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

July 15, 2013
Minutes – Open Session

The CSAP Drug Testing Advisory Board (DTAB) meeting convened at 9:00 a.m. on July 15, 2013 in the Seneca/Rock Creek conferences rooms in the SAMHSA Building, 1 Choke Cherry Road, Rockville, Maryland 20857 and via web conference.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on July 15, 2013 from 9:00 a.m. to 5:30 p.m. The meeting was closed to the public on July 16 from 9:30 a.m. to 4:00 p.m. and July 17, 2013 from 9:00 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. Courtney Harper Lias
Ms. Susan Mills
Dr. Jasbir Singh
Dr. Donna Smith
Mr. Jim Swart
Dr. Steve Wong

Call to order

Dr. Janine Denis Cook, the Designated Federal Official of the DTAB, called the meeting to order at 9:00 a.m. Dr. Cook provided announcements to both the on-site and remote attendees.

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 the fiscal year 2013 are September 10-11, 2013. She also stated that the presentations during the open scientific session were accredited for continuing education.

Ron Flegel, Director of DWP, welcomed all attendees. He stressed how DWP supports the Federal Drug-Free Workplace Programs and SAMHSA's mission of reducing the effects of substance abuse in America through its workplace drug testing programs. He described how the addition of alternate specimens to the Federal Workplace Drug Testing Programs would complement urine drug testing and outlined the HHS staggered timeline for researching these alternate specimens.

Fran Harding, Director of CSAP, welcomed the public, DTAB members, DWP staff, and our federal partners. She explained the role of the DTAB and reviewed the progress of the two recommendations made by the Board regarding the inclusion of oral fluid as the alternative specimen and additional schedule two prescription medications in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (MG). She applauded the Board for adhering to the HHS staggered timeline for researching alternate specimens. Ms. Harding described SAMHSA's mission as detailed in its eight strategic initiatives and how the work of the DTAB is aligned with this mission.

Dr. Eleanor Katz, the Chief Medical Officer for SAMSHA, explained how she is approaching this meeting as a clinician, based on her work with monitoring programs for impaired health professionals.

Federal Custody and Control Form (CCF)

Charles LoDico explained that the 2010 CCF expires on September 1, 2013 and described the process for obtaining a three year extension from 2013 to 2016 for this form. In 2010, the Office of Management and Budget (OMB), whose mission is to reduce cost and paperwork burden, placed a condition on the 2013 extension of the CCF. This condition required that SAMHSA evaluate the adoption of an electronic form. Mr. LoDico described the working group process used for the electronic CCF (eCCF) evaluation. He listed those documents that will be revised once the eCCF is approved and adopted.

Previously Announced DTAB Recommendations

Ron Flegel explained how the proposed revisions to the MG for both oral fluid and urine are currently in the review process. Other DWP initiatives include revising the Medical Review Officer (MRO) Manual for the interpretation of workplace prescription drug results, specifically the synthetic opiates, and special research projects to aid in the interpretation both urine and oral fluid test results.

DTAB's Process for Evaluating the Scientific Supportability of the Hair Specimen for Federal Workplace Drug Testing

Dr. Janine Cook described SAMHSA's objective for, and the duties of, the DTAB as outlined in its charter. The key duty of the DTAB is to provide advice to the SAMHSA Administrator, and it does this in the form of recommendations. She provided a regulatory history of hair testing, beginning with the April 13, 2004 proposed revisions to the MG in which hair, sweat, and oral fluid were proposed as alternate specimens to urine. In the final MG published on November 25, 2008, urine was listed as the only specimen type. The reasons for this decision were outlined in the 2008 final MG preamble. HHS recommended a staggered timeline for issuing guidance on the alternate specimens that would allow for further study and research. DTAB was charged with

following this staggered timeline and began with the evaluation of the scientific supportability of the oral fluid specimen at the January 2011 DTAB meeting. Today, it will begin assessing the scientific supportability of the hair specimen in federal workplace drug testing programs. The steps that the Board will use for this evaluation were described in detail.

A Historical Perspective of Hair as a Drug Testing Matrix

Dr. Michael Walsh, President of the Walsh Group, provided a history of hair as a drug testing matrix and the history of the federal government's consideration for including that matrix in the federal program. His dateline for the history of hair analysis stretched from 1858 with the report of finding arsenic in hair, to 1977 with the procedure for liquefying hair prior to drug testing, to 1980 with the introduction of chromatographic confirmatory techniques, to 1995 with the introduction of hair proficiency testing (PT) programs, and to the present with new and improved analytical techniques. Hair as a specimen in the federal workplace drug testing programs has been under consideration since 1987. In 1990, the National Institute of Drug Abuse (NIDA) along with the National Institute of Justice (NIJ) sponsored a two-day review of the science of hair testing for drugs of abuse. The Society of Forensic Toxicologists (SOFT) consensus report stated that workplace hair testing was premature. In 1992, SOFT issued a revised consensus report that identified deficiencies in the knowledge of hair analysis. In 1993, the National Institute of Standards and Technology (NIST) conducted four rounds of PT for the laboratories performing drugs of abuse analyses in hair. The overall detection rate was 89% with a 5% false positive rate. In 1994, DWP convened a second review of the science of hair testing for drugs of abuse testing and concluded there were too many unresolved analytical issues. In 1997, the DTAB also reviewed the science of hair. In 1998, DWP formed an industry stakeholder group which advised on the integration of hair into the federal programs. From 2000-2007, the National Laboratory Certification Program (NLCP) conducted 23 rounds of PT, with analytical performance improving with time. In 2004, DWP published proposed revisions to the MG to include hair. When the final MG were published in 2008, urine remained the only permitted specimen. In 2009, RTI issued a final report on distinguishing between cocaine use and contamination. In 2009, the Federal Bureau of Investigation (FBI) suspended its hair testing in non-criminal cases. Over the last 25 years, research into workplace hair drug testing has been financially supported by NIDA, SAMHSA, the Department of Justice, and NIJ. This has resulted in improved methodologies and laboratory analytical performance. Remaining scientific questions include mechanisms for drug/metabolite incorporation into hair, wash kinetics and metabolite ratios, contamination, hair color bias, use versus exposure, all contributing to the interpretation of test results. Four states and one territory (Iowa, Montana, Oregon, Vermont, and Puerto Rico) prohibit or limit the use of hair in workplace drug testing. Workplace hair testing was an issue in the Boston Police case civil suit.

Hair Characterization, Collection, Preparation, and Stability

Dr. Peter Stout, Senior Research Forensic Scientist in the Center for Forensic Sciences at RTI International, presented on hair morphology and characteristics, collection of hair specimens, preparations of hair specimens, and the stability of the hair specimens. Hair is a very complex structure with a very complex growth process. The morphology of hair is highly variable both between and within individuals. Within individuals, the morphology of hair changes with age, time, treatments, and other factors. Hair is composed of 65-95% protein; >30% water, depending on pH; and lipids, pigment, and trace elements. The primary protein is keratin, with its high sulfur content and complex structure. Pigmentation is caused by melanocyte products, which include the melanins – eumelanins causing black hair pigmentation and pheomelanins causing red and yellow pigmentation. Melanin is the primary component of hair with which drugs associate. Multiple, complex, interrelated deposition pathways, classified as endogenous or exogenous, exist for drugs to interact with the hair matrix. The endogenous pathways for deposition of drugs into hair include diffusion, transportation, entrapment, binding, melanins, sebum, and sweat. Exogenous deposition pathways include direct and sweat redistribution. Hair for drug testing is predominately collected from the occipital apex of the head by snipping. Once collected, the strands are orientated by near root end. Sample preparation methods include decontamination, physical or mechanical preparation, and chemical digestion. Unfortunately, there is little consensus on the relative efficacy of these methods. Decontamination protocols for sample preparation include no treatment; brief rinsing with water or aqueous buffer, alcohols, other organic solvents, or detergents; vortexing or sonication; and extensive sequential washes with or without wash analysis and mathematical

calculations. Mechanical sample preparations include cutting hair to fit glassware, finely snipping hair, shredding hair, and pulverizing or powdering hair. Chemical digestion procedures to prep hair include no treatment; direct extraction; supercritical carbon dioxide treatment; treatment with sodium thiosulfate or sodium sulfide; and enzymatic, aqueous, acidic, or basic digestion, or a combination of any of these digestions. Use of mass spectrometry (MS) for drug analysis is a common technique that can distinguish chemical structures; one limitation is that MS will only analyze what is extracted. Radiotracer analysis is a research technique that is not commonly used in human testing laboratories. This method shows where the tracer is but not what it is. It will measure and estimate all incorporated tracer. Hair that has not been subjected to cosmetic treatment or environmental exposure is quite stable.

Hair Analysis for Drugs: Cutoff Concentrations, Analytes, and Stability

Dr. Christine Moore, Vice President of Toxicology Research and Development of Immunalysis Corporation, presented recommended initial and confirmation cutoffs from the 2004 proposed MG, the 2010 European Workplace Drug Testing Society (EWDTS), and 2012 Society of Hair Testing (SoHT). These cutoffs differed between these groups for amphetamines and cannabinoids on screening cutoffs and for amphetamines and tetrahydrocannabinolic acid (THCA) on confirmation cutoffs. The metabolites found in urine and hair vary by specimen types. For cocaine immunoassays, benzoylecgonine (BZE) is the most prevalent analyte detected in urine followed by cocaine, cocaethylene (CE), and norcocaine while in hair the analyte order is cocaine, BZE, CE, and norcocaine. For heroin immunoassays, the morphine 3- and 6-glucoronides are the primary analytes detected in urine followed by morphine, 6-AM, and heroin while in hair the analyte order is 6-acetylmorphine (6-AM), morphine, heroin, and the glucuronides. For cannabinoid immunoassays, THCA is the primary analyte detected in urine followed by 11-hydroxy- tetrahydrocannabinol (THC), and THC while THC is the primary analyte found in hair followed by THCA and 11-hydroxy-THC. In general, basic drugs incorporate well into hair; thus the parent incorporates to a greater extent than the metabolites. Conversely, acidic drugs are not well incorporated. The 300 pg/mg cutoffs for phencyclidine (PCP) are appropriate based on a study of positive results from known PCP users. For cocaine, proposed cutoffs of 500 pg/mg are consistent between societies; detection of metabolites varies because of formation through degradation and presence as contaminants. Studies of known cocaine users have shown that the proposed cutoffs for parent drug and metabolites will identify cocaine users. Data from a study involving controlled methamphetamine administration supported the proposed cutoff of 300 pg/mg for methamphetamine with at least 50 pg/mg amphetamine, but a lower cutoff should be considered. Studies of methylenedioxymethamphetamine (MDMA) in hair are very limited, so a ratio requirement for MDMA/methylenedioxyamphetamine (MDA) should be considered. Though the societies also differ in their cutoffs for THC, it is recommended that screening should be for the parent THC with confirmation of THCA to minimize the claim of passive exposure. For opiates, studies have shown that the detection of 6-AM identified heroin use in 100% of the subjects and the suggested cutoffs seem appropriate. The presence of morphine suggests heroin or morphine intake but not codeine. There is a linear relationship between the frequency of heroin use and morphine and 6-AM concentrations in hair. Studies for hydrocodone, hydromorphone, oxycodone, and oxymorphone are very limited and either secondary to drug analyses in the hair of heroin and cocaine users or from post-mortem tests, where high concentrations were found in hair with drug use. Limited studies have shown that drugs are stable in hair for years. Other issues for consideration include extraction efficiency from authentic hair specimens; the extent of drug conversion during extraction, especially for BZE and 6-AM; and drug stability in hair during transportation and storage.

Initial Testing for Drugs of Abuse in Hair Specimens

Dr. David Engelhart, Laboratory Director at Omega Laboratories, presented initial testing cutoff levels for cocaine, opiates, amphetamines, PCP, and THC or THCA from the 2004 proposed MG, SoHT, EWDTS, Omega Laboratories, Quest Diagnostics, and Psychemedics Corporation. The target analytes were cocaine, methamphetamine, THCA, morphine, and PCP. All screening methods were competitive binding immunoassays, either homogeneous or heterogeneous. The advantages and disadvantages of homogeneous and heterogeneous immunoassays were compared and contrasted. All positive immunoassay results must be confirmed by chromatography and MS for forensic defensibility. Also, enrollment in a PT program is used to verify the sample preparation, recovery/extraction efficiency, analytical sensitivity, analytical specificity, precision, accuracy, and cross-reactivity of the immunoassay. Dr. Engelhart presented data that Omega

Laboratories submitted to the Food and Drug Administration (FDA) for the 510(k) clearance of its immunoassays for screening for drugs of abuse in hair. These data included intra- and inter-assay immunoassay precision studies for spiked samples at eight different concentrations for cocaine, THCA, and oxycodone and concordance studies between immunoassay and gas chromatography (GC)/MS at five different concentrations for cocaine, THCA, and oxycodone. Hair requires pre-analytical sample preparation techniques, which may involve buffers, organic solvents, acid or alkaline hydrolysis, and/or enzymatic digestion. Data from Omega's FDA submission were presented on the impact of a toxin removal shampoo, an adulterant, on its ELISA immunoassays; the ineffectiveness of this product was confirmed. Omega's 510(k) data on hair hygienic treatments, such as bleaching, permanents, dyes, and relaxers, showed insignificant effects of these treatments on negative specimens. The effects on positive hair specimens were within the standard uncertainty (<20% except for bleaching and permanent effects on PCP) of the GC/MS confirmation assay. Study data submitted to the FDA included agreement, cosmetic treatments, external contamination, precision, recovery/extraction efficiency, shipping stability, long term stability, cross-reactivity, detection limits of ELISA and GC/MS, and traceability. Existing hair standards include College of American Pathologists (CAP) and ISO/IEC 17025 standard accreditations and EWDTS and United Nations guidelines.

Hair Testing Methodologies: Confirmatory Testing

Dr. Michael Schaffer, Vice President of Laboratory Operations for Psychemedics Corporation, described confirmatory testing in hair. For sample cleanup and preparation, it is important to secure a new portion of the remaining intact hair specimen to ensure homogeneity. The wash procedures and the subsequent wash analyses are critical to address external contamination. The hair must be prepped in such a way as to maximize drug recovery from inside the hair shaft. From a quality assurance (QA) standpoint, the initial screening test must be FDA cleared. Certification from CAP and the ISO/IEC 17025 standard for external quality assurance (QA), enrollment in an external blind quality control (QC) program, and participation in an external PT program (SoHT or Arvecon GB) are important. Internal QC measurements should be tracked and assessed using Levy-Jennings charts. Measurements of analyte uncertainty should be performed annually. The use of MS for confirmation is recommended because it is capable of measuring the trace levels of drug present in hair. The guidelines of the National Laboratory Certification Program (NLCP) and the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS), including full scan, selected ion monitoring acquisition, chemical ionization, and tandem MS (necessary for marijuana and cocaine), should be adopted and followed. Manufacturer's recommendations for tuning and resolution should be adhered to. Validation of the MS procedure should involve the use of certified standards and controls and deuterated internal standards. Validation studies should include linearity; within and between run precision; accuracy at the limit of detection (LOD), limit of quantitation (LOQ), and the upper LOQ; interference; carryover; and ion suppression. In addition, studies should verify that the method is rugged enough to work reliably in production mode. Whether GC or liquid chromatography (LC) is used with MS depends on the analyte; for instance, LC is best for amphetamines and cocaine and its metabolites while GS is acceptable for THCA. For accurate data interpretation, the chromatography should be evaluated for resolution, peak shape, signal to noise ratio, etc. The certifying scientist must be able to distinguish between negative, positive, contaminated, adulterated, and invalid samples.

Hair Proficiency Testing

Dr. Jeri Ropero-Miller, Senior Research Forensic Scientist in the Center for Forensic Scientist at RTI International, provided an overview of the 2000-2007 NLCP pilot PT program, the 1995-present SoHT PT program, and other hair PT programs. For the NLCP pilot PT program, up to 13 laboratories participated in the 23 rounds, with cycles 1-8 focusing on method optimization, cycles 9-11 focusing on reproducibility, and cycles 12-23 focusing on intra- and inter-laboratory variability. The most notable finding was the large variability in reported results. Focusing on the three 2007 pilot PT cycles, the six or seven participating laboratories investigated accuracy and precision by quantifying each analyte five times over multiple runs. These PT samples were produced in one batch using decontaminated authentic hair from known drug users or fortified with drug analytes and stored at room temperature prior to shipment. Laboratories were instructed not to decontaminate the hair samples and to perform confirmatory testing only. Target drug concentrations for THCA, amphetamine, methamphetamine, MDA, methylenedioxyethylamphetamine (MDEA), MDMA, cocaine,

BE, norcocaine, 6-AM, morphine, codeine, and PCP were 1.5 to 3 times the 2004 proposed MG confirmatory test cutoffs. Technique variations between laboratories include test menu, internal standards, sample preparation, and pretreatment, digestion, and extraction methods. All confirmatory methods were by MS. The change in the mean concentrations for the amphetamines and THCA by challenge was displayed graphically. The changes in the mean concentrations with time by laboratory were given for amphetamine, cocaine, and THCA. The variabilities in the mean percent coefficient of variation (CV) by cycle for amphetamines and THCA were presented and compared to those of urine. Percent CV for all hair analytes were compared graphically to those for urine and oral fluid PT challenges.

Practical Aspects of Drug Testing in Human Hair

Dr. Jim Bourland, Scientific Director at Alere Toxicology, began with an overview of the hair collection process, which involves cutting the hair with a scissors close to the scalp at 2-3 different locations at the occipital crown or posterior vertex and aligning the hair by its root ends. Challenges to the hair collection process include no or very short head hair, head hair weaves, collection of body hair, claims of contaminated hair, and collector variability in cutting the hair. The contents of a typical hair collection kit were described. The accessioning of the hair specimen requires two cutting and one weighing step that are not required for urine or oral fluid. Ideally, hair should be accessioned in a dedicated and isolated accessioning area that has the necessary supplies and humidity control to reduce static electricity. The hair specimen is usually washed pre-analytically to remove external contamination. Since hair is not a liquid matrix, other pre-analytical treatments are necessary, including digestion and pre-extraction of the drug. The extraction procedures vary by drug and metabolite. Challenges to these treatments include leaving the drugs and metabolites intact, recovery, and time. Hair confirmation methods include chromatography in combination with MS. The drugs and metabolites detected in hair and their cutoffs were shown from two different laboratories. A study was presented in which 7,000 hair and urine specimens were analyzed for specific drugs. The majority (70.3%) were collected for pre-employment. The positivity rate for hair was greater than that for urine for marijuana, amphetamines, and cocaine. This difference could be explained by pharmacokinetics and drug use patterns. The use of both matrices yielded the highest detection rate. Interpretation issues associated with the hair specimen include external contamination, whether a positive result was derived from use or exposure especially for marijuana and cocaine, positive results in children, and hair color (melanin content) bias. To illustrate the issue with positive hair results in children, methamphetamine exposure data were presented on children aged 5 months to 12 years. These results were compared to those from adult methamphetamine users. The adults had higher concentrations of both methamphetamine and amphetamine than the children. The children, though, had higher methamphetamine to amphetamine ratios than the adults. A similar study was performed comparing marijuana exposure in children and adults. Again, the adults had higher concentrations of THC and THCA than the children while the children had higher THC to THCA ratios than the adults. Can the results of these studies be used to distinguish exposure in the children from use in the adults? Other aspects for consideration in interpretation include the frequency of use in the last 90 days, the pattern of use, denial of use, etc.

Hair Drug Testing Data

Dr. Barry Sample, Director of Science and Technology in Quest Diagnostics' Employer Solutions, presented drug testing data on positive prevalence rates and concordance for paired hair and urine specimens. These routine, paired hair and urine specimens (n = 193,000) were submitted for drugs of abuse testing from workplace, criminal justice, and family/social services and tested using immunoassay for screening and GC/MS for confirmation. The reasons for testing included pre-employment (73%), random (12%), and other (15%). The overall positivity rates were 12.6% for hair and 7.6% for urine, a 66% difference. Overall, 85% of specimens were urine/hair negative, 4.7% were urine/hair positives, 2.8% were urine positive/hair negatives, and 7.9% were urine negative/hair positive. For amphetamines, hair positivity was 5.9% while urine was 2.1%; concordance was 1.5% for urine/hair positives, 93% for urine/hair negatives, 0.63% for urine positive/hair negative, and 4.4% for urine negative/hair positive. For methamphetamines, hair positivity was 5.9% while urine was 1.8%; concordance was 1.5% for urine/hair positives, 94% for urine/hair negatives, 0.37% for urine positive/hair negative, and 4.5% for urine negative/hair positive. For cocaine, hair positivity was 4.8% while urine was 0.65%; concordance was 0.55% for urine/hair positives, 95% urine/hair negative, 0.1% urine positive/hair negative, and 4.3% urine negative/hair positive. For marijuana, hair and urine positivity were

3.4%; concordance was 1.9% for urine/hair positives, 95% for urine/hair negatives, 1.5% for urine positive/hair negative, and 1.5% for urine negative/hair positive. For opiates, hair positivity was 0.23% while urine was 0.52%; concordance was 0.1% for urine/hair positives, 99% for urine/hair negatives, 0.42% for urine positive/hair negative, and 0.13% for urine negative/hair positive. For PCP, hair positivity was 0.049% while urine was 0.048%; concordance was 0.027% for urine/hair positives, 99.93% for urine/hair negatives, 0.021% for urine positive/hair negative, and 0.021% for urine negative/hair positive. The Drug Testing Index provides workplace drugs of abuse testing laboratory data since 1998 on more 140 million urine, oral fluid, and hair specimens to date divided into the categories of federally-mandated, safety-sensitive workforce and U.S. general workforce. The overall drug of abuse positivity rates for urine and hair in the general workforce have decreased. For urine tests in the general workforce, the majority were pre-employment tests (70-85%) followed by random tests (5-15%). Positivity rates for pre-employment and random tests were higher in the general than the federally-mandated workforce. Likewise, hair positivity rates were higher for pre-employment than random. In the general workforce, amphetamine positivity rates have decreased in hair while rates have increased in urine. Cocaine positivity rates have decreased in hair while rates have decreased in urine in the general workforce. Marijuana positivity rates have remained somewhat steady in hair while rates have decreased in urine in the general workforce.

Public Comments

Public commenters on the topic of drug testing in hair were:

Robert Bard, Managing Director of Healthcare Technologies Consultants;
Lane Kidd, President of the Arkansas Trucking Association;
Raymond Kubacki, CEO of Psychemedics Corporation;
Don Osterberg, Senior Vice President of Safety, Driver Training, and Security for Schneider National;
Abigail Potter, Research Analyst for the American Trucking Associations;
Carl Selavka, Forensic Toxicologist and Director of Northeastern Bioscience Associates;
Greer Woodruff, Senior Vice President of Safety and Security for JB Hunt Transport Incorporated; and
Ted Shults, Chairman of the American Association of Medical Review Officers,

The open session adjourned at 5:30 p.m.

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

These minutes were formally considered, amended, and approved by the DTAB via email.