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

Drug Testing Advisory Board

July 12-13, 2011

The Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) meeting was convened at 9:00 a.m. EDT on July 12, 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 July 13, 2011 from 10:00 a.m. to 12:00 p.m. EDT. The meeting was closed to the public on July 12 and July 13, 2011 from 12:00 p.m. to 3 p.m. EDT.

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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
Douglas	Allen	FRA/DOT
J Mac	Allen	Superior Training Solutions, Inc
Suzanne	Allison	Clinical Reference Laboratory
Tom	Anthony	Smart Start
Aimee	Arnold	Drug Screens Plus
Daniel	Augenstene	ONDCP
Bohdan	Baczara	DOT/OST-ODAPC
John	Beach	Energy Dispatch, LLC

First name	Last name	Affiliation
Sherry	Bender	Affiniton
William	Bennett	ACL LABS
Kimberly	Blake	Siemens
Heather	Britt	Applicant Insight
Mary	Brown-Ybos	DISA, Inc.
Sarah	Buchanan	Health and Medicine Counsel of Washington
Nathaniel	Butlin	Biophor Diagnostics, Inc.
Lindsay	Cammel	Omega Laboratories, Inc.
Patrick	Campbell	Aegis Sciences Corp
Yale	Caplan	National Scientific Services
Pamela	Carter-Coleman	IRS
Chanda	Chhay	CASET Associates
Paula	Childs	Childs International
Jared	Cooper	RTI International
William	Corl	Omega Laboratories, Inc.
Angela	Crosby	Occupational Care Consultants
Dale	Dirks	Orasure
Ken	Edgell	PTC/AMRO
Pamela	Edwards	Labatory Corporation of America Holdings
Jennifer	Fan	SAMHSA
James	Ferguson	FirstLab
Ron	Flegel	HHS/SAMHSA/CSAP/DWP
Dean	Fritch	OraSure technologies, Inc.
Jennifer	Greer	NASA Shared Services Center
Erica	Harbison	RTI International
Francis	Harding	HHS/SAMHSA/CSAP
Eugene	Hayes	SAMHSA/CSAP/DWP
Giselle	Hersh	HHS/SAMHSA/CSAP/DWP
Flo	Hockin	Thermo Fisher Scientific
Jenny	Hoffmann	Roehl Transport Inc
Marilyn	Huestis	NIDA, NIH
Cindy	Ingrao	DOT/OST/ODAPC
Ted	Johnson	Quest Diagnostics
Prentiss	Jones	South Bend Medical Foundation
Keith	Kardos	OraSure Technologies, Inc.
Patrice	Kelly	U.S. Department of Transportation, ODAPC
Robert	Kelly	Member of the public
Josephine	Kenney	First Advantage
Brenda	Kirby	Federal Aviation Administration
Prabhakaran	Koteel	Laboratory Corporation of America
Barry	Kurtzer	DriverCheck, Inc., Ayr, Ontario, Canada
Shannon	Lalley	American Airlines
Mitchell	LeBard	MEDTOX Laboratories, Inc.
Donna	Leimgruber	IU Health Occupational Services
Marie	Lin	Lin-Zhi International, Inc.

First name	Last name	Affiliation
Nicholas	Lomangino	FAA
Veronica	McCray	DNF Safety Board
Lisa	Milligan	Gamma-Dynacare
David	Mineta	Office of National Drug Control Policy
John	Mitchell	RTI International
Christine	Moore	Immunalysis Corporation
Paul	Moorman	South Bend Medical Foundation
Douglas	Mullen	Air Transport Association
Gerald	Nagel	US Department of Agriculture
Jim	Nolte	Thermo Fisher Scientific
Brad	Petty	National Occupational Health Services & National Background Reporting
Jackie	Pirone	OraSure Technologies
Abigail	Potter	American Trucking Associations , Inc.
Matthew	Respicio	Clinical Laboratories of Hawaii, LLP
Carol	Rest-Mincberg	HHS/SAMHSA/CSAP/DWP
Anne	Roberts	Quest Diagnostics
Mary	Rush	Professional Drug Screening Services, Inc.
Naiara	Salgado	HHS/SAMHSA/CSAP/DWP
Robert	Schoening	U.S. Coast Guard
Christine	Secor	US NRC
Carl	Selavka	Northeastern Bioscience Associates, LLC
Hyden	Shen	HHS/SAMHSA
Theodore	Shults	American Association of Medical Review Officers
Gerald	Siefring	Siemens Healthcare Diagnostics Inc.
Mark	Snider	U.S. DOT
Bill	Sowers	HHS/SAMHSA/CSAP/DWP
Paul	Speidel	Psychemedics Corporation
Jack	Stein	ONDCP
Alison	Stockdale	DOI
Ernest	Street	EWJ-Street Consulting
Marsha	VandeHei	Schneider National, Inc
Ellen	Voie	Women In Trucking, Inc.
J Michael	Walsh	The Walsh Group
John	Ward	Union Pacific Railroad
David	Whiteside	J.B. Hunt Transport, Inc.

Call to order

Dr. Janine Denis Cook, the Designated Federal Official (DFO) of the DTAB, called the meeting to order at 10:03 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. Dr. Cook introduced the members of DTAB, the staff of the Division of Workplace Programs (DWP), and distinguished guests. She announced that the date for the last DTAB meeting for the fiscal year 2011 is tentatively scheduled for September 12th and 13th. Whether this meeting will be open or closed will be announced later. Dr. Cook introduced and thanked Carol Rest-Mincberg for her leadership to the Division.

Welcome and Opening Remarks

CAPT Carol Rest-Mincberg, Acting Director of DWP, explained the role of DWP in the Federal Drug-Free Workplace Programs under the delegation of authority from the Secretary of HHS. She described that the mission of SAMHSA is to reduce the impact of substance abuse and mental illness on America's communities. Drug testing supports that prevention mission by being one of the largest public health prevention programs in the country and by impacting the public health and safety and national security of every person in this country. There are 400,000 testing designated positions in the federal workforce and 12 million workers in the regulated industries that are drug tested. Drug testing is a universal prevention as well as a selective deterrent and thus saves lives and prevents injuries; empirical evidence shows a decline in illicit drug use since the beginning of this program.

At the last three DTAB meetings, DTAB followed a multiple-step process to assess the scientific sufficiency of oral fluids as a potential alternative specimen for inclusion in the Mandatory Guidelines. As we move forward, we need to partner with labor, industry, consumers, scientists, and legal council to further our mission.

Deliberation and Vote on Proposed Recommendations

Dr. Janine Denis Cook, the Acting Chair of DTAB, began by reviewing the key aspects of the charter under which DTAB operates, including providing advice to the SAMHSA Administrator. The Office of General Counsel at SAMHSA recommended that DTAB should provide advice to the SAMHSA Administrator in the form of an official written recommendation. The process for developing those recommendations was reviewed.

Since January 2011, the DTAB has been evaluating the science of oral fluid to determine if the science supports its inclusion as a potential alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Based on that evaluation, DTAB has proposed a recommendation for deliberation and vote:

> Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

DTAB members voiced their support of this recommendation.

The DTAB recognizes the emerging drug threats posed by the misuse and abuse of psychotherapeutic prescription drugs. Therefore, DTAB proposed a second recommendation for deliberation and vote:

> DTAB recommends the inclusion of additional Schedule II prescription medications (e.g., oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Again, DTAB members voiced their support of this second recommendation.

A closed ballot written vote of the Board members was taken for each recommendation.

Review of Request for Information Responses

LCDR Eugene D. Hayes, senior public health advisor in DWP, discussed the Federal Register Notice Request for Information that was published June 10th with a 60 day public comment period. This Request for Information sought peer-reviewed scientific information on oral fluid as a potential alternate specimen in the Federal Workplace Drug Testing Programs. Questions were posed in five categories: drug analytes and cutoffs, specimen validity, specimen collection, collection devices, and testing. The specific questions posed were: what analytes should be measured in oral fluid for the initial and confirmatory tests; what initial and confirmation cutoffs should be used for the oral fluid drug tests; should the oral fluid drug testing panel be expanded to include Schedule II prescription medications; are biomarkers needed to validate the oral fluid specimen and are there appropriate biomarkers or tests for the oral fluid specimen that would reveal adulteration, substitution, and/or dilution; how should an oral fluid specimen be collected; as a donor, would you prefer to provide an oral fluid or urine specimen; what should be the technical requirements for an oral fluid specimen collection device; and what technologies are available to perform initial and confirmatory testing on oral fluid specimens?

The comment period ends on August 9th, 2011 at the close of business. Methods for commenting include on-line, fax, email, and regular mail. Notice of this request was forwarded to the laboratories, medical review officers (MRO), our subject matter experts, and the working group members. To date, two comments were received.

Public Comments

Lindsay Cammel, Regulatory Affairs Representative, spoke on behalf of Omega Laboratories, one of the major hair testing laboratories in the United States with over 10 years of experience in hair testing and over 6,000 clients worldwide. Omega is very encouraged to see that the study of alternative matrices is in progress. Omega offers its support in facilitating the acceptance of hair testing, including data gathering. Regulated industries would like the option to use hair testing because urine testing does not always detect drug use.

Dr. Jim Ferguson is the Medical Director for the Professional Health Monitoring Program at FirstLab, Course Director for the American Society of Addiction Medicine (ASAM) comprehensive MRO training course, a Fellow of ASAM, author of the *MRO Team Manual*, and a Director of the Medical Review Office of Certification Council. He applauded the process of including oral fluid and Schedule II drug testing. Issues to consider with these two initiatives include specimen volume and the need for biomarkers in oral fluid for validity testing since one can never assume that any given collection has been well observed. In urine testing, the burden of determining that each specimen is consistent with normal human urine is borne by the laboratory, and it needs to be that in oral fluid as well. Just as with urine testing, donors will attempt to beat the oral fluid test. MROs have no business reviewing results that do not have either complete chains of custody or evidence that the lab was testing a valid specimen. Dr. Ferguson warned of the difficulty that MROs face in reviewing positive laboratory results for Schedule II drugs to determine whether an acceptable, legitimate medical explanation exists for the confirmed positive result. Neither the labs nor the MROs can address whether or not a donor is impaired, whether or not a donor is taking the medication as prescribed, whether or not a donor is taking it at work, or most importantly, whether or not a donor is fit for duty. He requested the development of a collaborative program between employers, regulators, MROs, and occupational medicine physicians to craft, implement, and maintain a comprehensive fit-for-duty program.

Abigail Potter spoke on behave of the American Trucking Association (ATA), which is composed of the United Federation of Motor Carriers, State Trucking Associations, and National Trucking Conferences. ATA is pleased that DTAB is reviewing alternative drug testing matrices and strongly recommends that DTAB examine and improve hair testing because highway safety is critically important to our industry. The use of hair testing during pre-employment screening allows them to confirm that they are placing the safest drivers on the road. Hair testing is hard to adulterate and provides, on average, a 90-day detection window for all drugs, whereas urine tests detect between 48 hours to seven days. ATA has shown that between 2.35 and 10.4 percent more drivers were caught with hair tests than urine tests. In the last year, ATA has seen a dramatic increase in the number of trucking companies that are using hair testing in conjunction with urine testing for pre-employment. This drug testing data is shared with those trucking companies who are inquiring about prospective drivers.

Mr. Ted Shults is the Chairman of the American Association of Medical Review Officers. He stated that he has never heard the role of this agency in this public service initiative stated as he heard this morning. Regarding Schedule II drugs, there are public health issues to address, including technology, policy, employer costs, and substance abuse. Issues for MROs in reviewing Schedule II narcotic analgesics are the definition of a valid prescription and the length of time for which these drugs can be used under that prescription. In going from an illicit drug to a drug that is primarily used legally, the challenges are the establishment of reasonable parameters that do not interfere with the medical treatment for bona fide pain patients and other individuals. To establish these parameters, involvement of the medical community and other federal agencies will be required. Mr. Shults stated that he is thrilled oral fluid testing is moving forward. He commended SAMHSA on its transparency and efficacy over the last seven months.

Ms. Ellen Voie is the President of the Women in Trucking Association, which encourages the employment of women in the trucking industry, promotes their confidence, and minimizes obstacles faced by women working in the trucking industry. She stated that urine testing is burdensome and discriminatory to women due to anatomical differences and the challenges faced by women in the urine collection process. In addition, urine

testing provides only a two to seven day drug detection window, the specimen can be adulterated by the donor, and not all drug use is detected by the urine test. Trucking companies have begun implementing hair testing programs for safety reasons. Ms. Voie asked the DTAB, HHS, and ODAPC give the trucking industry the option to use hair testing for pre-employment and random drug testing.

Mr. David Whiteside is from J.B. Hunt Transport, Incorporated. He was pleased to hear that oral fluid was recommended and the opportunity to evaluate other alternative matrices for testing, including hair, is one the horizon. Because oral fluid has a shortened window of detection, for pre-employment purposes, the oral drug test may not necessarily deter people from entering the trucking industry who are using illegal drugs or using illegally-obtained drugs. To date, 50,000 hair test results indicate that hair testing is superior to urine in pre-employment tests for detecting the use of illegal or illegally-obtained drugs. From May 2006 through March 2011, more than 2,700 drug-using drivers were identified with the hair test who had passed their urine test. For those employees subjected to pre-employment hair testing, rates for random drug testing performed shortly after hire declined by more than 79 percent. If the goal of SAMHSA, DTAB, and ODAPC is to prevent drug-using drivers from operating vehicles, then the best testing specimen to best achieve that goal is a hair test.

Mr. Nathaniel Butlin is the Director of Operations for Biophore Diagnostics (Webcast audio is unclear. No written statement submitted.)

Ms. Jenny Hoffmann is the Plant Supervisor and the DER for Roehl Transport, a provider of truckload and logistics services. Roehl recently began hair follicle testing and would encourage the DTAB to permit hair follicle testing only in place of the urine drug testing as currently required by the DOT. Hair follicle testing is considered acceptable for use by regulated and non-regulated industries, as well as federal, state, and local governments; the FBI; the FDA; and the DoD.

Dr. Marie Lin is the President and CEO of Lin-Zhi International. (Webcast audio is unclear. No written statement submitted.) From their studies of different oral fluid collectors, they found the best method for oral fluid collection is a neat oral fluid collected in a 50 mL centrifuge tube with a screw cap. This method is user friendly and cost effective.

Mr. Carl Salavka of Northeastern Bioscience Associates, LLC expressed that he was impressed that the DTAB has an accelerated process for reviewing alternative matrices for toxicological testing. He stated that from 1999-2001 DTAB formed a hair testing working group to develop consensus standards that were incorporated into the 2004 proposed rulemaking. The international community has developed guidelines on hair testing cutoffs, proficiency testing, and laboratory requirements. For the opioids, he would be interested to learn the proposed oral fluid cutoffs. He applauded the two step recommendation process proposed today.

The tally of the DTAB votes on the recommendations is as follows:

> Recommendation number one: Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.
> The vote by the members of the DTAB was unanimous.
>
> Recommendation number two: DTAB recommends the inclusion of additional Schedule II prescription medications (e.g., oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.
> The vote by the members of the DTAB was unanimous.

A letter addressed to the SAMHSA Administrator will be signed by all members of the Board recommending that she approve these recommendations.

Dr. Cook adjourned the open session at 11:28 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.