PROCEEDINGS

Substance Abuse and Mental Health Services Administration (SAMHSA)
Center for Substance Abuse Prevention (CSAP)
Drug Testing Advisory Board (DTAB) MEETING

January 26, 2011

One Choke Cherry Road
Rockville, Maryland 20857

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P R O C E E D I N G (11:00 am)

Call to order

Dr. Cook: A very excellent winter morning to everyone. I am Janine Denis Cook, the Designated Federal Official of the Drug Testing Advisory Board or DTAB. As the DFO of the DTAB, I now officially call this meeting to order.

First, I have a few announcements. We are in the middle of a nor'easter here on the East Coast. One part of the storm came through this morning. The second part of the storm is supposed to hit about 4:00 pm this afternoon. Historically, we have always adhered to the agenda and its listed times. Because of the storm, we are not. We are going to speed things up.

For those of you who are calling in from the outside, we will inform you of the time when we are going to break for lunch and when we will return for the afternoon open session. Our goal is to be finished today by 3:00 pm. For those of you here onsite, we have a copy of the agenda on the registration table. For those of you that are joining us remotely, the agenda should be posted in your reading pane.

A few weeks from now, both the minutes and the proceedings of this meeting will be posted on the DTAB website. I have provided the link for you here on this slide. You can also access the DTAB website from the Division of Workplace Programs Drug Testing website.

For those of you that have 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 onsite, 3 x 5 cards are located in the back on the registration table for your to record your questions. Please leave your questions with one of the staff that is manning that table. Secondly, if you are attending the meeting remotely, you can submit your questions via the chat pod, which I will describe shortly. Submitted questions will be considered by the Board during the closed session. The public comment period was originally scheduled from 4:30-5:00 pm. That will change because of the weather. When we conclude the regular part of the agenda, we will move directly into the public comment period.

Currently, there are eleven attendees who have registered to make public comments. If anyone else wishes to give public comment and has not yet registered, you may register onsite at the registration table or via the chat pod, 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. All public comments will be included in the meeting minutes, as well as the transcripts. 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.

Please silence any electronic devices that you have because these will interfere with both the AV equipment, as well as the transcription equipment.

I have some housekeeping announcements for our onsite guests. Restrooms are located just outside of the conference rooms to your right. For breaks, the attendees are welcome to purchase refreshments in the break room, which is located down the hall to your right at the Uncommon Café. This service is in operation from 7 am until 2 pm. Please wear your SAMHSA ID badge while you are in the building. If you are planning to leave the building either for lunch or at the end of the day and plan to attend tomorrow, please keep that badge with you because you will need it to reenter the

building.

At the registration table here onsite, you will find the menu for the Uncommon Café, as well as a list of other local restaurants. The schedule for the SAMHSA shuttle service is on the registration table for those who want to go to a local restaurant located in the King Farm Area.

For our guests who are attending remotely, I have some instructions regarding Adobe Connect. Our hosts for the Adobe Connect are Erica and Jared. I want to thank them for all of the hard work they have done to make this meeting possible. What you see on your computer screen is your virtual "room". Each presentation will be visible in the "share pod", which is the largest pod and takes up most of the screen. The "attendees list" pod displays a list of everyone in the room with us today. At the top of the attendees list, there is a "my status" dropdown arrow. These "my status" options are a great way to communicate with us. For example, the "stepped away" status lets us know that an attendee has temporarily stepped away from the room and the "raise my hand" status lets us know that you have a question. The "chat" pod allows you to submit a question to us at any time, concerning either a technical problem or pertaining to the material. There is a white bar at the bottom of the chat pod. Simply take your cursor and click in that white bar. This will allow you to type your question; hit "enter" to send your message. All questions submitted pertaining to the presentation material will be taken under consideration by the Board in the closed session. Again, if you have any technical problems, please feel free to submit them in the chat pod. The virtual room has a maximum capacity of 100 attendees. Please note that only those participants that have logged into the room only calling in will not be able to provide comments.

Welcome and Opening Remarks

Dr. Cook: Now, I will take off my DFO hat and assume my duties as Acting Chair of the Drug Testing Advisory Board. In this capacity, I want to officially welcome everyone who is attending the meeting, both here on site and electronically.

It is important for the DTAB members to understand their mission as written in the DTAB charter and how that meshes with the mission of SAMHSA. SAMHSA, the Substance Abuse and Mental Health Services Administration, is an agency within the U.S. Department of Health and Human Services. HHS assumes the authority for administering the Federal Drug-free Workplace Programs and the Secretary has delegated that authority to SAMHSA.

The DTAB is responsible for providing advice to the SAMHSA administrator and for recommending areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing those recommendations. The DTAB is also charged with reviewing the science related to new drugs of abuse and methods necessary to detect their presence. In addition, the DTAB evaluates SAMHSA's National Laboratory Certification Program for Federal workplace drug testing programs.

Within SAMHSA, the staff of the Division of Workplace Programs provides support for the DTAB and is responsible for all drug-free workplace issues, including the Mandatory Guidelines.

I would like to take a brief moment to tell you about SAMHSA's work as a way of highlighting the importance of DTAB to SAMHSA's mission. SAMHSA's mission of reducing the effects of substance abuse and mental illness in America has an obvious and clear link to the goals of workplace drug testing. In fact, four of the five roles that SAMHSA plays, excluding its funding role, are reflected in drug testing programs. Also, the first of SAMHSA's eight strategic initiatives is prevention of

substance abuse and mental illness, which address the objectives of workplace drug abuse prevention directly.

In implementing these roles, SAMHSA has articulated key messages to express the conceptual core of our mission. These key messages emphasize the importance of behavioral health, including decisions about substance use and abuse, to the individual and the community and highlight the productive continuum of prevention, treatment, and recovery. Workplace drug testing plays a key role in the behavioral health continuum.

SAMHSA's guiding principles focus on committed people working collaboratively to achievable goals. DTAB will be working in partnership with you, the public, to ensure that the Federal Drug-Free Workplace Programs continue to serve as deterrence to substance abuse that is protecting national security, public health, and public safety.

At this time, I would like each member of the Drug Testing Advisory Board to introduce him or herself.

Dr. Brown: Lawrence Brown, addiction medicine specialist at the Addiction Research and Treatment Organization, Brooklyn, New York.

Dr. Bowers: I am Larry Bowers, the Chief Science Officer of the U.S. Anti-doping Agency.

Dr. Bourland: I am Jim Bourland, the Laboratory Director and Director of R&D for Meritox.

Ms. Farrell: Good morning. I am Laurel Farrel. I am here as a forensic toxicology consultant.

Ms. Chandler: I am Phyllis Chandler, a Lab Manager and Responsible Person for Laboratory Corporation of America in North Carolina.

Mr. Swart: Good morning. My name is Jim Swart. I am the Director of the Office of Drug and Alcohol Policy and Compliance with the Secretary of Transportation at U.S. DOT.

Dr. Smith: I am Donna Smith, the Regulatory Affairs Officer for a third party administrator and MRO firm located north of Philadelphia, Pennsylvania called First Lab Incorporated.

Ms. Rowland: Hi. Barbara Rowland, the Director of Laboratory Operations for Quest Diagnostics in Lenexa, Kansas and also a Responsible Person.

Mr. Bonds: Good morning. Robert Bonds with Amtrak HR Labor Relations. I am here as the consumer advocate of the donor.

Dr. Harper: I am Courtney Harper, the Director of the Division of Chemistry and Toxicology Devices at the Food and Drug Administration.

Dr. Wong: Steven Wong, Professor of Pathology, Director Clinical Chemistry and Toxicology for Wake Forest University School of Medicine.

Dr. Cook: This meeting would not have been possible without the invaluable assistance that I received from my coworkers. At this time, I would like members of the Division in Workplace Programs to please introduce themselves.

Mr. Shen: Hyden Shen, Policy oversight lead.

CMR. Sean Belouin: Sean Belouin, Pharmacist.

Mr. LoDico: Charles LoDico, forensic toxicologist.

Mr. Flegel: Ron Flegel, forensic toxicologist.

Ms. Rest-Mincberg: Carol Rest-Mincberg, Acting Director.

Dr. Cook: I would like to introduce Carol, who just introduced herself, who is currently the Acting Director of the Division of Workplace Programs. All of us in the Division of Workplace Programs want to take this opportunity to publicly thank Carol for the leadership she has provided to the Division for the last six months. Thank you, Carol.

Ms. Rest-Mincberg: I want to thank the staff for making me look good. Before I came to this program, I did not have any background in this area and they have made it easy for me to do a good job.

Because of the weather, I am going to ask that my prepared remarks be inserted into the record; they will be available on the website. There is nothing in there that people have not heard before. My presentation contains the legal basis for our drug testing and elaborates on the charge of the DTAB.

In the interest of time, I will now introduce our CSAP Center Director. The Division of Workplace Programs, which administers the drug testing program, is within the Center for Substance Abuse Prevention in the Substance Abuse and Mental Health Services Administration, within the Department of Health and Human Services. The Director of the Center for Substance Abuse Prevention is Fran Harding. She is one of the leading experts in all forms of prevention, with a focus on alcohol and drug programs and behavior health. She serves also as the SAMHSA lead for the Strategic Initiative on Prevention of Substance Abuse and Mental Illness. Prior to federal service, she was with the State of New York as the Associate Commissioner of the Division of Prevention and Recovery at the New York State Office of Alcohol and Substance Abuse Services, where she was responsible for the development of policy and guidelines for alcohol and drug abuse and gambling prevention, treatment, and the recovery program. It is my pleasure to introduce her.

Ms. Harding: Thank you. Good morning. You now know I am from New York. This, even though it has been classified as a nor'easter, is not a nor'easter to me. This is just a day in the life, with a few inches of snow mixed in with a little ice and mostly doused with some water, which will make us a little nervous, but we will all survive it. Back home, I currently have over three feet of snow outside my window. This is a pleasure to actually bring the snow down to you. I am sorry if it causes some of you pain, but just imagine how pretty it is going to look tomorrow morning when you get up. You have to look at the positive -- always the positive.

As the Director of SAMHSA's Center for Substance Abuse Prevention, I welcome all of you, the Drug Testing Advisory Board, which is being convened following a two year break. There have been many advances in these last two years. Therefore, we will have much to discuss in the next two days.

We rely on the members of the Drug Testing Advisory Board to apply the latest scientific evidence, legal consideration, and consumer advice for the important agenda items before you. Drug testing technologies, medical review officer organizations, and electronic custody of control forms are all part of your tasks. We look forward to the knowledge and expertise that you bring to drug testing program.

As the meeting goes forward, we will be learning a lot.

Now, it is my job to explain to you why do you reside in the Center for Substance Abuse Prevention. Drug place testing is a unique program within SAMHSA's Center for Substance Abuse Prevention, which is managed on behalf of the Office of National Drug Control Policy. Unlike most of SAMHSA, it is a regulatory program that deters the use of illicit drugs. The program does not award grants or contracts, and it does not work directly with the states and the communities - something very different to SAMHSA. Unlike most of SAMHSA, it has a permanent and separate legal authority that does not require a periodic reauthorization.

Unlike most of SAMHSA, the staff expertise is in toxicology, chemistry, forensics, and pharmacology, and, of course, the law, something that is very unique to this particular division. Yet, ironically, as defined by the Institute of Medicine, the Drug-free Workplace Program has both a universal prevention, as defined as strategies that benefit the entire population, and selective prevention in that targets specific subgroups. The Drug-free Workplace Program is the largest universal prevention program within SAMHSA because it protects everyone in the United States from injury and death by managing workplace drug testing. The selective nature of substance prevention is that you target 400,000 federal employees in testing designated positions and more than 12 million workers in the federally-regulated industry. Empirical evidence demonstrates that universal prevention effectively decreases injury and death among the general population and selective prevention among tested workers has resulted in a continuing decline in illicit drug use since the creation of this program. You are a vital part of SAMHSA, and we are very grateful for the work that you do.

Now, I have the pleasure of introducing our next speaker who will give you his greetings from SAMHSA. Dr. Broderick serves as SAMHSA's Deputy Administrator. As the Deputy Administrator, Dr. Broderick is responsible for providing executive direction and leadership to approximately 525 hard working staff members and for managing our fiscal budget of approximately 3.3 billion dollars. Dr. Broderick has served for 34 years in the U.S. Department of Health and Human Services as a commissioned officer in the United States Public Health Service. He has extensive experience as a clinician, as well as in health prevention operations, health policy development, program assessment, and management. Rear Admiral Broderick provides leadership in implementing innovation that keeps SAMHSA in the forefront of behavior and public health. On a more personal note, he is a strong advocate, one of our strongest supporters in the field, and certainly one of our best friends. Without further ado, let me introduce to you Dr. Broderick.

Dr. Broderick: Thanks, Fran. Thank you all for coming out today a particularly challenging weather day. I want to thank Ed Jurith for joining us today. Ed is the General Counsel for the Office of National Drug Control Policy in the Executive Office of the President. Ed, it is always nice to see you. Thank you for attending.

I want to thank the Board for providing us the advice and guidance that is so important to SAMHSA as we administer this regulatory responsibility. I bring greetings to the audience and the Board members from Pam Hyde, our Administrator. Under Pam, SAMHSA is experiencing much vitality and change.

The Drug Testing Program, as one of our regulatory responsibilities, is extremely important to the nation. And, I want to thank you for all that you do for us. I look forward to reviewing with the Administrator the proceedings of this meeting as soon as they are available and considering the advice that you provide to us relative to the Drug Testing Program.

Also, those of you who have chosen to provide testimony at the end of the meeting, I know that will be of assistance to the Board and will be of help to us, too. Thanks very much for being here. I look very much forward to reading the proceedings of the meeting. Thanks.

Mr. Jurith: Good morning. My name is Ed Jurith. I am from the Office of Legal Counsel at the Office of National Drug Control Policy, and it is a pleasure to be here with you this morning. This is a great meeting. At this meeting, I can attend to my anti-doping responsibilities with Larry Bowers, consult on methadone programs with Larry Brown, and, of course, catch up on old war stories with my buddy, Mike Walsh. For me, it is a very helpful meeting to be at this morning.

It is a pleasure to be here this morning on behalf of the Office of National Drug Control Policy. A drug-free workplace is an integral part of any comprehensive and successful national drug control strategy. David Mineta is the ONDCP Deputy Director for Demand Reduction. David chairs the Interagency Committee on the Federal Drug-Free Workplace. Unfortunately, David could not be with us this morning because of other travel commitments, but he sends his best and looks forward to hearing the results of this meeting. As we go about putting together the National Drug Control Strategy for 2011, I think it is important that we be mindful of the important role that drug testing and a drug-free workplace plays in our strategy developments.

I have taken on an interesting responsibility this year outside of work. I am teaching a course at American University Law School on drug policy in the law. It has been really a fascinating experience to do this. For the first few lectures of this semester, I have been discussing the history of drug control and the legal underpinnings of drug control. For this week's class, we will be talking about the cocaine crisis of the 1980's and the legal development that grew out of that. In preparing for this week's lecture, I was researching the Anti-Drug Abuse Acts of 1986 and 1988, President Reagan's Executive Order and the establishment of the Federal Drug-Free Workplace in 1986, the subsequent Executive Order by the first President George Bush which established the Federal Drug-Free Workplace program. What struck me in reviewing these historical documents is the importance of Drug-Free Workplace and drug testing as common themes in our recent history in dealing with drug abuse in America. The role that DTAB plays, the role that we play collectively on this issue, is vitally important to how we approach the problems of drug abuse and its consequences in our nation.

It has been my pleasure as a member of the staff at ONDCP to work with SAMHSA's Drug-Free Workplace Program since its creation. I have been in this field about 30 years, and I believe the Drug-Free Workplace Program at SAMHSA has made an incredible contribution to our efforts over the years. The Drug-Free Workplace Program and the DTAB have made invaluable contributions to making our nation healthier and safer and to making America's workplaces healthier and safer. It is important to build on this progress, to advance our technologies, and to be on the cutting edge of policies and practice that reduce the consequences of drug use and drug abuse. Particularly important to our work in this current environment is the standardization of oral fluid testing methods.

ONDCP Director Gil Kerlikowske has made the reduction of incidence of drugged driving a key initiative of ONDCP and the National Drug Control Strategy. Looking at some of the data, research shows that drugged driving poses a significant threat to public safety. One in three drivers with known drug test results who were killed in 2009 tested positive for drugs. One in eight nighttime drivers tested positive for an illicit drug in a survey conducted within the last three years by the National Highway Traffic Safety Administration (NHTSA).

According to the Monitoring the Future Study, (MTF), last year approximately one in eight high school seniors reported that in the two weeks prior to the survey, they had driven after smoking marijuana.

This is a significant issue. It is an issue that Director Kerlikowske has focused on. The Obama Administration has set a goal of reducing the prevalence of drugged driving by ten percent by 2015. We have taken on this responsibility. We have accepted this assignment to develop policies, to build programs, to build an infrastructure with state and local governments, to work with our law enforcement agencies, and to help our treatment providers to figure out how we can respond in a comprehensive way to the problem of drugged driving. In addition to the drugged driving laws at the state level and the prevention and education programs directed at drugged driving, it is equally important to standardize oral fluid testing in drug testing labs as part of our efforts to detect the presence of drug use by drivers. A corollary to this is the development of scientifically viable roadside testing devices that can test for the presence of drugs in a uniform and scientifically agreed upon and viable manner.

This is a big part of our responsibility, and we look forward to the work of the DTAB and the Division of Workplace Division Programs, working in partnership with ONDCP and our other federal colleagues, including the Department of Transportation to really pull this initiative together. The refinement of oral fluid testing can advance our efforts to combat drugged driving, as well as bring useful tools to our overall goal of reducing drug use in the workplace. ONDCP looks forward to working with all of you in this effort. It is my pleasure to be with you today. Thank you so much.

Dr. Cook: We are ahead of schedule, and so, we will begin the afternoon session. At this point, I welcome Jim Swart of the Department of Transportation to provide his federal update.

Federal Drug Testing Updates

DOT Drug Testing Update

Mr. Swart: First of all, welcome everyone to the DTAB meeting. I appreciate the interest that HHS and the Office of National Drug Control Policy have for the DOT program, as well as for our working relationship. On behalf of the Secretary of Transportation, we are pleased at DOT to be part of the DTAB and pleased, this morning, to be able to provide the DOT update. Secretary Ray LaHood supports the DTAB efforts. The Secretary has also shown support for the transportation industry's programs that the DOT and U.S. Coast Guard colleagues manage across the transportation system. The Secretary believes that this program is the cornerstone of safety at the DOT. He also supports the components of this drug-free workplace program, which includes the education, testing, and treatment for those who test positive.

My office has a myriad of missions at DOT. We work with all of our DOT agencies and advise the Secretary and those agency administrators on national and international levels and issues. For example, for the medical marijuana, we work closely with all of our DOT partners, as well as with ONDCP and HHS, to develop our position on that issue. We have worked with Federal Motor Carrier Safety Administration on the drug and alcohol issues within the industries, the Mexican and the Canadian issues, the FFA with Nigerian aviation, and the pipeline community on the hazmat materials of methamphetamine laboratories. We also have worked with the FTA and the Coast Guard on post-accident testing scenarios, as well as the FRA and the HHS on suicide prevention. We attend training and conferences. We prepare all of our recommendations and guidelines in a plain language format.

At DOT, safety and security of the traveling public are imperative. We are a demand reduction program, which is implemented in conjunction with the President's Strategy on National Drug Control. We are a demand reduction effort, and as such we also want to reduce alcohol misuse in the transportation industries for obvious reasons.

We totally believe that prevention and treatment are key components to any of our programs. Therefore, we have successful compliance with treatment for anyone who tests positive. All drug-positive donors must accept substance abuse treatment before entering back into the workplace.

In addition to the safety and security, we ensure the fairness and the integrity of the testing program. We ensure that the testing is accurate, scientifically suitable, and forensically sound. That is also a mission for DTAB, we believe.

We have to balance privacy/confidentiality with our safety mission at DOT. This program has due process. We use HHS-certified laboratories and evidential alcohol testing devices. We have medical review officers and substance abuse officers in place throughout our program. Of course, we have administrative law judges and arbitrators, who weigh in on whether or not proper decisions were made. So there is an entire gate-keeping effort within our program to ensure the integrity and the fairness of the program.

Our DOT agencies conduct inspections and audits. All the systems have to be auditable and reviewable by the DOT agencies. In terms of the fairness and the integrity of the program, everything is in fairly simple language and thus easy to understand by employers, employees, and our inspection and audit teams.

We have a long and storied program history. Yes, there are war stories that many of us share through the years. The Omnibus Transportation Employee Testing Act of 1991 will celebrate this October its 20th anniversary. This Act was the triggering mechanism for the program to come into its own. Throughout the history of the program, we have had Supreme Court challenges that we have won. We have had district court challenges as recently as two years ago that we have won. The most recent decision, which we won unanimously, was for direct observation on all follow-up and return-to-duty tests. Thus, this program has a basis in legal jurisdiction. We are a federal program, and everything we do has to pass federal court muster. We try to harmonize on regulations, as in the October 1st harmonization with HHS on laboratory issues.

This is our family portrait gallery. DOT is above ground, on the ground, underground, and on our nation's waterways. Here is what we do, and all of us are DOT.

For our program, there are seven different regulations. Any time a regulation is prepared, it is vetted by seven policy offices and at least seven attorneys, even before we disseminate it within the DOT. The DOT agency regulations are the who, what, where, when, and why of testing. 49 CFR Part 40, which is the Office of the Secretary and my office's regulation, addresses how this happens. We strive for a one DOT approach for collections, for the laboratory tests, for medical review officers and how they operate, for the alcohol testing program, for the substance abuse professional process, for evaluating the treatment and/or education that an individual may need to address his/her substance abuse problem, and for the records and confidentiality of the drug and alcohol testing.
The employees of the various industries that we regulate under this program include pilots, truck drivers, subway operators, ship captains, pipeline controllers, airline mechanics, locomotive engineers, bus drivers, armed security personnel, among others. The DOT program has a great number of folks out there every day, day and night, 24/7, who can impact on the safety and security of the traveling public.

When a situation occurs where we do have calamities, either on the road or in the air, and whether or not those are drug and alcohol-related, people generally find out about it. The DOT conducts the

lion's share of federal testing at the HHS-certified laboratories. So what the DTAB recommends here will be vitality important to our program and to the DOT agencies, as well.

The drug testing data since 2005 indicates that laboratory positive results are on the decline. That is good news. We have seen within the past year and a half that amphetamines have nudged above cocaine for the first time in history. But marijuana is the most prevalent, and rising, drug that is used, which is consistent with the ONDCP data as well.

We have implemented new testing procedures. Along with HHS, we have lowered the cutoff levels for cocaine and amphetamine. We have eliminated the initial test for morphine as a means to obtain 6-AM or heroin positives. By the end of the month, we will have three months worth of data that will be a compared to the last six months prior to the rule's implementing. Thus we can assess the impact of 6-AM screening and confirmation and the impact of lowering the cutoffs for cocaine and amphetamine. We are looking forward to inspecting the data that the laboratories have for the past six months of 2010. We are also testing for MDMA. I believe the data and statistics from ONDCP and others will show that it is not just a club drug anymore. As we hire people, especially young people, in the transportation industries, I think we are going to see more MDMA.

Everybody is interested in the immediate future of the DOT program, and so we will go over these with you. There are some serious issues regarding prescription medication use which is reflected in ONDCP, our own testing programs, the DAWN data, and others. We are interested in the prescription medications that are used frequently with no legal basis, meaning that person does not have a legitimate prescription for it. We are also interested in looking within the DOT at those DOT agencies who have medical standards to learn where licit use of medications can cause impairment, and thus, must be assessed in terms of medical qualifications.

We are also very interested in the DTAB focusing on alternative specimen testing. In this particular session DTAB will be looking at oral fluid testing. Ed Jurith did mention that oral fluid is a key component for the Office of National Control Strategy. It is also a key component for the DOT. We want to ensure that any alternative specimen testing has the forensic science in place, has regulations in place for its use, and that just like we passed Supreme Court and district court muster in other parts of our program, that this one hits the mark, as well.

Looking at medical marijuana issues, we were heartened when many of the proposals for recreational use are defeated. We have a position on medical marijuana related to use of it by transportation employees in which we stated simply do not use it; you cannot use it. You will be found positive if you test positive for it.

We are also interested in violation databases. The Federal Motor Carrier Safety Administration is developing a database of employee violations, similar to the ones that the Coast Guard has for mariners and that FAA has for pilots. We are also working on holding service agents accountable for the work they do for the DOT as well.

Finally, we fully support the DTAB efforts, and we are really pleased to be part of the DTAB. We are really pleased that we are reconvening the meetings and very pleased to be here today.

The DOT program managers are Jim Keenen of FMCSA, the Bob Schoening of the Coast Guard, Lamar Allen of the Federal Railroad Administration, Rafael Ramos of the FAA, Stan Kastanas of the Pipeline and Hazardous Materials Administration, and Jerry Powers of the FTA. We also have the FMCSA, the Federal Motor Carrier Medical folks, a program operated by Maggi Gunnels, and Benice

Lester in the audience. We are a one DOT effort, and we involve as many people in the culmination and in creation of our regulations as possible. What the DTAB meeting does is give voice to those folks within DOT.

I have a small, but energetic and innovative staff. Patrice Kelly is our Deputy Director, Bob Ashby is our attorney since the dawn of the program, Mark Snider, Bohdan Baczara, Cindy Ingrao, Yale Caplan is our Laboratory Consultant, John Sheridan is our consultant for statistics, and our administrative staff, whom we could not live without, are Vicki Bellet and Maria Lofton.

Finally, this is our website which we hope that everyone is familiar with. We think collaboration is important. We believe our website is very user friendly where answers are easily obtained on many issues related to drug and alcohol DOT program matters. Please sign up for our list serve so you can receive messages from us on a periodic basis.

In conclusion we believe our efforts at DOT help make the transportation industry safer. We join forces with the Office of National Drug Control Policy in seeing that decreasing the demand for drugs and enhancing our treatment efforts makes our communities better. We are pleased to be part of DTAB and pleased that the DTAB is being regenerated and revitalized. We look forward to your involvement with the program. Thank you very much.

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

Mr. Swart: Thank you.

Dr. Cook: I want to introduce Hyden Shen, who will be providing an update on the Federal Drug-Free Workplace Programs.

Federal Drug-Free Workplace Programs

Mr. Shen: Good afternoon. I will be providing a broad overview of the Drug-Free Workplace Program to give you a better understanding of why we have the DTAB and why we do drug testing.

The program has been in existence for 20 plus years. There are currently three guiding principles that serve as the basic foundation for the Drug-Free Workplace Program. The first one is the Executive Order 12564, the second one is Public Law 100-71, and the third one is the Mandatory Guidelines. The Executive Order was signed September 15, 1986 by then President Reagan who stated “the Federal government, as the largest employer in the nation, can and should show the way towards achieving a drug-free workplace through a program designed to offer drug users a helping hand and at the same time, demonstrating to drug users that drugs will not be tolerated in the federal workplace.” What the Executive Order did in 1986 was to direct agency heads to establish a specific program that had specific policies and procedures for a drug-free workplace. It also mandated the creation of an employee assistance program so that individual employees could help themselves and their families. The other components of the Executive Order that were mandated were training for supervisors and their employees on a drug-free workplace and the creation of a drug testing program or a deterrent program for individuals in sensitive positions or for those individuals who wanted to voluntarily participate. It also directed the agency heads to identify specific individuals that we designate as testing designated positions. These individuals work in public health, public safety, or national security positions where a momentary lapse in attention could result in consequences that could not be remediated by the administrative process.

The second component that serves as the basic foundation for the Drug-Free Workplace is Executive Order 100-71. In 1986, the agencies came together to develop a template plan to ensure consistency throughout the program and to put into place specific guidelines. The Executive Order required two key components. First, without a plan certified by the HHS Secretary and a report to Congress, the agencies were not allowed to use appropriated funds for federal drug testing. The second part of the public law was the creation or the designation that HHS should develop mandatory guidelines. The Mandatory Guidelines established laboratory procedures, technologies, a chain of custody, and lab certification standards and procedures, and specified the drugs for which employees may be tested. On October 1, 2010, the new revisions to the Mandatory Guidelines went into place. Throughout the 20 plus years of the program, the Mandatory Guidelines have been seen as the gold standard in workplace testing.

Ed mentioned this morning that the Drug-Free Workplace Program has been in existence since 1986. The Anti-Drug Abuse Act of 1988 established the National Office of Drug Control Policy. In 1991, the White House designated the ONDCP as the overall lead for the Federal Drug-Free Workplace Program and Chair of the Interagency Coordinating Group Executive Committee. The Committee is comprised of representatives from the Department of Health and Human Services, the Department of Justice, and the Office of Personnel Management and is chaired by the Office of National Drug Control Policy. On behalf of ONDCP, we staff this Committee and we staff the program in carrying out the specific policies and procedures.

Thank you.

Dr. Cook: Do any members of the Board have a question for Hyden?

We just received notification that the Federal government will be closing two hours early today. Thus, we will break for 20 minutes for lunch and then we will reconvene.

For those of you in the audience on site, your only lunch option may be to try the café, which is outside this conference room and down the hall to your right. For the DTAB members, we will meet back in the library on the second floor. We will return in 20 minutes at 12:20 PM.

(Break)

Dr. Cook: I would like to call the next open session of the Drug Testing Advisory Board to order. I would like to introduce Colonel Tim Lyons of the Department of Defense, who will be providing Federal drug testing updates for the DoD.

DoD Drug Testing Update

COL Lyons: Thank you very much for having me. It has been several years since I was last here. My last time I gave an update on the Department of Defense and our approach to opiate testing, which I will also talk a little about today. Most of my presentation will be an update. My name is Tim Lyons. I work with the Armed Forces Medical Examiner, which is located about a mile away. We were formerly part of the Armed Forces Institute of Pathology (AFIP), but since AFIP was disestablished and closed, we are now separate entity and fall under the Medical Research Command located at Fort Detrick. Captain Kevin Klette is the Director of the Drug Testing Program for the Department of Defense. He could not be here today because he is conducting an inspection at our Navy lab in Jacksonville.

I will begin with a historical perspective from the last 20 plus years of what we test for in the

Department of Defense. Notice the similarities with the civilian program. We do test for more drugs than the civilian program. I want to draw attention to the more recent changes that we have had. In 2004, we started screening specifically for 6-AM. Prior to that, we were detecting 6-AM through our opiate screening followed by our opiate confirmation for codeine and morphine. Then we would do a 6-AM confirmation. Several years ago, we started using a 6-AM kit that detects 6-AM. We do 100 percent testing for 6-AM.

Soon after that, we dropped barbiturates from our testing panel. In 2005, we added oxycodone/oxymorphone, which are currently pulse tested at a rate of 20 percent of the specimens selected randomly. I will discuss our plans are for the future for oxy- and hydrocodone. At about the same timeframe, we dropped LSD from our test panel primarily because the positivity rate was low. In the 15 or so years that I have been in the program, I think I have gone to court on one LSD. We also just recently removed MDEA from the test panel, but we are still testing for MDMA and MDA. I will discuss our future plans for modifications to our test panel as I continue through the presentation.

Here is what we currently test. The ones marked in black are those for which we do 100 percent screening. Testing for marijuana, cocaine, and amphetamines are by regulation, that is, every specimen that is sent to one of our six laboratories must be, by regulation, tested for those three analytes. The designer amphetamines and the 6-AM are tested per policy, which requires 100 percent testing. There is some wiggle room if we wanted to drop or reduce testing. Since the first three drugs are by regulation, it would take a change in the Federal law or regulation to change that. The ones in red (oxycodone, oxymorphone, codeine, morphine, and PCP) are pulse-tested drugs, meaning these drugs are pulse-tested at a target rate of 20 percent. I recently made a recommendation to drop the PCP because we do not have any positives for PCP whatsoever. The only positives received in our laboratories are all related to post-mortem cases or the testing we perform for Baltimore and Washington, DC. In our military population, we do not see PCP.

The six laboratories are limited to those analytes. If there is any testing that has to be done beyond that then those specimens, they are forwarded to our toxicology lab or the medical examiner where we can test for just about anything out there, from prescription drugs to synthetic cannabinoids. All special testing, including oral fluid, must come to our laboratory because the six drug labs do not have the testing capability.

Another small part of our program is steroid testing. For steroids, we have a contract with the UCLA laboratory for steroid testing. We test about 400 specimens a year for the whole Department of Defense, which is very small when you compare to the six million specimens in our random program. These are just probable cause or investigative specimens. We have a very high positive rate, which means that the Commanders are pretty good at identifying people who are using steroids. Thus, we are not spending too much money testing specimens for steroids that turn out to be negative. Few of these actually proceed to litigation for many different reasons. Most are related to the dietary supplements that are available such as the precursor hormones.

Here are our cutoffs. Once again, you will see some similarities and some differences. For those of you that have been in the program for a while, you know that these differences have existed for quite a while. We have actually converged with some of the analytes as far as our cutoffs, but we have also moved farther away in some, such as the opiates, for example. The most recent change was with the amphetamines. The confirmation cutoff for amphetamine and methamphetamine was at 500, which was lowered about three or four years ago to 100.

In our laboratory, we conduct prevalence tests for the program as a whole. For prevalence testing, we

randomly select specimens that screened negative at the laboratories and test those specimens for other analytes that are not currently part of our program. For example, since we dropped LSD from our testing battery, we now are obligated every two years to do a prevalence test to determine if the usage of LSD has returned or if there may be a reason to test for it. We also have done prevalence test for other drugs, such as prescription drugs, including salosin. This is a list of some of the prevalence tests that have been done in recent history, with some drugs done more than once. The most recent prevalence study we did was in March 2009 when we tested about 15,000 random specimens for the benzos, hydrocodone, LSD, and methadone to determine the positivity rate. By our regulation, if we have a positivity rate that exceeds 0.25 percent, then we have to consider adding that drug to the test program. I do not think it will be a surprise that there are two that exceeded that 0.25 percent by quite a bit, actually. Those two are the benzodiazepines and hydrocodone, which really did not surprise us because we have many young service members that are pretty banged up and are prescribed pain and/or sleep management-type drugs. Because of this, we have a very high prescription rate for hydrocodone and benzodiazepines that is reflected in those random samples. When we cross-reference with the prescription database to look at the valid prescriptions versus the individuals that are screening positive, about 80 percent of those drop out, meaning that 80 percent of them are due to a valid prescription. There are quite a few that did not have valid prescriptions, especially for hydrocodone. It is a true threat, at least for the DoD. As far as the DoD is concerned, hydrocodone is definitely a threat for our readiness and our safety. With that, I will brief at the end with some of our plans for hydrocodone testing in the future. We conduct prevalence studies to get a pulse on what is going on out in our testing population. We do them about every two years, and we vary what we test for, depending on what we think a threat may be.

Here are some of the trends that we see, not only with prevalence testing, but in our laboratory data as well. As I mentioned, we have six different laboratories: the Navy with three, the Army with two, and the Air Force with one. On average, we test about six million specimens per year between those six laboratories. These are some of the trends we have seen in recent history in the data. The big change in the last couple of years deals with the amphetamine class of drugs. Historically, the majority of our amph positives were all d-meth with very few that was amphetamine only. That has changed dramatically. Now, when I do inspections, such as the recent one at the Tripler inspection in Hawaii and the Brooks lab in San Antonio before that, I have to really struggle to find a d-methamphetamine because they are all amphetamine-only positives. The majority of those are related to Adderall use, as far as we can tell. This is related to a change in the population. For many, many years, we did not prescribe Adderall for our service members. We did not have many people on Adderall, period. But now, the kids that are entering the military are with valid prescriptions for Adderall. Since they enter the military on Adderall, that prescription use continues while they are in the military. This use is now triggering our amphetamine screening, which causes us to spend a lot of time confirming Adderall positives. Obviously, the intent of this screening test was to detect d-meth, which we are not seeing anymore.

Synthetic cannabinoids are in the media now. I receive about 20 calls a day and emails about spice from all around the world, from three star generals down to corporals. Our laboratory has had a method to detect synthetic cannabinoids for quite a while. This fall we received the standards for the metabolites, so now we can detect the synthetic cannabinoids in blood and urine as well as in post-mortem cases. Currently, we only handle investigative cases only. There is a big push from the field, including generals and the admirals, to start doing random testing for spice. Since there is no screening method, we do testing by LCMSMS; random testing is just not feasible. It would cost about 25 million dollars to test for spice on a random basis. Thus, we can only do is investigative cases to keep the costs down. Otherwise, I would be flooded with thousands of spice test requests a month. For commanders that do not like this approach and want to have their units tested, they are making

the decision to spend money and are sending their specimens out to contract labs, like NMS; it is costing them quite a bit of money.

Another designer drug is mephedrone. There is media hype about bath salts which contain mephedrone. We have detected mephedrone in some of our investigative and post-mortem cases. We are doing a prevalence study on mephedrone in some random units to determine if we have any mephedrone positives.

The last issue is the prescription drug abuse, which is our real threat to safety and readiness. On the post-mortem side, we do not get kids dying from spice but we definitely have kids dying from prescription drug overdoses every day. I am trying to stop and then redirect the train. If they want to throw money at drug testing, then that they should throw it at prescription drug use and not at spice. I have not had a lot of success yet. Next, I will describe our plan or our approach and our ideas on the prescription drug side. This is an adjunct to what I presented to DTAB two years ago when we had just started doing opiate testing. Currently, we perform an opiate screen for the codeine and morphine with confirmation of positives. We have a separate screen for oxycodone/oxymorphone in which we test only 20 percent of our specimens and follow with confirmation of positives. I have applied for funding which would allow us to increase oxycodone/oxymorphone screening up towards 50 percent or even higher.

Our plan for the hydrocodone/hydromorphone is dependent on our budget. With our current budget, we cannot afford to test for hydrocodone/hydromorphone because the positive rate is just too high. We would be doing as many or more confirm tests for hydrocodone as we do for THC. That would kill our labs without additional budget, additional instruments, and additional personnel. If we do get that money, our tentative plan is to start screening for hydrocodone/ hydromorphone later this year. Currently, there is not a kit that we can use specifically for hydrocodone/hydromorphone like we have for oxycodone. This would be nice because then you could go straight to confirmation with the positives. We use several opiate kits that have a high cross-reactivity for hydrocodone for screening. The ideal would be one screen that has high cross-reactivity for hydrocodone/hydromorphone. There are several screening kits out there that have very little cross-reactivity to hydrocodone so these screens would be used for codeine and the morphine. Basically, you will have three opiate screens in total: one for oxy, one for codeine/morphine, and one for hydrocodone. Confirmation testing would be done on the positives. This is our tentative plan right now.

With hydrocodone, there will be many positives. We have developed a pharmacy database which contains the valid prescriptions, which we can cross reference or integrate with our LIMS. When a service member is screened for hydrocodone and is positive, our LIMS will query the pharmacy database to determine if that individual has a valid prescription; if so, we would not waste the time and energy to confirm use pursuant to a valid prescription. However, if the positive screening result is found not to be related to a valid prescription after querying the pharmacy database, that specimen would proceed forward for confirmation because that would be considered a valid positive or a true positive. In this way, we would keep our numbers down and not crush the labs with high positive rates. This is the plan that we hope to be moving forward with by this summer. The labs are now validating their confirmation methods. We have several different options. One is to perform one confirmation for all of the opiates, that is, detecting all the opiates in one extraction with one confirmation with GCMS; this is the method we are recommending because it is our current procedure and it works pretty well. There are other options, as well.

If we go procure the funding, the other aggressive thing that we will do is to add benzodiazepines to our random testing in late 2011 or early 2012. The approach would be use one of the available benzo

screening kits. We have not determined which one is the best for us yet. Our panel would include about five benzos, but we haven't determined which five, though we do have a rough idea. At that time, we would begin random screening for the benzodiazepines.

This is a pretty aggressive stance which will add a lot of work for our laboratories. We have identified a true threat through our prevalence studies from hydrocodones and benzodiazepines, and with that we have an obligation to ensure our readiness and safety by bringing those methods online, even though they are very difficult and will cause a lot of issues for the labs. If we ignore those threats and there is a plane crash that kills 50 people because somebody was on hydrocodone, we will be asked why aren't you testing for that. We can't say that we knew it was problem, but it was too hard to do.

Do you have any questions about our program or what our approaches are? Yes, sir?

Dr. Brown: In the interest of time, I hope that we will have an opportunity to dialogue with some of the presenters because I have personally been withholding some of my questions. I have questions pertaining to the steroids and the prescription drug abuse. For the steroids, what is the rationale for your investigative approach? What type of manifestations cause a concern for the military?

COL Lyons: It is a good question. Our approach is totally different because we view it as more of a health issue and not a safety and readiness issue. This is in contrast to most of the drugs we test for within the Department of Defense which are drugs that could impair an individual and thus cause problems with safety and readiness. Steroids are the exception. I am not worried about somebody on steroids with a weapon, but I am worried about his health. The reason we started doing steroid testing in 1999 was because once it became a scheduled drug, an illegal drug, and we could not ignore it. But we approach it more as a health issue and not a safety issue.

Dr. Brown: Regarding prescription drug abuse, I am interested in the guidance that you give to your medical review officers when there is legitimate use and a valid prescription. Could a military person get a prescription in January and continue to use it in June?

COL Lyons: Another great question. That is a big problem, and discussions have been held concerning what is a valid prescription with MROs and also at meetings like SOFT. Right now, I think it is going to be within several months is a valid prescription.

Obviously, we have lots of hurt kids that are on lots of chronic pain management. We receive post-mortem and investigative cases where people were on four or five different opiates at the same time and have been for four to six months. How you define a valid prescription is something we have not totally nailed down yet, but we will just make the decision. We may pick three months or we may six months, and then we will just go with that.

Ms. Farrell: Tim, I have a question. When you test for benzodiazepines, will you take the same approach with that class of drugs as you are taking with the hydrocodone where you will compare the screen results to the pharmacy database and then not confirm those?

COL Lyons: That is what we like to do, except with the benzos, it is not as clear cut as it is with the opiates because of all of the metabolites which will require a little bit more thinking. We would hope to use it in some fashion to minimize what we confirm. Another issue is the whole slew of benzodiazepines out there, and it is hard to make a direct correlation with a prescription. We will have to think about that one a little bit. Anything else?

Dr. Cook: Thank you, Tim. I want to introduce Charles LoDico, forensic toxicologist within Division of Workplace Programs.

Highlighted Changes: The Mandatory Guidelines for Federal Workplace Testing Programs (73 FR 75122, November 25, 2008)

Mr. LoDico: Thank you, Janine. Welcome to a DTAB meeting that hopefully will produce some very valuable information sharing and will propel us into the next dawn.

Today I will give two presentations. My first one is going to be on the Highlighted Changes: The Mandatory Guidelines of Federal Workplace Drug Testing Programs that was published in the federal register on November 25, 2008 at Volume 73 starting on page 75122. This presentation is focused on the substantive changes made in the newest Mandatory Guidelines.

Regarding the historical perspective of the Guidelines, the initial publication was in 1988. The first revision to the Mandatory Guidelines occurred in 1994 when there was a change in the volume of specimen collection from 60 mL to 30 mL for a single collection. Also, in the collection of the urine sample, there was an option for a split specimen. Also in that revision, we reduced the cutoff concentration of marijuana metabolite initial screen from 100 nanograms to 50 nanograms per mL. In 1997, we did the reverse, based on decisions and DTAB Board meetings, and raised the cutoff concentrations for both the initial screening and confirmation for opiates from 300 nanograms per mL to 2000 nanograms per mL for morphine and codeine. We also required that 6-acetylmorphine, which is a marker for heroin, be tested when the morphine concentration in confirmation was 2000 nanograms per mL or greater. In the fourth revision, which was published November 13, 1998, implementation was delayed due to problems with the availability of the screening kit from the manufacturers. The last significant revision occurred in 2004, where we codified the requirement for every specimen to receive validity testing. In November 25, 2008, we revised the Guidelines again. With that revision, there were three effective Federal Registered Notices that impacted that original publication. Immediately after the Guidelines were published in November 25, 2008, we discovered a misprint of the effective date, so we did a corrective publication, which was published on December 10, 2008. There were elements that prevented us from meeting the effective date of May 1, 2010. Through our Office of General Council, the implementation was postponed to October 1, 2010 with the publication on April 30, 2010, just one day before the effective data was to be in place.

In the rest of my presentation, I will discuss the changes that were made in that particular document. HHS has thoroughly restructured the 2008 Mandatory Guidelines into an easy to read, plain language format with subparts organized by subject matter areas. In contrast to the old Mandatory Guidelines, the text is dividing into many more sections with fewer paragraphs to make it easier to find regulatory provisions. It uses a question and answer format directed at the reader, and when appropriate, uses personal pronouns. Generally, pronouns refer to who/what must perform a required action. This regulatory style arose out of our goal to harmonize the Guidelines with our sister agency, the Department of Transportation, DOT, wherever possible. It was DOT's 2000 49 CFR part 40 that HHS used to template the revision to the Guidelines. DOT received a plain language award known as the No Gobbledygook Award from former Vice President Gore's National Partnership for Reinventing Government in recognition of improved clarity of the regulation. Thank you, DOT, for setting the standards by which HHS writes its Mandatory Guidelines. Here's to you, Jim.

One of the major changes in this document was that we revised the requirements for specimen collection. We also revised standards for collectors and collection sites. Another major part of the Guidelines was to revise the laboratory testing requirements by adding new analytes and lowering

cutoffs. We allowed new technologies for confirmatory drug testing. We also added a new type of testing facility known as an Instrumented Initial Test facility (IITF). We also revised the qualifications for the Medical Review Officers. And lastly, we revised the Federal Custody and Control Form.

Why did it take so long between the publish date and the implementation date? First, manufacturers of immunoassay test kits had to modify their kits to ensure compliance with any applicable statutory and regulatory requirements before commercialization of the kits. Secondly, HHS certified the laboratories to validate and implement the new immunoassay test kits. Thirdly, the NLCP, which is a contractor to the Division Workplace Programs, had to challenge the certified laboratories with performance testing samples to ensure that test kits and test results satisfy the required performance criteria. Lastly, other Federal agencies and the various industries needed time to implement new and revised procedures that were in compliance.

I will now focus some of the Guideline changes for the collectors and collection site. This is a schematic diagram of the process for specimen collection. Typically, the donor goes to the collection site and provides a specimen. There are specific quality assurances, including the collector's qualification, a designation of a collection site, the security element in that collection site, the chain of custody which documents the individuals and the manner in which the test was performed, the limited access to authorized personnel, the privacy that is given to the donor so that they can produce a specimen that does not violate their privacy, the integrity and the identity of the specimen beginning with collector review of the temperature indicator on the collection container, and the manner in which the sample has been packaged and transported to the testing facility, whether it be the laboratory or the Instrumented Initial test Facility.

The Urine Specimen Collection Handbook was revised for the 2008 Mandatory Guidelines. This document can be found on our Division of Workplace Program website. This document provides additional guidance to the specimen collector in fulfilling his or her function in performance of the duties specified under the Certified Federal Agency Plans and the requirements of the Mandatory Guidelines for Federal Workplace Drug Testing Programs. This supplemental document supports some of the changes in the Guidelines that I will address. The specimen collection subparts include Subpart B, which addresses specimens; Subpart D, which addresses collectors; Subpart E addresses the collection site; Subpart F addresses the Federal Custody and Control Form; and Subparts G and H address the collection container and the collection procedure, respectively.

Under the Subpart B - Specimens, the first questions is what type of specimen will be collected? This has not changed; urine is the only specimen. In section 2.2, the reasons for testing are provided: applicant pre-employment, random, reasonable suspicion, post-accident, return-for-duty, or follow-up. Section 2.3, how is each specimen collected, is new in that it requires that urine be collected as a split specimen. In the previous Guidelines, the collection was for a single specimen and the split specimen was optional. All collections must have a split section in the Federal program. Sections 2.4 and 2.5 discuss the manner in which the collector splits the specimen that is collected. Typically, 45 mL of specimen is collected, with 30 mL split into the primary bottle and 15 mL into the B bottle.

Under Subpart D, the Collectors, we also have different questions and new sections. In the previous Guidelines, this information would not be found in the body of the Mandatory Guidelines, but would be as part of the supplemental guidance document, which would either be the Collector's Handbook or, in the other instance, the MRO Handbook. This change was to harmonize more with the CFR part 40. The new questions in this section are what are the requirements to be a collector, what are the requirements to be a trainer for collectors, and what must a Federal agency do before an individual is permitted to collect a specimen. This last question only affects the Federal agencies that now must

review a collector's qualifications and does not relate to a DOT collection. Now we are set in a regulatory requirement as to how do we identify what a trained collector is. Again, these are all codified, as opposed to supporting through a supplemental guidance document.

The next areas of the Guidelines that affect collection are Subpart E, which is a collection site, and Subpart F, which is a Federal Custody and Control Form. All Subpart E - Collection Site questions are new, including where can a collection take place, what are the requirements for a collection site, how long are the collection site records stored, and how does a collector ensure the security and integrity of a specimen at the collection site? Subpart F, the Federal Custody and Control Section, is very specific about what form is used for collecting a specimen. That form is the OMB-approved Federal Custody and Control Form that is currently in place today.

The Subpart G, whose information was previously found in supplements, discusses collection containers. This section is detail-oriented in discussing what a collection container is and the restrictions associated with the type of containers and bottles that can be used to collect urine.

The Subpart H - Collection Procedure provides very detailed information on the collection procedure.

Subpart K - Laboratory and Subpart L- IITF are new areas. This flow chart schematic depicts a full service urine drug testing laboratory from specimen receipt to final report.

The significant Guidelines changes in the laboratory testing include the requirement for two new initial drug test analytes: 6-acetylmorphine and methylenedioxymethamphetamine (MDMA) and its analogues MDA and MDEA. Under the new Guidelines, the initial testing of all specimens for 6-AM is required, regardless of confirmatory morphine concentration. For MDMA, the target analyte is used to screen for these specific analytes with the new confirmatory test analytes being MDMA, MDA, and MDEA. The drug test cutoffs were lowered for amphetamine to 500 ng/mL for the initial test cutoff and 250 ng/mL for the confirmatory test cutoff for both methamphetamine and amphetamine. The cocaine initial test cutoff was also lowered to 150 and confirmatory to 100 ng/mL. This table gives the drug cutoff concentration parameters. Everything marked in dark bold were changed in the testing of the specimen.

New confirmatory test technologies are a new provision. In the previous Guidelines, only GC/MS was required for confirmation. Because of new technologies, we included GC/MS/MS, LC/MS, and LC/MS/MS. The Federal law requires HHS to establish comprehensive standards for Federal drug testing programs, to include requiring the use of the best available technology. This addition shows our commitment.

For the Instrumented Initial Test Facility performs only initial drug tests, including test to determine specimen validity. They can only report negative, negative and dilute, and rejected. The specimens must be sent to a certified lab if the specimen may be drug positive, adulterated, substituted, or invalid. The IITF must be certified under HHS to perform Federal employee drug testing. Because of DOT's rule prohibiting use of the IITF, this only applies to the Federal employee drug testing. This schematic depicts how, typically, the specimen is generated, starting with the donor and the collector, received at an IITF, and finally reported only for negative, rejected, or testing or negative-dilute. If it needs additional testing, the specimen is sent to the lab and then those are reported to the MRO.

Under Subpart M – MRO, there are a host of new questions. The most significant is section 13.1 - who may serve as an MRO. Commander Sean Belouin will discuss this in more detail.

On our website are our MRO documents, including the list of HHS- approved entities that certify MROs and the 2010 MRO's Case Studies. These studies allow the MROs to study cases similar to theirs and learn our rationale on how they should be reported out to the employer.

Subpart N, which is a split specimen test, describes the details of how a split specimen is handled. This was not described in the previous Guidelines.

Subpart O discusses specimen rejection criteria. This was previously found in the supplemental MRO handout, and now it is part of the Guidelines.

Changes to the Federal Custody and Control Form include its use by the IITFs in addition to the labs, the designation of the Federal testing authority under which the specimen was collected, the new drug analytes (MDMA, MDA, and MDEA), and the revised MRO reporting section on Copy 2 for primary specimens. This is the currently available Federal Custody Control Form. This is the notice of the OMB action for the 2010 Federal Custody and Control Form, which has an expiration date of 2013. These two sites have example of the CCF and also guidance about the use of the form. There is a transition time of a year for the old 2000 form, which is still available at many collection sites. Effective October 1, 2011, the use of the 2000 CCF will be considered a correctable flaw it received at the lab. On the DWP website are the Federal Custody and Control documents.

The slide depicts the current and future activities concerning alternative specimens from the 2008 Guidelines. Ron Flegel will provide more updates on that issue.

Lastly, here is our website address. We encourage you to view it.

Dr. Cook: Do any members of the Drug Testing Board have any questions for Charlie? Thanks, Charlie. I want to remind everyone that we are speeding up the agenda because impending storm number two for today, as well as the fact that the Federal government will be closing two hours early.

Next, I want to introduce Wayne Chalk of the NRC, who will be discussing the updates to his Fitness for Duty Program.

Federal Drug Testing Updates

NRC 10 CFR Part 26 Fitness for Duty Program

Mr. Chalk: Good afternoon. My name is Wayne Chalk. I am from the U.S. Nuclear Regulatory Commission. Thank you very much for having me here today to speak to you about Fitness for Duty in the Regulatory Programs for this country's nuclear power.

My background is in physical security. I have 25 years experience between the military and the private sector working for a government contractor, and I have a little over two years with the NRC. I have no science background; my degrees are in English, History, and Industrial Security. So I apologize before I deliver my briefing because I do not have the background that those in this room have.

One good thing you need to know about me is I brief like I play golf. I'm not very good, but I am fast. I will talk to you today about the background of our program, the mission of the NRC, how we value safety, the Fitness for Duty Program, and why we care about safety and security.

The NRC's mission is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of the public health and safety, to promote the common defense and security, and to protect the environment. The most important words out of that statement are the protection of public health and safety. If you hear anything about the NRC, it is usually in conjunction with those words. This is what we are most concerned about, and everything else falls under that arena. Our rule that governs the NRC Fitness for Duty Program is Part 26, published March 31, 2008.

Next, I want to discuss the safety and security for our programs and our facilities. This map shows where the nuclear power reactors are located in the United States, with a heavy concentration east of the Mississippi. There are 104 reactors at 65 sites or plants. Besides our operating plants, we have a nuclear renaissance with the many new applications for new reactor construction under consideration right now - 18 to be exact. This slide just shows what the different designs are and in what part of the country they are in. There is large concentration in the Southeast United States. The AP 1000s are the design that is furthest along in the application process.

Safety and fitness for duty goes hand in hand in our industry. These are some of the items that we use for defense and depth -- the people and the safety-related structure systems and components. We have redundancies in these SSCs. We have medical and access requirements for our operators. In addition to that, we have physical protection, including detection aids and communication and response.

There are four components that maintain fitness for duty: drug and alcohol compliance as per Fitness for Duty part 26, background checks as part of our access authorization program, training and behavioral observation for the human factors interaction, and fatigue management as per 10 CFR part 26.

The photograph depicts our composite adversary force that we use in our security force on force drills. The left side photograph is of a control room with control room operators.

This slide shows why we are concerned about safety and security. At Chernobyl, the worst possible scenario involving a nuclear power plant happened. You can see it is April 25, 1986; you can see the statistics and the data. This data is updated continuously; as time goes by, the more they find.

Paul Harris is our Senior Program Manager. Our Branch Chief is Craig Erlanger. Our branch is the Office of Nuclear Security and Incident Response, Division of Security Policy, Integrated Security Coordination and Policy Branch. Are there any questions? Thank you.

Dr. Cook: Thank you, Wayne. I want to introduce Commander Sean Belouin of the Division of Workplace Programs who will update you on the Medical Review Officer Certification process.

Medical Review Officer (MRO) Certification

CDR Belouin: Good morning. I am Commander Sean Belouin with the Division of Workplace Programs at SAMHSA.I will address some key Mandatory Guidelines changes regarding the certification of MROs and the approval of MRO training and certification organizations by HHS.
As you know, an MRO is a licensed physician who must possess either a MD or a D.O. degree. He or she must possess knowledge regarding the pharmacology and toxicology of illicit drugs and have completed specific training necessary to serve as an MRO. He or she must have satisfactorily passed an examination by a nationally-recognized organization that certifies MROs or subspecialty board for

physicians performing a review of Federal employee drug test results.

These entities and boards must have been approved by the Secretary for the Department of Health and Human Services. Regulations related to MROs are found in Section 13.1 through 13.9 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs. For this presentation, special focus is being placed on section 13.1.

MRO entities and boards for physicians performing reviews of Federal employee drug testing must be approved by the Secretary of HHS. As part of the revised Mandatory Guidelines that went into effect October 1st, all nationally-recognized MRO certifying entities and boards for physicians reviewing Federal employee drug tests must seek approval by the Secretary for certifying MROs who review Federal employee drug tests. The MRO certifying entities and subspecialty boards must submit to HHS for review their qualifications as an MRO certifying entity or subspecialty board. They must also submit a sample examination that would be required by physicians to pass as part of their MRO certification.

Based on an HHS annual objective review of each MRO certifying entity and subspecialty board's qualifications and content of their sample examination, the HHS Secretary will publish annually those entities and subspecialty boards that are approved to certify MROs for Federal employee drug tests. This review is completed with a recommendation submitted to the Secretary of HHS.

On December 8, 2010, the HHS Secretary approved the following MRO certifying organizations that offer both MRO training and certification through examination: the American Association of Medical Review Officers (AAMRO) and the Medical Review Officer Certification Council (MROCC). Additionally, the HHS Secretary approved the following MRO certifying organizations that offer just MRO training, but not the certification: the American College of Occupational and Environment Medicine (ACOEM) and the American Society of Addiction Medicine (ASAM). This training offered by ACOEM and ASAM can be used as a prerequisite for certification testing offered through either AAMRO or MROCC.

Moving forward, Federal agencies will need to ensure that MROs have been trained by one of the four organizations and certified by either AAMRO or MROCC. Here at DWP, we have begun the process, drafting a series of frequently asked guidance questions that will provide guidance to the MRO entities that train and/or certify MROs and the MROs, themselves, that review Federal agency donor specimen test results. We anticipate posting these guidance questions on our website in the very near future.

For complete information, refer to Subpart M - Medical Review Officer from the Mandatory Guidelines Sections 13.1-13.9 in the December 8, 2010, Federal Register Notice Volume 75, Number 235, which detail the HHS approval of MRO training and certification organizations. Links to these will also be posted on our website. Thank you.

Dr. Cook: Do any of the Board members have a question for Sean? Thank you, Sean. I forgot to mention that Sean's presentation, as well as the ones that Charlie and Ron are about to give, are issues that DTAB will evaluate in the future. We are presenting these three so that you are mentally prepared for them in the future.

I want to welcome Charlie LoDico back to the podium to give you an update about the Electronic Custody and Control Form.

Electronic Custody and Control Form (CCF)

Mr. LoDico: This presentation is focused on the Electronic Custody and Control Form, which is not currently offered in our Program. What prompted us to consider one? For our last Federal Custody and Control Form submission to OMB, OMB asked a pertinent question of what makes this document so valuable that it cannot be made into an electronic document. Their terms of clearance for the approval of the next CCF in 2013 include that the Agency shall provide a progress update on adoption of electronic forms in an effort to reduce burden. SAMHSA was encouraged to explore ways to convert the Federal Drug Custody and Control form into an electronic form. This is the mission that we have been given.

The November 17, 2009 Federal Register Notice, in which we published our proposed changes to the CCF, had a 60 day comment period. We received 161 responses from individual commenters and 427 letters with identical content. Comments were received from certified laboratories, third party administrators, collection sites MROs, printing firms, employers, health organizations, and interested individuals. The majority of the commenters supported the proposed changes to the federal CCF. A similar majority also commented on the desired availability of an on-demand CCF and provided the benefits associated with an on-demand CCF. I have listed seven true benefits of an electronic or on-demand CCF. Commenters said there are the problems with a pre-printed CCF.

We pursued the next step which was to evaluate the HHS current electronic document policies. To our surprise, there are two that are very noteworthy. One was from FDA: 21 CFR, Part 11 published in the Federal Register Volume 62. It provides the criteria under which FDA would consider electronic signatures to be equivalent to full handwritten signatures. The other significant electronic document policy from HHS was from the Office of the Secretary concerning adoption of national standards for safeguards to protect the confidentiality, integrity, and the availability of electronic protected health information.

I did a review of the Government Paperwork Elimination Act, which is OMB's charge to the Federal agencies to reduce the paperwork of new rules. It encourages Federal government to use a range of electronic signature alternatives. The Act specifically states that electronic records and the related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form.

There is a good foundation for regulatory support of an electronic document. The characteristics of trustworthy record include its reliability, authenticity, integrity, and usability.

Lastly, here are SAMHSA's objectives. SAMHSA will seek public comment specifically on the standards to be established concerning electronic signature, non-repudiation of an agreement for digital signatures, third party software for managing Federal CCF information, what is a unique specimen identification number, the legally-binding equivalent of traditional hand-written signatures in a forensic arena, the security of data transmission over telecommunications systems and networks, and the integrity of the document content.

It is hoped that through these objectives and through the Board's review and recommendation that we will have a process to write a Federal Register Notice, which will then allow the use of these electronic documents in our program. Thank you.

Dr. Cook: Do any Board members have any questions for Charlie? Thank you, Charlie. I would like to present Ron Flegel, a forensic toxicologist within the Division of Workplace Programs, who is going to

talk to you about alternative matrices.

Alternate Matrices

Mr. Flegel: Hi. I am Ron Flegel. I am the Government Project Officer over the NLCP program. Today I will talk to you about alternate matrices. I will specifically review for Board members what was published in 2004 and provide the main objectives of my talk today.

As stated in the 2008 MPR, alternate matrices will require further examination and additional studies. Since originally proposed in 2004, there has been a continued evolution of new forensic technologies and laboratory analysis. In the November 25, 2008 Federal Register Notice, significant issues were raised by Federal agencies during the review process concerning the use of alternate specimens, including hair, oral fluid, and sweat patch specimens, in Federal workplace drug testing programs. Because of these concerns, further examination and additional study and analysis are required.

The rejected specimen data from 2009 to May of 2010 shows that a volume of less than 30 mLs, which is considered quantity not sufficient (QNS), was 68 percent. Broken seals or evidence of tampering was 24 percent. The CCF missing the collector name and/or signature was six percent while an incorrect CCF was 1.5 percent.

The parameters for the development of the 2004 Guidelines are scientific acceptability, the court and legal acceptability, community acceptability, FDA approval, establishing cutoffs, the quality assurance and performance testing that NLCP provides, and the cost/benefit to the employers doing the drug testing.

Issues around reliable workplace drug testing programs, including collection site, donor, specimen, collection devices, collectors, transportation of specimens, etc., are an integral and important part of workplace drug testing programs.

This figure depicts the drug testing timeline profile of blood, oral fluid, urine, and hair. The issue is raised are these different matrices complementary or not complementary? It is a question that we have to look at.

The proposed specimens are listed here. For the 2004 proposed alternate matrices, we looked at the reasons for test, such as pre-employment, random, reasonable suspicion, return to day, and follow-up, and what primary specimen that we could use.

These were the proposed specimen amounts that were proposed: 100 mg hair, 2 mL neat specimen for oral fluid, FDA cleared “patch” worn for seven to 14 days, and 45 mL urine, with 30 mL in the primary and 15 mL in the split. The analytes and cutoffs that were proposed in 2004 for urine, hair (pg/mL), oral fluid, and sweat are listed here.

Also, in those Proposed Guidelines, we had the Point-of-Collection Test, which was a very key component for those alternate matrices. What is a POCT? It is an initial test conducted at the collection site. POCT devices can be non-instrumental and visually read or instrumented or visually read by the instrument. We have requirements for POCT devices, including FDA cleared and listed on the HHS Conforming Product List, which would be published in the Federal Register and on the HHS website. The specimen types proposed for testing using a POCT were oral fluid and urine.

These are some of the comments that were among the 285. It is important for the Board to review this

because this will lead us into tomorrow and our discussion about alternate matrices.

The definition of collection of oral fluid was previously defined as the fluid collected by insertion of an absorptive collector into the mouth. A neat specimen was proposed. The oral fluid specimen is comprised of several different components which differ to a great extent between the individuals. The collection of a neat specimen is not the best per one of the commenters.

Collection methods that we propose were spitting versus collection devices. These are original public comments received on this topic, which are also posted on our website. There were a number of comments addressing a lack of dignity, an increased collection time, biohazard, etc. Devices are becoming available that help in the area of specimen standardization and reliability and integrity. From 2004-2011, there has been a significant increase in the knowledge around specimen collection.

Commenter disagreements centered around the required volume of 2 mL of the specimen, neat versus collection devices, determination of the volume of collection and/or split specimens, and the method of splitting it into an A and B. At that time, determining the exact volume was difficult. It may be difficult to manipulate or split a viscous sample. Commenters requested specific guidance on how to mix and transfer oral fluid and recommended that HHS allow the use of two collection devices for a split oral fluid specimen collection.

Other comments concerned the examination of oral fluid and wait time around the collection process. The collector must confirm with the donor that the donor doesn't have anything in the mouth, especially adulteration products for the oral fluid collection that can be inserted in the mouth. Commenters both recommended and dismissed an observation period of varying lengths of time regardless of donor claims. Several commenters discussed the allowable reasons for testing using oral fluids. The proposed 2004 Guidelines required collection and testing of urine with each oral fluid sample which disputed based on scientific reasons, with comments received with and without the references. Several comments were submitted concerning the detection of marijuana. I think this is a valid concern based on a study which stated the detection of THCA in oral fluid is needed, preferably with negative ion LC/MS/MS. As Charlie spoke about earlier, the use of this new technology is permitted in the laboratories as of October 1.

Several commenters discussed oral fluid specimen validity and whether IgG is acceptable. They question the need for SVT testing. Testing oral fluid pH can be suborned with a commercially available lozenge which alters saliva pH. Again, there are a number of adulteration products out there. I have a display of multiple adulteration products for urine, oral fluid, sweat, etc. Commenters argued that the Guidelines do not explain the meaning, purpose, and rationale for IgG testing. The presence of IgG only proves that specimens contain proteins. Concentrations of IgG to indicate an undiluted specimen have not been established. All these comments must be considered by the Board as it reviews the science of oral fluid.

Hair was also proposed in the 2004 Guidelines. Commenters discussed the use of body hair and disagreed with limiting collection to head hair for the following reasons: collection of body hair is less invasive than observed urine collection and applying and removing the sweat patch, employers with existing programs do not get objections to the collection of body hair from their employees, and the fairness issue for women and men.

Hair color effect of on drug concentrations is another issue. Several papers were published since 2004 regarding that issue. Commenters disagreed on bias issues in hair, unless also discussing bias issues with urine, sweat, and oral fluids. I believe there will be challenges on the basis of racial bias

for that. Commenters suggested that melanin concentrations could be measured and drug concentrations in hair be normalized for melanin.

Hair contamination from environmental exposure was addressed in the preamble at the time. Comments were received around the metabolites of PCP and amphetamines. We have implemented MDMA, ecstasy, for urine. Second hand smoke is an issue with THC. The presence of cocaine metabolites in hair could be hydrolytic products derived from exogenously deposited cocaine. Comments were received on these environmental exposure issues.

Comments were received on the suggested 100 mg specimen amount. Some wanted more; some wanted less. Does it become a fairness issue of males versus females around how much you can collect? Commenters suggested maintaining the 100 mg size and then splitting that. Issues were raised with the collector assessment of proper amount and how the collector could determine the weight of the hair sample without something at the collection site to do that.

Regarding hair specimen validity testing, the question was raised whether SVT is needed since this is an observed collection. The 2004 proposed hair specimen validity testing were argued to be unrealistic. It was argued that trained collectors should be able to distinguish synthetic or substituted hair from real hair and thus eliminate the need for the validity tests listed in the Guidelines.

Commenters discussed the confirmatory tests cutoff concentrations around THCA. It is suggested that confirmatory test cutoff for THCA in hair be raised from the proposed concentration of 0.05 picograms to one.

Several commenters discussed the environmental exposure issues surrounding sweat. There was concern expressed over the possible environmental contamination of sweat patches. Suggestions included having the donor complete a questionnaire to reveal contamination concerns. There were privacy issues with the application and wearing a patch. Applying and removing a patch would require the same gender as the donor. Some commenters expressed concern over the stigma to employees in wearing a patch. Comments discussed the length of time to wear a patch. We proposed three to seven days. Studies indicate that the majority of drug appears within the first 24 hours. Commenters discussed sweat patch validity testing and the appropriateness of testing for lactic acid and other SVT issues. Comments suggested pH testing around the sweat patch.

We received comments about all matrices, including what analytes to test for, fairness to individuals tested using different matrices, drug detection times, the complementary nature of the matrices, and the relationship of cutoff values between matrices. There were expressed concerns that it was not equitable to test Federal employees using different matrices with different detection windows.

All issues that were raised are all issues that will have to be resolved.

Detailed guidance will have to be provided to Federal agencies on the selection of appropriate matrices, specifically, when a Federal agency would test what specimen. The collection procedures in the proposed Guidelines lack sufficient detail for all the different matrices. As Charlie had mentioned earlier, we have supplemental information on our website that deals with MROs and collection procedures, etc.

In closing, there are basically five things that I wanted to review for the Board. These included the review of the 2004 Proposed Mandatory Guidelines and the 285 public comments. Most of the Board is new to those, but maybe you have read the Alternate Matrices Proposed Guidelines. Additional

studies need to be undertaken for the alternate matrices. New forensic technologies have advanced the science greatly for alternate matrices. As Janine mentioned, the Drug Testing Board provides advice to the SAMHSA Administrator and will recommend guidance as to how we proceed with this. DTAB will begin the next steps tomorrow in the review of the science of the alternate matrices.

I want to thank you. Any questions from the Board?

Dr. Cook: Thank you, Ron. At this point, AV has requested a 5 minute break so that we can prepare for the public comment period. So if everyone could be back in five minutes, please?

(Break)

Public Comments

Dr. Cook: Robert Bard?

Mr. Bard: Thank you very much for allowing me the opportunity to comment to the Board. My name is Robert J Bard. I am a regulatory attorney. I am not being paid for the comments and the comments do not necessarily reflect the opinion of any of my clients.

As I commented during the 2009 DTAB meeting, I am again repeating my concern as to the lack of progress being made by Federal agencies specific to the use of hair as an approved matrix. The Federal agencies involved have a duty and legal responsibility to protect the American public, in general, and to aid regulated industry, specifically, by adding hair testing to the tools that employers can use as part of the drug testing program.

Federally-regulated industry must use urine specimens for required drug testing. The inherent problems of controlling the urine sample and the ultimate loss of privacy and humiliation for some individuals is a testament to the need to provide alternatives to the employers and employees, alike. Most private employers are free to choose the drug testing methods and matrices they wish to use in their drug testing program. However, DOT-regulated companies are not afforded this same freedom. Transportation industry wants and needs the best and most advanced tools available to combat potential drug abuse by employees.

The lack of approved hair testing is a serious issue to the transportation industry and places all at a risk of liability due to negligent supervision. We know of deaths that were caused solely by the lack of more advanced approved testing methods for the transportation industry. To prevent claims of negligence, industry is forced to conduct double testing for drug use, one test to meet DOT requirements and a second to cover potential liability requirements.

Jobseekers look to companies that use only urine testing as a means to avoid detection. This is not right and it is not safe for any American who puts his or her life at the hand of a drug using employee in the transportation industry.

Science is on the side of hair testing. The myths that have been proffered historically have been debunked. Please note there are articles available for this information. The FDA had and is clearing hair testing as a device that further supports the science of the method.

The legal system has embraced the use of hair testing as a the method of evidentiary requirements introduced in Daubert versus Merrill Dow, and now referenced as the Daubert Rule. The science is

sound. In military law reviews, summer of 2006, Major Kevin J. Christner speaks very emphatically and offers a strong rationale for the use of hair testing in the military to avoid the problems that are seen in urine testing for drugs.

I want to thank Mr. Flegel for his comments and I would like to offer that the bottleneck that we see at SAMHSA and DOT and their contractor to move hair testing forward needs to be worked on and industry needs to be brought into the picture and a community back-up situation to make this move forward is needed immediately. Thank you very much.

Dr. Cook: Thank you, Mr. Bard. Bill Corl?

Mr. Corl: I will read very quickly because I know we are short on time. Thank you, members of DTAB and guests for listening to my comments and question. My name is Bill Corl. I am a Chief Operations Officer for Omega Laboratories, which is one of the major hair testing laboratories in the United States.

Omega has clients worldwide, including many government entities and multinational organizations. Omega has over ten years of experience in hair testing. As the leading hair drug testing laboratory, we find ourselves in the position of being asked weekly by clients and prospective clients why hair testing has not been approved for Federally-regulated industries and what are we doing about it? These questions have dramatically increased over the last couple of years so we find ourselves compelled to address this group with our concerns. Federally-regulated industries need to be given the approval to use the best available technology to fight illegal drug use and abuse in the workplace. Hair testing will be a great addition to drug testing programs as an option for pre-employment and random testing.

Urine, hair, and other test matrices all have their place in the overall scope of testing. Hair testing is a secure, reliable testing method that is difficult to adulterate. Urine tests are passed by drug users every day. This is evidenced by the major industry that has evolved to supply drug users with adulterants and devices to create invalid urine test results.

Hair testing increases the time period over which drugs can be detected, as compared to urine. It is easily collected, transported, and stored. It is less likely to transmit bio-organisms than urine and is more difficult to adulterate.

I have submitted a written statement of five of the most often heard defenses for the lack of approval and the facts that address these statements. Given the fact that hair testing is widely accepted in most industries, in court systems, state, Federal, and local courts, and is scientifically proven, why has it not been brought to the forefront to complement urine testing? At the request of the Federally-regulated industries that we serve, what can Omega do to help facilitate the approval process? Thank you.

Dr. Cook: Thank you, Mr. Corl. David Evans? David Goncalves?

Mr. Goncalves: Hi, thank you for giving me the time to make this comment. My name is David Goncalves. I am the General Manager at DrugPak LLC. For those of you who are unfamiliar with DrugPak, for 20 years we have been making drug testing management software. We have placed 1200 systems. About half of those are actively enrolled in our support program. That covers over 100,000 employers and over three million DOT-covered employees.

I am excited to see that we are making some progress towards the electronic chain of custody form. I have seen this before ten year ago with the Paperless Lab Initiative. That was very exciting then. I am looking forward to making more progress.

We are not early adopters on this. Our entire culture has adopted most, if not all of the required technologies, every manageable manifestation of an electronic CCF has been vetted in terms of security, non-repudiation. It has been thoroughly tested in the free market and overwhelmingly accepted in matters of national security, personal privacy, and safety.

As the de facto representative of the DrugPak users and their clients, I feel it is my responsibility to say that this vast segment of the drug testing industry is ready for the electronic chain of custody. As a member of DATIA's Electronic Data Standards Committee, I am confident that my sentiments are shared by my esteemed colleagues on the Committee and I applaud DATIA for that effort.

On that note, I would like to extend to the Drug Testing Advisory Board the whole hearted support of DrugPak and offer our resources, expertise, and cooperative spirit to directly aid in the process of establishing open standards for the electronic transfer of drug and alcohol testing information. Thank you for your time.

Dr. Cook: Thank you. David Koons? Murray Lappe?

Dr. Lappe: Thank you, Dr. Cook. Hi, my name is Murray Lappe. I am a physician and a Medical Review Officer. My expertise or experience in drug testing dates back to 1983. I founded National Medical Review Offices, the largest MRO service organization in the world, using information technology, handling more than eight million drug test results each year.

In the first decade between 1990 and 2000, my employees handled more than 100 million Custody and Control Forms. We estimated that the cost of printing, mailing, faxing, merging, storing the CCF added four dollars to the cost of every drug test and single handedly brought down more service providers than any other part of the drug testing process. Additionally, the CCF form is paper and manual format actually increased errors and was the rate limiting factor in the reporting of drug test results in a timely manner.

I then created e-screen on the premise that a properly implemented technology platform integrated at the point of collection can eliminate errors and bottlenecks and take cost out of the drug testing process. Ten years ago, e-screen introduced the first Electronic Custody and Control Form. To date, we have processed more than ten million Custody and Control Forms in a totally paperless electronic format with the following benefits.

CCFs are created on the fly in real time at the point of collection. New accounts are created instantly. There are no wasted forms when service agents are changed. You can send forms electronically to remote collection sites. There has not been a single legal challenge in the last ten years. The software has error checking to eliminate affidavits. We have had zero affidavits in the past ten years required. And 90 percent of the cost of processing the CCF has been eliminated.

On January 4, 2011, FMCSA issued regulatory guidance concerning electronic signatures and said on this date, effective immediately, the FMCSA will allow anyone to use electronic methods, so long as the electronic documents and signatures accurately reflect the information in the record. I will not read all of it.

I urge DTAB to recommend to HHS to take similar action as FMCSA and issue regulatory guidance to allow the use of electronic versions of the Federal CCF. Once again, I want to urge DTAB to unbundle urine point-of-collection testing from the alternative matrices and put a working group together to evaluate the benefits of pre-screening negatives at the point of collection using the already obtained urine sample. Thank you very much.

Dr. Cook: Thank you, Steven. Abigail Potter?

Ms. Potter: Thank you so much for allowing me to speak. I am Abigail Potter with the American Trucking Associations. Some of you may the American Trucking Associations as the united federation of motor carriers, conferences, state trucking associations, and suppliers. We encompass and we reach out to almost 37,000 companies.

One of our main concerns -- you know, our members are very concerned about safety. It is one of our number one top priorities. Making sure that the drivers out on our highways, our workplace, are the safest that they can be, carriers want to make sure they are the safest by using drug tests and having alternative specimens, particularly hair testing, to give a wide range of the background of the drivers that are out on the road.

With the handful of our motor carriers that are doing both urine analysis and hair testing have found a strong benefit of doing both, even though the financial costs are tremendously high. That is mainly due because they can reduce their accident risk, particularly, and also their liability risks. ATA strongly recommends that regulations get pushed forward on hair testing.

Also, I have been asked by Ellen Boyd to make a comment, if that is all right. It is a letter. I can also put it into the record, if that might make it a little bit quicker. For the Women in Trucking Organization, she is also a very big proponent for hair testing because of women with direct observation issues and some discrimination issues. I will just put this in the record for everyone. Thank you so much.

Dr. Cook: Thank you, Abigail. Stephen Lee?

Mr. Lee: Good afternoon. My name is Stephen Lee. I am Executive Vice President and Chief Science Officer of OraSure Technologies. I would like to thank DTAB and SAMHSA for the opportunity to make public comment as they consider future guidelines for oral fluid testing in Federal workplace drug testing programs.

For many years, OraSure has been the market leader in oral fluid drug testing in both worksite and criminal justice applications since the FDA approval and deployment of the Intercept Oral Fluid test system. The acceptance and use of Intercept Oral Fluid as a suitable sample for drug testing has grown over the past 10 years from approximately 100,000 samples being tested in 2001 to over two million samples per year being run today.

The factors that drive the use of oral fluid testing are its simplicity, convenience, and relative resistance to sample adulteration. Additionally, oral fluid has been successfully upheld in multiple court cases and thus provides a precedent for future legal defensibility.

The Intercept test system has been demonstrated to be an effective tool for oral fluid drug screening for over ten years. Rates of drug positive results remain relatively consistent from those originally reported in 2001 on approximately 77,000 samples to those recently reported based on over four and a half million samples collected from 2005-2009. These data have indicated that the cutoffs

established using the Intercept test system are effective in detecting drug use at rates similar to those obtained with urine testing.

In partnership with Roche Diagnostics, OraSure is working on a major advancement in the field of oral fluid drug testing with the development and deployment of oral fluid tests that can be carried out on random access, automated laboratory instruments. The availability of these fully automated oral fluid assays will greatly improve the efficiency and throughput at which laboratories can process and test oral fluid samples.

The assays representing the initial launch menu, the so-called 9-5 test, have been developed for use with the current Intercept oral fluid collector and are in various stages of validation to support FDA 510(k) approvals. A number of these assays have 510(k) submissions currently under active review by FDA. The cutoffs of these assays are expressed as values representing concentrations in neat undiluted saliva.

The performance of these tests has also been verified in comparison to the Intercept micro-plate enzyme immunoassays, which provides linkage to the millions of samples previously run using the micro-plate format. We believe that when deployed these test systems will represent a new state of the art with regards to the accuracy, precision, and convenience of oral fluid drug testing. Performance data from these assays has been presented at various scientific meetings and also published in peer-reviewed literature. We strongly recommend the DTAB review the existing state of the art of FDA-approved test systems in the course of their deliberations on suitable guidelines for oral fluid drug testing in Federal workplace drug testing programs.

With regard to future product development, OraSure is developing a new and improved version of its oral fluid sample collector. This is being designed to increase the reproducibility of sample volume collection, as well as increase the total volume of sample collected. A critical vector in the new design is the use of an indicator to determine when adequate sample has been collected.

We look forward to working with DTAB in order to understand how the content of eventual guidelines for oral fluid drug testing and Federal drug testing programs may affect the design requirements for future products. We strongly believe that the oral fluid collector, the assay reagents, and the instrumented test platform need to be considered together as an overall test system and applicable standards be developed in the context of results delivered by that test system.

In closing, we respectfully request that SAMHSA and DTAB thoroughly evaluate the current and impending state of the art of oral fluid test systems before issuing final guidelines that could affect the ability of industry to deploy new products and/or impact the user acceptance of oral fluid. OraSure welcomes the opportunity to provide additional technical data characterizing their current and future product development on a confidential basis, if necessary, in order to assist this Committee in its deliberations. Thank you.

Dr. Cook: Thank you, Mr. Lee. Marsha Vandehei of Titletown, USA?

Ms. Vandehei: My name is Marsha Vandehei. I am from Schneider National. Thank you for the opportunity to talk to you today about hair follicle testing.

Schneider is the parent corporation of four major interstate carriers. Taken together the Schneider motor carrier operates in excess of 13,000 tractors and 35,000 trailers and employing more than 12,000 drivers, utilizing services of over 1,800 independent contractors and operating throughout the

United States and Canada. We average about six million miles per day.

For many years, we were satisfied with the urine drug testing program and its ability to detect drug use and keep unsafe drivers off the road, but the fact remained that we continued to see positive random and post-accident test results. This fact was unacceptable to us. The pre-employment urine drug test has become an IQ test. Applicants know that when they apply for a position they will have to pass a urine drug test. This is not such a hard thing to accomplish. The drug users only need to stay clean for three days or they only need to visit a health food store or browse the internet products to help beat the drug test. Over 750,000 websites today sell products to mask the metabolites in urine.

Schneider National has been conducting hair testing on our driver applicants since March of 2008. We are proud to share our results with you today. Thus far, we have conducted 19,349 drug tests. Of those, 793 tested positive. 728 of those applicants received a negative result using urine. Thus hair testing has kept 700 drug users out of a Schneider truck. Positive rate for hair for us is 4.1 percent, whereas urine is 0.34. Pre-employment hair testing has resulted in a 58 percent reduction in our random testing, 83 percent reduction in our post-accident positive test results.
Recently, in Colorado, a truck driver was arrested for suspicion of drunk driving after driving the wrong way down the highway and colliding with a motor vehicle, killing the driver and injuring the two passengers. This truck driver had previous applied for a job with Schneider National, but was turned down after failing our non-DOT hair follicle test. As an organization, we knew this man was a risky hire, but we could not share this information with other carriers through the regulated drug and alcohol check process. We could have prevented this tragedy, if the law only allowed us to.

We propose implementing hair testing for the purpose of pre-employment and random drug testing. The longer window of detection makes this the most attractive method to detect a pattern of use. Urine drug testing is still the best option for post-accident, reasonable cause, and return-to-duty follow-up testing, as it allows the motor carrier to determine if the individual is under the influence at that given point in time. Having the ability to use both methods of testing allows the motor carrier to create a more comprehensive drug testing program, therefore keeping unsafe drivers off the nation's highways. Thank you.

Dr. Cook: Thank you, Marsha. David Whiteside?

Mr. Whiteside: I think my comments can be very brief because I will say I am 100 percent in support of what Marsha just said. I am David Whiteside. I am the Senior Director of Compliance with J.B. Hunt Transport. We also are one of the larger companies around in the trucking business. We have approximately 11,000 drivers.

What I would like to do today is single in on our data and that is that we have had almost 46,000 paired results where we have both the hair test and the urine test. I would like to offer that data to DTAB at request, to be able to be analyzed and try to find a better way to deal with hair testing than just saying, well, we have these concerns so we are not going to look at it anymore.

I would like for some good solid science to go dig into some of the concerns that have been voiced so we can rule out or make adjustments as needed to be able to use this as an alternate specimen type. I believe what is happening with oral fluids is a very good thing to give roadside officers an opportunity to be able to detect the drugged driver on the roadside. But the best opportunity to save lives is to do it on pre-employment with a detection window that is longer, has less opportunity of adulteration and substitution, and will be able to detect users before they get behind the wheel of a truck and, therefore, be able to keep them from being involved in a drug-use crash.

The last thing I would like to do is one of the slides talked about external contamination. I am sure most of you have heard about the FBI laboratory and some of the changes that they made with the use of hair testing analysis on cocaine. But I do have a follow-up on the letter to the editor from the Forensic Journal of Analytical Toxicology, Marc Lebeau and Madeline Montgomery. We feel our colleagues are correct in their observation of the utility of hair analysis for drugs. In fact, our laboratory continues to offer this service for numerous other drugs that do not share the same interpretive challenges as cocaine. We reiterate that we continue to test for cocaine in hair samples collected from subjects who have no legitimate reason to have cocaine exposure.

I do not believe truck drivers have any legitimate reason to have cocaine exposure. Therefore, to use the argument that the FBI lab that has undercover agents who are being exposed that they stopped testing for cocaine, I do not believe that is a valid argument to say that the legitimacy of hair testing of truck drivers is valid.

Dr. Cook: Thank you, David. This is the final call for David Evans, David Kuntz, and Steven Soifer.

One of the commenters is having difficulty logging in. We do have a copy of his comments, so I will read them for him. My name is Dave Kuntz and I am the Executive Director of Analytical Toxicology at Clinical Reference Laboratories in Lenexa, Kansas. I would like to thank DTAB and SAMHSA for allowing me to offer comment as Guidelines for oral fluid testing in Federal workplace drug testing programs are considered.

Clinical Reference Lab has been conducting external clinical trials for the new homogenous assays from Roche Diagnostics and OraSure Technologies. These semi-quantitative and qualitative assays utilize the Roche KIMS technology and the current Intercept collection device. The trials were designed to evaluate the screening with the homogenous assays, in comparison with the currently approved micro-plate assays. The trials were conducted with a mix of repository and spiked samples. All discordance between the two assay systems were resolved by LC/MS/MS. The homogenous assays had excellence performance in our trials. The assays yielded a high level of agreement between the OraSure Intercept micro-plate EIA in all cases greater or equal to 95 percent and with LC/MS/MS in all cases greater than 99 percent in this study.

The homogenous assays provide a significant improvement to overall laboratory workflow. The current ELISA platforms only provide batch testing using microtiter plates and organizing data for reporting is much more difficult and slow. Since many laboratories have automated equipment within their laboratory, it would not require any additional outlay of money for equipment purchases, nor would the laboratories have to develop new data interfaces between instrumentation and the laboratory computer systems.

The FDA clearance of homogenous assays will enable further utilization of oral fluid and allow laboratories to achieve testing efficiencies similar to urine testing. I urge DTAB to review the existing technologies and the new assays in development as formal guidelines are established for oral fluid. Providing that the various companies bring their homogenous assays to market, oral fluid testing will become more useful and efficient as an alternative to urine.

Dr. Cook: I want to discuss our contingency plans for tomorrow. If it is business as usual, we will reconvene tomorrow at 8:30 am in this room. If the Federal government has a two hour delay, we will reconvene tomorrow at 8:30 am in this room. If the Federal government is closed, the DTAB will convene in the Rockville Sheraton in the Irvington Room at 8:30 am. Since the DTAB members are

here, we will continue with the meeting.

Do I have any questions from the Board at this time? To keep tabs on any closings related to the Federal government, I recommend that you listen to 103.5 FM or visit http://www.WTOPnews.com.

I will adjourn this DTAB session. Thank you, everyone, for attending.

Whereupon, the meeting adjourned at 3:00 pm.