizations using electronic CCFs for over ten years has processed over fifteen million samples without collecting one affidavit. Laboratory issues with CCFs include field inventory, waste ratios of 1.8-2 to 1, receipt of outdated CCFs, and outdated MRO information on CCFs.

For the information printed on the back of the CCF, including the public burden statements, privacy statements, and instructions on how to complete the CCF, the acknowledgement and consent of this information could be done electronically.

Issues concerning electronic documents that still need resolution include security and encryption to protect the integrity of the information and the use of electronic or digital and digitized signature, where electronic digital signatures are cryptographic mechanisms that actually encrypt information through the use of some kind of biometric or digital certificate and digitalized signatures are facsimiles of a signature created with a stylus and a signature pad.

Traditional Forms and Electronics Forms - The Benefits and Pitfalls of Both

Ms. Kathy Petrick, the President of American Solutions for Business and the American Diversity of Business Solutions, addressed how the current form is used, its strengths and weaknesses, an overview of the electronic process, the options that are currently available, and the strengths and weaknesses associated with that. The current form is a hard copy, five part, 9 ½ by 11 inch form. Part one is the test copy facility which accompanies the specimen to the laboratory. Part two is sent to the medical review officer either by fax or mail. Part three stays with the collector and is typically kept at the collection site. Part four is the employer copy and is sent by mail or fax. Part five is the donor copy and is given to the donor upon the test completion. The laboratories are responsible for purchasing the forms and may customize the form through overwriting or embedding data in the bar code. Advantages include hard copies for filing, wet ink signatures, and legal strength for process validity. Pitfalls include the paper-intensive five part form; waste ratios ranging from 1.5-7 to 1; ecological impact; labor and cost in form production, shipping, mailing, faxing, and filing; and form completion errors.

Current electronic CCF systems include the eChain system by MedTox, the eScreen system by Murray Lappe, the FormFox system by Compliance and Information Systems, and private systems by LabCorp and Quest. To date, about 15-16 million specimens have been processed using the form/label combination instead of a five-part form with no challenges.

In a plain paper solution, the information is captured electronically and then printed out as a form/label combination plus five additional sheets. Plain paper costs, which would be borne by the collection site, include coaching software, toner, paper, and printer maintenance.

The digital laser carbonless set option has the information laser-printed on paper that contains carbon capsules that allows a signature to go through all forms. Disadvantages include the variety of laser printers that are in the field and their differing paper feeding characteristics. Advantages include carbon through, information capture, and software coaching to reduce errors.

For electronic forms with paperless output, less paper is used, information is available on-line, and coaching software reduces errors. Disadvantages include no hard copy and no wet ink signature.

Concerns for an electronic CCF include security standards for data and legal enforcement challenges concerning no hard copy and no wet ink signatures.

OMB Approval Process

Mr. Charles LoDico, a chemist within DWP, explained the Office of Management Budget (OMB) process for approving a federal Custody and Control Form (CCF). The current 2010 CCF has an expiration date of 8.31.2013. In its 2010 Notice of Action, OMB stated that prior to the next approval of this CCF package, SAMHSA shall provide a progress update on adoption of electronic forms in an effort to reduce burden. The OMB approval process takes between 18-24 months. Because there are currently 26-28 months until that deadline, the process to examine alternatives to a paper form must begin now.

OMB clearance ensures compliance with the 1995 Public Law Paperwork Reduction Act, regulations 5 CFR Part 1320. The objective of the Paperwork Reduction Act is to minimize burden on the respondents, to minimize cost to the Federal government, to maximize the quality and utility of information, to ensure that all applicable laws on privacy and confidentiality are followed, and finally to allow the maximum opportunity for public comment. The 1998 Government Paperwork Elimination Act (GPEA) specifically requires that electronic records, and their related electronic signatures, are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. Two policies exist now in HHS for electronic signatures. One is FDA's 21 CFR Part 11, which provides the criteria under which FDA would consider electronic signature to be equivalent to full handwritten signatures. The other is the Office of the Secretary for HHS' 45 CFR Parts 160, 162, and 164, which provide the national standards for safeguards to protect the confidentiality, integrity, and the availability of electronic protected health information. As part of the CCF process, SAMHSA will investigate the electronic signature, a non-repudiation agreement for a digital signature, third-party software for managing Federal CCF information, unique specimen identification numbers, the security of the data transmission, and integrity of the document content.

The OMB clearance process at SAMHSA first involves the creation of the CCF, routing and approval through SAMHSA, publication of a Federal Register Notice giving the public 60 days to comment on the proposed CCF, 30 day public notification that the OMB package will be submitted to HHS, submission of the OMB package to the SAMHSA's clearance officer after the 60-day comment period, HHS review of the OMB package, HHS submission of the OMB package to OMB, and OMB 60-day action on the package. OMB can pursue one of four actions, including approving it for a three-year period, approving it for only six months, disapproving it, or requesting withdrawal and resubmission. If approved, OMB issues a Notice of Action which permits the chain of custody form to be used as intended.

DTAB's Process for Evaluating the Scientific Sufficiency of the Oral Fluid Specimen for Federal Workplace Drug Testing

Dr. Janine Cook, DWP chemist, outlined DTAB's multiple step process for evaluating the scientific sufficiency of the oral fluid specimen for Federal workplace drug testing programs. At the end of each step, DTAB will evaluate that scientific evidence to ensure that it is sufficient before proceeding with the next step in the process. Per the preamble of the 2008 Mandatory Guidelines, HHS proposed a staggered timeline for evaluating alternate specimens. Because of the scientific information available on oral fluid, DWP began that timeline with oral fluid. For step one, the DTAB was charged with assessing the state of the science of oral fluid as an alternative specimen at the January meeting. Step two involves identifying the science that currently exists for oral fluid with the help four lead scientific experts. Step three, the review the current state of the science as we know it, was done on day two of that January DTAB meeting. Step four includes performing an exhaustive literature search on oral fluid drug testing; to date, about 620 peer-reviewed references have been identified. These references will be used as citations for the preamble of the possible proposed revisions to the Mandatory Guidelines to include oral fluid. For step five, a template was created by melding the oral fluid portions of the original 2004 proposed revisions with the 2008 Mandatory Guidelines question-answer format. This template allowed easy identification of what we knew and what we didn't know. The known topic areas served as preliminary consensus statements. Step seven was to identify areas that needed further research because of insufficient supporting literature. The five topic areas identified as needing further research were analytes and cutoffs, specimen validity testing, collection, collection devices, and testing. For each one of those five areas, a question was drafted. For analyses and cutoffs, what are the appropriate analyses and cutoff concentrations for the initial and confirmatory tests? For specimen validity testing, are there appropriate markers or tests for oral fluid that would reveal adulteration, substitution, and/or dilution? For collection, what

are the requirements for collecting an oral fluid specimen? For collection devices, what are the requirements for an oral fluid collection and device? For testing, are LC/MS/MS or other methodologies a viable alternative to immunoassay as an initial screening test? To mine through the literature to uncover the science to answer these questions, we identified other scientific experts who will serve on working groups. Other areas of concern have been identified and forwarded to the different Federal agencies for their input. Step eight involves publishing a request for information in the Federal Register, in which we will be asking the public and stakeholders about those five topic areas that we have identified. For step nine, the information that we receive back from the public will be discussed at the next July meeting on the 12th and the 13th. And finally, for step 10, at the September meeting, the DTAB will deliberate on the state of the science of oral fluid, and at that point decide whether they should recommend oral fluid as an alternative specimen. The DTAB, based on the state of the science research and after addressing those significant science, legal, and policy concerns raised by the public commenters and Federal agencies in response to the 2004 proposed revisions, will, or will not, recommend proposed revisions to the Mandatory Guidelines to include oral fluid as an alternate specimen type. If they recommend this, the proposed revisions will be published in the Federal Register, and we will seek public comment on those proposed revisions.

Public Comments

Mr. Bill Corl is the Chief Operations Officer for Omega Laboratories, one of the major hair testing laboratories in the United States with over ten years of hair testing experience. The advancements in hair testing over the last five years have placed it as one of the most accurate and reliable drug abuse testing methods available. Hair testing programs can be accredited by CLIA, New York State Department of Health, ISO/IEC 17025, and the College of American Pathologists. The German Society of Toxicological and Forensic Chemistry has over 50 hair testing laboratories worldwide that are participating in a quarterly proficiency testing program. Federally-regulated industries should be given the option to use the best available technology to fight illegal drug use in the workplace. Hair testing improves the success of drug testing programs because it increases the time period over which drugs can be detected, as compared to urine. It is easily collected, transported, and stored, and it is less likely to transmit bio-organisms than urine and is more difficult to adulterate. Mr. Corl asked why hair testing, which is widely accepted and scientifically proven, has not been fast-tracked like oral fluid testing. Statistics from three major trucking firms showed that their random urine test rates dropped significantly after implementation of hair testing programs for pre-employment.

David Martin, Chairman of the Drug and Alcohol Testing Industry Association (DATIA) explained that DATIA is the largest and oldest drug and alcohol testing industry association that represents thousands of MROs, TPAs, laboratories, and collection sites. DATIA applauds and supports the work of the Board, especially electronic documents, which will save time, increase efficiency, and make the overall system of drug testing more consistent within this global digital age.

Eric Quilter, CEO of Compliance Information Systems (CIS), explained that his company is a provider of information management solutions, including FormFox, an electronic CCF. He supports the substance abuse prevention industry, including employers, laboratories, third party administration firms, MROs, and collection sites. He also supports SAMHSA's efforts in researching electronic alternatives to the current paper CCF. Software-assisted chain of custody is a tool used for millions of drug testing transactions every year. These systems improve process, quality, reliability, and turnaround time and decrease the overall cost of drug testing. SAMHSA must specify minimum standards for the use of digitized signatures and data information security. Many commercially available devices and software capture the image of the signature and its biometrics. Resources exist within the industry to assist SAMHSA with establishing guidelines for implementing the technology for Federal testing.

Dr. Cook adjourned the open session of the Drug Testing Advisory Board 3:40 p.m. EDT.

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
Acting Chair, DTAB

These minutes were formally considered, amended, and approved by the Drug Testing Advisory Board using email.