

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

**Meeting of the
Drug Testing Advisory Board**

**August 7, 2015
OPEN SESSION**

**SAMHSA Building
Sugarloaf Conference Room
One Choke Cherry Road
Rockville, Maryland**

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Proceedings (9:00 a.m.)

Call to Order and Welcome/Introductions

Dr. Cook: Good Morning. I am Janine Cook, the Designated Federal Official (DFO) of the Drug Testing Advisory Board or DTAB. As the DFO of DTAB, I will officially call this meeting to order.

The DTAB has its own website located at the link shown on the slide. Posted on the DTAB website are the DTAB charter, the roster of board members, and meeting information, including past, present, and future meetings. Dates for the fiscal year (FY) 2016 DTAB meeting dates will be posted within the next week or two on the website. Per the DTAB charter, we plan to meet four times in FY16, with two scheduled to convene on-site at SAMHSA, as well as by web conference, and two by web conference only. Which meetings will convene in open or closed session or on site or by web conference only will be decided at a later date.

If you have any questions or comments concerning the material presented during this open session, please submit your questions and comments by pressing star 1 to contact the operator if you are off site. If you are onsite, index cards are available on the registration table for recording your questions. Please leave your questions with a member of the DWP staff. Submitted questions and comments will be considered by the Board during the closed session.

The public comment period is scheduled to begin at 11:00 a.m. today, although the exact time will be dependent on our progression through the agenda. Currently one person has registered to give public comment. If anyone else wishes to give public comment and has not registered, notify the Verizon operator by pressing star 1, if attending remotely, or by notifying one of the Division of Workplace Programs (DWP) staff. The public comment period is restricted to the time allotted and the time will be equally distributed among all commenters. Public comments will be included in the meeting minutes as well as in the transcript. If possible, please provide either a hard or electronic copy of your comments to be shared with the transcriptionist to ensure your comments are recorded accurately. The Board will not respond to any public comments this time but will take them under consideration in the closed session.

For our onsite participants, restrooms are located down the hall to the right and also to the left of the guard station. Since there are no scheduled breaks in the morning session, please avail yourself of the facilities as needed. The registration table is located at the back of the room if you need any assistance. Located down the hall to the right is a café which you are welcome to visit anytime during this meeting. Please wear your SAMHSA ID badge while you are in the building. Please silence your electronic devices because these will interfere with both the audio/visual as well as the transcription equipment.

For our offsite participants, if you need to contact the Verizon operator, please do so by pressing “star one”.

Since you are listening using your phone, please mute your computer speakers to avoid audio feedback. You may also want to mute your phone unless speaking if you anticipate any noise in the background.

I want to welcome our DTAB board members: Jennifer Collins; Tony Costantino; Jim Ferguson; Ron Flegel; Greg

Grinstead; Marilyn Huestis; Patrice Kelly; Courtney Lias, who is sitting in for Denise Johnson-Lyles; Susie Mills; Madeline Montgomery; Christine Moore; Buddha Paul; and Jasbir Singh. Welcome back to Courtney. In the past, she has served as a Board Member, as well as an ex-officio representing the Food and Drug Administration (FDA).

I also want to recognize our DWP staff: Ron Flegel, Sean Belouin, Jennifer Fan, Deborah Galvin, Gene Hayes, Giselle Hersh, Charlie LoDico, Coleen Sanderson, and Hyden Shen. I also want to recognize our intern, September, who has kindly offered to help us out today.

We treasure the relationship between the Board, DWP, and our federal partners. Though I have not done so in the past, I want to recognize all of our distinguished federal partners, including those serving on the Board. Colonel Tom Martin from the Department of Defense, Patrice Kelly from the Department of Transportation (DOT), Madeline Montgomery from the Federal Bureau of Investigation, Courtney Lias from the FDA, Marilyn Huestis from the National Institute on Drug Abuse (NIDA), Paul Harris from the Nuclear Regulatory Commission (NRC), Ian Rucker and Connie Foster from the Department of Health and Human Services (HHS) Office of General Counsel (OGC), and Jasbir Singh from the Veterans Administration.

The dates for the FY16 DTAB meetings are October 26-27, 2015. In 2016, meetings are scheduled for February 18-19, May 19-20, and July 26-27.

Ron Flegel, the Director of the DWP as well as the Chair of the DTAB, will now extend his warm welcomes.

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)

Mr. Flegel: Thank you, Janine. I do apologize for my voice; we had lots of discussion yesterday, so it is a little hoarse today.

Since I did not do this at our last DTAB meeting, today I want to provide a comprehensive overview of what we have accomplished over the last two years and those things yet to come to fruition. From the DTAB standpoint, I will highlight the goals, milestones, or objectives that we have set. Then I will provide current updates of where we are in the Program.

As Janine has already said, I want to thank the DWP staff for the hard work that they have done, as well as the subject matter experts (SME), and the Board members for all that we have accomplished over the last year.

The goal of the DTAB is to assist SAMHSA in the implementation of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) for urine and oral fluid and the evaluation of hair as an alternate specimen over the last two years.

The public comment session has closed for both oral fluid and urine, and we have begun our review of all the received comments. I want to thank the public, the stakeholders, and the laboratories for submitting comments. We have received many good comments, which we will review later in the Program.

I compiled a comprehensive list of all our publications because federal agencies, as well as the public, are not aware of our research accomplishments and the technical papers we have written. We will post these publications on the website that have been undertaken by SMEs, DTAB members, DWP staff, etc. In the non-smoker exposure to secondhand cannabis smoke study, the effect of room ventilation on marijuana concentrations in different matrices, including urine, oral fluid, blood, and hair, was studied. The hair specimens from this study have not been tested yet. We have also researched the metabolism and excretion of prescription opioids at different concentrations as well as disposition of oxycodone. Finally, we examined the effect of room ventilation on the physiological, subjective, and behavioral/cognitive effects of cannabis smoke on the smoker as well as the exposed subject. Publications in submission or preparation include the metabolism and excretion patterns of oxymorphone.

Next is a compendium list of the presentations that we have given since 2013. At the 2014 Society of Forensic Toxicologists (SOFT) annual meeting, we gave a number of presentations based on the technical papers that I mentioned earlier, including oxycodone, hydrocodone, prescription opioid abuse, and the oxycodone and hydrocodone metabolic urinary profiles. Other presentations included the disposition of oxycodone and hydrocodone in oral fluid. These were important studies because the study results provided the information we needed to write the proposed oral fluid Mandatory Guidelines. Upcoming presentations include a presentation at National Safety Council Congress at the end of September entitled is "Weed and Your Workforce: What You Need to Know." Also we are giving presentations at the 2015 SOFT annual meeting which address three different aspects - government oversight and regulations around the oral fluid as well as urine, the studies that we have completed and how those have answered the questions that we have asked, and the role of our future objectives and they fit into other national issues such as oral fluid standardization for driving under the influence of drugs. One of those presentations is about the role of establishing drug testing standards for contemporary drugs. Another is the pharmacodynamic dose effects of oral cannabis administration. Some of our special studies include the cannabis vaporization study that we are doing in conjunction with NIDA, in which occasional and frequent cannabis smokers were in a double blind, randomized, crossover, placebo-controlled design where participants inhaled vaporized cannabis at a concentration of 6.9 percent. Oral fluid, urine, and blood were collected as part of that study. The pharmacokinetic and the pharmacodynamic effects of oral cannabis consumed at low, medium, and high doses were researched. Oral fluid, plasma, and hair were collected for nine days post consumption. This study also involved subjective, behavioral, and cognitive performance assessments to evaluate the time course of the consequences of oral cannabis ingestion among the study participants. Hopefully, we will have an abstract and technical paper produced on this study. Other publications worth mentioning include methamphetamine and amphetamine d,l-isomer concentrations in human urine following controlled Vicks VapoInhaler administration and morphine and codeine concentrations in human urine and oral fluid following controlled poppy seeds administration. Publications that have been submitted include the urine initial and confirmatory test results from non-smokers exposed to secondhand cannabis smoke; the effects of room ventilation on the physiological, subjective, and behavioral/cognitive effects of non-smokers exposure to secondhand cannabis smoke; simultaneous plasma and oral fluid morphine and codeine concentrations after controlled administration of poppy seeds with known opiate content; and the disposition of oxycodone in oral fluid and blood following a controlled single dose administration. This study is important to provide us with concentrations in urine and oral fluid following a single dose to help us better understand the concentrations associated with a valid prescription.

Some of our milestones include the DTAB's two year review of the technical and scientific issues surrounding hair testing, input from the hair testing industry, and the review of the public comments in response to Request for Information (RFI), which we will soon hear about.

Regarding the Medical Review Officer (MRO) Manual revisions, Dr. Richard Hilderbrand, along with Sean Belouin and Jennifer Fan of our Division, spearheaded this initiative. The revisions were to ensure consistency with the proposed revisions to the urine Mandatory Guidelines. The revised Manual also had a placeholder for the proposed oral fluid Mandatory Guidelines once they are final. The MRO Working Group has 12 members who are listed here. Also, DWP staff participated on these conference calls, which occurred almost every month. We have accomplished most of what we wanted to do, so hopefully the final version will be ready for review soon. Some of the major issues that were addressed are the prescription opioid drugs, including oxycodone, oxymorphone, hydrocodone, and hydromorphone, and the hydrocodone combination drugs which were rescheduled to Schedule II last year in October/November, I believe. One of the most important questions that we asked is what is considered a valid prescription under the Drug-Free Workplace Programs and how will that be interpreted by a MRO. Other issues include the addition of the electronic Federal Custody and Control Form (CCF), for which we have received several public comments and for which we are grateful. Hopefully, we will have laboratories using the electronic CCFs very soon. We also addressed the Mandatory Guidelines permitting the transmission of a scanned image of the completed MRO copy of the Federal CCF. The revised Manual also will address laboratories reporting insufficient volumes for urine and oral fluid. Currently, we have case notes associated with the MRO Manual. For the revised Manual, we will have to develop new case studies and decide how we will provide those. These case notes will be very important around the prescription opioids.

Some of the DTAB objectives are the review of the public comments to the proposed urine and oral fluid Mandatory Guidelines, the review of the final draft of the urine and oral fluid Mandatory Guidelines, the evaluation of the scientific

supportability of hair, and the implementation of the MRO Manual. Yesterday, the Board reviewed the public comments on urine and oral fluid in closed session. Some short term objectives are the review of the RFI public comments for hair and the public comments to the proposed urine and oral fluid Mandatory Guidelines. In the future, we hope to review of the final urine and oral fluid Mandatory Guidelines in October.

Our future goals include the development of a drug free workplace programs database. This is a collaboration between SAMHSA, the federal agencies, and a contractor to create a real-time database for federally regulated drug tests. The federal agency and federally regulated drug tests from both DOT and NRC are in Phase II of this project. The data in the database include specimen number, federal agency, test type, collection site, drug test results, quantitative data, and demographic information by zip code only. No personal information will be allowed. The database is an aggregate of data and is not by donor. We believe it is very important to collect this information as quickly as possible, especially for the prescription opioids. The data from the Annual Survey Report (ASR) is about a year behind by the time we receive all the data from the federal agencies. We need data real-time so we could evaluate the questions that are asked to us by federal agencies, such as the positivity rate, for instance, of cannabis. We also want to be able to provide true total and non-negative data for individual and combined federal agencies. We would like to provide geographical distributions of dilute and non-negative specimens for individual and combined federal agencies. Some of the advantages of establishing a regulated drug testing database are the increased data reporting accuracy, real-time information, the consolidation of drug testing result data, and the potential for about an 80 percent reduction in agency burden when generating the ASR. Some of the potential long range opportunities are the incorporation of the electronic CCF; standard variables across laboratory reporting; replacement of the non-negative specimen list; the participation of other federal agencies that have their own reporting formats, which is DOT and NRC; real time data within hours to days; and the detection of federal agency trends or drug test results when asked. One of the most important factors for the federal agencies is a single reporting method for laboratories, which should streamline laboratory reporting.

Other Program goals include training course modules for inspectors and laboratory personnel, continued research into alternative specimens for inclusion in the Mandatory Guidelines, development of supporting guidance documents for alternative specimens, and revision of the current urine and oral fluid Mandatory Guidelines based on the DTAB recommendations.

The timeline for the Mandatory Guidelines, which has previously only shared internally, will now be shared externally. The steps and timeline for the approval of the oral fluid and urine Mandatory Guidelines is shown here. This is what we are adhering to. Currently, we are at the drafting of the responses to public comments step. I have set the date for the step as Monday, August 10. The review by DTAB would be optional and is scheduled for October 15, with completion targeted for the end of October. The second phase occurs when we begin the final routing process. Steps include submission to SAMHSA clearance officer, processing by the Office of Management and Budget (OMB), review by other federal agencies, incorporation of recommended federal revisions, and finally publication of the final as a Federal Register Notice (FRN). For those that have followed the displayed routing process, recommendations are sent to DWP for SAMHSA final review and action. That is basically where we are currently. We also have a second part, which is the same as the previous time table before.

In summary, we will continue to partner with DOT and NRC to harmonize the Mandatory Guidelines for urine and oral fluid. It has been great harmonizing with them in all aspects, which has allowed us to accomplish so much. We will continue to communicate with the laboratories on Program issues. We want to continue advancing the technology and science in the Program. I have also embarked on addressing emerging drug testing issues and trends, including designer drugs. Other priorities include Program oversight and review; and studies and tasks regarding alternate matrices; marijuana issues, including reclassification or rescheduling and how that would impact our Program; synthetic opiates; and prescription drug use.

I want to thank everybody for attending. I appreciate your time.

Dr. Cook: Thank you, Ron. Do any members of the Board have questions for Ron? If so, please state your name.

Thanks, Ron. Our next speaker is Charles LoDico, who is a chemist within the DWP. He will be providing a review of the

public comments to the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs for both urine and oral fluid. Charlie.

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

Mr. Lodico: Welcome. I will briefly go through the summary of public comments that were submitted for both the oral fluid and urine proposed Mandatory Guidelines, which were published in the Federal Register (FR). The FRNs were published May 15 of this year. The first proposed notice was for the revisions to the Mandatory Guidelines using urine. The citation for this FR is 94 FR 28101. The other proposed guideline change is the proposed Mandatory Guidelines using oral fluid. The citation was 94 FR 28054. Both of these proposed Mandatory Guidelines had a 60 day public comment period. The purpose of the notification was for the public to have an opportunity to review our proposed Mandatory Guidelines, and for the public to comment on all aspects of the Mandatory Guidelines. Both of these publications were posted on the government website at the following URL: <http://www.regulations.gov>. At that particular URL, the public had the opportunity to write their comments, submit them, and acknowledge a receipt for comment. Embedded in the preamble of the proposed rule are the HHS requested comments on certain items. I will discuss those for each of the proposed Mandatory Guidelines for both the oral fluid and urine. First, I will review the comments to the urine proposed rule, then I will follow-up with the oral fluid comments.

In the urine proposed revision to the existing Mandatory Guidelines, HHS sought specific comments on two very critical points of the revised Mandatory Guidelines. One was the change in cutoff for pH for what would be considered an adulterated specimen. Currently, a specimen is considered adulterated the pH is less than 3. We proposed raising that cutoff to a pH less than or equal to 4. On the alkaline side, we proposed raising it to greater than or equal to 11. Additionally, we wanted the public to make specific comment on the requalification of the MROs, including considerations of the different types of training and reexamination. We proposed five years after the initial requalification as the appropriate time for requalification.

What is the breakdown of comments? For urine, a total of 123 commenters responded, which equated to 427 individual comments to the revision to the Mandatory Guidelines. There was cross-pollination because some of the comments that were relevant to the urine also applied to the oral fluid proposed Mandatory Guidelines. A total of 104 individual comments were from individuals who did not identify themselves with any group. Nine of the commenters were from professional organizations, two from HHS-certified laboratories, one from a collector, two from employers, and five from MROs and/or third party administrators (TPA). The professional organizations that were identified are listed here and represent a cross group of interested stakeholders. We had a good sampling of interest for these proposed and revised Mandatory Guidelines.

Some of the specific comments I will share with the public now. Nine commenters commented specifically on the addition to the analyte panel of the synthetic opiates -oxycodone, oxycodone, hydrocodone, and hydromorphone. Seven of the commenters agreed that they are valid or acceptable additions to the profile panel. Two commenters dissented. For the synthetic opiates, three commenters agreed with the proposed cutoffs. Six commenters disagreed with the initial or confirmatory test cutoffs for one or more of the drugs. There was not a consensus as to the screening or confirmation cutoffs. That will be a challenge for the Board in deliberating on the contents of the final Mandatory Guidelines.

When the total commenters to the oral fluid and the urine documents are combined, there were 240 total commenters. When those are broken down further, 168 commenters, or 70 percent, addressed a single issue, the social anxiety disorder known as paruresis. Those specific 168 commenters signed their comments as "unknown" or "anonymous." All of those 168 commenters favored alternative specimen tests. The paruresis comments consisted of a form paragraph that addressed this one specific issue.

Three commenters addressed the need for a cost benefit for the revisions to the urine Mandatory Guidelines. Six commenters had a specific issue relating to the initial test analytical requirements. The proposed initial test analytical requirements allow non-immunoassay kits to be used to initially screen a specimen. In the current Mandatory

Guidelines, this is not allowed. There were six commenters that had varying opinions as to whether or not this proposed change is valid.

The next comments are related specifically to the oral fluid proposed Mandatory Guidelines. HHS wanted specific and direct comments on the following very important points. The first one is the need for a validity test, specifically, the use of an albumin or immunoglobulin G (IgG) validity test. The second important specific comment is whether HHS should list FDA-cleared oral fluid collection devices, similar to the current listing of HHS-certified labs that occurs monthly. Should the FDA-cleared oral collection devices be published in the FR or posted on our website? The other important consideration that we wanted the public to weigh in is the inclusion of the tetrahydrocannabinolic acid (THCA) as a test for marijuana use. There is a lengthy description and discussion in the preamble that justifies the selection of the parent tetrahydrocannabinol (THC) analyte in the drug testing panel rather than the THCA. Also, we wanted the public to discuss whether it is appropriate to lower the cutoffs for both the screening and confirmation tests for the oral fluid parent THC compound. Lastly, we wanted to know the laboratories ability to test for THCA, how many labs can do it successfully and robustly, and also the cost associated with that testing.

For the oral fluid proposed Mandatory Guidelines, we received responses from a total of 117 commenters who submitted 373 comments. These 117 commenters represented 85 individuals, 11 professional organizations, 5 HHS-certified laboratories, 7 manufacturers, 6 MROs and/or TPAs, 1 laboratory, 1 employer, and 1 law firm. The number of manufacturer commenters is an appropriate number because they are interested in the rules that we have put forth concerning collection devices and performance criteria. Again, there was a cross-pollination of comments both for oral fluid and urine. A variety of different interested stakeholders representing a very good cross-section and users of our program with varying interests submitted their comments.

Let us look at some of those the specific and general comments that were received. In total, 10 commenters agreed with oral fluid testing. They wanted to embrace it as part of a comprehensive process that included urine and oral fluid testing. They saw a benefit in adding oral fluid into the Mandatory Guidelines. But of course, three commenters disagreed, and they had voiced their opinions and their concerns.

There were 19 commenters that weighed in as either pro or con about a specific oral fluid validity test. The majority of those opposed to the need for a validity testing argued that collecting of an oral fluid is essentially a direct observed collection. Therefore, they argued, there is no need to have a validity test incorporated in the analyte testing process because of the very limited amount of specimen that is collected.

The majority, or 39, of the comments were related to the proposed cutoffs. There were some really good discussions about the cutoffs both for the initial and the confirmatory tests. Many of the commenters requested justification for changing the cutoffs as compared to the 2004 proposed alternative specimen Mandatory Guidelines, which had specific cutoffs for both screening and confirmation.

There were 14 commenters discussing the marijuana parent and its metabolite THCA. The commenters were split with some agreeing that THC is a proper analyte to test and some questioning the parent and wanting the carboxy metabolite included. There were four comments on the other drug analytes.

Regarding the comments relating to the collection device performance requirements, some commenters offered suggestions or improvements on the language that we use for the description for the performance requirements. These comments were all valid and should be reviewed and considered if that is the direction we decide to take.

Some commenters challenged the cost/benefit analysis for oral fluid. The other nine comments related to the initial test analytical requirements, which allowed the use a non-immunoassay kit or instrument for screening.

There were 16 comments that were applicable to both FRNs concerning the MRO requalification and training. One of the stakeholders was a MRO group that shared with us the need for additional training.

Across all these comments we received, opinions were not uniform and in agreement. There were discussions in

certain topic areas where there is disagreement. Going forward, we must develop a process where the public is served with the best information and also with the best response. Board members and DWP staff don't have all the answers, and the public can have very good information that we need to consider. All comments are discussed, reviewed, and presented; no comments are dismissed as off the chart. We will collate all comments into a spreadsheet format first, relying on our RTI contactor to develop that. Using the spreadsheet, we will review the comments as an aggregate group and determine the number of comments relating to a particular section. We will begin with the proposed Mandatory Guidelines and address every section and any related public comments. Once we have completed a final draft, we share this document with the DTAB, with our federal partners, the HHS OGC, and SAMHSA leadership. Once that is complete, we make a final decision based on consensus among all these players and draft a final document. We submit the final draft document to OMB, which as Ron has indicated, will proceed according to the timeline for the different stages of review and/or acceptance.

I hope I have given you a quick summary of all of the comment submissions to the proposed Mandatory Guidelines. If you have any questions, I'd be happy to answer them.

(No Response)

Thank you.

Dr. Cook: Thank you, Charlie. Our next presenter is Sean Belouin, a Commander in the United States Public Health Service and senior pharmacology and regulatory policy advisor within the DWP. Sean will be a review of the public comments received in response to the Request for Information (RFI) on hair. Sean.

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

Dr. Belouin: Thanks, Janine. I will briefly review the comments received on the RFI on hair specimens.

The questions posed in the RFI were divided into six topic areas. These six topic areas were hair specimen, collection, specimen preparation, analytes/cutoffs, specimen validity, and testing. In total, there were 20 questions that were posed to the public in the six different topic areas. There were three questions for hair specimen, four for collection, four for specimen preparation, four for analytes and cutoffs, three for specimen validity, and two on testing.

In total, we received input from 35 commenters. Those 35 commenters submitted 295 comments. There were four requests to extend the comment period for the RFI from the original 30-day comment period. Our Administrator approved the extension of the comment period to 60 days, which ended on July 29. There were 165 comments in response to the 20 RFI questions. There were 59 general hair testing comments. There were approximately 50 inappropriate or not substantial comments that we did not include.

In the first of the six topic areas, hair specimen, 55 comments were received. Fourteen comments discussed acceptable body locations from which to collect hair. Thirteen comments discussed alternatives when head hair is not available. Seven comments addressed the effects of hair treatments on drug concentrations in hair. Twenty-one comments were related to reasons for hair testing.

The second topic area dealt with the issue of collection. Ten comments discussed training requirements for a collector of hair specimens. Six comments were on acceptable protocols for the collection of hair specimens. Fourteen comments discussed the standards for hair collection, including specific instructions on how to close to cut the hair specimen to the skin, determination of authenticity of the hair specimen, types of cutting instruments to be used, decontamination of cutting instruments, and the collection kit requirements. Lastly, eight comments addressed the amount of hair that would be required to be collected.

There were 23 comments on specimen preparation. Four comments addressed analyte-specific wash and decontamination procedures, six on protocols for hair specimen preparation, three related to the criteria for acceptability of a specific wash and decontamination procedure, four comments on published studies demonstrating

effective wash procedures, four relating to whether adjustments should be made for drug concentrations in wash fluids, and two related to calculations for those adjustments.

For the analyte cutoff topic area, there were 17 total comments. Four addressed the appropriate analytes to be measured in hair by the initial and confirmatory tests, six comments on the initial and confirmation cutoffs for analytes in hair, four comments related to criteria to distinguish external contamination from drug use, and three comments regarding metabolites or other biomarkers to confirm the use and to distinguish drug use from external contamination.

For specimen validity, 16 comments total were received. Seven discussed biomarkers/tests to verify authentic human hair, five comments were appropriate biomarkers/tests for adulteration and substitution, two comments were about whether an invalid result is appropriate for hair, and two comments addressed the criteria to classify a specimen as and “invalid result.”

Lastly, there were 11 comments on the topic of testing. Five comments were on the issue of available testing technologies, three comments on the best sample for quality control and proficiency testing, two comments were on how quality control/proficiency testing samples should be prepared, and one comment was on best method to prepare contaminated hair samples versus drug user hair.

That summarizes the breakdown of public comments received for the RFI on hair specimens. Thank you.

Dr. Cook: Thank you, Sean. Do any members of the Board have questions for Sean? If so, please state your name first.

(No response)

Thank you, Sean. Our next presenter is me, and I will discuss DTAB’s process for evaluating the scientific supportability of alternative specimens for the Federal Workplace Drug Testing Programs.

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

Dr. Cook: At the June meeting I gave a very detailed presentation on the Board itself, what its mission is, and the history of alternate specimens in the Drug Free Workplace Programs, as well as I reviewed the recommendation process. Included in that presentation was everything the Board has accomplished over the last two years regarding hair as an alternate specimen.

I want to quickly review the recommendation process, which includes the Federal Advisory Committee Act requirements for an advisory council to propose a recommendation. A recommendation is proposed from a voting member or chair of the DTAB. The language of that recommendation is clearly proposed in writing. The Board must deliberate on that recommendation in open session. A quorum of voting Board members must vote by closed ballot on the recommendation in open session, with the majority needed for approval. Only an aggregate tally of that vote will be presented in open session to the public participants. If passed, all Board members sign a recommendation letter. That signed recommendation letter is forwarded to the SAMHSA Administrator for her approval or disapproval. If the Administrator signs the recommendation letter and if it is approved, the proposed Mandatory Guidelines will be drafted by DWP, very similar to the process that Ron had described with the oral fluid and the urine Mandatory Guidelines. That draft will be reviewed by the Board, and it will be published in the FR for public comment.

So after two long, hard years, and as one of the members said, this is one of the most difficult decisions and process we have ever had to go through, the Board is now ready to make a recommendation on hair as an alternative specimen. The Board finalized the language of that recommendation. The proposed recommendation is: “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.”

We have a quorum of voting Board members present here today. The voting Board members, which are a subset of the total Board, will now deliberate on that recommendation. I welcome all voting members of the DTAB to weigh in on this recommendation and begin the deliberation process. Any comments from the Board, please?

(No comments)

Dr. Cook: Since there is no deliberation, we will now move into the voting phase. Each of the voting Board members has received a ballot on which they will mark whether they agree or disagree with this proposed recommendation. Once they have voted, I would ask them to fold it in half and I will come around and pick them up.

(Pause)

Dr. Cook: At the end of today's open session, I will read the ballot tally.

Though we are running ahead of schedule, we will move into the public comment period. We have one public commenter who has registered to give public comment at this time. Andrea Wohleber is from the Transportation Trades Department of the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO).

Operator, is Andrea on the line?

Operator: (Instructs caller)

Public Comments

Ms. Wohleber: (comments inaudible.)

Dr. Cook: Thank you, Andrea. Andrea, please state your comments again. Several of the Board members could not hear you. Could you speak a little bit louder this time?

Ms. Wohleber: I work for the Transportation Trade's Department at the AFL-CIO. We work for 32 different unions to help represent their transportation worker interest. We filed comments on all three of the dockets that you mentioned earlier today, including the hair specimen docket. We expressed our concern for hair specimen testing. I just wanted to note, as I am sure you all are more familiar than I am, the traditional process of DOT adopting HHS standards. There is a bill in Congress that we have some concern for, and I just wanted to highlight it because I know you are all closely involved in the process here. It is a bill that would begin allowing bus and truck companies to begin hair testing immediately before you all have put national standards in place. We just wanted to flag that as something that is moving through Congress. It was included in the Senate Transportation Bill that was passed last week. I just wanted to highlight that to make sure everyone was aware that that is moving through Congress now. That was all. I appreciate your time.

Dr. Cook: Thank you, Andrea. Does anyone else who is not registered to give public comment wish to give public comment at this time? I will begin with those that are here onsite.

(No response)

Dr. Cook: Next I will ask if anybody who is attending by webconference and wishes to give public comment, please press star 1 and the operator will allow you to speak.

Operator: We have none at this time.

Dr. Cook: We have come to the end of the open session. Therefore, I will adjourn the open session, and the Board will proceed into the closed session. We will take a short break to make sure all the lines are clear before we go into the closed portion. Thanks everyone from the public for attending.

Sorry, I forgot to read the recommendation vote. We have nine voting members on the Board, and the vote to approve the recommendation is unanimous. I thank the Board for their two years of hard work on this initiative.

(Vote is approved unanimously.)

Now I officially adjourn the meeting.

(Whereupon, the open portion of the meeting adjourned.)