

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION  
DRUG TESTING ADVISORY BOARD**

**December 12- 13, 2006**

The Drug Testing Advisory Board was convened for its meeting at 8:30 a.m. on December 12, 2006, in the SAMHSA Building (Rock Creek Room), 1 Choke Cherry Road, Rockville, Maryland.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public on December 12 from 8:30 a.m. to 3:35 p.m. The meeting was closed to the public on December 13 from 8:30 a.m. until adjournment at Noon to develop the revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Board members present:

Robert Stephenson II, Chairman  
Dr. Alberto Gutierrez  
Dr. Estela Estape  
Dr. Jennifer Collins  
Dr. Henry Nipper  
Lisa Tarnai-Moak  
Pat Pizzo  
Dr. David Kuntz  
Ann Marie Gordon

Others present for all or a portion of the meeting were:

Dr. Donna Bush, DWP, CSAP  
Dr. Walter Vogl, DWP, CSAP  
Charles LoDico, DWP, CSAP  
Ron Flegel, DWP, CSAP  
Dr. John Mitchell, RTI International  
Dr. Mike Baylor, RTI International  
Dr. Peter Stout, RTI International  
Dr. Jeri Roper-Miller, RTI International  
Susan Crumpton, RTI International  
George Ellis, DOT  
Dr. Yale Caplan, DOT Consultant  
Tim McCune, NRC  
COL Ron Shippee, DoD  
Leo Cangianelli, The Walsh Group

## **TOPICS DISCUSSED IN OPEN SESSION**

Note: The transcript for the open session is available on the Internet at:  
<http://workplace.samhsa.gov>

### **Opening Remarks**

Mr. Stephenson convened the open session of the Board meeting.

The Board members introduced themselves.

Dr. Bush stated that the DTAB charter was renewed for another two years. The expiration date is now June 15, 2008.

Dr. Bush stated that two individuals have been nominated and approved as new Board members; however, because the paperwork has not yet been completed they cannot attend the meeting as Special Government Employees. She fully expects the two individuals to be able to attend the next meeting as Board members.

### **HHS Update**

Dr. Bush reviewed the status of the proposed Guidelines published in the Federal Register on April 13, 2004. She stated that the document that was submitted to the Office of Management and Budget (OMB) by the Secretary of Health and Human Services was withdrawn from OMB on June 30, 2006. Since we are in the rulemaking process, we cannot provide any additional comments at this time.

Dr. Bush stated that OMB has authorized the continued use of the Federal Custody and Control Form for another 3 years. The new expiration date is September 30, 2009. The OMB approval also includes sections B and C in the laboratory inspection checklist, the laboratory application that is completed by a laboratory interested in becoming certified, and all of the recordkeeping, reporting requirements, and burden hours associated with the Mandatory Guidelines.

### **DOT Update**

Mr. Ellis (DOT) stated that Mr. John Bobo, the Director of the Office of Drug and Alcohol Policy and Compliance, was appointed to another position within DOT and that Jim Swart was serving as the Acting Director for the office.

Mr. Ellis gave an update on the status of the following documents: (1) the final rule revising the requirements for urine specimen validity testing has not yet been published because of budgetary

issues; (2) a new rule adding marriage and family therapists to the groups of individuals that are permitted to provide substance abuse professional services was implemented on September 22, 2006; and (3) a new alcohol breath tube has been approved by the National Highway Transportation Safety Administration (NHTSA) and DOT's Part 40 is being revised to incorporate products that are placed on the NHTSA conforming products lists.

### **NRC Update**

Mr. McCune (NRC) stated that NRC's revised 10 C.F.R. Part 26 fitness for duty program regulation has not yet been approved by the commission. The current draft document has incorporated specimen validity testing. The schedule is to have the final rule to the commission within a few months. The NRC requires licensees to report results from their fitness for duty programs and the NRC Office of Information Services expects to have a web based reporting system in place within the next year rather than using a paper copy reporting program.

### **DoD Update**

COL Shippee (DoD) provided a brief summary of the military drug testing program. He mentioned that DoD is considering establishing an oral fluid testing program at military entrance processing stations and is considering using a collection procedure that has a separate tube containing an aliquot that the lab uses for screening rather than opening a specimen bottle for conducting the screening test.

### **Special Note**

Mr. Stephenson requested that the following statement be included in the minutes of the meeting: "This is a caveat given when asked by a participating laboratory to present their data, this applies to both hair testing and oral fluid testing at this time: Data are from the National Laboratory Certification Pilot Performance Testing Program for Oral Fluid that is still under development and may not yet accurately portray the characteristics of an oral fluid test. Data are used with permission in the Department of Health and Human Services (HHS) for comparative purposes only. The data do not constitute any recommendation either expressed or implied by HHS of any product cited in this poster. Viewers of this information are cautioned of the limited utility of comparing the performance of one participant against the mean group performance at this time."

Mr. Stephenson wanted to ensure that results from the pilot performance testing program for hair and oral fluid specimens were not misused.

### **Pilot Performance Testing (PT) Program for Hair**

Note: The PowerPoint slides for this presentation are attached to the meeting transcript that is on this website.

Dr. Mitchell (RTI International) presented an update on the results of the PT samples sent to hair testing laboratories for cycles 12 through 17. This presentation focused on the current efforts to achieve accuracy and precision, such as, using webcast meetings to provide feedback as soon as possible after each PT event, encouraging group development of methods and solutions to observed analytical problems, and increased dialogue between the NLCP and the participating labs. Dr. Mitchell reviewed the current project study design and then discussed the PT results for each drug/metabolite. Results from these PT cycles suggest that several of the participating labs are approaching the overall accuracy and precision that will be required of certified labs.

### **Pilot Performance Testing (PT) Program for Oral Fluid**

Note: The PowerPoint slides for this presentation are attached to the meeting transcript that is on this website.

Dr. Mitchell (RTI International) presented an update on the results of the PT samples sent to the oral fluid testing laboratories for cycles 10 through 15. The study design for these recent cycles was similar to that used for the hair pilot PT program. Dr. Mitchell discussed the PT results for each drug/metabolite. Results from these recent PT cycles indicate a dramatic improvement of the labs in satisfying the proposed Guidelines, most of the participating labs demonstrate the precision required for the confirmatory tests, and the within and between lab precision has improved to the point that most participating labs would have a 95% probability of meeting the 20% requirements.

### **Evaluating Workplace Testing Results from a Medical Review Officer (MRO) Data Source**

Note: The PowerPoint slides for this presentation are attached to the meeting transcript that is on this website.

Mr. Cangianelli (The Walsh Group) started the presentation by providing an overview of the relationship between drug test results reported by the laboratories and MRO verified results, the background and history of the project, the databases that were used, the methods used, and the data elements that were used for the analysis. The data includes results for 164,432 regulated specimens and 667,751 non-regulated specimens.

Dr. Baylor (RTI International) then presented the results of the analysis, including a geographical distribution of the donors in the study, reasons for testing, percentage of lab positives reversed by MROs, MRO verified positives and reversals as a percent of total specimens tested, and percentage of lab positives reversed by MROs by drug class.

The study results indicate that federally regulated testing focused equally on pre-employment and random testing while non-regulated was primarily focused on pre-employment and a significant number of laboratory positive results were reversed during the MRO review process.

### **External Contamination of Hair with Cocaine: Evaluation of External Cocaine Contamination and Development of Performance Testing Materials**

Note: The PowerPoint slides for this presentation are attached to the meeting transcript that is on this website.

Dr. Stout presented the findings from a study conducted by RTI International to evaluate the ability to remove external contamination from hair that was contaminated with cocaine and to characterize the development of performance materials that could be used to evaluate the hair testing industry's decontamination procedures. He described the study time line (that is, what procedures were done on the samples over time) and the procedure used to contaminate the hair samples. Dr. Stout then described the sampling procedure and how the samples were sent to the participating labs. Each lab analyzed 195 samples, of which there were 47 blind controls (22 were positive and 25 were negative) and they were packaged so that the labs had a positive and negative blind with the samples to be decontaminated and samples not to be decontaminated.

There were several conclusions from this study. First, it will be difficult to develop hair PT samples that will demonstrate that all cocaine analytes applied to hair by dry transfer can be removed from hair by current decontamination procedures. Second, there is no simple relation of the concentrations of cocaine, benzoylecgonine (BE), cocaethylene (CE), or norcocaine with total melanin. Third, the large variability in results from samples decontaminated by laboratories using different decontamination strategies suggests that reinstating the use of these strategies will increase the variability in the current pilot PT program. Fourth, analysis of the data suggests that the differences in positive rates between laboratories may be independent of decontamination strategy and laboratory decontamination method. Fifth, the presence of trace quantities of CE and norcocaine in the cocaine used in the study confounded the use of ratios, cutoffs, and other mathematical criteria to distinguish a contaminated sample. Sixth, external contamination of hair with powdered cocaine hydrochloride resulted in the presence of cocaine, BE, CE, and to a lesser extent norcocaine that was resistant to removal over 10 weeks of model hygienic treatment and laboratory decontamination. Seventh, contamination of the surface of hair may result in the incorporation of analytes into the hair without wetting the hair. Eighth, the application of wash criteria in conjunction with metabolite ratios may distinguish external contamination.

### **Legal Cases/Precedents in Drug Testing (Past 15 Months)**

Note: The PowerPoint slides for this presentation are attached to the meeting transcript

that is on this website.

Dr. Tom Chamberlain (Consultant) presented a review of cases and precedents in drug testing during the past 15 months. He cited cases involving constitutional issues, statutory issues, special needs issues, employment cases, and cases involving MRO decisions.

## **Public Comments**

Steven Soifer made a statement on behalf of the International Paruresis Association expressing concern that almost half of the public comments on the proposed HHS Guidelines were related to shy bladder, but nothing appears to be happening to accommodate people with this social anxiety disorder.

Bill Thistle (Psychemedics Corporation) made several comments on the external contamination study results presented by Dr. Stout. Several of his major comments were as follows:

1. It is not necessary to remove all of the contamination from samples collected for drug testing, but only necessary to be able to identify and distinguish samples that are positive, negative, or contaminated.
2. When RTI used the Cairns wash method practiced by Psychemedics, all of the contaminated samples tested were correctly identified as contaminated through the application of the wash criteria and the benzoylecgonine metabolite-cocaine ratio.
3. RTI's paper demonstrates that effective wash procedures can distinguish contaminated hair from hair positive due to ingestion when appropriate wash and metabolite drug ratio criteria are applied.
4. The use of 15 milligrams of cocaine for this study is not a normal contamination event. If you use that amount for a hair study, the same amount should be used to evaluate urine and oral fluid specimens.
5. Any potential presence of cocaethylene as a contaminant is resolved by using a cutoff for cocaethylene that is above the potential cocaethylene contamination.

Dr. Virginia Hill (Psychemedics Corporation) expressed concern with Dr. Stout's conclusion that there is no effect of decontamination on the rate of positives. She stated that Psychemedics uses all of the wash information as well as the cocaine and benzoylecgonine concentrations and ratios to report a specimen as positive or contaminated. Dr. Hill emphasized that you cannot do hair testing without a decontamination procedure and some kind of evaluation of the wash and the remaining drug in the digest.

The open session ended at 3:35 p.m.

## **TOPICS DISCUSSED IN CLOSED SESSION**

The Board discussed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing

Programs.

### **Adjournment**

The meeting adjourned at Noon on December 13.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

/SIGNED/

Donna M. Bush, Ph.D., D-ABFT  
Executive Secretary, DTAB

/SIGNED/

Robert L. Stephenson II, M.P.H.  
Chair, DTAB

These minutes will be formally considered, amended, and approved by the Board using email.