

**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

**September 3, 2014
Minutes – Open Session**

The CSAP Drug Testing Advisory Board (DTAB) convened on September 3-4, 2014.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on September 3, 2014 from 9:00 a.m. to 3:15 p.m.

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Board Members in Attendance

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

Call to order

Janine Denis Cook, Ph.D., the Designated Federal Official of the DTAB, called the meeting to order at 9:00 a.m.

Welcome, Introductions, and Opening Remarks

Dr. Cook, Acting Chair of the DTAB, provided housekeeping announcements to both on-site and web conference attendees. She recognized the Board members, Division of Workplace Programs (DWP) staff, and federal partners. Dr. Cook announced that the fiscal year 2015 DTAB meeting dates will be forthcoming.

Opening Remarks and the Status of the Previously Announced DTAB Recommendations

Ron Flegel, B.S., MT(ASCAP), M.S., Director of DWP, welcomed all attendees and thanked the DWP staff. The proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG) for oral fluid and urine have been reviewed by the Office of Management and Budget (OMB) and federal agencies. The received comments and recommendations are being addressed. DWP staff is updating the Medical Review Officer Manual to include additional prescription drug results. Ron announced that OMB published its final notice for the electronic Federal Chain of Custody

Form. Special research projects conducted in conjunction with the National Laboratory Certification Program include dosing studies with poppy seeds, over the counter nasal inhaler containing L-methamphetamine, hydrocodone/oxycodone, and hydromorphone/oxymorphone; a study of passive marijuana exposure; the effect of tooth whiteners on oral fluid results; a study of drug analyte stability in neat and buffered oral fluid; a study of analyte stability and recovery in oral fluid collection devices; and a study characterizing current immunoassays and different confirmation methods for synthetic opiates. He also described DWP's Prevention of Prescription Drugs in the Workplace Initiative.

Workplace Issues Related to the Decriminalization/Legalization of Marijuana

Deborah Galvin, Ph.D., Principal Social Scientist, DWP, announced that state-sanctioned use of marijuana is increasing. Laws at the federal, state, and local levels may differ, resulting in confusion about how changes in marijuana laws relate to employers' workplace policies. Though the courts continue to uphold a company's right to a drug-free workplace, it is imperative that employers discuss with their employees their drug-free workplace policies. The Office of National Drug Control Policy definitions for legalization, decriminalization, and medical marijuana were presented. The definitions for legalization and decriminalization were further explained in layman terms. Marijuana continues to be classified as a Schedule I drug under the Controlled Substances Act. The Department of Justice stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws, thus clarifying the federal government's prosecutorial position.

Products for Subverting Drug Tests

Anastasia Donovan, Intern, DWP, conducted an internet search to determine the abundance of drug test subversion products available for online purchase. Using Google® and Yahoo® search engines to research 19 different search terms, 23 different websites offering 83 drug test subversion products were found. The number of websites offering subversion products by specimen matrix was 19 for urine, 7 for oral fluid, and 7 for hair. The number of advertised subversion products by specimen matrix was 59 for urine, 10 for oral fluid, and 14 for hair. These subversion products are classified as detoxification, substitution, or alteration products.

Unique Components of Hair

Peter Stout, Ph.D., D-ABFT, Senior Research Forensic Scientist in the Center of Forensic Sciences at RTI, described how hair morphology is highly variable. Currently, both hair, specifically hair microscopy, and fiber analysis are undergoing scrutiny in the forensic science community. He reviewed the key components of the hair strand and illustrated the microscopic morphological characteristics of human hair. Dr. Stout demonstrated the different uptake patterns of external dyes applied to human and mouse hairs. At the microscopic level, staining human hair with rhodamine B and examining the strands microscopically will not differentiate the racial background of the hair donor. Examination of the ultrastructural cuticle appearance of knotted hair demonstrated both intra- and inter-individual variability in cuticle appearance. The microscopic appearance of cotton, nylon, acrylic, and spandex fibers are distinct from that of human hair. The microscopic appearance of mammalian fibers from sheep, mouse, rabbit, cat, squirrel, and dog were shown.

Unique Drug Metabolites in Hair

Peter Stout, Ph.D., stated that drugs and their metabolites can be measured in hair, with the parent drug being the most prevalent. Tetrahydrocannabinolic acid is an established unique drug metabolite present in hair that can be used to distinguish use from contamination. Ethyl glucuronide, a specific marker of excessive alcohol ingestion, was found as a contaminant in hair treatments. 6-acetylmorphine (6-AM), a biomarker of heroin use, can be formed in situ from heroin contamination. There were no apparent correlations between self-reported opioid dosing for hydromorphone, morphine, codeine, and 6-AM and measured concentrations. Research on methamphetamine and phencyclidine (PCP) in hair has not been extensive. Potential biomarkers include adducts between melanin intermediates, which are formed during melanin synthesis, and amphetamines, nicotine, and cotinine. Thiol adducts with amphetamines, cocaine, opiates, and PCP are promising because these adducts are only formed in vivo. For cocaine, the norcocaine is not useful because it is a minor constituent of coca leaves and can also be formed during cocaine synthesis. Similarly, cocaethylene can be produced from ethanol. The Federal Bureau of Investigation (FBI) study published this year examined washed hair from drug chemists and cocaine drug users. Based on the study results, a flow chart of laboratory criteria to distinguish cocaine-contaminated hair from cocaine use was developed. Analytes included in the algorithm were

cocaine, cocaethylene, norcocaine, and the para-, meta-, and ortho-hydroxycocaines. Cocaine-n-oxide is labile and thus not amenable to analysis. Two other cocaine studies were also described.

Hair Pigmentation Literature Review

Jim Bourland, Ph.D., D-ABFT, Scientific Director at Alere Toxicology, presented a summary of 54 peer-reviewed articles published from 1992-2014 on the binding of drugs to hair melanin. The articles were grouped into the following categories: animal studies, human in vitro studies, general human studies, human controlled dosing studies, retrospective statistical studies, and review articles. The animal studies were performed in rodents, either rats, mice, or guinea pigs. Incorporation of drugs in rodent hair of different coloration, either on the same or different animals, was studied. Basic drugs have greater affinity for melanin than acidic drugs and thus were found in greater concentrations in more pigmented hair. In the human in vitro and general studies, basic drugs were again found to have a greater affinity for melanin binding sites and were found in greater concentrations in darker versus lighter hair. Though cosmetic hair treatments could reduce drug concentrations, drug remained present in dyed or bleached hair. Hair porosity may also affect drug incorporation into hair. In the human controlled dosing studies, normalizing drug concentrations to melanin content may reduce the melanin bias. Reducing the drug cutoff concentration may also decrease the effect of melanin bias. Also, individual differences in sweat and sebum secretion of drug could affect drug incorporation into hair. For the retrospective statistical studies, no statistically significant difference in bias was found between urine and hair drug results. Differing results were found between hair color and analyte recovery. In the review articles, since the melanin content increases with hair pigmentation, more drug is incorporated in darker colored hair, specifically for the basic drugs versus acidic drugs. The eumelanins account for more drug incorporation than pheomelanins. Differences in drug uptake into hair are dependent on hair permeability, cosmetic hair treatments, personal hygiene, and route of administration or exposure.

Food and Drug Administration's (FDA) Notice on Regulation of Laboratory Developed Tests

Denise Johnson-Lyles, Ph.D., Toxicology Branch Chief of FDA's Division of Chemistry and Toxicology Devices, discussed FDA's July 31st notice to Congress on its intent to publish two draft guidances - one on the regulatory framework for laboratory developed tests and the second on medical device reporting for these tests. These guidances are expected to be published in a draft notice for a 90-day public comment period in late September or early October. Included in the draft guidance proposal are the definition of a laboratory developed test, some examples, and FDA's rationale for the proposed regulatory framework for this category of test. The proposed regulatory framework is a risk-based approach, with those laboratory developed tests with the highest risks being phased in first. The regulatory requirement for these tests will be effective after the guidances are published in final form. Forensic use is defined by the FDA as those tests that are for law enforcement only and are under enforcement discretion for all requirements.

Public Comments

Ms. Abigail Potter with American Trucking Association reviewed the J.B. Hunt data presented at the July 2013 DTAB meeting. These data included 16,000 paired urine and hair drug test results and the resultant ratios, which showed no statistical significance evidence of hair pigmentation bias. J.B. Hunt implemented a pre-employment hair testing program in addition to urine testing because their random urine testing positivity rate was stagnant at 3.5 percent. After implementation, their random positivity rate decreased to zero. In the transportation industry, safety is paramount, with a goal of zero fatalities and zero drivers positive for drugs. Implementation of hair drug testing will impact transportation safety by preventing fatalities. The hair test provides a 90-day detection window, thus identifying the chronic user. HHS has demonstrated its acceptance of hair testing as an effective and viable method for detecting controlled substances through the FDA's 510(k) clearance process, which involves the submission of scientific evidence. To date, the three major hair testing labs have all voluntarily submitted to the 510(k) clearance process.

Kyle Hicks is a Regulatory Affairs Specialist at Omega Laboratories, one of the three major hair testing laboratories in the world with over 14 years of industry experience. He thanked the Board for investigating some unique and important aspects of hair testing. He stated that the three major workplace hair testing laboratories have performed studies specifically addressing these aspects in their FDA 510(k) clearances, including subversion products and wash procedures. Kyle offered the services of Omega for any questions or concerns the Board may have on hair testing.

Carl Selavka, a forensic toxicologist and director of Northeastern Bioscience Associates, stated the public comment period is important to the acceptability of the Board's deliberations. Unfortunately, the rest of the world has surpassed the U.S. in the use of alternative matrices for drug testing. Laboratories need to learn from one another by sharing information. Additionally, we should never rely on just one type of test to provide all the information necessary to appropriately address questions raised in a given case. Finally, he advised the Board to not let the regulatory nature of its mission delay this information, especially from its use in non-regulated environments.

Raymond Kubacki is CEO of Psychemedics, which has performed drug testing in hair for over 25 years. He stated that Psychemedics has a continuing interest in assisting DTAB by, for instance, providing key published references. He clarified that Psychemedics' wash procedure is not patented, but only its method of extracting drugs out of the hair is. In fact, Psychemedic's wash procedure was used by the FBI in the study discussed earlier.

Greer Woodruff of J.B Hunt reminded the Board of the 61,000 paired urine and hair specimen data he presented at the July 15, 2013 DTAB meeting. To date, J.B. Hunt has conducted over 71,000 paired hair and urine tests over the past nine years, and he stated that there was not a single allegation or lawsuit claiming a false positive or a biased test. For the last seven years, J.B. Hunt has not had a single post-accident urine positive result from any driver who had been subject to a hair test. Hair testing identifies lifestyle drug users and deters drug use, which is improving highway safety. The FBI study validated Psychemedics' wash criteria and presented an algorithm for determining external contamination, an issue that has hindered the advancement of hair testing. Unlike the urine collection, hair collection is observed, making substitution nearly impossible. Hair adulteration and detoxification are ineffective. With regards to hair pigmentation, Psychemedics has established procedures to remove the melanin, which should address the issue of ethnic bias. The application of the four fifths rule to over ten thousand donor results found no disparate impact on any ethnic group.

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