

**Substance Abuse and Mental Health Services Administration’s (SAMHSA)
Center for Substance Abuse Prevention (CSAP)
Drug Testing Advisory Board**

August 7, 2015 Minutes – Open Session

The CSAP Drug Testing Advisory Board (DTAB) convened on August 6-7, 2015.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on August 7, 2015, from 9:00 a.m. to 10:15 a.m.

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Board Members in Attendance

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| Dr. Jennifer Collins | Dr. Courtney Lias (for Dr. Denise Johnson-Lyles) |
| Dr. Janine Denis Cook | Ms. Patrice Kelly |
| Dr. Anthony Costantino | Ms. Susan Mills |
| Dr. James Ferguson | Ms. Madeline Montgomery |
| Mr. Ron Flegel | Dr. Christine Moore |
| Dr. Greg Grinstead | Dr. Buddha Paul |
| Dr. Marilyn Huestis | Dr. Jasbir Singh |

Call to order

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

Welcome and Introductions

Dr. Cook reviewed the items posted on the DTAB website. She provided instructions concerning questions for the Board and the public comment period. She gave housekeeping announcements to the onsite and web conference attendees. She recognized the Board members, Division of Workplace Programs (DWP) staff, and federal partners. Dr. Cook announced the dates for the fiscal year 2016 DTAB meetings: October 26-27, 2015 and February 18-19, May 19-20, and July 26-27, 2016.

Opening Remarks – Status of the Proposed Revisions on the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Urine/Oral Fluid) and the Request for Information (Hair)

Ron Flegel, Director of DWP and DTAB Chair, introduced the DWP staff. He reviewed the goals of the DTAB, which include the implementation of the final Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) for urine and oral fluid and the evaluation of hair as an alternate specimen. He also presented the milestones reached by the Board in their review of the scientific supportability of hair testing, which included the two year review of the technical and scientific issues, input from representatives from hair testing laboratories, and review of the public comments to the Request for Information (RFI). Mr. Flegel outlined the projects that will be tackled by the Board in the near future. The publications, professional presentations, and manuscripts in preparation that were associated with DWP staff since 2013 were reviewed. Mr. Flegel described the special studies, including the inhalation of cannabis vapor and the pharmacokinetic and pharmacodynamic effects of oral cannabis, which DWP has supported. Other DWP updates are the revised Medical Review Officer (MRO) Manual, training course modules for laboratory inspectors and responsible persons, continued research into alternative specimens, and the development of a real time Drug Free Workplace Programs database. The timeline and routing process for the final Mandatory Guidelines were presented.

Review of the Public Comments to the Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Urine/Oral Fluid)

Mr. Charles LoDico, who is a toxicologist and chemist within the DWP, reviewed the public comments for the two Federal Register Notices (FRN) on the proposed Mandatory Guidelines for urine and oral fluid. The FRNs were published on May 15, 2015 with a 60 day comment period ending on July 14, 2015. For both of these documents, HHS requested targeted comments on certain items, including the pH cutoff for adulteration and requalification of MROs for urine and the validity test, listing of Food and Drug Administration-cleared oral fluid devices, the inclusion of tetrahydrocannabinolic acid (THCA) testing for marijuana use, lower tetrahydrocannabinol (THC) cutoffs, and the laboratories' ability and cost for THCA testing.

For the urine proposed revised Mandatory Guidelines, 123 commenters, representing a variety of stakeholders, submitted 427 comments. The submitted comments addressed the proposed addition of synthetic opiates and their cutoffs, paruresis, the cost/benefit of the proposed revisions, initial test requirements, and MRO requalification.

For the oral fluid proposed Mandatory Guidelines, 117 commenters, again representing a variety of stakeholders, submitted 373 comments. Besides commenting on the targeted items, the commenters addressed the collection device performance requirements, the cost/benefit of oral fluid testing, and the initial analytical requirements.

Mr. LoDico reviewed the process for the preparation and approval of the final Mandatory Guidelines.

Review of Public Comments to the Request for Information (Hair)

Sean Belouin, a Commander in the United States Public Health Service and senior pharmacology and regulatory policy advisor within the DWP, reviewed the public comments to the RFI for hair. He outlined the topic areas covered in the RFI and the number of questions associated with each topic. For the RFI, 35 commenters submitted 295 comments. Among these, 4 requested an extension to the comment period,

which was approved; 160 responded to specific RFI questions, including hair specimen, collection, specimen preparation, analytes and cutoffs, and specimen validity; and 63 were general hair testing comments.

DTAB's Process for Evaluating the Scientific Supportability of Alternative Specimens for Federal Workplace Drug Testing Programs

Dr. Cook reviewed the Board's process whereby the DTAB proposes a recommendation to the SAMHSA Administrator. After two years of evaluating the scientific supportability of the hair specimen for Federal Workplace Drug Testing Programs, the Board was ready to deliberate and vote on the following recommendation in open session: "Based on the review of the science, DTAB recommends that SAMHSA pursue hair as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs, including performance standards that sufficiently address external contamination and hair color impact." The voting Board members unanimously approved the recommendation.

Public Comments

Andrea Wohleber, from the Transportation Trades Department of the American Federation of Labor and Congress of Industrial Organizations, stated that her organization is concerned with hair specimen testing. She alerted the Board about the bill before Congress that would allow bus and trucking companies to conduct hair testing before HHS has implemented hair testing national standards.

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