

Department of Health and Human Services (HHS)  
Substance Abuse and Mental Health Services Administration (SAMHSA)  
Center for Substance Abuse Prevention (CSAP)

**CSAP Drug Testing Advisory Board (DTAB) Meeting**

Open Session

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SAMHSA  
Sugarloaf Conference Room  
One Choke Cherry Road  
Rockville, Maryland

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Call to Order: 10:30 a.m. E.S.T.

## Welcome, Introductions, and Opening Remarks

Dr. Cook: Good morning. I am Janine Cook, the Designated Federal Official and Acting Chair of the Drug Testing Advisory Board or DTAB. As DFO of DTAB, I officially call this meeting to order. First, I have a few announcements. For those of you on site, a copy of the agenda is on the registration table. For those of you who are joining us remotely, a copy of the agenda was emailed to you this morning.

The DTAB has its own website located at the link shown here on the slide. The DTAB website is also accessible from the Division of Workplace Programs (DWP) webpage. Posted on the DTAB website are the DTAB charter, roster of Board members, and meeting information, including past, present, and future meetings. Within a few weeks, the minutes, proceedings, and presentations from the open session will be posted on the DTAB website.

For those of you with any questions concerning the material presented during the open sessions, we have two options for you to submit your questions to the Board. First, if you are attending on site, three by five cards are located on the registration table for you to record your questions. Please leave your questions with the staff member manning the registration table. Secondly, if you are attending remotely, you can submit your questions by contacting the operator at star one. Submitted questions will be considered by the Board during the closed session.

The public comment period is scheduled to begin at 4:00 p.m. Eastern Standard Time today, although the exact time will be dependent on our progression through the agenda. Currently, there are two attendees who have registered to make public comment. If anyone else wishes to give public comment and has not registered, you can register onsite at the registration table or notify the Verizon operator by pressing star one if you are connected electronically. The public comment period is restricted to the time allotted, and the time will be equally distributed among all the commenters. Public comments will be included in the meeting minutes as well as in the transcript. Please provide either a hard or electronic copy of your comments to be shared with the transcriptionist to ensure that your comments are recorded accurately. We will not be responding to any public comments at this time, but they will be taken under consideration in the closed session. Please silence your electronic devices because these will interfere with both the audio/visual as well as the transcription equipment.

First, I want to publically and personally thank those Board members who retired in October after four years of service to the Board: Jim Bourland, Larry Bowers, and Barbara Rowland. I will miss them dearly. I would like to introduce our new Board members: Tony Costantino, Greg Grinstead, Susie Mills, and Jasbir Singh. Marilyn Huestis joined the Board in June as an ex officio member, and this is her first public meeting. I would also like to introduce our returning members to the Board: Bobby Bonds, Larry Brown, Phyllis Chandler, Laurel Farrell, Courtney Lias, Donna Smith, Jim Swart, and Steve Wong. Not here with us today are Marilyn, Courtney, and Steve.

I also want to recognize our DWP staff: Ron Flegel, Jennifer Fan, Giselle Hersh, Charlie LoDico, Coleen Sanderson, Hyden Shen, and Elaine White. I also want to recognize Phameca Morgan, our intern, as well as Bill Sowers, our contractor who manages our Drug-Free Workplace Helpline.

There are several other distinguished guests that I want to recognize: Dave Mineta and Ed Jurith from the Office of National Drug Control Policy (ONDCP), Paul Harris from the Nuclear Regulatory Commission (NRC), Patrice Kelly and Cindy Ingrao from Department of Transportation (DOT), and Ian Rucker from Office of General Council (OGC).

We have scheduled tentative dates for the two remaining FY13 DTAB meetings, which are listed here. The July meeting will convene in both open and closed sessions, while the September meeting will be held by teleconference in closed session. Both the DWP and DTAB websites are listed here.

Finally, I would like to introduce Ron Flegel, the Director of the Division of Workplace Programs. Ron assumed the directorship last May, and this is his first official public meeting of the DTAB. Thank you.

Mr. Flegel: Thank you Janine. First, I would like to thank everyone for attending today's DTAB meeting. I appreciate everyone being here on this rainy day. I would also like to acknowledge the DWP staff for everything they do each and every day to help answer and guide decisions made for the Federal Drug- Free Workplace Programs, which we oversee.

It will be clear from today's presentations that we support SAMHSA's mission of reducing the effects of substance abuse in America through our workplace drug testing programs.

I would also like to report that the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) are in the review process. These proposed revisions to the Mandatory Guidelines for both oral fluid and urine will serve to enhance this regulatory program, which is designed to deter illicit drug use in federal agencies and the regulated industries. In 2011, ONDCP entered into an interagency agreement with SAMHSA to support the development of guidelines on toxicology laboratory standards for detecting drugs and their metabolites in oral fluid. While the focus was to develop the federal guidelines for workplace drug testing, these guidelines are critical in developing standards that may be used in roadside detection devices needed for drugged driving enforcement in the future.

DWP is also currently revising the Medical Review Officer (MRO) Manual for the interpretation of workplace prescription drug results. In 2010, more than 38,300 Americans died from prescription drug overdose deaths, with opioid painkillers responsible for a significant number of these. Workplace drug testing may be one of the keys to early intervention.

Now I have the pleasure to introduce Fran Harding. Since May 2008, Fran has served as a Director of CSAP. Also, as part of the executive leadership exchange within SAMHSA, she served as Director of SAMHSA's Center for Mental Health Services for six months, thus expanding her behavioral health perspective. A veteran of state government, Fran spent many years in the New York State Office of Alcoholism and Substance Abuse Services, where she was responsible for development of policy and guidelines for alcohol, drug abuse, and gambling prevention, treatment, and recovery programs. She is also recognized as one of the nation's leading experts in the field of alcohol and drug policy. I am very happy to have her here with us today.

Ms. Harding: Good morning and welcome to the first quarterly meeting of SAMHSA's CSAP Drug Testing Advisory Board for 2013. I would like to recognize and welcome the returning and new members to DTAB, our federal partners from ONDCP, DOT, Department of Defense (DoD), Department of Justice (DOJ), NRC, Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), all of CSAP's DWP program staff, and all of you from the general public.

SAMSHA's DTAB is a scientific expert panel that recommends changes in the federal drug testing program to SAMSHA's Administrator, Pam Hyde. Based on evidence-based practice and peer-reviewed literature, two recommendations were put forth by the DTAB in July 2011 for Pam's consideration, and in January 2012, Pam approved the following two recommendations:

1. Based on review of the science, DTAB recommends that SAMSHA include oral fluid as the alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.
2. DTAB recommends the inclusion of additional schedule two prescription medications in the Mandatory Guidelines.

These two recommendations are in the process of being incorporated into the proposed revisions to the Mandatory Guidelines. These are significant enhancements to this regulatory program which is designed to deter illicit drug use in federal agencies. I am very happy that they are going forward.

Through its eight strategic initiatives, SAMSHA's mission is outlined. I am proud to serve as the lead for SAMHSA's number one strategic initiative: the prevention of substance abuse and mental illness. It is under

this initiative that the Federal Workplace Drug Testing Programs fit into the larger prevention picture and in CSAP. There are four goals in this initiative. Goal one calls for a range of responses to substance abuse and mental health conditions, including existing symptoms and complications. Goal two focuses on the prevention of underage drinking and adult problem drinking. The focus of goal three is on preventing suicide and suicide attempts among several populations that are at high risk, including youth, Native Americans, and alike. Goal four addresses the misuse and abuse of prescription drugs, which is a growing concern in our country and has brought Ron, Jen Fan, myself, and others to the table on several occasions. So I thank you for your help.

The recommendations proposed by the DTAB directly support and align with many of the goals and the strategies within strategic initiative number one. As defined by the Institute of Medicine, workplace drug testing is both universal prevention, defined as strategies that benefit the entire population, and selective prevention, which targets specific subgroups. These selective prevention efforts affect approximately 400,000 federal employees and 12 million workers in the federally-regulated industries who are subject to drug testing in the workplace. Workplace drug testing is the largest universal prevention program within SAMSHA because it protects everyone in the U.S. from injury and death by managing workplace drug testing. Empirical evidence demonstrates that universal protection effectively decreases injury and death among the general population. Selective prevention among tested workers has resulted in a continuing decline in illicit drug use since the creation of this program. In addition, the standards for drug testing spelled out in the Mandatory Guidelines, which are administrated by SAMSHA, affect 50 million people who are drug tested as a condition of their employment. The actions that you assist us with are affecting a huge percentage of the American public. Workplace drug testing is one key example that demonstrates that prevention indeed works. Again, thanks to all of you and our federal partners for your continued guidance and expertise. Give yourselves a round of applause for all the work you have done and the work you are going to do in the future.

It is my pleasure to introduce to you my colleague David Mineta. He is currently the Deputy Director of the Office for Demand Reduction in the White House Office of National Drug Control Policy. David was confirmed unanimously by the Senate in June 2010. David is a longtime advocate and champion for drug abuse prevention and treatment services. With deep roots in the community from his days as Deputy Director for Asian American Recovery Services, he now oversees ONDCP's Office of Demand Reduction, which promotes drug abuse prevention and treatment programs and has a special focus on programs for individuals in addiction recovery. Please welcome my friend Dave Mineta.

Mr. Mineta: Let me first thank Fran, Janine, Ron, and the DWP staff. Fran is an amazing leader for federal substance abuse prevention policy and services. She visited me when I worked in California to learn what is going on in the field and how policies, specifically those related to SAMHSA, were working. Ever since that encounter, I have had immense respect, fondness, and friendship for Fran; once in here in D.C., I have counted on that more than ever. President Truman said if you want a friend, you'd better go get a dog. Though true, I count Fran as probably one of my closest friends here in D.C. Though our friendship preceded my coming to D.C., you have to depend on those folks you knew before coming here.

I would also like to thank our federal interagency partners because without you, none of this would work. We have such a robust and impressively mature system throughout the federal government.

To the DTAB members, you all work very hard in a way that most folks do not really understand. I appreciate the opportunities for a meeting open to the public, so that people can see and understand how much work you have done and will do. Thank you very much for accepting membership on the DTAB.

For the stakeholders and all of you on the phone, thank you again for joining us this morning.

A key priority of the Obama Administration is preventing drug use before it even starts. It is also a very central key priority for ONDCP and also the National Drug Control Strategy itself. The consequences of illicit drug use in America's workforce include job-related accidents and injuries, absenteeism, increased healthcare costs, and lost productivity. These consequences are important for our young people who are entering the work force and for others already engaged in the work force. Therefore, it is important to ensure a drug-free workplace. Workplace programs provide that clear policies regarding drug use, offer prevention and education opportunities for employers and supervisors, conduct drug testing to detect and deter use, and support referral and treatment for those who have substance use disorders, can play a very significant role in reducing the demand for drugs throughout our nation and helping drug users get into treatment. These programs provide employees with the opportunities to self-identify and receive care. Often such programs give employees an opportunity to return to the same or similar job in the same industry, thereby creating an incentive to succeed in their recovery and resume a fulfilling career. This also has multiplier effects on their family members and

those around them who actually benefit from that treatment and move into recovery. Consequently, drug-free workplace programs are beneficial for our labor force, employers, families, and communities in general.

To those of you in the audience or those patched in by phone, if you are involved in drug testing or the collection process, it is imperative that we maintain the accuracy and integrity of the drug testing progress as well as protecting the confidential nature of the donor's medical information and assuring that the interpretation of results are forensically and scientifically supportable.

Finally, I would like to applaud the DTAB for their hard work on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, including oral fluid testing, as well as the chain of custody forms, and the medical review officer certifications. This is coming at a very important time for the nation as a whole, and we appreciate the scientific updates that the DTAB have guided and the recommendations, and also SAMHSA in their leadership for moving this forward.

It is a pleasure and honor to join you today. We look forward to the discussion. Thank you all very much.

Dr. Cook: Thank you Ron, Fran, and Dave. We really appreciate your support. Now we will provide status updates on three different DWP initiatives that are currently in progress. One of the reasons for these updates is bring the four new Board members up to speed with what is going on. I want to introduce Commander Jennifer Fan who will be providing the MRO Update.

### **Medical Review Officer**

Dr. Fan: Hi. I am Jennifer Fan, and I am here to provide a brief overview and update on what we are doing in regards to MROs and MRO entities.

According to the Mandatory Guidelines, a Medical Review Officer is defined as a licensed physician who has either a M.D. or a D.O. degree, has knowledge regarding the pharmacology and toxicology of illicit drugs, has completed the training necessary to serve as an MRO, and has satisfactorily passed an examination administered by a nationally-recognized entity that certifies MROs or a subspecialty board for physicians performing a review of federal employee drug test results; these entities must be approved by the HHS Secretary.

In regards to MRO entities, they must be nationally recognized. They must submit their qualifications and a sample MRO examination; these materials are annually reviewed objectively and approved by the HHS Secretary. Now, for this last approval cycle, the interested MRO entities who sought approval from the HHS Secretary submitted their information to us on July 16, 2012. We have reviewed these requests and forwarded our recommendations to the Secretary. The Secretary approved these entities. The full list was published in a Federal Register on January 14, 2013. At the bottom of this slide is the link to that Federal Register notice. The entities that were approved this last cycle for providing both training and certification of MROs are the American Association of Medical Review Officers (AAMRO) and the Medical Review Officer Certification Council (MROCC). The American College of Occupational and Environmental Medicine (ACOEM) and American society of Addiction Medicine (ASAM) were reviewed and approved as training only organizations; MROs completing training with one of these organizations can sit for the exams that are given by the approved entities.

DWP's MRO workgroup convened its first meeting on April 2, 2012. Its primary mission is to aid SAMHSA in determining the steps in the MRO verification process in regard to program objectives, developing specific workplace definitions, and reviewing the standards and practices. The secondary mission is to advise SAMHSA in drafting guidance for the consistent interpretation of donor drug test results. The objective will be to create a more comprehensive MRO Manual that will deal with all illicit drug use, the newly added synthetic opiates, and oral fluid drug test results. There are seven members who are either MROs or who are very familiar with MRO responsibilities. Our federal partners are also invited to these meetings. To date, we have had four meetings in which we have also discussed the electronic Custody Control Form (eCCF) and how MROs will be affected by the eCCF. We have also discussed the MRO process, qualifications, and donor privacy protections. We have compared the Mandatory Guidelines to the MRO Manual to determine what we can improve, especially related to the DTAB's recommendations, which were approved last year by our Administrator, to expand the federal drug testing panel to include additional Schedule II drugs. We are examining how to clarify and resolve MRO interpreting issues with these substances and incorporate these into the MRO Manual and the MRO case studies. We have had a really busy year. We will definitely convene more meetings, and hopefully, there will be a wonderful newly revised MRO Manual. Many of the things that we

discussed in the work group resulted in modified or proposed recommendations to the year-end Mandatory Guidelines. There will be good information forthcoming.

This last slide shows key references for your information.

Dr. Cook: Do any of the Board members have questions for Jen?

Mr. Harris: I am Paul Harris with the NRC. Does the MRO handbook go out for public comment?

Mr. Harris: No. I believe someone from the NRC is part of the workgroup.

Mr. Harris: Will it not go out for public comment?

Dr. Fan: The MRO Manual will be reviewed by DTAB members.

## **Custody and Control Form (CCF)**

Mr. LoDico: Good morning ladies and gentlemen. I am Charles LoDico, and I will provide you with an update on the 2013 CCF. The current form, which we refer to as the 2010 Federal CCF, is the CCF that is currently available to the laboratories, collectors, and the MROs. This form is referenced on our website. The 2010 form originated from the 2007 CCF, which had to be modified in step four to include the receipt at the lab or the IITF and in step one to include specific testing authorities. The 2010 Federal CCF, Office of Management and Budget (OMB) control number 0930-0158, expires on 8.31.2013 and will no longer have OMB approval. SAMHSA was given a provisional approval for the 2010 form with the condition that the next iteration of the form be available as an electronic document. With this task, we needed to address the concerns that SAMHSA has for an electronic format.

DWP developed and convened a working group, which was given specific tasks to address, including electronic signatures, nonrepudiation agreement for digital signatures, and third party software for managing the federal CCF information. Additionally, we wanted to address what is a unique specimen identification number, how it is generated, who generates it, who controls that number, and whether there can be duplicates if there are different systems available. We also wanted to know the legal binding equivalents to the traditional handwritten signature in a forensic arena, the security of data transmission, and the integrity of the document content.

Listed here are working group members from 2010, representing a cross-section of different stakeholders. Ms. Kathy Petrick is a forms manufacturer, Dr. Jennifer Collins is a responsible person (RP) at one of our HHS-certified laboratories, Ms. Susan Mills is one of our new Board members and an RP at a HHS-certified lab, the departed late William Lynn was also an RP, Mr. Neil Fornter was part of the DOT laboratory, and Bohdan Baczara is a federal partner. This 2010 working group received assistance from our National Laboratory Certification Program (NLCP) contractor, RTI International, with Dr. Michael Baylor as the lead person. The 2010 CCF came from this group's imagination and their willingness to work together and advance the program. The working group finalized the 2010 CCF form, which received OMB approval in October 2010 and was then issued to the laboratories and the collectors. This approval had an attached condition. OMB wanted us to evaluate how to make this system consistent with current technology. We also needed to address the Paperwork Reduction Act, which requires that the government explore new ways of reducing the paperwork burden by converting forms into electronic documents.

Our 2013 eCCF working group members include some players from the 2010 working group, and additionally, Dr. Barry Sample of Quest Diagnostics, Mark Snyder of DOT, Mr. Eric Quilter and Dr. Murray Lappe who both use eCCFs in non-regulated industries, Dr. Todd Shouldberg who is a MRO, and Dr. John Mitchell and Ms. Susan Crompton who are our contractors at RTI. Their efforts have produced some much needed information sharing and experiences. In addition, our RTI contractor has been vital in ensuring that this effort adheres to our timeline so that we can meet our approaching expiration date.

I want to share information from these meetings as well as our accomplishments. The slide lists the many meetings we have had, beginning with the first one on January 27, 2012, in which an introduction to the project was given and the foundation was set for what we are trying to establish. At the following meeting, we assigned tasks and established an outcome. The next three meetings were a continuation of that discussion. At the last meeting, I am proud to announce, we finalized the working group recommendations. The outcomes for this working group were focused in three areas: the risks and benefits of an electronic CCF, standardization of terms and definitions, and the operational considerations.

For the risks and benefits, though there are too many to list, I wanted to share with the Board the key areas that we focused on. The group working discussed the risks and benefits specific to the federal agencies and employers, the collection sites, and the laboratories. This strategy reflects the foundation of how our

program operates, beginning with the agencies, the collection sites, the laboratories, and ending with the MROs who represent the gatekeeper element of review. Lastly, we discussed how to incorporate this into a data litigation package. We generated almost a dozen or so terms and definitions. These definitions were not created from our imagination but were adopted from references, of which four are listed here. Our philosophy was to not recreate the wheel but to examine the existing wheel and determine how best to modify it. One of the references is an FDA final rule for electronic records and signatures. We also relied on a National Institute of Standards and Technology special publication, an OMB circular, and a Government Accountability Office (GAO) report. These definitions and information will serve as the foundation for the updates to our required documents.

On this slide, notice that the operational considerations are the same as those for risk and benefits because they address the similar individuals or entities that are a part of the Guidelines.

I wanted to share this flow diagram as a visual of the key elements requiring discussion and the issues identified as problematic or needing to be addressed in some manner. Notice that there was some thought into having the CCF mirror the specimen process, beginning with the employer scheduling a collection, to the collection site, to the laboratory, and the MRO. At the collection site, we have identified situations in which the CCF could be either electronic or a handwritten request form.

Because of this element of process, we, as a regulatory body, first looked at what is currently available in a paper format and researched how we can adapt or modify that into an electronic format. We recognize that there are many similarities between the two formats, but that there also are some changes that will be required. We need to look at what those changes are and if they are significant enough to cause a problem.

The last slide lists those documents that are impacted by the eCCF. The first one is the MRO Manual because there is a section in it describing how the MRO would receive the CCF. Currently, it is received by fax or as a pdf. How will the CCF information be delivered to the MRO from the electronic version? The Manual has to address that. Similarly, with the Collection Handbook, we will have to modify that document to include the electronic collection process. Lastly, the NLCP Laboratory Checklist must be revised.

Concerning the question asked by Paul about the review of the MRO Manual, the MRO Manual is a guide document and not a proposed rule. As such, it is similar to the Collection Handbook and the NLCP Laboratory Checklist, which are documents that are internal to our control and written as guidance for the MROs, collectors, and laboratories. When those documents are reviewed and modified, the Board is involved to address some of the changes; we encourage their participation in this process.

There is no question that we will have to do this and have it completed by the expiration date of the current 2010 CCF. Though we are not proceeding not as fast as I would like, we are on the right time course for submitting the CCF document in an electronic format. At this time I will field any questions.

Dr. Brown: Is your confidence at such a level that you do not need a plan B?

Mr. LoDico: Plan B is that there is no OMB-controlled federal CCF. Plan A is that it will be completed on time. The reason why I have such confidence is that the content of the CCF has not changed. Whereas the previous iteration of this document had multiple changes which required review, this document is a simple continuation of the form; the content has not been changed in any way. OMB is encouraging us to demonstrate effort on the electronic CCF and to include documentation of this effort in the submission packet. We had our preliminary meeting with our SAMHAS OMB officer, and she agreed that the electronic CCF will demonstrate a vast improvement in burden hour reduction for the collection site, the laboratories, and the MRO. We need to formulate that in the package and then insert the form.

Mr. Flegel: I would like to add to that. We do plan on extending the expiration date of the current paper copy because we see a use for that as we go forward, continuing until those forms expire, etc.

Dr. Brown: I guess that response gave me more confusion, I must confess. You will have two forms in use at the same time, a paper and an electronic. When will the paper version really expire?

Mr. LoDico: Dr. Brown, just as we did when we converted the 2010 form, we recognized that there needed to be a form draw down. For instance, the forms that were available on October 2010 were the new CCF as well as the old CCF. We allowed the laboratories to have a one year grace period for exhausting their supply of old forms.

We envision that we will allow the use of a paper form for the laboratories to receive properly collected specimens. As time goes by and those forms become exhausted, the laboratory must recognize that they will need to train and service their collection sites to address the new format. We do not envision that we will flip a switch and one day everything is converted. Like in previous changes, especially when there is a significant content change, we need a period of transition.

Dr. Smith: My concern has to do with long-term. I understand where you are coming from, however, even though the federal CCF services the Federal Employee Drug-Free Workplace Programs, one usage of that form is by private sector employers. It is fine to say that you can go ahead and phase this out once the laboratories are prepared to receive everything electronically. But you have literally thousands upon thousands of employers, small businesses, mobile collectors, etc. And I think it will take much longer than a year for them to have the availability of technology and the economic investment of technology to do that. And I think that the Board and the Division of Workplace Programs have to be conscious of that.

Mr. LoDico: This is no different from three years ago when we had a content change in the CCF. Existing forms at the laboratories and collection sites had to be destroyed after a year's time, which represented dollars. So we were very sensitive to that particular concern. If I recall, we extended the discard date to one year. And because DOT had up to December or November of that year, we actually extended it by another 60 days. These extensions were published in an NLCP Alert. Both DOT and DWP were monitoring these changes. As a matter of fact, we asked the certified laboratories on a daily basis how many specimens were being received on the old forms to monitor the transition to the new CCF.

This will not be any different. With this next transition, the timing issue will probably be raised by the laboratories. We will deal with it based on how difficult that transition will be. What I am trying to communicate to the Board is that we are not insensitive to these issues. We will continue to be very conscious about how these forms can still be incorporated and used. We will give the laboratories sufficient amount of lead time by informing them of what will happen when so they will not be blindsided when it does. Patrice?

Ms. Kelly: Just echoing what Dr. Smith was saying, there will be plenty of opportunity for us to work out the logistics of how this gets implemented. Just as the Internal Revenue Service has allowed people to file their taxes either electronically or by paper for a decade now, I cannot imagine that there will be situations where no one can ever file their taxes on paper again.

Consider a collection performed in an oil field or at a nuclear power plant where there is no cell phone or internet reception. These are logistical issues that we must work out, and we will be realistic about them.

Mr. LoDico: Maybe I did not adequately describe the intent of the OMB ruling. It stated that SAMHSA did not have a CCF available as an electronic document. By making it available, we are now complying with that ruling. This ruling represents laboratory requests because they recognize that this improves efficiencies for them. Therefore, we will not hold back that technology. In the past, we have been reluctant because of the potential for legal challenges. Our working group so far has ascertained that there is not a challengeable legal condition that would prevent the laboratories from using an eCCF. Phyllis?

Ms. Chandler: On the laboratory side, we do still see those old forms. We have about 30 or 50 a day that we have to chase down. Occasionally, we still see a 2000 form.

Mr. LoDico: Thank you.

Dr. Cook: Next on the agenda is Ron Flegel who will provide an update on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

## **Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs**

Mr. Flegel: Currently, the proposed revisions to the Mandatory Guidelines for oral fluid are in the review process, which involves the myriad steps of SAMHSA's controlled correspondence process. Afterwards, it will be routed to HHS with a 60 day comment period. Once at HHS, it is reviewed by a committee, and when approved by HHS, it will be routed to OMB. OMB will have another 60 days from receipt to request review of the document from other federal agencies. Comments from the federal agencies will be forwarded to DWP for consideration. Finally, the proposed revisions will be published in the Federal Register for public comment.

The urine Guidelines are in the review process also. One of the DTAB recommendations addressed the addition of additional synthetic opiates to both the oral fluid and urine drug testing panels. Later in the meeting, I will be presenting some of the studies we have done to the public.

There are other tasks and individual projects that the DTAB members will discuss in closed session.

Dr. Cook: Do any of the Board members have questions for Ron? We will reconvene at one o'clock.

## **Federal Drug Testing Updates**

Dr. Cook: I now convene the afternoon session of DTAB. I apologize for the delay, but sending people out to lunch in the rain took longer than anticipated. This afternoon we will hear updates from our federal

partners regarding their drug testing programs. These updates are to inform our new members about the status of our program within the other federal agencies and also to provide the latest testing data.

Providing the DOT update is Cindy Ingrao, Senior Policy Advisor in the Office of Drug and Alcohol Policy and Compliance (ODAPC) within the DOT.

## **DOT Drug Testing Update**

Ms. Ingrao: Thank you Janine. I am Cindy Ingrao, and I work for the DOT. I am representing Jim Swartz who is our Director at ODAPC, and I will be providing our program update.

This is our Secretary's mission statement. Our Secretary really believes in what we do. Our program is included in this mission statement because the Secretary views drug and alcohol programs as vital to transportation safety. In his statement about our program, he says that though we have worked hard to reduce accidents related to drug and alcohol use, we need to remain vigilant. The Secretary also supports programs that have prevention education, supervisor and employer training, drug and alcohol testing, and opportunities for recovery from substance abuse.

What does our office do? We advise the Secretary on national issues, such as medical and recreational marijuana use, and international issues, such as the National American Free Trade Agreement (NAFTA). ODAPC is responsible for writing and interpreting the CFR Part 40 regulation, which is really the how-to of drug and alcohol testing for the transportation industry.

We strive for a one DOT approach, not only for our drug and alcohol programs but also for medical qualification standards and for how to handle prescription medications. We work closely with ONDCP, other departments, and foreign governments. Our program history started with the Omnibus Act of 1991, from which we derive our authority. In 2000, we had a major regulation rewrite. In 2009, we had a unanimous court of appeals decision to have all return-to-duty and follow-up testing conducted as direct observations. The court ruled there that if an employee fails a drug test, there is a diminished expectation of privacy. In 2009 and 2012, we issued statements that the use of marijuana for medical and/or recreational purposes was not permissible. Federal law states that marijuana remains a schedule I drug, which means it may not be prescribed, administered, or dispensed for medical use. Therefore, MROs in our industry are not permitted to verify a test as negative based on an employee's claim of marijuana use, regardless of whether it was prescribed by a physician.

In the Omnibus Act of 1991, Congress directed the Department to drug and alcohol test safety-sensitive employees and directed us to incorporate HHS scientific and technical guidelines for the industry program. That directive included scientific methodologies used by the laboratories and the drugs for which we test, which is why we are limited to testing for schedule I and II drugs only. The HHS scientific and technical guidelines are critical to our program, which is why we have a huge interest in the outcome and we believe harmonization is important.

As far as our program goals, the Department's number one priority is safety. We support the nation's demand and supply reduction efforts, with prevention and treatment as key components. We are required by law to ensure fairness and integrity. We do this by maintaining employee privacy and confidentiality and by accuracy. We also ensure integrity by requiring entities to be auditable and reviewable by DOT agencies.

Our DOT agencies regulate the who, what, and when of drug and alcohol testing. This slide presents our distinct agencies, as well as the Coast Guard, which follows 49 CFR Part 40 regulations under a memorandum of understanding.

Some inspectors are specialized in drug and alcohol audits and some are not. Some of ours are federal inspectors and some are state inspectors. A majority of employers and employees are regulated under the Federal Motor Carrier Safety Administration. We are the world's largest regulated drug and alcohol testing program with over 5.5 million tests performed in 2011. The importance of HHS and the gatekeepers cannot be overstated.

There are nine program components that every transportation employer must have in place regardless of the industry. Those are policies outlining program requirements, prevention education and information about drug and alcohol abuse, supervisory training on how to identify substance abuse, strong and accurate drug testing, physician review of positive drug results of drug tests, and strong and accurate alcohol testing.

Employees who violate DOT regulations must be removed from safety-sensitive duties. They are evaluated by a substance abuse professional, and they must successfully comply with treatment. Following successful compliance, they are eligible for duty, but no company is obligated to return them to duty or to hire them.

HHS has designated in their Guidelines the five panel test. We test for the same 11 drugs under the five panel. The red ones identified here are Schedule I illegal drugs, while the ones identified in black are Schedule II, which can be legally prescribed.

Since 2008, the laboratories have been submitting to us DOT-only data on a semi-annual basis. From January to June 2012, more than 2.9 million tests conducted in that six month period. This slide shows our number of positive tests. Marijuana continues to be the most prevalent drug in the industry. Amphetamines are on the rise. After a rise, cocaine fell this last period. By percentages, the increase in the percent positives in 2011 for amphetamine and cocaine appear to be attributed to the new cutoff levels that were instituted with the October 2010 final rule. Our laboratory data are consistent with DEA and ONDCP data as well.

This slide shows two different pie charts. The first pie chart shows the positive test results that the laboratories report, and the second shows verified test results that the MROs report. We define downgrades as positive laboratory results that the MRO verifies negative because of a legitimate medical explanation. Downgrades are apparent, particularly for amphetamine and opiates, which is no surprise.

What is on our horizon? We are anticipating oral fluid testing and testing for the four synthetic opiates as recommended by the DTAB. We are taking a closer look at how MROs report safety concerns on the downgrades and how those safety concerns integrate with DOT agency medical standards. We are considering performing a marijuana impairment study, and we stay current with federal law and state legalization of marijuana.

Listed here are our DOT Agency Drug and Alcohol program managers, who are great group of people, and our staff. With me here today is Patrice Kelly, our Deputy Director.

Our website is a great source of information, and we always encourage people to sign up for the ODAPC list serve.

Thank you. Are there any questions from the DTAB?

Dr. Cook: Cindy, I have one. With Secretary LaHood stepping down, do you anticipate any different focus within the agency?

Ms. Ingrao: Not as of yet. We have not had any new course of direction. Secretary LaHood has been focused on distracted driving and high speed rail and infrastructure. Patrice, do you want to add anything?

Ms. Kelly: As this time, we do not have any reason to believe that the Deputy Secretary, John Porcari, is stepping down. Both John Porcari and Ray LaHood have been in the meetings that Jim and I also attended. They are both very plugged into our programs. So we do not have any reason to think the ship is going to change course at all. Thanks.

Dr. Brown: I have a question. You mentioned that you are conducting impairment studies. Can you share with us the rationale for actually conducting such studies? What is the objective for such studies?

Ms. Ingrao: We are anticipating the possibility that marijuana may potentially be rescheduled to something other than a Schedule I drug. If that occurs, we would like to have impairment studies conducted, similar to alcohol and the per se laws. Do you want to add to that, Patrice?

Ms. Kelly: Yes, I do. What we are finding now in those states who are introducing their medical marijuana legislation is their tremendous problems with traffic incidents. So our division and NHTSA within the Department of Transportation are particularly tuned in on this issue and looking into it from a highway and traffic safety perspective.

Dr. Cook: Patrice, are those involved in these accidents being linked to marijuana use? Are they performing drug testing in emergency rooms?

Ms. Kelly: To answer that question directly, yes, there are many screening and brief intervention studies being conducted, and they are making those links. It is an area where we are finding a connection.

Ms. Ingrao: Thank you.

Dr. Cook: Providing us with the DoD drug testing update is LTC Tom Martin. I want to welcome him to his first DTAB meeting. He is a Deputy Director of Drug Testing and Program Policy in the Office of the Undersecretary of Defense for Personnel and Operational Readiness and Safety. CAPT Kevin Kleet is his Director. Kevin has assisted the Board for several years now, but he is retiring April 1<sup>st</sup>. He has asked Tom to provide to you the DOT update today.

## **DoD Drug Testing Update**

LTC Martin (via telephone): I will be taking over for Captain Kleet, and I will arrive in D.C. in June.

I will present to you a brief overview of DoD drug testing. In general, service members in the DoD need to operate in a drug-free environment. It is a readiness issue because military members are on duty 24/7. Drug abuse or misuse can compromise the mission or mission readiness. In addition, over the last decade we have been in operations around the world where illegal drugs are either manufactured or readily assessable. We have ways to detect their use and results accordingly. Additionally, our population is a high risk population, comprised of 18 to 25 year old males who represent about a third of the overall military force but account for two thirds of the overall positives in our program.

Listed here are the current panels tested at our military laboratories. There are six DoD drug testing laboratories, three Navy, two Army, and one Air Force. The drugs listed here are tested: marijuana, cocaine, amphetamine, designer amphetamine, heroin, oxycodone, hydrocodone, hydrocodone, codeine, and morphine. Up until October 1, 2012, oxycodone, oxymorphone, hydrocodone, hydromorphone, codeine, and morphine were pulse tested; that is, a certain percent of specimens were tested for those drugs. Based on the Chairman of the Joint Chiefs of Staff mandate, the specimens are now tested at a 100 percent level for those drugs. We also added benzodiazepine testing beginning November 15, 2012. We test approximately 10 percent of the specimens for benzodiazepine. Any other drugs that a different commander or unit may request to be tested are sent to the Armed Forces Medical Examiner System, Division of Forensic Toxicology, which has the ability to test for a variety of other compounds.

There is an emergence of prescription drug abuse, which has transferred over into the military population. In this slide, the blue line at the bottom represents DoD positives from the drug laboratories over the last 20 to almost 30 years. The top pink line represents results from a health survey that is typically administered every three to four years. This survey asks the participants about their drug use over the last 30 days and whether that use is illegal drug use. In 2005, the survey incorporated questions about prescription drug use. The overall laboratory drug positive rate stayed essentially steady at around one percent. In 2005 to 2008, there is a significant increase in the number of members reporting misuse of prescription drugs. We have not yet received the 2011 survey data, but we do not expect it to decrease.

An important factor is that DoD can conduct prevalence testing rather quickly to monitor other abused drugs on the horizon that we may want to add to the testing panel. For typical prevalence testing, we collect between 30,000 and 40,000 specimens previously reported negative from the six laboratories, and we test those for whatever drugs we think are a threat and that we may need to add to the testing panel. One caveat about the data is that the data are derived from previously negative specimens. Therefore, the prevalence rate might be a slight underestimation of the true rate because those service members who tested positive for other drugs were not included in these studies. Another issue arises because we have to perform a large number of tests which typically necessitates an immunoassay kit for screenings. For example, we changed test panels quickly to respond to a LSD threat. We were able to show over time through prevalence testing that we were not seeing LSD anymore, so that analyte was quickly removed from the panel. Also, for instance, we demonstrated through prevalence testing that ecstasy (MDMA) and oxycodone had significant positive rates, so they were added to the testing panel.

Here is a short summary of some of the recent prevalence testing that we have done and the positivity rates. Benzodiazepines, in particular, were tested on three separate occasions. In 2007, the rate reached 0.55 percent. For a drug to be added to our panel, the prevalence rate must be at least 0.25 percent. However, the specimens in that study were from service members who were in the theater or deployed, and the data do not reflect whether they had a legitimate medical prescription.

Every two to three years, we are mandated to conduct prevalence testing on those drugs that were removed from the panel. In 2013, we have two pending prevalence studies scheduled to occur later in the year for LSD and barbiturates. These analytes were dropped from the panel several years ago, and it is time to test our population to determine if they needed to be returned.

We approach drug demand reduction at DoD in a systematic manner. It is a readiness issue for us, and we need to ensure that our service members are ready to answer the call wherever they are deployed. I touched on prescription drug use, which has grown substantially over the last several years. As part of our program, we need to develop a better deterrent for misuse of those prescription drugs, and it involves more than just testing service members' urines. We need support from the medical community, in particular, from those prescribing the medications, to get better control of what they prescribe, how much they prescribe, and to require monitoring of their patients and our service members for their medications. In addition, we educate our service members, especially our young service members who are prescribed these medications, and let them know what treatment as well as rehabilitation services are available to them if they are needed.

Another aspect of this readiness issue is drug testing in the commander program. The commander is required to test a certain number of service members or to conduct a certain number of tests per year. To truly increase this deterrence factor, the commanders must increase the number of random unannounced collections they conduct throughout the year. Therefore, the young service member knows that he can be tested any day at any time. This will hopefully decrease the possibility that he or she will make a mistake and use abuse either legal or illegal drugs. When a positive result comes back, the commander must adjudicate that positive result, whether it is a non-judicial punishment, reprimand, etc.

We prepare a report of all the laboratory data and share that with the line leadership, the commanders in the field, and the other task forces, including the pain management, accident prevention, and suicide task forces.

Next, I want to describe some of our initiatives in the past year, including prescription medications. On May 1, 2012, we began testing our service members' specimens for hydrocodone, initially at a rate of 25 percent that will increase to 100 percent by September 30, 2013. During that same time period, our other opiates - codeine, morphine, oxycodone, and oxymorphone - are being pulse testing, likewise, these opiates will be 100 percent by September 30<sup>th</sup>. Benzodiazepine testing began in November, and currently, testing is at around a 10 percent level, which is where it will stay due to funding constraints; the funds are not available at this time to increase that testing.

We were able to increase our laboratory capacity by marrying up our drug results with the DoD Prescription Drug Portal, which allows us to correlate positive results with service members' prescription history. These data are utilized in the Electronic Medical Review Process. How does this portal work? For any service member who uses TRICARE insurance, his/her prescription is automatically entered into a database. Information from that database is compared to urinalysis results. Depending on the specificity of our screening test, presumptive positive results from a screening test that is highly specific are cross checked against the prescription histories of the service members over a certain time period to determine those with valid prescriptions. No confirmation testing would occur, thereby, further testing would stop. If the screening test is not that specific, all presumptive positives would proceed to confirmation. After confirmation, all confirmed positive results are checked again against that database. If there is a valid prescription that would account for this positive result, those results would not be forwarded to MRO for verification. We call this process an electronic Medical Review Process (MRP). One of the issues with this database is that our service members who are not on active duty will not use TRICARE when they return to the civilian population; therefore, their data are not in the database. Their positive results in all likelihood cannot be adjudicated with this electronic review and must proceed to the MRO for adjudication.

In the last few slides, I want to address hot topics within DoD: synthetic marijuana or cannabinoids or Spice. Most of us are aware of the unique challenges associated with Spice testing. Even though legislation was passed to outlaw many of the synthetic cannabinoids, other synthetic cannabinoids not yet listed as illegal are being manufactured. Right now, as far as DoD is concerned, we do not perform random synthetic marijuana and cannabinoid testing at the six DoD laboratories. Part of the reason is that we do not have a rapid screening procedure to analyze the large numbers of accessioned specimens. The Armed Forces Medical Examiner System (AFMES) Division of Forensic Toxicology has the capability to test for synthetic cannabinoids. Commanders in the field can submit specimens to AFMES under probable cause, meaning there is a reason to believe that a service member is abusing synthetic cannabinoids. Prior to the legislation that outlawed many synthetic cannabinoids went into effect, an Army prevalence study was performed by AFMES on slightly over 20,000 specimens from the active duty Army throughout the world. The positive rate was 2.4 percent in their study. Remember from earlier in my briefing that a rate of 2.5 rate or greater is the criterion to have a drug added to the testing panel. Regardless, this is a very high rate. However, without a rapid screening procedure, we are unable to add this drug to our panel at this time. In FY13, post-legislation, we are planning another prevalence study to determine if there has been a decrease in the positive rate. AFMES will be conducting the testing for that study as well. We have also partnered with NIDA to evaluate different instrumentation to determine whether new technologies may be an option to incorporate into our laboratories. Even though we have very limited capability within DoD to test our service members for synthetic cannabinoids, testing is available and the confirmed positive results that come from those can lead to persecution and removal of those service members from military service, if that is the direction the panel wants to go.

That concludes my short briefing on where we stand at DoD. Now I will open the floor up to questions.

Dr. Brown: This is Lawrence Brown. I want to thank you for a very comprehensive review of DoD. I have two questions. One is derived from a presentation by CAPT Klette, the person who you will succeed. He shared with us that there was some limited anabolic steroid testing. I do not recall seeing it in your presentation today. I asked a question of him why was this testing done, and he shared with me and the group that it was led by a guidance from a commanding officer. Do you recall anything of that type?

LTC Martin: I can tell you how we conduct our steroid testing. If the commander suspects steroid abuse in a service member, he can request that test. We will send those specimens to a contracted laboratory to do the testing.

Dr. Brown: The second question I have has to do with the prescription drugs on your electronic medical review process. You mention that it was also contingent on some period of time, specifically, if a prescription is entered into an electronic database and if it is within some period of time, it may be viewed in some particular way. Can you share with us what that period of time is that would make a prescription, prescribed by a licensed physician and dispensed to a service member, not congruent with an acceptable medical use in the military?

LTC Martin: For the database that we are using for that electronic review, that time period for the prescription fill or dispense date must be within 45 days of the urinalysis or collection date. If it is outside that window, then the testing will occur and it will be forwarded to a MRO for adjudication.

Mr. Bonds: Would it be possible to obtain your protocols for the electronic MRP?

LTC Martin: I will have to get back to you on that. I am not sure if I can give you that.

Dr. Cook: Any other questions from the Board?

Dr. Smith: The correlation between the Medical Prescription Database and oxycodone and amphetamines test results is done at the screening level, correct? If there is a valid script on file within 45 days, then the specimen does not go for confirmation, correct?

LTC Martin: Yes. I will address the two drugs separately, since it is a little different for the amphetamines. For oxycodone, it is rather simple. If the screen is presumptively positive and there is a valid script within that 45 day window, no further testing will occur.

For amphetamines at the screening level, we use several different amphetamine immunoassay kits as well as a methamphetamine-specific kit from a separate vendor. We employ an algorithm whereby an amphetamine only specimen would account for an amphetamine positive; the result would be adjudicated or no further testing. If there is any indication that there is methamphetamine, then the specimen will continue on in the testing process.

Dr. Smith: The cross matching of hydrocodones, hydromorphone, codeine, and morphine positive test results with the prescription database is done after confirmation, correct?

LTC Martin: Yes.

Ms. Farrell: Tom, this is Laurel Farrell. Regarding the DoD Prescription Drug Portal and your limitation to TRICARE prescriptions, many of the states have their own prescription drug monitoring programs now. Has there been any communication between DoD and those states to gain access to that prescription information? Is that set up as a national database that you can access and/or potentially this program could eventually access?

LTC Martin: I know at this time there has not been any discussions with the states, but it is something that we definitely will consider as a possibility.

Dr. Cook: Has there been an increase in the number of positive results related to the impact of the Wounded Warriors?

LTC Martin: I do not have a breakdown of those data, but I do not think it is significant enough to be the sole reason we are seeing the high increase in the positive rate. I would have to examine the data more closely to provide a better answer.

Dr. Cook: Thank you. Are there any other questions for Tom? Thank you very much.

LTC Martin: Thank you.

Dr. Cook: Next Paul Harris of the Nuclear Regulatory Commission will provide an update on the NCR 10 CFR Part 26, their Fitness for Duty Program. Paul is a Senior Program Manager in the Fitness for Duty Program of the U.S. Nuclear Regulatory Commission.

## **NCR 10 CFR Part 26 Fitness for Duty Program**

Mr. Harris: Thank you very much for inviting me to present once again to the DTAB. Thank you, Ron and the Board, for listening to the NRC. Similar to DOT, we are keenly aware of the activities occurring within HHS because we do try to leverage your Guidelines into our regulations when we amend them.

My name is Paul Harris, the Senior Program Manager at the NRC. I provide oversight to the Drug Testing and Alcohol Testing Program in the commercial nuclear power Industry. I will provide a brief introduction to some background information, but most importantly, I will present some technical and industry performance issues.

I would like to leave you with an understanding of why the NRC's Fitness for Duty (FFD) program helps provide reasonable assurance that persons who have access to NRC licensed facilities are fit for duty and can safely and competently perform their duties. I want you to understand recent industry performance and the current technical issues.

I firmly believe that the NRC's FFD Program results in a direct contribution to public health and safety. There are a number of individuals at nuclear facilities that cannot be impaired from substance abuse or alcohol-related abuse. We have to ensure that these people can perform their duties and responsibilities safely and competently.

Part 26 was implemented in 1989. It was one of the first major federal laws for drug testing in the nuclear industry. The first law was focused on commercial power reactors and applied to those individuals who have unescorted access to NRC facilities. It also applied to those people who had certain access to strategic nuclear material and to those who had access to certain type of information. In March 2008, we did a significant revision of Part 26, including broadening the applicability of Part 26 to category one fuel cycle facilities, transporters of strategic nuclear material, and specific other individuals, especially those who provide emergency response capabilities to the nuclear power plants if an event were to occur. Also, we enhanced the alignments between FFD requirements and access authorization under the security umbrella. Originally, FFD focused on drug testing and behavioral observation; this was broadened that to include access authorization requirements. These requirements ensure that someone has an appropriate background to enter a nuclear power plant. Now FFD has a very strong link to security. We also incorporated fatigue requirements into FFD under the same umbrella. Fatigue requirements have been in existence for a long time for airline pilots and others. Per our requirements, a person must be unimpaired by the start of the shift. We regulate hours on site as well as off site by requiring mandatory time off between shifts and mandatory days off. We also limit the amount of work hours that an individual can perform on a weekly basis.

Part 26 also incorporates a defense-in-depth program. Coupling drug and alcohol testing with access control requirements provides a layer of defense as does our behavioral observation program. A number of individuals at the power plant do not have this defense-in-depth, primarily security officers, which I will discuss more about later.

Our FFD strategy is displayed on this one simple graph. The workers must be fit for duty, trustworthy, and reliable. The Commission's regulations apply to on-site and off-site use of illicit substances. If an individual's on site drug test is positive for an illegal substance, we assume that the person has violated the FFD Program and sanctions can be taken against that individual.

As this picture shows, the security officers that provide oversight and security at these power plants use rather large guns. In a number of states, lethal force is authorized under certain circumstances, and we are currently engaged in rulemaking to ensure that both federal and state laws are conforming. Security officers have to perform with due diligence and vigilance, similar to the DoD. They often operate in harsh environments at the nuclear power plants when providing security, so they have to be constantly awake.

We are currently evaluating end-rule making, which I cannot discuss right now because it is preliminary information, to expand the drug panel.

The FFD Program elements are listed here, including employee assistance programs, drug testing, and behavior observation programs. The licensees who implement the Commission requirements at the commercial nuclear power plants and the category one fuel cycle facilities also have to adopt a policy statement. That statement contains specific requirements, including identifying which individuals must be tested to ensure that they are fit for duty, having these individuals provide consent for testing, identifying which drugs will be tested, and acknowledging that sanctions will be taken against individuals who test positive on confirmatory testing. Our determination of fitness, item number nine, parallels DOT requirements. Our determination of fitness involves both a MRO and a substance abuse expert (SAE), which is equivalent to the DOT substance abuse professional. NRC has additional requirements for the SAE, including certain qualifications that parallel DOT. We try to leverage the HHS Guidelines for these determinations, such as the guidelines for the MROs that Jen spoke about earlier. Line item 10 is our connection to security. We are concerned about anyone who has malfeasance against the commercial nuclear industry, including trying to steal materials or sabotage a nuclear facility. Therefore, FFD aligns well with security requirements.

The NRC is in a rather unique situation in the federal government because we can take sanctions against any individual. Thus, it is imperative that the confirmatory results are not litigable. We do not want to go to court, so a positive must be a positive. The work that HHS did with DOT and the DTAB on the 6-AM, for instance, was critical to us because it provided a definite positive for drug testing, which ensured that we do not have to pursue litigation for that analyte. We have four levels of sanctions we can leverage against individuals. The first sanction, for a first time drug or alcohol positive test, is a 14 day denial from authorization, which means that the individual must be removed from the facility for 14 days. For the second positive test, the individual is removed for five years. There is almost a zero tolerance within the Commission and the nuclear industry on the use of illicit drugs or the abuse of other substances, including over-the-counter or prescription medications. The third offense is even more egregious and is permanent denial. There is no tolerance for those who cannot adhere to the program by abstaining from drug use and have complete disregard for the potential impact of his or her drug use on public health and safety by having access to a nuclear NRC facility. The fourth sanction is criminal sanctions. The NRC is in a unique situation because of the Atomic Energy Act and the Energy Reorganization Acts that provides the Commission with the ability to criminally sanction individuals who willfully violate Commission regulations. Currently, the staff is assessing whether the Commission's enforcement manual needs to be updated to address criminal sanctions against individuals. In Part 26, we are allowed to take criminal sanctions against individuals who are taking drugs, including illegal drugs or over the counter drugs that are in violation of the Commission's FFD policy. Typically, we reserve the criminal activity sanction, known as our NRC order to the individual, where we would order the individual never to work at a nuclear facility in the country. That has happened on a number of occasions to supervisors and operators who operate commercial nuclear power plants and are issued licenses by the Commission to do that function.

The next slide depicts what it means to be fit for duty. Much discussion centered on this, and it is open for more discussion because of the many different perspectives of what it means to be fit for duty. Our rule states that you cannot be under the influence of any legal or illegal drug as determined by the cutoffs and determination of fitness. The per se requirement states that if your concentration is below the cutoff, you fit for duty. But, are you impaired? We consider you are unfit for duty if your concentration is above the cutoff. We do not address the impairment issue because of the per se requirement. However, through our behavior observation program, an individual can be noted as impaired and removed from his or her duties and responsibilities.

We also have a requirement to not be impaired by acute or cumulative fatigue. We state that the individual must not be sleep deprived and mentally and physically capable of safely and competently performing assigned duties. Notice there is no qualification here on physical capability. Whether the person is unfit to perform his duties is determined through a behavior observation by individuals at the nuclear power plant. A person who cannot physically perform his duties would drive the determination of fitness. Through the determination of fitness, it is assessed whether the person is fit to perform that duty.

The man depicted on the bottom right is a technician. There are many technicians at nuclear power plants who perform work on safety-related structures, systems, and components. Those individuals also adjust the electronics and mechanical systems. Oftentimes, they perform these activities alone. Though they have supervisory oversight and behavior observations by independent quality assurance inspectors, they are working by themselves. This situation is equivalent to the armed security officer who is guarding the facility. Both must watch what they are doing. Technicians undergo post maintenance testing, which should identify latent problems. But what would happen if the technician placed an incipient failure inside of a valve or inside of a motor control center? Is that individual fit for duty? I do not think so. That is why we tie fitness for duty to security and examine both elements.

We do have a mission. In the group that I lead, we provide oversight of and direct support to licensing inspection and regulatory development. Focusing on the inspection element, we have continual oversight of these nuclear power plants through the use of resident inspectors. At the typical power plant that has one reactor unit, we have two resident inspectors. They provide oversight of the power plants, they are onsite full time, they live in the community, and they work odd hours, covering both day and night at the power plant for continuous coverage at these sites. These resident inspectors make their own observations on licensee implementation of our programs. They follow up on events, occurrences, and drug-related activities.

Certain findings by the resident inspectors are forwarded to me and Will Smith, who is a lead at the NRC for the evaluation of drug and alcohol events at sites. We receive notification if a supervisor or licensed operator tests positive on a drug or alcohol test. Additionally, we are notified of every positive test through our

electronic reporting data system. Currently, about 85 percent of all licensees provide electronic reporting of Fitness for Duty events to the NRC, providing us with prompt notification.

Internally, we are in preliminary discussions concerning rulemaking for Part 26, and that has not yet been announced to the public. We are examining oral fluid and hair testing to determine if that can help us identify and deter drug use. Also, we will update our urine testing requirements, following the HHS Guidelines, to include the synthetic opiates. We are interested in prescription drug abuse, including the drug cocktail issue.

Does a medical review officer have access to the state databases? Does the MRO at the commercial nuclear power plant have that access when reviewing the results of someone who tested positive for a prescription drug? We would like to know more about that. Will the MRO guidance be made public? I think that answer was no. I like the DoD requirement of 45 days for a valid prescription. We did an anonymous survey at a recent MRO conference. Of the 100 participants in the survey, and an overwhelming number, about 90 percent, of MROs wanted a clear definition of what constitutes a valid prescription. Also, NRC licensees and inspectors want clearer guidance on what a valid prescription is.

Initiatives at NRC include aligning more with HHS certification program for MROs and with the DOT collection process. However, we will add some additional items to these, similar to what we currently have in our rule. Expect more to come through the rulemaking process.

In the commercial nuclear industry, 76 entities report data to us. About 80 percent submit the data electronically. We conduct 178,586 total tests and have 340,000 to 350,000 people in the commercial nuclear industry. Our overall positivity rate is about 0.6 percent. There were 37 drug and alcohol events involving licensed operators and the supervisors reported to the NRC. Ninety percent of all the tests involved marijuana, alcohol, and cocaine; the breakdown, shown here, has remained steady for the last few years. This graph shows the breakdown by positivity rates by drugs. Electronic reporting helps us focus our efforts. For instance, the drug data indicate that it might behoove us to identify more people before they gain entry into the power plant. I would not have 37 reportable events because I could stop them at the gates.

Another initiative is the training of the employees, including notifying them of employment assistance programs. Also, we strive for more robust testing on pre-access testing. Typically, about three times as many contractor vendors test positive for drugs and alcohol than licensee employees, which is not unexpected. However, there are many licensees, or owner operators of these commercial nuclear power plants, that are hiring from local union halls. They are communicating that there is zero tolerance. If someone tests positive on pre-access, he/she will not be hired. The licensees are also implementing a one and gone policy. Many licensees are going above and beyond the NRC regulatory requirements for sanctions of 14 days, 5 years, and permanent; they are saying we are not going to hire you anymore. That word is reaching the union halls. So we expect to see more pre-access testing for the contractor vendors. On this next chart, notice the dotted line representing the contractor/vendors sloping down towards the permanent employees at commercial nuclear power plants line, which has been relatively steady. We are doing regulatory research on how we can lower these numbers and what is a reasonable number to achieve.

The Commission's regulations are based upon a reasonable assurance that individuals are not impaired. The Commission understands that there cannot be 100 percent assurance, so the word reasonable is used here. What is a reasonable level and how much harder should we work to lower it further?

This next slide is based on electronically reported data, which represent about 80 percent of the industry. Data are broken down by follow-up, post-accident, for cause, random, and pre-access testing. Notice the random testing line there. Mostly the same drugs are detected in random testing as in pre-access testing. So why am I still letting these people inside the power plant? If these people are inside the power plant, how do we ensure they are not impaired while on duty and performing responsibilities prior to a random drug test? I would like to identify them when they are having issues or might be impaired. They should request that the Fitness for Duty program personnel remove them from their duties if they are on a drug that might cause impairment while on duty.

Post-accident post-events are of concern for the Commission as well as any other safety-oriented agencies. We track these events as well. Notice that the contractor/vendors line is skewed to significantly more positives, as we said for random testing. I failed to include the pre-access data. The reason the pre-access data were omitted is because it is about three times larger than the random testing data. This gives you an idea of the number of power plant contractor vendors that think that they are going to do their pre access testing.

We are a proponent of outreach, and I thank Dave Mineta and Ron Flegel for inviting us to these meetings. The more people we talk to, the more we learn. We are open to discussion, and we want to hear more. We do not want to bypass either HHS or DOT; as a federal agency, we want to go along with everyone

else. Our population is a little bit different than DOT and the federal workforce. We are always interested in new ideas and better ways of doing things. Fatigue management is not within our organizational structure but resides instead with Kamishan Martin of Human Factors.

I will be happy to answer any questions.

Dr. Smith: On the last slide, what is the title of the x axis? What do those numbers represent?

Mr. Harris: The number of occurrences or the number of positives.

Dr. Smith: For the 120 random positives, is that in a year or is that total?

Mr. Harris: Yes, this represents 2011 data. We operate one year behind.

Dr. Smith: What strikes me is that, in comparison to the DOT statistics, alcohol is a significant percentage of the incidents and the random test positives, particularly for the licensee, with a lower cutoff.

Mr. Harris: We utilize a time dependent alcohol limit. Basically, it is 0.04, but it is time-dependent depending on how much time they spend at work down to 0.02.

Dr. Smith: The 2011 drug testing data are for the SAMHSA/DOT analytes, correct?

Mr. Harris: Yes, we test the same five drug panel. Alcohol is an issue, and we monitor that. The behavior observation program is one of the key elements, and we are accessing how we can improve our inspection process to better inform licensees about what kind of physical characteristics are indicative of substance abuse impairments.

Mr. Bonds: Thank you Paul for your presentation. In reference to your survey, would the MRO want a clear definition of the threshold for prescription medication and its expiration? Is there a recommendation of what that threshold will be?

Mr. Harris: No, we did not ask that question.

Mr. Bonds: Were there any other relevant questions in that survey that would be helpful to the Board?

Mr. Harris: We did not publish the results of that survey.

Dr. Cook: You had mentioned when you had spoke in May 2011 that there were new applications submitted for power plants. Is that still the case?

Mr. Harris: Yes. Though I cannot speak for the Office of New Reactors that does the licensing of commercial nuclear power plants, in May 2011 we had 18 license applications. That number is now 16. Currently, there are two separate sites building commercial nuclear power plants, the Vogel Site and the VC Summer. This construction involves a total of four units, with two units on each site.

Dr. Cook: With this construction, you will have a workforce that is comprised of construction workers. As a result, do you expect to see an increase in your positivity rate?

Mr. Harris: That's a great question. The Office of Regulatory Research has evaluated what is a good number to use as a performance metric. There is no position yet on what is a good number for random positive testing rates. It is reasonable to me that we will see an increase in positive rates because of the changing work force coming into the power plants.

We have a nuclear safety culture. An employee at a power plant is always within the nuclear environment, thus we expect to see very low positive rates. When we start hiring people from the surrounding communities and states, they might not have that same culture as the nuclear employees. So we do expect to see an increase. However, with the electronic reporting that we have implemented, we can identify the sites now with increased positive rates.

The fitness for duty program manager at VC Summer informed me that they brought in over 6,000 temporary employees to that site to build that nuclear power plant. We are very interested to see his data. He says his positive rate was very low. So that licensee is doing a great outreach with the local communities to ensure that they are screening people before they have access to the sites.

Mr. Bonds: What part of the country was that?

Mr. Harris: VC Summer is down south in South Carolina.

Dr. Cook: DoD, depending on the service, has very specific testing rates. Does NRC dictate the random testing rates or are they determined by the licensee?

Mr. Harris: It is interesting that back in the 1989 rulemaking we wanted 100 percent random testing rates. Looking at the statistics for 100 percent random testing rate, you are only testing 67 or 68 percent of the people once a year. There was much discussion back then, and in 1994 we lowered that to 50 percent random testing rates. On our historical graphs posted on our NRC webpage, there is a bump in the random testing rates because the testing rate was lowered from 100 percent down to 50 percent. At 50 percent, only 35 percent of the people each year are tested. Lowering that random testing rate decreases the number of individuals in your population who are being tested to a number that is much lower than people think. It is still

50 percent, but 50 percent of the population is being tested rather than 50 percent of the individuals being tested.

Dr. Cook: Is the nuclear industry workforce relatively stable?

Mr. Harris: Currently, from what I hear from the inspectors, the nuclear workforce is very stable. Many of the licensees ask for the same contractor/vendors because they know they are performing right. This is a mature workforce as well, meaning that the ages and experiences of the individuals are higher. But similar to other private industries, there is still an influx of young individuals taking the places of those who retire.

Dr. Cook: For the behavioral fatigue assessment, what is the assessment rate? I assume it is either random or for cause.

Mr. Harris: As I mentioned, Kamishan Martin, of the Office of Nuclear Reactor Regulation, analyzes that data, and it is all electronic as well. I could get that for you, but it is also posted on our website.

Dr. Cook: Are the inspectors continually doing assessments when they are onsite?

Mr. Harris: The NRC inspectors are onsite permanently, but they rotate facilities every five to seven years. They observe and watch the licensee implementation of the programs for fatigue monitoring and for drug and alcohol abuse. Because they attend the daily management meetings, they know what occurrences and events are happening. They will also review all corrective action reports. They have a general inspection procedure that requires them to look at certain things, but they have the latitude within that inspection procedure to inspect other areas as well. We have additional inspectors who go to the facilities periodically to specifically look at fitness or duty issues.

Dr. Cook: Our last presentation of the day, an update on the Federal Workplace Drug Testing Programs, will be given by Ron Flegel.

## **Federal Workplace Drug Testing Programs**

Mr. Flegel: I want to thank all the federal partners for presenting their updates. It is important for DTAB and the public to hear our federal partners' updates. If you have any questions during my presentation, please feel free to ask.

There are a number of ongoing projects that I had hoped to speak about to the DTAB and the public, but currently I am not able to do that for several reasons and for that I apologize.

I will present our NLCP drug testing data through 2012. In the future, we anticipate the ability to collect the NLCP data on a more regular and timely basis. Our goal is a data collection process that will be only three to six months behind. This is especially important going forward as we begin the new testing for synthetic opiates, both in the regulated and nonregulated industries.

This is a trend analysis of the number of regulated specimens tested from January 2003 to December 2012. That number was about 6.6 million in 2003 and peaked in 2007 at about 7.99 million. With the recession that ensued in 2008 and 2009, the numbers plateaued. Those numbers have since gradually started to climb in the regulated industries. Specifically looking at regulated specimens in annual increments from 2009 through 2012, the number of specimens tested in 2009 was five and a half million and a little over six million last year.

These data represent the regulated specimens reported as positive, adulterated, invalid, and/or substituted from 2009 through 2012. In 2009, there were around 87,000 specimens reported positive while in 2012 that number was over 110,000.

The number of specimens reported as invalid for low pH from 2009-2012 is shown in green. This number remained relatively the same in 2009 and 2010, increased in 2011, and then leveled off again in 2012. The number of specimens reported as invalid for pH is in red; this number actually increased through 2011 and into 2012.

This graph shows the specimens reported invalid for pH from 2009 through 2012 as a percentage of total reported invalids. In blue is the percentage of invalids reported for pH, while the red represents the reported low pH results as a percentage of invalids reported.

In the last part of 2011, laboratories located in specific geographical regions, such as Texas, reported increases in the number of low pH invalids. In 2012, the low pH invalids started to decrease. We thought perhaps this was not just a trend of low pH values, so we decided to take a closer look. Increasing specimen pH values in winter is a trend that we have not seen in the past. Typically, pH increases with time and temperature. Increasing pH values are not expected in the wintertime. We do not know if this low pH phenomenon is related to substituted specimens, a specific adulterant, or the use of synthetic urine. The number of high pH specimens has remained relatively consistent with seasonal expectations, while the number of low pH specimens did change over time, especially at the end of the year.

These data represent regulated specimen testing. For 2009 versus 2010, there were slight increases from about March through December for 2010. Comparing 2009 to 2011, a similar pattern is evident, but the increases are greater. Also similar is the 2009 to 2012 comparison. So as you can see the testing rate on the regulated industry has come back over time going into 2012.

This slide shows a schematic of regulated specimens testing from 2009 through 2012. It is taken into account all analyzed specimens throughout the one year and broken it down by the month in which the specimen testing occurred.

The slide depicts the number of regulated specimens reported as positive, adulterated, invalid, or substituted and the month and year in which that reporting occurred. From 2009 to 2011 there was a large increase in the number of specimens being tested, especially during the March through the December time period. In 2012, as the economic recovery starts, there was a significant increase in testing numbers in all the regulated laboratories. This graph is a cumulative representation of the previous graphs. Will this trend continue? We will see in 2013.

These data are specimens reported as positive, adulterated, invalid, or substituted categorized by drug. In October 2010, we had changed the Guidelines, lowering the cutoffs for both methamphetamines and cocaine. I included this chart to determine if there was a trend with those drugs that coincided with the lowered cutoffs. Notice the numbers are relatively stable from 2009 to 2010. Based on this change, we would expect an increase in the amphetamines and BZE or cocaine. From 2009 through 2011, an increase was seen for those drugs. Most of the other drugs remained relatively the same with a slight decrease in the THC. Compared to 2012, for the amphetamines specifically and to a lesser extent for BZE, an increase was seen. There was a small decrease for THC specifically in 2012 when compared to historical data.

2013 will be an interesting year based on state marijuana legislation. At a meeting that I attended last week, Director Kerlikowske announced that he endorsed the Administration's stance on marijuana. I was happy to hear that; it is a very important message to send.

During the recent CADCA conference, a number of issues were discussed. About 50 percent of the meeting agenda centered on the decriminalization of marijuana, specifically in those two states. For the Board members, we will provide to you as much information as we can. Please keep attuned to what is out there and what is happening on this front. It is definitely an issue that we will hear more about in the future.

In this cumulative data slide for the number of specimens reported as positive, adulterated, invalid, or substituted from 2009 to 2012, notice the expected amphetamine increase. In 2012, amphetamine positives are still increasing while BZE positives have decreased. In 2012, THC has decreased over time in the regulated industry.

This slide shows the total number of specimens reported as invalids from 2009 to 2012 as compared to the number of high and low pH-related invalid specimens. This is a mirror image of some of the previous data but examined a little differently. The pH issue will present some challenges for us in the future. We want to examine both synthetic urine and adulterants as potential causes for this increase in pH invalids. We also want to determine whether there is a legitimate medical explanation for these pH invalid results.

In summary, after the implementation of the revised Guidelines on October 1<sup>st</sup>, 2010, there was a 5.4 percent reduction of the number of specimens tested, but an increase in the percentage of specimens reported as drug positive. The major drugs responsible for the increase in the number of specimens reported as positive were those whose cutoffs were lowered, specifically cocaine, amphetamine, and methamphetamine. There was a smaller increase observed for morphine and codeine.

Now I would like to switch gears. We have several ongoing studies and projects. Based on the DTAB recommendations, we felt it was incumbent on us to investigate synthetic opiates.

I would like to present to DTAB one of our relatively small studies. Aliquots of 12,663 regulated specimens were de-identified and tested using DRI, KIMS, CDIA, and EMIT II reagents using a cutoff at the 300 ng/ mL morphine level. Of these, 266 exhibited an immunoassay response that was equal to or greater than 300 ng/mL morphine cutoff. Of those initial 266 test positives, 254 were positive by DRI, 162 were positive by KIMS, 253 were positive by CDIA, and 238 were positive with the EMIT II. Shown here are the initial test positives and the initial test positive percentages based on the 12,663 specimens. These 266 reactive specimens were then confirmed by GC/MS analysis for codeine, morphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone using a 100 ng/mL cutoff. There were 35 specimens in which no drug was found. The number of specimens with hydrocodone only was 40 and hydromorphone only was 13. Both hydrocodone and hydromorphone were present in 116 specimens. Both oxycodone and oxymorphone were found in 29 specimens while codeine and/or morphine were in 33. Remember, these numbers reflect drug detection at concentrations greater than 100 ng/mL.

The analyte distribution of synthetic opiates in these positive specimens is important in determining appropriate initial as well as the confirmation test cutoffs. As you can see from this chart, 58 percent of the specimens containing codeine and 42 percent of those containing morphine had concentrations greater than 1000 ng/mL. However, the number of specimens with drug concentrations greater than or equal to 100 ng/mL was only 19 for codeine and 38 for morphine. In this program, those are the two analytes for which we test.

There were a total of 156 specimens that contained hydrocodone at concentrations greater than 100 ng/mL. Based on the numbers from our current program, 19 for codeine and 38 for morphine, comparing that to 156 specimens found for hydrocodone, there are significantly more synthetic opiates detected in this study. The largest number of hydrocodone-containing specimens, 38 percent, was found in the greater than 1000 ng/mL range. In the concentration range from 100 to 299 ng/mL, a similar percentage of hydrocodone-containing specimens, 33 percent, was found.

In the 100 to 199 ng/mL concentration range, look specifically at hydromorphone. Hydromorphone is about nine to ten times more potent than morphine. The lower concentrations should represent prescription use of hydromorphone, which explains the higher percentages found at the lower concentrations. Whereas, in the upper concentrations of 1000 to greater than 2000 ng/mL, you would not expect to find increased percentages of hydromorphone. But in this study, there are relatively high percentages of hydromorphone greater than 1000 to 2000 ng/mL. In this study, there are 129 specimens containing hydromorphone at concentrations greater than 100 ng/mL, with 62 percent in the 100 to 299 ng/mL range and 13 percent in the greater than 1000 range.

There were 31 specimens identified as containing oxycodone. Of these, 62 percent contained this analyte at concentrations greater than 1000 ng/mL, 13 percent were in the 200 to 299 range, and 11 percent were in the 400 to 499 range.

34 specimens were found to contain oxymorphone, with 82 percent of these having concentrations that exceeded 1000 ng/mL.

This study, involving a small sampling of specimens from the regulated industry, yielded distribution data of actual specimen concentrations. It provided a feel for the scale of quantitative levels of opiates that we may expect.

This chart displays the total number of specimens tested, 266, over the concentration range from 100 to 2000 ng/mL by the response rate of the different initial immunoassay tests and how many confirmed positive. Overall, most of the reagents are performing equally regarding the confirmatory levels. Specifically, from 300 to 2000 ng/mL, they perform relatively similarly in all of our NLCP laboratories. That is important to know the performance of the immunoassay response for detecting the actual drug in a urine sample.

In another very small subset of regulated specimens, we wanted to assess the identification of oxycodone and oxymorphone with a specific oxycodone assay. We deidentified 2,892 regulated specimens and analyzed them using the oxycodone assay at the 100 ng/mL cutoff. These specimens underwent confirmatory testing for oxycodone and oxymorphone. 14 of these specimens were initial test positive, and 12 confirmed positive for oxycodone and oxymorphone. The positivity rate in this specific subset was 0.42 percent, while the confirmation rate was 85.7 percent, which is the immunoassay positive responses at a cutoff of 100 that confirm positive.

It is important to try to balance our current opiate testing with the synthetic opiates. With a positive immunoassay result, what is being confirmed? Are we actually confirming for what we screened positive?

In summary, yes these individuals in safety-sensitive positions are using semi-synthetic opiates, specifically hydrocodone, hydromorphone, oxycodone, and oxymorphone. The implications of this use, including legal, medical, or safety-related, can only be implied until the testing for these compounds begins and positive results are verified by an MRO. In our study, these were deidentified specimens, and thus we do not know if these donors had valid prescriptions.

That will end my presentation for today. Are there any questions from the Board on this study? The presentation that Jen gave this morning on MRO interpretation will be very important going forward.

We will have to answer comprehensively for both urine and oral fluid on MRO interpretation, what constitutes a valid prescription, and a number of other issues. It is a big undertaking that we have. So hopefully, in an upcoming DTAB meeting, we will have more information regarding that. Thank you.

## Public Comment

Dr. Cook: We now come to the public comment period of the open session. Two people have currently registered to give public comment. We will begin with Abigail Potter of the American Trucking Associations, Inc.

Ms. Potter: Hi. Before I get started, I want to talk about the presentations that I thought were really great today, particularly that from the DoD. It seems that DoD is starting to make proactive efforts in identifying the threats that are occurring and performing testing to try to stop new abuse.

We are very concerned about synthetic marijuana and bath salts. With the current testing protocols, we cannot identify it; there is no way of really knowing. One requirement of DOT is that drivers are required from using any type of substance that could prevent them from driving. So this goes into what kind of prescriptions can be used. For us, anything that could harm your driving ability is prohibited.

Going back to NRC, we are very happy the hair testing topic was brought up. I will go into this a little bit more in detail. So thank you for being proactive and moving forward in trying to prevent drug abuse in all our organizations.

I am with the American Trucking Association. ATA is the United Federation of Motor Carriers State Trucking Association's national trucking conferences created to promote and protect the interest of the trucking industry directly and through its affiliate organizations. ATA encompasses every type and class of motor carrier operations.

Since this is my fourth public comment before the DTAB, many of you might be familiar with the subject of hair testing. Since 2007, ATA has supported the adoption of alternative specimens into the U.S. DOT's drug testing program. We are pleased that DTAB is moving forward on oral fluid testing standards. However, many of our members are extremely troubled by the lack of discussion this Board has had on hair testing. The last time DTAB discussed the issue of hair testing in a public meeting was seven years ago. DOT looks to SAMHSA and the DTAB for guidance to reforming their drug testing standards, and if SAMHSA is not proactive in identifying the new threats to the federal drug testing program, then DOT is not making the necessary changes to ensure that our waterways, our railroads, our skies, our pipelines, and our highways are as safe as they could be. A lot has changed over the last seven years with regard to hair testing. Hair testing, as you might already know, has grown in popularity for pre-employment screening. Ten percent of Fortune 500 companies, including Northrop Grumman, Lockheed Martin, and many of our automotive industries are doing air testing. It is extremely prevalent in Europe, China, Japan, and Brazil. Within the U.S., I am aware of 23 major motor carriers that are conducting hair testing during the pre-employment screening process. These companies have found that hair testing, particularly for pre-employment screening, has significant advantages compared to urine testing. With the longer window of detection, up to 90 days, we are able to find the lifestyle user. We are able to see a background of what that person is going to do. This really helps companies weed out the drug users before we place them behind the wheel, which is our focus. We will catch them eventually, but we would not want to see it in a post-accident situation or random test. We want to catch them before we place them behind the wheel.

For instance, one large national trucking company has reported that 90 percent of driver applicants who fail hair tests manage to pass the pre-employment urine test. Hair specimens are usually easier to collect, collection is less invasive, and hair is much more difficult to adulterate. As a result, drivers are far less likely to be able to subvert the testing process, as seen with the thousands of pH levels. Some of that is probably just the individual, but a lot of that is probably subversion. This problem was identified in a 2008 GOA report.

Congressional leaders are recognizing the importance of hair testing with our industry. Last year HR6641 was introduced, which would have required the Secretary of DOT to establish a pilot program in conjunction with HHS to study the benefits of using hair testing for pre-employment drug tests for commercial vehicle operators. Legislation in support of hair testing is expected to be introduced again this year. A legislative mandate requiring the development of hair testing standards is on the horizon, and it is something that will occur. ATA hopes that DTAB will end its seven year moratorium on hair testing and finally establish hair testing standards for safety-sensitive employees that DOT can adopt.

The numbers are just staggering. One of our major carriers has conducted 40,000 hair tests since 2007. Their post-accident rate in 2007 was around 2.6 or 3.0 percent; in 2012 it was zero. They had zero positives in their post accident tests. That is significant, and it shows that they are weeding out the people.

DOT's 2011 numbers for the random positive rate was 0.09 percent, which is the lowest it has ever been. The rates for companies that are doing hair testing are 0.25, and these are gigantic companies. I would recommend that this Board look at and review what has changed in hair testing, especially FDA clearance. It is wonderful that our industry is growing.

Why would motor carriers decide to triple the cost for pre-employment screening if there were problems with it? There are significant benefits for safety-sensitive employees. I would recommend that this Board review hair testing in the near future. Thank you.

Dr. Cook: Thank you Abigail. All public comments will be taken under consideration by the Board in closed session tomorrow. Our next registrant to give public comment is Bill Corl of Omega Laboratories, Inc.

Mr. Corl: Good afternoon everyone. First and foremost I would like to thank the members of DTAB and all guests for listening to my comments today. My name is Bill Corl, and I am CEO of Omega Laboratories. Omega is an oral fluid testing lab and is currently one of the world's largest hair testing labs. Omega has over 12 years of experience in the industry, testing for clients across the globe. Many of our U.S. clients operate within federally-regulated industries. I am here today at the request of some of these companies to help support the addition of hair testing methodology to the Mandatory Guidelines. My colleague Kyle will hand out a case study that we have done over the last two years. In response to previous DTAB inquiries regarding data on synthetic opiates testing, I would like to present real world data on the prevalence of synthetic opiates in motor carrier testing. The data compiled represented candidates tested in 2011 from a large Midwestern carrier. The population was comprised of 12,197 donors seeking employment within the transportation industry. This population represents varying demographics, with donors spanning across the U.S. Each of the donors submitted a DOT urine sample and a corresponding hair sample, tested in accordance with the College of American Pathologists laboratory accreditation requirements. These real world statistics demonstrate the valid concern for synthetic opioid usage in motor carrier workforce. Hair testing uncovered 432 synthetic opiate users, of which 111 were found to be positive after MRO review. Based on these numbers, it is possible that synthetic opiates could become one of the leading positive drug classes. As the data shows, hair testing in general yields a greater number of positive results than its urine testing counterpart. It is for this reason that a growing number of employers in regulated industries are choosing to add hair testing programs under their company authority. Though urine testing is still effective for post-accident testing, the data suggest that it is no longer effective at screening donors for pre-employment. When DTAB is ready to review the effectiveness of hair testing, Omega and I am sure the other hair labs will be ready to support your decision with years of data like I just submitted. Thank you for your time.

Dr. Cook: Thank you Bill. Does anyone on site wish to give public comment that did not register? Does anyone who is attending remotely like to give public comment?

I adjourn the open session of the DTAB, and I thank everyone for attending.

Adjournment