PROCEEDINGS

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

May 3, 2011

One Choke Cherry Road
Rockville, Maryland 20857

Table of Contents

P R O C E E D I N G S (10:00 A.M.)

Call to Order
Welcome and Opening Remarks

Dr. Cook: Good morning. I am Janine Cook, the Designated Federal official and Acting Chair of the Drug Testing Advisory Board, or DTAB. As the DFO of DTAB, I officially call this meeting to order.

First, I have a few announcements. For those of you here on site, a copy of the agenda is on the registration table. For those of you that are joining us remotely, Jared has just e-mailed you a copy of the agenda. Within a few weeks, the minutes, proceedings, and presentations from the open session will be posted on the DTAB website. I have provided the link for that website here on this slide. You can also access the DTAB website from the Division of Workplace Programs Drug Testing webpage.

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 on site, 3 x 5 cards are located at the back on the registration table for you to record your questions. Please leave your questions with a staff member at the registration 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 begins at 3:30 p.m. Eastern Daylight Time today. Currently there are four attendees who have registered to make public comment. 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 of the commenters. All public comments will be included in the meeting minutes, as well as in the transcript. Please provide either a hard copy or an electronic copy of your comments, to be shared with the transcriptionist, to ensure your comments are recorded accurately. We will not be responding to any public comments at this time.

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

I would like to introduce the members of the Drug Testing Advisory Board: Bobby Bonds, Dr. Jim Bourland, Dr. Larry Bowers, Dr. Lawrence Brown, Phyllis Chandler, Laurel Farrell, Dr. Courtney Harper, Barbara Rowland, Dr. Donna Smith, Jim Swart, and Dr. Steve Wong.

I would also like to introduce the members of the Division of Workplace Programs because this meeting would not have been possible without their invaluable assistance: Captain Carol Rest-Mincberg, Jennifer Fan, Ron Flegel, Eugene Hayes, Giselle Hersh, Charles LoDico, Hyden Shen, Bill Sowers, and Elaine White.

We have scheduled the DTAB meetings for the remainder of the fiscal year. The tentative dates are July 12 and 13 and September 12 and 13. We have not decided which of those dates will be open or closed, but as soon as we do, we will let you know.

I would like to introduce Carol Rest-Mincberg, who is currently the Acting Director of the Division of Workplace Programs. All of us at the Division of Workplace Programs want to take this opportunity to publicly thank Carol for her leadership she has provided to the division for the last ten months. Thank you, Carol.

CAPT Rest-Mincberg: Thank you. I would like to thank the staff for making me look good. I am the Acting Division Director for the Division of Workplace Programs, which is within the Center for Substance Abuse Prevention (CSAP), which is part of Substance Abuse and Mental Health Services Administration (SAMHSA), which is an agency in the U.S. Department of Health and Human Services (HHS). On behalf of all those

entities, I welcome you. Under a delegation of authority from the Secretary of HHS, SAMHSA's Division of Workplace Programs carries out the HHS role in the Federal Drug Workplace Testing Program. This fits in within SAMHSA's general mission, which is to reduce the impact of substance abuse and mental illness on American communities. SAMHSA does this in a variety of ways, including giving voice and leadership in behavioral health, substance abuse and treatment, funding service and capacity development, setting regulations and standards, and funding practice improvement. To this end, SAMHSA has eight strategic initiatives, which are available for you on the SAMHSA website at http://www.samhsa.gov/. I will speak briefly about one of the strategic initiatives, which is the prevention of substance abuse and mental illness. Workplace drug testing is one of the largest public health prevention programs in the United States. This program impacts the public health, safety, and national security of every person in this country, every minute of every day, whether they are on the roads, flying in a plane, taking a bus, riding a train, living near a nuclear power plant, on the waterways, or near the vicinity of any of these things. Because regulated industries test for illicit drugs, lives are saved and injuries and disabilities are prevented every second of every day. The Institute of Medicine refers to this as universal prevention because it benefits the general public. But in addition to implementing universal prevention in this program, we also implement selective prevention for substance abuse because, among the 400,000 Federal employees and the 12 million non-Federal employees in the regulated industries that are drug tested, illicit drug abuse is prevented. Empirical evidence demonstrates a continuing decline in illicit drug use since the creation of this program. Unregulated private employers find this so compelling that they recognize the value of drug testing. There is now an additional 50 million workers tested as a condition of their employment, which deters people from using illicit drugs.

Behavioral health is essential to your general health. You cannot have good general health without good behavior health because it improves health status. Prevention and treatment for substance abuse lowers costs for families, for businesses, and certainly for government. Prevention works; it is evident in this program, with data to support that. For those people who need treatment, there is effective treatment, and people recover.

I want to again thank everyone for coming, thank the staff for all their work, and thank the members of the DTAB. Hyden Shen will speak next.

Mr. Shen: Good morning, my name is Hyden Shen, I am the policy oversight lead for the Federal Drug-free Workplace Programs. This morning I will provide you with a broad overview of our direction on alternative specimens within the Federal Drug-Free Workplace Programs.

On April 13, 2004, HHS issued a Federal Register notice, proposing revisions to the Mandatory Guidelines to establish scientific and technical guidelines for alternative testing specimens in addition to urine. On November 28, 2008, HHS issued the final notice of the revisions to the Mandatory Guidelines for the Drug-Free Workplace Programs that went into effect October 1, 2010. The decision in 2008 was to continue with urine specimen testing only and to conduct further study and research on alternative specimens. The decision to continue with only urine specimen testing was based on public comments, which expressed scientific, legal, and public policy concerns regarding the use of alternative specimens. Likewise, HHS had its own concerns. Currently, the urine drug testing program is considered the gold standard in the field. In considering alternative specimens, HHS decided to investigate the state of the science and the legal defensibility of alternative specimens or matrices. There are three specific issues. One, the data from the pilot proficiency testing program showed that not all participants have the capability to test for all required drug classes, and that there are also issues regarding the accuracy of such tests. The second issue was that some drug classes are more difficult to detect than others, and the third was that specific drug classes that are difficult to detect may vary by the type of specimen used. However, HHS' position is that the use of additional testing matrices or specimens would compliment and strengthen the current drug-free workplace drug testing programs. The approach that HHS is taking is that each alternative specimen poses a series of different concerns. We are currently looking at the state of the science and legal defensibility of these alternative specimens and matrices. We will continue to provide opportunities for public comment. We may or may not be issuing one or more final notices in the Federal Register for public comment. Our overall goal within HHS is to continue pursuing scientifically sound and legally defensible ways to further strengthen the drug-free workplace programs and to utilize the state of

the science in modern technology.

The next step in the drug-free workplace programs is to investigate oral fluids. This decision was made and supported by over 620 peer-reviewed publications and by the current science. Based on the scientific research and studies, the DTAB will or will not recommend proposed revisions to include oral fluids in the Mandatory Guidelines for publication in the Federal Register, with the opportunity for public comment. Thank you.

Dr. Cook: Do any members of the Board have questions for either Carol or Hyden at this time? The next agenda item is the Federal drug testing updates, specifically for the 2010 lab result data. I would like to introduce Jim Swart, who is the Director of the Office of Drug and Alcohol Policy and Compliance, from the Department of Transportation.

Federal Drug Testing Updates -- 2010 Lab Results

DOT Drug Testing Update

Mr. Swart: Good morning everyone. Good morning Drug Testing Advisory Board and colleagues from HHS and ONDCP. Good morning to my staff; it is good to see you here. Thank you for the opportunity to update you on the DOT program this morning. My name is Jim Swart, and I am the Director of the Office of Drug and Alcohol Policy and Compliance within the office of the Secretary of Transportation. I bring personal greetings to everyone here, especially the DTAB members, from Ray LaHood, the Secretary of Transportation. He is very interested in the drug testing matters that are currently before this Board.

As I explained in the last meeting, this is our family portrait at DOT. We are the world's largest regulated drug testing program. We generally test over 5 million transportation employees annually. The drug testing program covers safety-sensitive employees in trucking, aviation, railroad, transit, pipeline, and the maritime industries. This slide shows the industry totals for the number of employees and employers that are regulated by each of the DOT agencies, including the United States Coast Guard, the Pipeline and Hazardous Material Safety Administration, the Federal Railroad Administration (FRA), the Federal Transit Administration (FTA), the Federal Motor Carrier Safety Administration (FMCSA), and the Federal Aviation Administration (FAA). The DOT program, as I said earlier, is responsible for over 5 million drug tests that are analyzed annually at the Department of Health and Human Services certified laboratories. Our primary law, the Omnibus Transportation Employee Testing Act, inextricably links us with HHS for those drug testing matters related to laboratory testing. Today, I will present to you some facts and data about that testing.

This slide shows our governing statute and our testing requirements related to that law. We incorporate HHS testing standards and procedures. Testing must have HHS-approved testing protocols. HHS laboratory certification procedures must be in place for all of the DOT tests that are conducted. We must use HHS-certified laboratories for all screening, confirmation, and split specimen testing. Finally, we are required to use the HHS Mandatory Guidelines to determine the drugs for which we test. Currently, the drugs that we test for are divided into five panels or categories. These drug categories include THC, cocaine, amphetamines, opiates, and phencyclidine (PCP). The drugs that are confirmed at the laboratories for these particular five panel drugs are marijuana, cocaine, amphetamine, methamphetamine, MDMA, MDA, MDEA, cocaine, morphine, heroin, 6-AM, and PCP. The drugs shown in red are Schedule 1 drugs. We do test for a number of Schedule 2 drugs currently, including cocaine, amphetamine, methamphetamine, codeine, and morphine.

The laboratory numbers from last year are given in the final column. Comparison data are provided back to 2005. This past year, testing increased over 2009. We think that is a good sign, perhaps of the economy improving somewhat. We also had a slight increase in the positivity rate. We had fewer invalid tests and more substituted and adulterated tests identified than in 2009.

The conclusions that we have drawn from this include that the positive drug testing percentage rate, which had been in decline, rose slightly in 2010 by 0.03 percent. Could that be as a result of the new testing that we

began in October? We do not know yet; additional data are needed to evaluate this. It is interesting that amphetamine positivity continues to be above cocaine for the fourth consecutive six-month reporting period. Prior to that, cocaine had been higher than amphetamine. Marijuana continues to be the most prevalent drug identified. Tampered-with specimens held steady, but we had a higher percentage of those tampered-with specimens that were actually identified as being substituted and adulterated rather than simply reported as invalid results. And again, as I said earlier, the total number of tests, which had been in significant decline since 2006, rose this past year.

There was a lot of interest in how the new rules that went into effect October 1st would impact the testing data. There were new cutoffs for amphetamine, methamphetamine, and cocaine and new procedures for 6-AM testing; and for the first time, we tested for ecstasy (MDMA), MDA, and MDEA. I have included the next slide, which provides a comparison between the third and fourth quarter data, which were graciously provided by the laboratories. The three months worth of data under the old rules are shown in the blue columns, and the three months' comparison with the new testing regimen is given. There were fewer tests performed in the fourth quarter than in the third quarter. However, there were more amphetamine positives and more methamphetamine positives than in the previous quarter. Though we did not test for the MDMAs, they are listed there as well. But despite having fewer tests performed, we think that might have had some impact on having more positives. Cocaine also had its detection cutoff lowered, and thus we expected to have more positives. We did indeed have nearly a thousand more cocaine positive results identified, despite having fewer tests that were performed. We also have information related to the new 6-AM or heroin testing, and people predicted that we would see a lot more 6-AM. There were any number of trends that were identified for us, and we decided to go back into some of our data points and examine each of the six-month periods leading up to the new rule implementation. These are new rules; these are the old rules here. We noticed that there was a trend beginning here. We had more 6-AM identified under the old rules here than in this previous six-month period. If you look back to 2008, at the various six-month periods, you will note that there was a trend toward more 6-AMs being identified under the old rules, with the biggest jump under the old rules occurring between this period and this period and this period. We have seen a ramping up of heroin being identified, and both under the old rules, the trend going up, and of course, under the new rules.

I would like to acknowledge the Program Managers who oversee the programs that regulate the transportation industries within the DOT program: Jim Keenan with FMCSA; Jerry Powers with the FTA; Raphael Ramos with the FAA; Lamar Alan with FRA; Stan Kastanas with Pipeline and Hazardous Material Safety Administration; Bob Schoening with the U.S. Coast Guard; and Linda Cross who operates the DOT internal program which follows the HHS Guidelines. Here is the website for those managers, which provides the managers' names, their regulations, their random testing rates, etc.

I would like to acknowledge my staff: Patrice Kelly; Bob Ashby, our General Counsel; Mark Snider; Bohdan Baczara, Cindy Ingrao; Yale Caplan, our laboratory consultant; John Sheridan, our statistician; Vicki Bellet; and Maria Lofton. Listed here is our website; please do not hesitate to go there because you will find a great deal of information, a good number of links to the program for employers, employees, urine collectors, etc.

Again, thank you for the opportunity to make this presentation, and I will entertain any questions that the DTAB members may have about our data.

Dr. Brown: Can you provide us your sense about the reduction in the total number of tests in the fourth quarter versus the third? I am just curious as to what might be the factors that explain that.

Mr. Swart: I cannot say for sure, but I think there was random testing that needed to be done. Employers perhaps conducted more random testing in the third versus the fourth quarter or perhaps they hired more people in the fourth quarter and needed to do pre-employment testing in the third quarter.

Dr. Brown: Have you ever evaluated through a survey the substantial differences between the quarters? It appears to me to be a big difference.

Mr. Swart: Yes. It would seem to be. Certain people are hired by the industries in the summer months and for the holiday periods as well. I just couldn't say. I do not know if that is a trend in the Federal government or in the Federal employee testing program.

Dr. Cook: I was negligent in not introducing Jack Stein, who is joining us here today from White House Office of National Drug Control Policy (ONDCP).

Our next speaker is Captain Kevin Klein, who is the Director of Drug Testing and Program Policy, the Office of the Assistant Secretary of Defense for Health Affairs in the Department of Defense.

DoD Drug Testing Update

CAPT Klette: Good morning, we certainly welcome the opportunity to update the DTAB on DoD's fiscal year 2010 drug testing program data. Since these data will not be published for several months yet, the views expressed in this presentation are those of myself and do not reflect the official policy of DoD, the Army, Navy, or Air Force.

The DoD has had a drug testing program since the early seventies and the obvious reasons are because our service members live in very close quarters and rely on the buddy system, where one sailor or soldier has the other person's back. The Military operates in locations where illegal and other drugs are readily accessible. Most importantly, our demographics include a high percentage of high risk populations, which we define as males between the ages of 18 and 25.

First, I will provide a basic overview of the program and then drill down specifically by each service component, whether they are active reserve or active military. The current panel of drugs that we screen for at a one hundred percent specimen testing rate includes marijuana, cocaine, amphetamine, methamphetamine, heroin, and the designer amphetamines, such as Ecstasy (MDMA) and MDA. We also conduct an extra element of testing, which we refer to as pulse testing, where the test frequency is 20 percent. The drug groups shown in red undergo pulse testing and include oxycodone, oxymorphone, codeine, morphine, and PCP. We also have the ability to do special request testing, which is conducted within the Armed Forces medical examiner system, which was formerly known as the Armed Forces Institute of Pathology. That group, on a limited basis, can conduct testing for barbiturates, benzodiazepines, synthetic opiates, ketamines, etc. They can test for pretty much anything for which a standard is available.

This slide gives the overall DoD drug testing performance from 2006 through 2010. Overall, our positivity rate has remained just above one percent. The 2010 mean testing ratio, which is how often we test service members, is 1.65, a rate which has remained steady throughout the years.

The DoD has a goal, which was adopted in 2008, as a quarterly reporting metric on wellness indicator. That was signed by the Principal Deputy Undersecretary of Defense for Personnel Readiness, and the stated goal was to try to keep the illicit positive rate at 2 percent or below. Despite the pressures of increased operations, the active duty forces overall are less than that 2 percent goal.

This shows the mean active duty testing rates by service. The Navy and the Marine Corps have remained at about three tests per person per year, followed by the Army, which is running about twice per year, and the Air Force, which is at one test per year.

This slide gives the active duty by service positivity rates from 2006 to 2010. The Navy and Air Force rates continue to exhibit lower positivity rates as compared to the Army and the Marine Corps. The positivity rates for Army, Marine Corps, and Navy show a decreasing trend, while the Air Force rate has remained steady through this period.

This slide shows the overall active duty drug positivity and testing rates from 2006 to 2010. Later, I will drill down to the reserve components and the National Guard not on active duty. In 2010, the overall mean test ratio was 2.18. The overall positive rate has decreased from 1.12 to 0.88 over this period of time, while the mean testing rate has remained steady.

Drilling down from the overall active duty population to identify specifically the high risk drug positive rates, you can see that in the Army's rates, from 2006 to 2010, do appear to be decreasing. In 2010, we had 2.5 percent rate for the Army, which is still above the DoD goal of 2 percent. The Marine Corps percent positive rate during this time frame is just slightly lower than 1.5 percent, the Navy rate is showing a decreasing trend from 2006 to 2010, and the Air Force's data have remained pretty much consistent at a low frequency percent positive.

This slide shows the positive rates for reserve components that are not on active duty, such as the reservist who drills two weekends on active duty during a one-year period. While the Air Force, Navy, and Marine Corps positivity rates are below the DoD goal of less than 2 percent, the Army reserve exceeded the goal in 2010 with a 2.28 percent rate. Also, the Navy and Air Force positivity rates have remained consistent from 2006 to 2010. Remember, the Navy test rate is three times per year and the Air Force test rate is once per year.

The Reserve component, not on active duty, high risk population drug positivity rates were 4.5 percent for Army and 2.34 percent for the Marine Corps. Both populations exceeded the 2 percent goal for the past five years. During this time course, we've been fighting in a war which has an impact on this. For both services, the high risk population positivity rates do appear to be increasing, although to a lesser extent for the Marine Corps. From 2006 to 2010, the Navy and Air Force high risk populations have remained relatively constant.

This slide depicts the National Guard component, not on active duty, positivity rates. These are those National Guard members that are drilling one weekend a month throughout the year. The Army National Guard exceeded the 2 percent goal for the past five years, at just slightly over 2.5 percent. The Air National Guard remains at a low positive rate.

This slide provides the positivity rate data for the National Guard component, not on active duty, high risk members, males ages 18 to 25. The Army National Guard High Risk population exceeded the 2 percent goal for the past five years, and the Air National Guard high risk population remained at a relatively low positive rate.

These higher rates are a bit disturbing. We at DoD annually query our Defense Manpower Data Center (DMDC) database to determine if specific units or locations have pockets of high drug use, and then this information is relayed to the services for potential remediation.

This slide gives a breakdown of the total DoD drug positive distribution. Marijuana comprises 67.4 percent of our laboratory positives, followed by cocaine at 13.2 percent, and D-amphetamine (5.6 percent) and D-methamphetamine (3.1 percent). We had a 2.8 percent positive rate for ecstasy (MDMA) and MDA, while PCPs were almost nonexistent in our population. Codeine, morphine, oxycodone, and oxymorphone are at low rates, but remember, these drug groups are tested at only a 20 percent frequency. Heroin was 0.6 percent. We had been screening for heroin specifically since 2005, and though the positive rate is low, our data show that its use is increasing.

The slide shows the drug positivity rates in blue from 1980 to 2008. Since 1998, illicit drug use has decreased dramatically. By comparison, the graph in pink shows a compilation of self-reported drug use over the past 30 days from all military services. This survey is circulated every three years, and since 1980, self-reported drug use has decreased from about 27 percent to less than 5 percent in 2002. Both of these indicators suggest that our program was very effective in deterring members from using drugs. In 2005, prescription drug testing questions were added to the survey, and the questions were related to the illicit use of prescription medications. In 2005, 5 percent of respondents admitted to nonmedical use of prescription drugs, and in 2008, that number took a dramatic jump to about 12 percent. From 2005 to 2009, in the high risk category,

psychiatric medication prescriptions rose in the military population by 42 percent. Another indicator during this time frame of prescription drug use was our prevalence testing, whereby a subsample of service member specimens that were submitted to laboratory and were reported as negative are tested for other drugs. We conducted prescription drug testing on those specimens to determine prevalence. In 2009, the date of our last prescription drug prevalence study, we demonstrated that prescription drug abuse exceeded illegal drug abuse. The Chairman of the Joint Chiefs of Staff received multiple briefings from scientists and line leaders on this growing abuse concern. In 2002, data indicated that oxycodone use was becoming rampant across the nation. In 2005, we began pulse testing for oxycodone and its metabolite, oxymorphone. Based on that data, the Chairman of the Joint Chiefs of Staff directed us to take a more integrated approach to testing for this emerging drug threat. In 2012, we will add hydrocodone and hydromorphone testing to our panel of tested drugs, and then later in that year, we will institute benzodiazepine testing.

Switching from the military perspective, there are 15 agencies in the Department of Defense that are under the HHS program, and overall, we had a 0.3 percent positive rate. In the column on the right is the percent positivity rate by agency. The two agencies highlighted in yellow did not test, and their new drug testing plans are currently being reviewed by SAMHSA.

That concludes my presentation. I would like to thank my staff, which is myself and Ms. Cindy Robinson. Thank you.

Dr. Cook: Thank you Captain Klette. Do any members of the DTAB have questions for Captain Klette?

Dr. Brown: I am a physician, so some of my questions may demonstrate that training. First of all, Captain Klette, I want to congratulate you and your robust staff for the outstanding work you continue to do. I have a couple of questions; one is concerning the differential rates and the mean testing rates by military branch. Can you share with us the reasons that perhaps suggest why that continues to be the case? On slide five it seems to suggest that there continues to be a differential rate between the military branches in terms of the mean testing rate.

CAPT Klette: Yes. DoD policy requires 100 percent testing each year. Individual services can test more frequently if they so desire. I am in the Navy, and the Navy firmly believes that the more tests that you perform, the more of a deterrence effect that you will obtain. Our data from the Navy population do show that. The Air Force tests one member per year; they employ a policy which includes what they refer to as smart testing, where the high risk group is targeted at a higher frequency than the rest of the members. But they do still test at once per year. The Army is in between that at twice per year.

Dr. Brown: That is very helpful. There are many other questions that I have, but I only have one more that I would like to quickly post. In the survey that was administered to service personnel, did it distinguish between prescription drug use and prescription drug abuse, and how was abuse defined for those who took the survey?

CAPT Klette: The survey focused on the illicit use of prescription medication. There were examples, such as are you taking those prescription medications to get high or you are using someone else's prescription? I could forward a more complete answer later if you wish.

Dr. Brown: That would be fine. Thank you very much.

CAPT Klette: Certainly.

Dr. Cook: If any of the DTAB members attending remotely would like to ask questions, please unmute your phone. If you have problems doing that, please send a message to Jared using the chat pod, and he will be able to help you.

Dr. Smith: This is Donna Smith. I have a question concerning the positivity rates for active duty on prescription

drugs. Does that reflect that the individual definitely did not have a legitimate reason to have that drug in his/her urine? In other words, they had no prescription or they were not being medically treated or authorized to use the substance. Or is that raw laboratory positive result data?

CAPT Klette: I did not hear the question very well; could you repeat it a little bit more succinctly?

Dr. Smith: I wanted to know whether the increasing positivity rates for prescription drugs, for example, for oxycodone or for any of the synthetic opiates, reflected laboratory data only or were that data evaluated in terms of whether or not a military member had an authorized prescription for the use of that medication.

CAPT Klette: Definitely. All of the prescription medications that we test for are required to go through a medical review officer process. Those that do have a valid prescription are not included in the data.

Dr. Smith: Okay. So the stated positivity rates mean that those were in fact specimens that contained oxycodone, for example, for which an individual had no medical authorization.

CAPT Klette: Definitely. Remember that this is at a 20 percent frequency. Those are MRO reviewed positives. If they had a valid prescription, they would not appear in the data set.

Dr. Smith: Okay.

Dr. Cook: Captain Klette, if you could just very quickly allude to how you have married your prescription system with your laboratory data system.

CAPT Klette: Currently, once the MRO review process is completed, and if the donor has a valid prescription, that result is removed before it is sent to our DMDC database. In the future, we are looking at performing a pre-MRO review. Once the initial test is complete at the laboratory, any presumptive positive results will be routed back through the Tricare and drug pharmacy database portals. If the donor has an active prescription on file, that information will be sent back to the laboratory and we will not proceed further with testing on those. If they do not have an active prescription, we will complete our process of performing an additional screen and then a confirmation test. The confirmation result from that process will still be required to go through an MRO process at the end of the cycle, because obviously there are some service members who may not get their prescriptions from the military and thus are not in the database.

Dr. Cook: Thank you. Do any other board members have questions for Captain Klette?

Our next speaker is Paul Harris, who is the Senior Program Manager for the Fitness for Duty program at the U.S. Nuclear Regulatory Commission.

NRC 10 CFR Part 26 Fitness for Duty Program

Mr. Harris: Good morning. I am the senior program manager for the Fitness for Duty programs at the Nuclear Regulatory Commission here in Rockville, Maryland. I am in the Office of Nuclear Security and Incident Response. We provide the technical oversight of security at NRC-licensed facilities, which range from 104 nuclear power reactors to 6 fuel cycle facilities to a number of material users of radioactive materials that fall under the regulatory auspices of the NRC.

I wish to thank the Drug Testing Advisory Board today for inviting the NRC to present the data results from our drug and alcohol testing program. We do include alcohol in our data, which I will explain more about in a slide or two. I would also like to specifically thank Janine and Carol for orchestrating this meeting.

Drug and alcohol testing at our nation's commercial nuclear facilities continues to be a vital element of the NRC's Defense and Depth strategy, which helps ensure the public health and safety, promotes the common

defense and security, and protects our environment. We cannot operate our nuclear facilities in a safe and competent manner with individuals who are unfit to perform their duties safely and competently. I am proud to say that the drug and alcohol performance indicators associated with the NRC's regulated industry continue to indicate that the vast preponderance of persons at these facilities are not under the influence of alcohol or any legal or illegal drug, and that these persons can safely and competently perform their duties.

However, there exist many quantitative indicators of drug and alcohol challenges that are present that can have an adverse effect on the safety and security associated with these commercial entities. In August 2008, the Drug Testing Advisory Board was informed by the Baltimore Shock Trauma Center, the University of Maryland Baltimore, of increases in societal use of prescription medications, and that there is no agreement on concentration levels that could cause impairments, and that with an aging population, the prevalence of prescription drug abuse has increased. We are seeing an increasingly aging population in the nuclear industry right now. If I may present data from Quest Diagnostics, Incorporated public website from August 2008 and January 2011, Quest presented data showing a 2 and a half times increase in the use of hydrocodone from 2003 to 2007 and a 3-fold increase in the use of hydromorphone during that same period, with hydrocodone being identified 2 to 3 times more than morphine over the same period. I thank Kevin Klette and my peer Jim Swart over at the DOT for presenting some discussion on prescription medications. We have similar and shared concerns of the abuse of these drugs within the workplace. Specifically, Kevin's data on what he labeled as a prescription drug threat show similar increases to the Quest Diagnostics data that has been on their website now for a few years.

The DoD program has a human reliability program, and I will discuss the parallelism with that implemented at the Nuclear Regulatory Commission. The public entrusts us to provide reasonable assurance that persons who perform safety and security-related activities at our commercial nuclear power facilities can perform their duties responsibly and professionally. If we lose this confidence, either by personal error, such as sleeping air traffic controllers or inattentive security guards, or by programmatic delays, such as not testing for so-called legal drugs that could represent a significant public health and safety concern, then shame on us. We need DTAB's support and HHS' leadership, guidance, and expertise. I believe HHS and DTAB are the silent heroes associated with our continuing effort to protect public health and safety.

Within the Nuclear Regulatory Commission, there are two drug testing populations. One drug testing program is for NRC employees. I do not represent that organization; that's a separate, independent organization from me. They perform the drug testing of myself, my coworkers, the NRC inspectors, and managers in the NRC. I provide the regulatory oversight of public employees who work at NRC-licensed facilities, such as power plants. Our regulation is 10CFR Part 26, Fitness for Duty Programs. Our regulations for these individuals at our power plants parallel the HHS Guidelines, and we leverage off the DOT requirements. Though we parallel the Guidelines, however, we have not yet implemented rulemaking to institute the November 25, 2008 HHS Guidelines to lower the cutoff levels for the amphetamines and cocaine and to test for MDMAs. There are reasons for that, and the primary reason is that we provide a defense in depth approach to the trustworthiness and reliability of our individuals at these power plants, and I am going to discuss that a little bit more in the next slide.

Our Fitness for Duty strategy I will discuss in the next slide, and drug and alcohol testing will be the slides after that. I wanted to mention up front and openly that I believe that our challenges are the synthetic opiates, marijuana use, and synthetic urines. We believe that drug cocktailing and prescription shopping are also concerns.

The Fitness for Duty strategy implemented per 10 CFR Part 26 is multipronged. We not only perform drug and alcohol testing, but we also perform fatigue management, which is captured under the umbrella of observing personnel performance in the conduct of their duties. We continuously conduct behavioral observations for every person who has unauthorized access to our nuclear power plants. In addition, we have a very robust access authorization program in which we perform initial drug testing like the majority of industries. We do criminal background checks for access authorization, which includes criminal history, psychological tests,

criminal background checks, financial history checks, and other background checks similar to the DoD access authorization. Thus, the core work group within the nuclear industry is very stable with little turnover, and they are highly professional and well-trained.

The lower left hand picture is representative of a nuclear power plant or fuel cycle facility. It illustrates the number of boundary areas in which people can gain access to this power plant. The innermost sanctum area within the buildings is called the vital area; that is where all the safety-related and security-related structures, systems, and components exist. Every person who enters that area also has to pass through a protected area, which encompasses the big fenced-in area that surrounds the power plant. This protected area is secured by watch guards and a highly trained, well-armed security force, making this area probably the best-protected commercial facility in the United States.

I mentioned we perform fatigue management. That fatigue management is coupled with our behavior observation program, which includes NRC's 50 percent random testing rate. Unfortunately, we do not catch everyone with 50 percent random testing rates. For instance, if a full-time employee is subjected to a 50 percent random testing rate, he or she has a 40 percent chance of being tested that year. That translates into a 60 percent chance of not being tested. Is 50 percent good enough or should I be testing at 75 or 100 percent? If I adopt a 100 percent random testing rate, only 65 percent of the people will be tested once a year. In the human reliability program implemented by the DoD at a number of their facilities, they have to test every person once a year. I believe also, Kevin correct me if I am wrong, they also implement 100 percent random testing rates. Thus, the DoD testing rate is significantly higher than the NRC. We are evaluating this.

One of the major concerns I have is our transient work force. A transient employee at a power plant is not a permanent employee but rather is there on a temporary basis, for example, three months out of the year. At a 50 percent random testing rate, only about 12 percent of the people are tested per year. I am not testing everyone at 50 percent, I am only testing a small number of that population because of the 50 percent random testing rates.

This data represent calendar years 2005 through 2009. In 2009, the NRC initiated electronic reporting of drug and alcohol testing events to the NRC. Data from 2009 and 2010 represent the beta years for implementing this initiative. Because not all licensees have electronically reported, we are having difficulty melding the electronic data with the paper copy data. Thus, the 2009 and 2010 data are broken out, and I will cover the 2010 data really quickly. The overall percent positivity rate for both licensee employees and contractors is about 0.6 percent. There is an influx of contractors whenever a power plant enters a refueling outage or if there is construction on the site. Whenever there are a number of contractors working on a site, the positivity rate increases at that site because the worker population is now more representative of society and the culture in the vicinity of that power plant.

For this period of time, about one-third of all the NRC licensees have lowered the blood alcohol concentration levels for testing. Though outside the scope of the Drug Testing Advisory Board, from a Fitness for Duty perspective and to provide confidence to the public, workers must not be under the influence of alcohol. Almost all of our licensees, or 104 sites representing about 67 corporate entities, have lowered their cutoffs for marijuana. Marijuana continues to be the highly prevalent drug of choice, as represented by other data presented. A number of licensees have lowered their opiate levels voluntarily; remember that I stated earlier that we have not required the mandatory implementation of the 2008 HHS Guidelines yet. Four licensees are testing for barbiturates, methadone, methaqualone, propoxyphene, and benzodiazepines. Our security force is very concerned about benzodiazepines. Right now benzodiazepines are not part of the current HHS testing panel. Benzodiazepines could adversely affect a security officer who needs to decide whether to use lethal force or not, and the armaments and guns that these folks are carrying makes me concerned that they are adequately drug tested for that drug class.

This slide presents an overall view of the dotted line. On top is our contractor rate for those short-term contractors at these facilities and the bottom is the licensee employees. Notice how our rate is relatively low,

with an average of about 0.6; that's about halfway between the two lines. What I want to establish are some performance indicators; I heard Kevin talk about his DoD performance indicators. I am not seeing a change in the positivity rates of licensee employees, so I want to lower that rate, and I am searching for ways of doing that.

This is an interesting graph showing the number of sites (y axis) by employment category. With the electronic reporting of data, I can dive deeper and deeper in the types of employment categories. The gray one is licensee employees, and the red one is contractors. I have 35 sites out of 104 that have zero positive hits on random drug testing at a 50 percent random testing rate. That concerns me because it is not representative of the expected positivity rates; I should be getting something. I have one site shown on the far right with a random testing positivity rate of 1.6 percent. Knowing this, I could direct an inspector to go to that site and provide them with this information and ask some detailed questions of the licensee, specifically, why they have high random testing rates. Similarly, notice how the employees, shown in the grey bars, quickly achieve about 0.6 to 0.8 positivity rates while the contractor data is skewed, flattening out at the much higher rates shown on the right. This skewed population represents the short-term contractors that I am worried about. This graph demonstrates to me what sites are having the problems. If a Florida or a Texas site, for example, has a high random testing positivity rate, I could send an inspector there to provide some assurance that we are testing properly.

One of the issues is subversion attempts. Speaking for myself and not for the Nuclear Regulatory Commission, this slide is a staff presentation of the 2009 data. For pre-access testing, we are seeing physical evidence and refusal to cooperate as evidence of subversion attempts. For instance, the donor presents for his test, and he is not following the collector's instructions. We are also seeing physical evidence and other subversion techniques and observed actions. With the electronic reporting, we are trying to be very specific to help identify where the problems are occurring. Perhaps the collectors aren't giving appropriate instructions, or perhaps the collection facility is not facilitating a reasonable collection, such that the individual is not able to follow the instructions of the collector. In the graph below is labor category by subversion attempts. The group with the most subversion attempts is maintenance. What group has the most number of employees entering the site during outages who are short-term contractors? Well, it is the maintenance personnel who perform welding, pipefitting, electrical wiring, etc. These maintenance personnel are from the union halls in the vicinity of the power plants that have the most subversion attempts. Other labor categories include security and HPRP (Radiation Protection and Health Physicists) who monitors the radiation contamination levels. The bin called "other" is meaningless to me, and I want to eliminate that category. Unfortunately, that is the way the data are right now.

The data for 2010 are a mixture of paper reports, which are very difficult to process because of budget and staffing constraints. With our electronic reporting, these are the current data we have for 2010, showing a 0.64 percent positivity rate.

We have a classification known as pre-access which is similar to pre-employment. To receive access to a nuclear power plant, the individual must undergo random drug testing. Other testing categories include random testing, for cause, post-event, and follow-up. The post-event category is muddied because some licensees perform for cause testing after an event. The follow-up testing category is for those individuals who have tested positive once and are now under a follow-up program.

Electronic reporting allows me to further evaluate my issues of concern. For pre-access testing of licensing employees, alcohol positivity rates have increased. Why? Individuals are coming to work, and they are nervous. To reduce their anxiety, they had one too many beers, and thus we are finding positive alcohol results. Marijuana positive results, of course, are representative of society. Notice that there are very few opiate, amphetamines, and cocaine positive results. The toxicologists, doctors, and other medical personnel might understand why I am not detecting these drugs with pre-access testing. Refusal to test occurs in pre-access testing.

For random testing, positive drug results are evident for cocaine and amphetamines. Refusals to test are occurring, as are positive results for amphetamines. We are not finding any post-events for cause testing because, as I said earlier, licensees are not categorizing correctly based on OSHA events. This I will have to fix. Positive results are occurring in follow-up testing.

So what do I conclude from this? Well, I am not detecting everything I want to detect. Individuals are working inside the protected area, and I am not detecting through testing the amphetamines, opiates, or cocaine that they are using. So how do I do that? Do I do that by hair testing? Well that might be an option. Right now, we are performing urine testing only. If the worker knows he is being tested soon, he can abstain for a few days to remove the drug from his system. Thus, we cannot detect his drug use. I have the data that show that now.

For the contractor vendors, the data were so skewed I had to display it in two different formats. Remember, these are preliminary data because only electronic reporting is included. Notice that marijuana is still very high, which is consistent with DOT and DoD data. Other positivity areas include alcohol, cocaine, and refusal to test.

Let me talk about refusal to test. The NRC is very strong in sanctions. We have no tolerance for drug or alcohol abuse in these facilities. But we are realistic in that people do take drugs. The first time someone tests positive for drug or alcohol, he is out for 14 days. The second time that occurs, the worker is banned for 3 years from working in the nuclear industry. For third time, which is the third strike, he is out permanently and forever from NRC licensed activities within the NRC community. That is a strong deterrent for individuals, and we hold licensees accountable for these sanctions on individuals. We have a national database that tracks every nuclear worker that has unescorted access into nuclear power plants to make sure that licensees are implementing this rule in compliance with our zero tolerance policy.

The majority of our positive rates are found in the random testing, for-cause, post-events, and follow-up categories. Notice under the top graph, the number of opiate occurrences shown in the very light blue. Only ten opiate positive results were found in the whole population of 2010 results. We are not detecting the opiates, including the prescription opiates. This, I think, demonstrates that we need to broaden that testing panel.

I am interested by labor category as to who is taking drugs in the nuclear power plant. I am concerned that I may have reactor operators in the control room on drugs; therefore, we are focused on those individuals, as well as the maintenance people and others who have unescorted access to the facility. The labor categories that are drug tested include maintenance, security, and HP/RP. Annually, we test about 168,000 people, a small number compared to DoD and DoT. Positive test results are found for marijuana, alcohol, cocaine, etc. as denoted by the different colors in each labor category. For all labor categories, the majority of the positives are for marijuana and alcohol. For the security force, shown in the bottom pie chart on the right, the testing rate is relatively low. The data indicate that security is a highly professional workforce with very few drug positive results. We thank the DoD for providing the nuclear industry with highly trained professional individuals who realize the importance of being fit for duty. The vast majority of operators at nuclear power plants are ex-Navy personnel. Most of security forces at power plants are special operations forces and security people from the Armed Forces.

I am really worried about the drugs that we are not testing for, such as barbiturates. I am also worried about those drugs that we do test for but are cleared from the body relatively rapidly and thus may not be detected.

Shown here are the 2010 drug positivity data for my reactor operators, divided by licensed and non-licensed operators. A licensed operator operates the power plants, direct operations, and controls reactivity. The non-licensed operators change the valves, start up pumps, and open and close circuit breakers. Notice the difference in positivity rates between the two groups. Most of the positive results are found on random testing. Very few positives are detected in follow-ups because once these individuals get their jobs, they want to keep them. So generally, when they come in for pre-access testing, they are drug-free. The stress of working may drive them to drink alcohol which is then detected on random testing.

Overall, the drug and alcohol positive rates remain low. My goal is to identify performance indicators that could help drive the positive rates down even further. One means under consideration by NRC is testing for the synthetic opiates. We are researching the possibility of rule-making for synthetic opiates, and we will be receiving support from external organizations as well on this topic.

As I said at the Society of Forensic Toxicologists meeting last year, synthetic opiates are the issue. There are owner operators of commercial nuclear power plants who are testing for synthetic opiates, primarily hydrocodone and hydromorphone. Because of drug cocktailing, I am concerned about oxymorphone, oxycodone, and perhaps the benzodiazepines. The use of the semisynthetic opiates with benzodiazepines is a security issue within the security guard force. I would like my MROs to investigate drug cocktailing, and I am thinking about making it a requirement. In July 2011, we have a conference in Chicago where we will be making a presentation to the nuclear industry to solicit stakeholder input on this initiative.

For calendar years 2009 and 2010, the data are paper-based and very difficult to sift through. Electronic reporting is improving data evaluation. With our Fitness for Duty program, I am responsible for providing reasonable assurance that there are no significant changes within the industry.

To detect prescription drug shopping, about 20 states now have prescription databases that can be searched by MROs. I think the majority of prescription shopping is associated with criminal activities. We're investigating whether or not private entities can gain access to that database to help inform MROs in their Fitness for Duty assessments.

I believe that hair testing will be a strong deterrence. My pre-access testing is not detecting some of the drugs that I think I should be finding. I think the administration of pre-access hair testing will be difficult. I am not sure how to implement that, but I am more than willing to listen to more intelligent people to figure this out. Also, the interpretation of hair testing positive results must be considered. A person comes on my site and has a pre-access hair test performed. We discover that he took marijuana sixty days ago. What do we do with that?

The last bullet is the NRC's defense in depth approach, which includes the behavior observation program coupled with fatigue and access controls to ensure that the person's fitness is appropriate to the safety and security activities that he/she is performing at the sites. This approach will allow the NRC to meet its strategic objectives.

One bullet that I did not list here is the use of oral fluid for drug testing. With the nuclear renaissance and the construction of new nuclear power plants, we will have a large temporary workforce of about five thousand individuals per site. I think oral fluid drug testing represents a significant benefit to those facilities, and I know that the owner/operators would be interested in this testing because of the time limits associated with oral fluid testing and the possibility of associated lowered costs. On the operations side where the size of the workforce is stable, oral fluid testing may not be so readily accepted by the industry if forced upon them by regulation. However, as an option, many people are nodding their heads yes to use oral fluids.

We need the help of the Drug Testing Advisory Board and HHS to develop solid legal and technologically defensible drug testing guidelines for synthetic opiates. We also need to address how to combat substitution through the use of synthetic urine. We have seen synthetic urine already at one of my nuclear power plants where they did not really know what to do with it, but clearly the donor was subverting the test and he had it on his body.

We are evaluating the adulterants listed in the HHS Guidelines and wondering whether or not we can improve our adulterant testing and possibly test for additional adulterants.

Ever since I accepted this position about two years ago, I questioned why we inform donors of the adulterants for which we test. And lastly, I think we need to develop a national database for tracking prescription drugs. From the 20 states that are performing prescription monitoring, I would like to obtain a database that my MROs

can consult to help inform their decisions on the fitness of their individuals, especially when dealing with the synthetic opiates.

I would be more than interested in hearing any questions. If anyone has a question, I will be more than happy to respond to it. Thank you very much.

Dr. Cook: Thank you Paul. Because we are running a little behind schedule, I request that all questions be held until later. I would like to introduce our next speaker, Ron Flegel, a forensic toxicologist within the Division of Workplace Programs. He will be updating you on the 2010 lab results for the federal workplace drug testing programs.

Federal Workplace Drug Testing Programs

Mr. Flegel: Thank you Janine. First of all, I would like to thank everyone for joining us today. Secondly, I'd like to thank the Federal agencies for sharing their data; it was really informative. I would also like to thank the RTI staff and specifically, Dr. John Mitchell, and especially, the laboratories that perform the testing for all of us here. Because of them, we can provide these data to you.

I will initially focus on the 2009-2010 data, and then later I will specifically examine the data prior to and after the October 1, 2010 implementation of the revisions to the Mandatory Guidelines.

Comparing the 2009 to the 2010 data, in 2010, the number of specimens tested was around 5.7 million, while the number of specimens tested in 2009 was 5.5 million, an increase of about 200,000. The number of specimens reported as drug positive, adulterated, invalid, and substituted increased from 88,500 in 2009 to 95,400 in 2010. While the number reported as positive was greater in 2010, the percentage of drugs reported positive in 2010 and 2009 was very similar, with the notable exception of amphetamines.

The number of specimens tested in the quarter after implementation of the revised Guidelines was 1.4 million, which was 81,279 less than the 1.49 million tested in the preceding quarter. In spite of the decrease in the number of specimens tested, the number of specimens reported as drug positive, adulterated, invalid, and/or substituted increased in the quarter after implementation to 24,982, which is about 1.76 percent, versus 24,700, which is 1.65 percent, in the prior quarter. The percent of specimens reported as drug positive, adulterated, invalid, and/or substituted from October through December 2010 was actually about 0.115 percent higher than seen from July through September 2010. This was about a 6.95 percent relative increase over that time period. The percent increase in specimens reported as drug positive, adulterated, invalid, and/or substituted from October through September 2010 was about 0.181 percent, higher than seen in the same period of 2009, which is about an 11.39 percent relative increase. We investigated the root cause of this increase. The specimens reported positive for marijuana from October through December 2010 increased about 0.102 percent but was a decrease of about 0.102 percent when compared to the July through September 2010 timeframe. Thus, there actually was a small decrease in the last quarter. Similarly, the number and percentages for adulterated, substituted, and PCP positive results were very similar for both quarters, with invalid results being slightly higher in the third quarter.

For those specimens that tested positive, I will present the breakdown by drug class. The percentage of amphetamine positive specimens increased by 0.083 percent, and the percentage of methamphetamine positive specimens increased by 0.34 percent from October through December 2010 when compared to the specimens reported pre-implementation from July through September 2010. The percentage of cocaine positives, as represented by the presence of benzoylecgonine, increased by 0.87 percent from October to December 2010, as compared with the specimens reported from July through September 2010. Keep in mind that the actual testing rate decreased in this fourth quarter as compared to the third, yet the positivity rates increased after the implementation of the new Guidelines on October 1, 2010. A slight increase in the number of opiates reported as positive, specifically codeine, increased. The percentage increase was 0.025 percent from October through December 2010 when compared to the July through September 2010 data. The

specimens reported positive for 6-acetylmorphine from October through December 2010 accounted for an increase of about 0.004 percent when compared to the July through September 2010 timeframe. Specimens were also being reported as positive for the designer drugs, specifically Ecstasy and MDMA; however, these drugs do not account for much of an increase in the overall positivity rate.

In summary, after the implementation of the revised Guidelines on October 1, 2010, there was about a 4 percent reduction in the number of specimens tested, but overall there was an increase in the percent of specimens reported as drug positive. Secondly, the major drugs responsible for the increase in the percent of specimens reported positive were those for which the cutoffs were lowered, specifically, cocaine, amphetamine, methamphetamine, and MDMA, on October 1. Finally, there were smaller increases observed with the 6-acetylmorphine and codeine. That concludes my presentation.

Dr. Cook: Thank you Ron. Again, I will hold questions until we are done. Our next speaker is Commander Jennifer Fan of the United States Public Health Service. Jen is also a member of the Division of Workplace Programs. She will update you on the Medical Review Officers' Certification process.

Medical Review Officer (MRO) Certification

CDR Fan: First, I will provide just a brief comment regarding prescription drug monitoring programs. There are actually 35 live programs, and I believe to date that 45-46 states have laws that allow the prescription monitoring programs to be created.

I am Jennifer Fan, and I have recently joined the Division of Workplace Programs. I have been on board since February and have assumed the duties of Commander Belouin. I will be providing a brief overview of the medical review officer certifying entities. Since much of this information was presented at the January DTAB meeting, I will be very brief.

An MRO (Medical Review Officer) must be a physician that has either an MD or a DO degree, knowledge regarding the pharmacology and toxicology of illicit drugs, completed training necessary to serve as an MRO, and satisfactorily passed an examination administered by a nationally-recognized entity that certifies MROs or a subspecialty board for physicians performing reviews of Federal employee drug tests, which has been approved by the Secretary.

An MRO-certifying entity must be nationally-recognized and must submit their qualifications and sample examination to SAMHSA. That information is subjected to an objective annual review and deemed acceptable before approval of the entity by the HHS secretary. The current approved MRO entities that are certified for training and certification of MROs are the American Association of Medical Review Officers (AAMRO) and the Medical Review Officers Certification Council (AAMROC). The organizations that are approved for MRO training are the American College of Occupational and Environmental Medicine (ACOEM) and the American Society of Addiction Medicine (AASAM).

The 2011 MRO entity approval timeline will be based on last year's timeline. MRO entities that are interested in seeking approval from the HHS Secretary must submit the information to us by August 2011. Once the Secretary approves the MRO entities, the list will be published in the Federal Register by September 2011.

We realized that the National Laboratory Certification Program has e-mails and notifications that impact MROs. Early last month, we contacted the four approved MRO entities to request the names of contact persons who can receive these NLCP notifications and disseminate them to their MROs, if appropriate. Currently, AAMROC, AAMRO, and ACOEM are receiving notifications; ACOEM has just begun this process.

At the January DTAB meeting, we discussed that we were developing MRO entity guidance in a FAQ format. Currently, we are in the process of drafting, reviewing, and revising this guidance. Hopefully, we will be finalizing this document in the next coming months for posting on our DWP website.

These are our key references, which are posted on our website as well. Thank you.

Dr. Brown: I must confess that this continues to be an interesting, but steep hill climb for me at my second meeting. I have a couple of questions, but I have a comment first. While my focus is on medicine and public health, I have sympathy for those who focus on public safety. I do not understand why we do not have a policy for direct observation of urine collection. Based on the scientific data that suggest behaviors to avoid detection in safety-sensitive positions, I am not sure why we do not have that as a policy. I am not in favor of taking peoples' privacy away, but at the same time, we have to understand that the definition of privacy has evolved over the decades. From a policy standpoint, that deserves some discussion, given the evidence I have seen here.

Also, I have a specific question for my colleague here, with respect to the prescription drug monitoring programs that exist. I think it is important to inform the audience that these programs vary in terms of their structure and their ability to answer important questions for physicians. So in some of them, physicians can find information that is robust, in others they are quite frankly worthless. The issue concerns the physician monitoring of employees, especially employees in the safety-sensitive positions, who are taking prescription medications. I think that when legitimately used, prescription medications are appropriate, but at the same time, the potential of abuse clearly exists.

With respect to the MRO certifying entities, how frequent is this process? Once an entity has been approved, how often do they have to be reapproved?

CDR Fan: It is an annual process. Each year the entities would submit information, which we would review and then send the list to the Secretary for her review as well. She would then approve or disapprove.

And you are right, the prescription drug monitoring programs are controlled by the states. That is why the structures are different. Some programs and some states only collect C2 medications while some collect C2 through C4 or C2 through C5. It varies from state to state.

Dr. Brown: Is there a policy reason why this is done annually? I am not sure the science really changes enough on an annual basis to have a policy decision that may have a business impact on some of these entities. Help me to understand. If that needs to be explored later on, then I have no objection to deferring your response to that one.

CDR Fan: As far as I know, it is per the Mandatory Guidelines, and it is reviewed annually.

Mr. Flegel: We can look at revising that later. Because of the turnover in MROs being accredited, within a year time frame, they could have fallen outside of the time that the MRO entity was actually teaching or trained those physicians as MROs. So initially, it is on an annual basis. As we look further down the road, the Guidelines may be revised to include a longer time frame.

Dr. Brown: This is the approval of the entity, not the approval of the MRO, right?

Mr. Flegel: Correct.

Mr. Stein: Good morning, I am Jack Stein with the White House Office of National Drug Control Policy. First, thank you for the presentations; they were all dynamite and really well put together. Paul, you made a very interesting comment that I am curious about your thoughts on, as well as any of the other panelists. First of all, we are talking about extremely low positivity rates, which are just great to see, in this drug testing program. You made the comment about you hope to bring the rates even lower. I am curious, what your thoughts are on that? Can drug testing contribute more to that process or should we be looking at other factors? Are there risk factors for these individuals that test positive that we do not know about, and thus, are not looking at but should

be appreciated?

Mr. Harris: The NRC has a similar program to the DoD. We perform drug and alcohol testing to determine the trustworthiness and reliability of the individuals. We are really trying to strengthen the behavior observation program at all these facilities because the drug testing rate is so low. We have the opportunity to observe these individuals at a more frequent and more robust programmatic way to identify whether or not a person is under the influence of any drug. One of the items I mentioned was for cause and post event testing. The for cause testing is clearly driven by behavior observation. If a senior reactor operator sees someone grab the wrong switch on the control panel, he has a duty to do something about that since such an action is contrary to the employee's training. Most licensees will automatically enroll that individual into a behavior observation program, in which the supervisor would ask the individual several questions, such as how are you doing, what's wrong, and are you tired. The supervisor will closely observe the employee, including his physical characteristics, because the tolerance isn't there. We have agency-wide metrics known as Strategic Metrics are Zero (MRZ) which dictates zero tolerance for events, such as accidents, overexposures to radiation, loss of materials, etc. Some operators are working while testing positive for drugs and alcohol, and they know it is part of their job not to work while unfit for duty. I will address this programmatic issue by strengthening the behavior observation program.

Mr. Bonds: I have just two quick questions. First, Ron, thank you for your presentation. On your next to last slide, you discussed the revised Guidelines and their impact on the positivity percentages. Were you able to normalize the percentage increase against the reduction of tests overall?

Mr. Flegel: We actually did not normalize against that for the quarters because what we wanted to evaluate was whether the Guidelines changes affected the positivity rates. Indeed, the positivity rated increased.

Mr. Bonds: But that is overall against all of the other specific drugs that you reported on.

Mr. Flegel: Correct.

Mr. Bonds: Thank you, Paul, for your presentation. Regarding your follow-up program, I am assuming that you have a mandatory program after initial identification. At what frequency are those tests performed and what is the length of time the person is in the program?

Mr. Harris: We have had a number of comments of this from substance abuse experts. Our regulations require the owner operators of nuclear power plants to hire substance abuse professionals, and they determine what the follow-up programs are and the frequency of testing. The NRC does not provide guidance to these medical individuals on what an adequate follow-up testing program is.

Mr. Bonds: So it is under the standards of that policy.

Mr. Harris: Yes, sir.

Dr. Cook: I conclude the morning session. We will reconvene at 1 p.m.

(Whereupon, a luncheon recess was taken at 12:00 p.m.)

Afternoon Session (1:00 p.m.)

Dr. Cook: Welcome to the afternoon open session of the Drug Testing Advisory Board. I now call this meeting to order. The first presenter of the afternoon session is Neil Fortner, who is Chief of Quality Assurance for the Air Force Drug Testing Lab. Neil will be providing information regarding the electronic custody and control forms.

Electronic Custody and Control Form (CCF)

Electronic Documents

Mr. Fortner: Thank you, Dr. Cook and members of the Drug Testing Advisory Board. It is good to be back here again. This is our standard disclaimer from the Department of Defense. Views that are presented here are not representative of anyone from the Department of Defense or any of those associated organizations.

If you stay in this business long enough, things come full circle. I was a member of the original group that worked on the seven-part custody and control form. In the early days, it was an arduous task to print these forms. Today we utilize a five-part form. But why an electronic custody and control form? The CCF process begins with a collection process, followed by sending the copies of the CCF to multiple individuals, including the laboratory, the donor, and the MRO. The problems associated with this paper CCF include the method of transmission of these forms, which is usually by fax to the MRO and by mail to the collector, the employer, and the lab; the donor also receives a copy and a copy is filed.

I would like to thank Jim for this information, although it is a little outdated. Looking at Department of Transportation's 2010 numbers, there were 5.4 million DOT tests. A five-part form, which includes the testing facility, MRO, collection site, employer, and donor copies, equates to 26 million pieces of paper that were circulating around the country. And I mean that literally because in a previous life, I ran a large third party administrator program with 13 MROs. Our biggest challenge was receiving copies of CCFs from collection sites; I had hundreds of people who were responsible for that. I do not think things have changed very much since then.

These are the problems that the industry currently faces. We print five copies of a carbonless form. Some of them are of better quality than others. By the time you fax ply 4 of a carbonless form, good luck reading it. Sometimes, collection sites insert copies in the fax wrong; the faxes come through, but they are blank. We mail copies; sometimes they get there, sometimes they do not. In today's electronic age, snail mail does not meet the demands of the industry, so it impacts on the turnaround time across the board. The MROs are constantly contacting the collection sites because they cannot process a drug test result without a copy of the Custody and Control Form; this has a significant impact on their business operation, including the turnaround time back to the employer and subsequent action on a donor. Many times a day, we would place calls to the collection sites to explain that we could not read the collection site copy sent to the MRO. We asked that the copy be made darker and re-faxed to us. Though this sounds insane in this day and age, it is the reality.

I contacted a MRO group that I used to manage and asked them for their data from the last seven days. These data are current as of two weeks ago. They processed 5800 DOT results. Of those, for 400 of them they could not read the donor signatures. Another 1300 CCFs they could not process because of missing information. Doing the math, about 29 percent of the CCFs received in a one week snapshot had issues that resulted in the results not being processed. Add to that the number of calls from MROs to collection sites and labs. This does not even address the problems where we cannot find the custody and control form or we cannot match a CCF with a drug testing result. This is one of the more common, frustrating features in the world of paper that we would live in. Other CCF issues include when the collection site does not check the temperature box. What happens then? Well, it goes into a limbo. The lab can receive and process the specimen, but the lab cannot report the results. The lab attempts to obtain an affidavit. If they cannot get an affidavit, they are allowed to report the results within a certain number of days. The turnaround time on a negative result from a problem is

about five days. Positive results might take a little bit longer. Bottom line, it delays the process and costs time and money. Having managed large drug testing labs, I know this is what happens. For instance, the lab receives a custody and control form, and the collector's name is illegible. It is a problematic issue.

I spoke to another smaller MRO organization and asked them to also pull data from a specific time frame for me. Of their ten thousand DOT-reviewed results, five percent had errors in the custody and control forms that they received, including unchecked temperature boxes, missing signatures, missing dates, and missing donor or employer information. The bottom line was, again, a delay in the reporting of results. This delay is anywhere from one to six days on the MRO side, not including the front end, which includes collection, transport to the lab, lab processing and testing (less than a day for a negative result and between one to two days for a positive result), and result transmission to the MRO.

I did speak to one MRO group that had actually done an analysis of the cost to chase these pieces of paper around. Their estimates suggested that it cost them an additional four dollars of direct costs per specimen over the routine cost of the MRO process required under the Guidelines to chase the pieces of paper. Though this does not sound like much money, but this is a very competitive industry with not much profit. Thus, four dollars per specimen is a lot of money in this drug-testing process.

From the lab side, there is a huge inventory of custody and control forms in the field, which equates to tens and hundreds of thousands of dollars. The laboratories send out 1.8 or almost 2 chain of custody forms for every one that is returned completed. This is a significant overhead in terms of burden and hidden costs that is carried by the lab. Not only that, it is not unusual. I have spoken to a number of labs in addition to my experience managing labs for many years. Labs receive chain of custody forms that are three to five years old. Because some are so old, I never even knew we had printed them. Where did they come from? In collection sites, these old CCFs are stashed who knows where. Because collection sites have to maintain an inventory of custody and control forms, it is another hidden issue that is out there.

The problems that present themselves, particularly in the laboratories, involve the MRO information on the custody and control form that is no longer consistent with what is in their database. It is a constant challenge to keep that database information current.

The non-regulated drug testing industry is moving forward with the electronic chain of custody. The business models will drive processes forward. When there are not regulatory requirements for a laboratory or a collection site to do that, the industry will find better, newer, faster, and maybe cheaper ways to do that. I have listed a snapshot of groups that are using electronic custody and controls forms. There are many other third party administrators and laboratories that are developing their own electronic chain of custody. Those listed are not the only groups using chain of custody in an electronic format, but these are some of the leaders. MedTox has its own proprietary electronic chain of custody. EScreen has had electronic chain of custodies and digital signatures for longer than most of the laboratories. FormFox is a unique third party provider with an open platform that many of the laboratories, Qwest being one of them, have been able to adopt into their systems. It is just one of the third party approaches that molds itself well to laboratories that cannot afford to develop their own electronic chain of custody. The large labs, such as Quest and LabCorp, are taking advantage of those different approaches, producing different electronic chain of custody approaches. It can be electronic because the donor information is downloaded to a collection site from an employer to schedule a collection. Or, an applicant to a company such as Home Depot, Wal-Mart, or Target can complete the application for a position at the company's applications center. The Human Resources person, if he/she decides to hire that individual, downloads the information about the donor, including Social Security number, address, etc., from the application directly to collection sites. When that individual arrives at a collection site, they present their ID and their information is ready to print. That is one less potential for error in that process.

I have provided the board with just some examples. One question is with all these different labs, how does an electronic chain of custody system accommodate different bar codes? If a donor goes to a collector that collects for five different laboratories, how does the collector get that right information sent to the right

laboratory? The most common approach is for the laboratory to pre-assign barcodes to that collection site, so that when that individual arrives and the collector pulls up the information, the collector can see that the donor is supposed to have a collection done today and that sample is supposed to go to Quest in Lenexa, Kansas. The information is pre-populated because of the assigned barcode, so the collector knows the account information, what test panel to request, and who the MRO is. All that information is generated on the spot from that download.

Each of the programs has different approaches. LabCorp is currently using print on demand, where the information is downloaded electronically, hard copies are printed, and the donor provides a wet signature. At the other end of the spectrum, MedTox has everything electronic. The information is downloaded, no chain of custody is printed, and a digital signature capture pad to used to capture the collector's and donor's signatures. The collection has assigned barcodes. No paper is printed at the collection site. The specimen is sent to the laboratory where the barcode on the specimen bottle is scanned and the information is populated. The lab can print a chain of custody, if needed, with donor signature, etc. There is a variety of electronic chain of custody approaches being used. Quest uses in between combinations, but I think that everyone is moving toward a common, standardized approach.

What are the advantages? The most significant advantage, based on where the problems currently exist in the program, is in the situation where a chain of custody is needed to send with the specimen bottle to the lab. That could be done right then and there. The most significant advantage is that all of the other forms that are sent to the lab, MRO, and employer do not need to be printed or faxed. They can be sent electronically as the collection is finished. The advantage is that you do not have to deal with the poor quality of a five-copy carbonless form, such as the fax of part four. If the collector needs to resend the CCF to the MRO, he/she pulls up that bar code and resends it electronically. The issue of chasing paper using is a fax or scan approach is now obsolete.

There is currently one category 5 lab that is using a full electronic chain of custody. They are processing about 12,000 specimens a day, with between 600-1000 of their non-regulated specimens being processed through a completely paperless chain of custody process. It seems to be working extremely well. The collection site uses their electronic collection process. The specimen bottle is sent to the laboratory where its barcode is scanned and the information is populated in the accessioning system. The MRO and employer automatically receive the custody and control form electronically. The donor receives a copy, and the collection site saves an electronic version. All the pieces of paper that exist in virtual space are transmitted electronically, thus improving the legibility of the information.

The other advantage of electronic custody and control forms is that fields can be made mandatory. If a mandatory field is not populated with the required information, then the collector is not allowed to proceed to the next field. It is what was called directed accessioning. The mandatory fields cannot be skipped or the collector would not be able to close out the collection. This provides the ability to have a much higher quality collection, so information is not skipped because of the mandatory fields.

One of the organizations that I referenced earlier has been using this version of electronic chain of custody for over ten years. In their estimation, they have processed over fifteen million samples using this process. They have not had to collect one affidavit in fifteen million collections. Why? It is because their system will not allow the collector to go on to the next step until they have entered all the information, so that potential loophole is eliminated.

The electronic CCF eliminates the need to fax or transmit scans of custody and control forms; everything is sent electronically. This huge inventory of custody and control forms that are out in the field is not needed.

One of the other advantages of the electronic custody and control form is that these are all web-based. This improves the ability to keep information current. MROs change, DERs change, and the appointed person at an employer changes. The web-based systems allow information to be kept current, in real time. Most collection

sites have computers. One of the things to consider is that different vendors or laboratories may have their own systems. Okay, I have Lab A with its system here, lab B with its system there, and lab C with its system here. Collection sites do not have space to have five different systems and printers for all the different vendors. With an electronic approach, you could use one computer system and one printer, with the different forms for different labs, differentiated by employer, all serviced through a common access port because they are all web-based. This eliminates the redundancy of having multiple systems in a collection site. The reality is the collection sites do not want to maintain five different systems.

There were questions earlier concerning the two-sided printing of the current custody and control form. The back of the different copies of the current custody and control form are printed with the public burden statements, privacy statements, and instructions on how to complete the custody and control form. I recently went to a physician for an ear infection. I had not been there for a while, so I had to sign my HIPPA patient confidentiality forms. All of that was done digitally. I read the forms and signed on an electronic pad that I acknowledged and consented. The same thing can be done for those statements that are currently printed on the back side. The donor, if desired, could read and acknowledge the stored version. If there is an issue whereby the donor said that he/she did not read the collection process instructions, the electronic signature is available to prove that he/she acknowledged reading it. This is currently done with double-sided printing on the backside of the forms. These issues could easily be addressed and are not a major challenge in terms of the development of electronic custody and control form.

All of these programs use encrypted transmissions. Certainly, whenever dealing with electronic documents, the security and encryption of how that form is structured and what the algorithms are used to protect the integrity of that information, whether it is Social Security information or other personal protective information, is important. The software programs that exist must ensure that the information cannot be compromised or altered. Though you cannot read my signature after I have signed it 25 times in one day, I do not want somebody trying to recreate it. Those processes must have that check and balance.

Next is probably the most controversial, or questionable issue, which is the use of electronic or digital and digitized signatures. I will talk about the difference between an electronic digital signature versus a digitized signature. This is one of the areas that require the most attention. Electronic digital signatures are cryptographic mechanisms that actually encrypt information through the use of some kind of biometric or digital certificate. For my work for the Air Force under the Department of Defense, I have a common access card that contains my information and is biometrically encrypted with my fingerprint. I must insert this card into my laptop to answer e-mail and to sign documents. When I sign, I create a digital certificate because that certificate is captured on my common access card. Digitalized signatures, used in such places as Wal-Mart, Target, Sears, or Home Depot, are created when after I run my credit card through and squiggle my signature on the signature pad using a stylus; this is not a digital signature. It is a digitized signature. It is a mechanism that attempts to capture a facsimile of what is considered a pen, ink, or a wet signature. It involves a mechanism where some kind of pen is used against a surface to capture that fluid movement.

In January, the Federal Motor Carrier Administration published criteria in the Federal Register, cited here, that provide non-specific guidance. It references the two documents mentioned by Charlie LoDico concerning the Paperwork Elimination Act and global definitions of electronic signatures used in commerce. These are fairly old, 1998 and 2000, and here we are in 2011 thinking that was a long time ago. But these are the documents that are out there as references. The first one is the Government Paperwork Elimination Act, which defines an electronic signature as something that identifies and authenticates a particular person as the source of that electronic communication. It does not elaborate on digital versus digitized but provides only the definition as an attempt to link that document or signature on a pad to an individual. In that process, the person is approving that transaction or approving whatever they signed for. Furthermore, the Act states that the process shall not be denied as a legal document in terms of the intent of that person in signing that document. Federal Motor Carrier Administration adds that if anyone provides an electronically signature, it is the equivalent of a legal document signature, if the function and the intent is equivalent with respect to accuracy and integrity and

accessibility of that signature. This signature process must apply with applicable Federal laws and agency rules. The Act does say that the information must be retrievable if requested by the agency within a specified timeline.

The application is used in retail, health care, banking, and third party vendors. In banking, for example, most of us do not need to sign anything anymore. At the ATM, when you enter your check for deposit, it is scanned and credited to your account. You are not asked to sign anything. I had an argument with a person once about signatures. I argued that you can sign anything you want on the back of the check and it will be processed. I have never tried it because I did not want to risk my check being rejected. It is an interesting concept, though.

I queried some of the labs that are using these approaches. The data generated at this point indicate that over sixteen million electronic custody and control documents using these digitized facsimile captures of wet signatures have been performed. None of the laboratories that are currently using these have had any problems in legal challenges, including where the donor challenged the test result by saying that it was not his/her signature. Sixteen million is a large number and represents a lot of experience. This is a good starting point and lays the groundwork for discussions going forward.

In summary, the electronic custody and control process is currently in use in forensic drug testing laboratories for non-regulated specimens. These processes are web-based, using a combination of all electronic and print on demand. All have encrypted transmission, using different mechanisms for input of donor, employer, customer, and laboratory information. They all seem to be working well because information is getting where it needs to go so that tests can be performed and billing performed. The labs use a unique specimen number, which allows the collection sites to service multiple laboratories. All are using digitized signatures. Thus, this business model is working well for this particular industry on the non-regulated side.

Any questions from the Board?

Mr. Bonds: Thanks, Neil. Referencing slide 14 on collector errors, I have a question for you and Jim. Were the 9000 tests a scientific sampling of the 84,000 positive tests in 2010 from the DOT? Was it that one year? I would imagine these were all MRO reviewed.

Mr. Fortner: These were not all MRO positives; I reviewed this many DOT tests during this time frame. I actually called them and asked how many in a given time frame, such as a month, two months, whatever time frame you can give me, were reviewed. So it was a very scientific sampling in terms of how did they come up with the 5.1 percent, because they actually counted every single issue they had and broke them down for me.

Mr. Bonds: So you just randomly contacted -

Mr. Fortner: I just randomly contacted a couple of MROs that I know.

Mr. Swart: So these reviews are of the paperwork.

Mr. Fortner: These are reviews of the paperwork. These are paper DOT-driven processes.

Mr. Swart: The paperwork had some error, some of which are not correctible flaws, none of these are fatal, but just some error that took the MROs -

Mr. Fortner: These are errors that caused additional delays in the MRO process, that's correct.

Mr. Bonds: Out of the 5.1 percent, I would imagine that represents the most common flaws, correct?

Mr. Fortner: Yes. That is correct. There were other ones, but then they are encountered in ones or twos.

Mr. Bonds: So how were they disposed of? Are those tests considered to be null and void? Are they rejected if you cannot capture that information?

Mr. Fortner: Not all of these are fatal flaws. An example of fatal, non-recoverable flaw included the missing donor signature. There is no way the donor will admit to that being his/her specimen, particularly if it is positive. Incorrect employer information can be corrected, but it takes a long time to determine who the report should be sent to. A missing collector signature but with a collector name will not be fatal. So some of these errors are recoverable, some of these are not. But all impact by delaying the process.

Mr. Bonds: Resolution is a matter of allocating resources and time.

Mr. Fortner: Right. It takes time and people to go track these things down.

Mr. Bonds: The percentage for which the test is rejected because of the chain of custody break is very small.

Mr. Fortner: In terms of fatal rejections, that would be correct.

Dr. Smith: If I understand the DOT regulations and the HHS Mandatory Guidelines, nothing listed here is a "fatal" or "nonrecoverable" error or omission. Even a missing donor signature, whether on a negative or a non-negative result, is a recoverable action. The donor does not have to come back and sign, but a statement from the collector stating that he/she forgot to have him sign or he walked out or whatever is acceptable. There is nothing here that meets the definition of a fatal or non-recoverable flaw or would require the laboratory or the medical review officer to reject the specimen for testing in the former or to cancel the test in the latter.

Mr. Fortner: Dr. Smith, would you agree that there is an effort from the MRO to resolve these before they process?

Dr. Smith: Yes, I would under the correctable. I thought that we were perhaps making a leap that was not warranted based on the current regulatory practice by saying that these represented tests that were not able to be reported, to "count", or to be considered forensically or legally sufficient.

Mr. Fortner: No, ma'am. That was not the intent of that information. This was information that delayed the process from the MRO perspective.

Mr. LoDico: Neil, I have one comment about this particular slide that I would like you to respond to. Even though these particular collector errors represent additional time that the MRO might have to involve themselves with resolution, one of the most important aspects that needs to also be considered is the very first item of that collector error list, which is temperature box not checked. In my opinion, this is the first step in the validity of that sample. If, in fact, the collector fails to do that very basic step, it casts some sort of doubt as to the validity of that specimen when it arrives at the laboratory. I want to put into motion the process of an electrified collector process, where the collector, through his/her computer screen, has certain steps that must be completed before going further. The collection cannot be closed unless those mandatory fields have been populated. This type of error jeopardizes the validity of that collection.

Mr. Fortner: I would agree with that whole-heartedly. If you examine the errors from collection sites, the temperature box not checked is one of the more common issues. All of these impact that whole review process, and every one of these could be prevented with a process that incorporated "mandatory fields" where the next step is not allowed until the previous step has been completed. If the first step is to read the temperature on the specimen bottle and that step is skipped, something in the back of my mind says what is wrong with this collection? Was it a cold sample? Should other steps been taken under regulatory guidance? Yes, sir?

Dr. Brown: I want to make sure that I clearly understand the strength of this information in the slide. I do

appreciate that there are errors and different types of errors. I am not sure of the take home message from this slide. My understanding is these 9,700 were not randomly selected but resulted from your polling of MROs to determine how many errors they had.

Mr. Fortner: I contacted two MRO groups. One group I know very well because I used to manage that organization; it provided 5000 in one week. The other one was a smaller MRO group that I know through my association with the Drug and Alcohol Testing Industry Association. I selected a smaller MRO group and one real large MRO group. Though this is not representative of the industry, the two small samplings provided the data. If you conducted a survey of MROs, I do not think this information would be inconsistent.

Dr. Brown: I am not sure we can say that unequivocally. It is important for us to make sure we understand the strength of the evidence that we are presenting here. I do not doubt, from the data you collected, that this was the rate. I am not sure I am willing to go to the bank to say that this is indeed the magnitude of the rate in the universe. Unless we can be clear that that is an unbiased sample, and it is not by virtue of the way that you collected the information, the real rate could actually be higher or lower.

Mr. Fortner: I would not disagree with that and certainly a larger sampling would not be inappropriate.

CAPT Rest-Mincberg: I want to thank you for all the information, and particularly for the snapshot that you gave us. Even if it is not representative, it gives us the idea on the kinds of things that we need to look at. Certainly, if it is costing MROs an additional two to four dollars per test across the number of tests, that is a significant amount of money.

I have a couple of questions in general, related to the chain of custody software that is used. Although it is not meant to be a data collection system, are they able to generate reports from it when they are done?

Mr. Fortner: Yes, depending upon the system that is used.

CAPT Rest-Mincberg: Some programs can generate better reports in the aggregate. For instance, if we wanted to look at the number of positives in one particular area, maybe geographically by zip code or by industry, there is software that might be able to that

Mr. Fortner: Once you collect information in a database, you can do a lot of things with it.

CAPT Rest-Mincberg: That would be useful to the industry, the field, and the government as a way of obtaining data without a huge additional cost.

My second question is that I know that you are at DoD. Although you do not work with the military treatment facility, you are on the drug testing side. Have you ever worked with the military on the chain of custody forms that are used for lab collections in the military treatment facilities? Is there anything that you know of that we can learn from that? Thank you.

Mr. Fortner: No. I have not worked with them on the treatment facilities. However, Dr. Aaron Jacobs is the program manager for the Air Force Drug Testing Lab. We are working down the road this week, doing expert witness training for the Department of Defense. When I informed him that I would be discussing electronic chain of custody processes with the Drug Testing Advisory Board, he scheduled us to speak at the TriService meeting in June about the implementation and development of electronic chain of custody processes. We are already doing a large part of that in DoD, at least in the Air Force, Army, and Air National Guard programs that are generating electronic CCFs through their random process collection program. Thank you very much.

Dr. Cook: Our next speaker is Kathy Petrick. She is the President of American Solutions for Business and the American Diversity of Business Solutions. Kathy will compare and contrast the traditional forms and electronic forms, including their benefits and pitfalls.

Traditional Forms and Electronics Forms - The Benefits and Pitfalls of Both

Ms. Petrick: Hello, everyone. I am Kathy Petrick. I work with American Solutions for Business and American Diversity Business Solutions. When I received a call from Charlie LoDico asking if I would be interested in talking to this group about chain of custody forms, both paper and electronic, I just about jumped out of my chair. I responded "Yes! I'd love to come and talk to you about that". This is exciting stuff for me. I want to thank Charles LoDico for the invitation today. I would like to thank Janine Cook as well, for hosting the meeting and having me here today, as well as to the entire DTAB Board.

I come to you by a little different background, and most of you do not know who I am. I would like to take a quick moment and talk about my background, so you know why I am here and what brought me here to discuss both the electronic and paper chain custody forms. I have been in the printing business for 27 years. The first eight years of that involved selling plate and composition systems. For the last 19 years, I worked for Moore Business Forms and Systems; some people may know them as R. R. Donnelly. They were a major print vendor at that time, and they were hiring new business development people. They hired me to work in conjunction with health care companies. Up in Minnesota, I stumbled across a laboratory called MedTox, which changed my career, what I did for a living, and what I am passionate about in the industry. We learned about the forensic toxicology industry through MedTox. We had the opportunity to understand how a form impacts this industry and what we could do to make this a more secure system. We examined several different label materials and a variety of vials. We came to this process with a goal; if I could find a universal label product that would work on all types of vials, including glass, polypropylene, etc., what could we do? That kicked off this entire program. At that point, I realized that we had developed some best practices that people could use throughout the industry. So I researched the industry, discovered who SAMHSA, your certified program, and the laboratories were and realized that those best practices and core competencies were something that we could use throughout the entire industry. I presented this concept to my company at the time, and voila, the National Drug Testing Program was developed. We took the things that we learned at that point, and I marketed those ideas to the other labs with a passion. I hope to make a positive contribution here today as well.

It was from 1996 when my national program started through 2001 that we kept looking for solutions to make the process better to leave you less legally challenged. For instance, I have applied and was awarded five patents: I have another patent that is still pending. One of those patents dealt with increased security features that could added into the label material. Another patent addressed compatibility with robotics because there is difficultly finding label material to work in conjunction with robotic equipment. The third patent was an attempt to reduce freight. The larger label factories are good at moving big samples around because of special contracts, etc. Some of the medium and the smaller guys have a harder time and struggle with that, so we were looking to help them reduce the cost around that. The last patent was for a radio frequency ID (RFID); we incorporated an RFID chip into the label material that would allow all of the data to travel on that chip with the specimen all the way through the testing process. The patent that is still pending has to do with RFID as well.

In addition to my patents, some of my other credentials include serving on the CCF working group from 2009 and 2010 with Charles LoDico and serving on the 2001 CCF working group with Walt Vogl where we converted the seven-part form to five parts. I am really proud of you today too, for examining how to take that form from five pages to even loss. Even though I might be a paper and a label manufacturer, the importance thing to me is how do we help this industry? How do we ensure the process has less cost, is more efficient, and has fewer errors? I do see this moving toward a paperless, or an almost paperless, system. I have been a speaker at DATIA and SAPAA. I am a published author of collection studies because we know that the collection sites are the weakest link. Why is that? Why are the errors happening there? Is it because they are making eight dollars an hour and cannot get a job somewhere else? In 2003, I was a member of the NLCP review panel. I have been a participant in the Society of Forensic Toxicologists for 14 years. In the last ten years, I have had a distributorship with a laboratory focused specifically on health care. I joke that I work in good drugs and bad drugs; sorry, but you guys are the bad drugs people. The good drugs people I work with include pharmacy

benefit managers.

I was asked to talk with you today about how the current form is used, its strengths and weaknesses, an overview of the electronic process, the options that are currently available, and the strengths and weaknesses associated with that. Many of you recognize this form. If you have not seen a hard copy, it is a five part, 9 ½ by 11 inch form. As a paper manufacturer, I can tell you that there are not many five-part forms in use anymore; most people have converted to either forms with less parts or laser solutions. I will talk a little about the pluses and minuses and how the form that we have today is used. Some of what I will say will be a review of what Neil has already told you, so sorry if the information is duplicated. We did not compare our presentations, and maybe we should have.

The laboratories procure the forms. They pay a range of prices from them depending upon the order size; the larger laboratories can negotiate competitive contacts, but the small and the medium-sized customers have a more difficult time with that. Labs overprint the forms. Many of them, especially the large labs, incorporate the information that the collection site needs by embedding data into the bar code, such as the MRO and the collection site information. There forms are then distributed to their collection sites. The total number of collections sites may number as high as 30,000.

When a drug test event is performed, part one is the test copy facility which accompanies the specimen to the laboratory. Part two is sent to the medical review officer either by fax or mail. Neil talked about some of the disadvantages of faxing. Part three stays with the collector and is typically kept at the collection site. Part four is the employer copy and is sent by mail or fax. Part five is the donor copy and is given to the donor upon the test completion. The hard copies are kept on file for several years.

What are the benefits of this? Even though we heard about some of the disadvantages, the system works and is good. We keep hard copies on file, we have wet ink signatures, and we have the legal strength for process validity. We know that it works, and it has been in place for many years.

There are pitfalls. Even as a paper manufacturer, I have to admit that it is a paper-intensive five part form. This is an issue considering the ecological impact and how important green is to everyone these days. Here is an opportunity to have a form with less parts, and hopefully to maybe minimize the paper to just a piece of label material.

I have spoken with Responsible Persons in the labs, especially those in the national drug testing program, about waste ratios. The figures that I heard were much greater - seven to one return rates, meaning I have to send out seven forms to get one back. You multiply that by five pages per form. That equates to 40 forms going into a landfill to create one specimen request. The waste ratios range from 1.5 to 1 as the lowest to seven to one as the highest. Time is invested in the production of the documents. At the plant, five individual copies are produced, which are subsequently married together in a collator. Then a label is either affixed or integrated into that and/or numbering or bar coding is applied. We verify that everything matches and there are no duplicates. In manufacturing print, a scale from one to ten is used to describe how complicated the print job is. Manufacturing the drug testing CCF is probably in the 8-9 range because it is more complicated to do. There is also the mailing and faxing of the form pages. People are investing a lot of time in these forms. The cost to manufacture the form does vary by the size of the laboratory, but everybody is paying a fee for those forms. With the waste ratios, it is really a concern about how do we reduce the paper burden. The shipping costs must be considered too. The forms are shipped from the plant to the laboratories. The laboratories are overprinting on them and then sending them on to the collection sites. Again, these forms are very labor intensive and very cost intensive. Add to this the collection site errors. Is there a way to deter these errors, and the answer is yes, there is. And lastly, Neil mentioned that the quality of fax copies to MROs or other parties are difficult to read. Why should it be difficult at all to read?

Regarding technology and the human race, I would like to veer from my presentation to show you a video from YouTube. (Video shown)

That was a pretty powerful and compelling video, and that is why I wanted to show it today. So what does that all mean to us? It is significant to this group in that technology advances are very clear. It took the radio 38 years to reach 50 million people, TV only 13 years, the internet just 4years, iPods only 3 years, and Facebook just 2 years. We are reaching people much more quickly with technology. In 1984, there were 1000 internet devices. In 1992, that number grew to over one million devices, while in 2008, that number is one billion internet devices. Technology is here; we need to embrace it and to move forward with it.

I will discuss briefly some of the systems that are out there, including the eChain system by MedTox, the eScreen system by Murray Lappe, and the FormFox system by Compliance and Information Systems. Others are out there, including private systems by Lab Corp and Quest. .

From my standpoint, there are two paths, the first path is paper and the second is paperless. Is there a transition step for us to take with that? First of all, with electronic forms, with paper plain forms are an option and also digital carbonless laser sets are another option. Or from a paperless standpoint, is there truly a way to be paperless with this, or is there a need to have a one-part form/label combination or label material only? Certainly label material only would be a goal, but for this group in particular, I have never been able to envision this less than one part with the label material. I think that one part, at least for now, is something that needs to be part of this.

Let us break each one out. With a plain paper solution, where the information is captured electronically and then printed out as a form/ label combination plus five additional sheets, you still have all of the paper copies. Plain paper, which is less expensive than printed, still has some cost associated with it. These costs include coaching software to reduce some of the collection errors, toner, paper, and printer maintenance; all of these are significant costs, especially for printing five parts per specimen. Right now, most of those costs are borne by the laboratory. With this option, the costs would be transferred. Toner typically costs 2-3 cents a sheet, printer maintenance is about 1 cent a sheet, and paper itself is about 3 cents for a five-sheet format. Summing that, the cost is about 20 cents per specimen for the collection sites to pick up. I do not know how that would shake out. I would be interested to hear the labs' opinions on that. I cannot imagine that the collection sites will assume those costs without trying to recoup or recover those costs somehow.

I do produce many, different chain of custody forms for people, some of which are Federally approved, many more that are not. You have created the standard for the rest of the industry.

This is a one-part form that I produced. It is a FormFox form. The first pink line is a perforation, as is the next. That middle part is the donor receipt followed by the label pod on the bottom which separates out. Thus, one part is generated. You have the option to create additional plain paper sets, for instance, if you needed an MRO or employer copy. In case anybody is interested, I do have a couple of real samples with me. I also wanted to show you the overprinted version of the electronic form. A unique bar code has been added up in the upper left hand corner; the employer and MRO information are printed. Donor and collection site information is also printed. In most systems, information location is intuitive and automatically printed. The donor receipt is on the bottom, and the label pod is the very lower portion of it. Bar codes from the top of the document match those on the label, so that the top form will match with the bottom one. There are millions of these in circulation. This form is successful, and this particular program has not been challenged. By the way, I have not heard of any of the electronic ones being challenged. At some point, that may happen. With the millions of specimens processed this way and knowing that nobody has challenged yet says something significant.

The second option would be digital laser carbonless sets. I do not know if you have heard of those or not; they are less known in the industry. It is something to consider if you want information carboned through. Essentially, instead of a set put together by the pin feeds and crimped together as a one-part form, the information is laser-printed on paper that contains carbon capsules. This allows the opportunity for a signature to go through all forms. This option is widely used in other industries, such as the gaming industry where cash

money is being exchanged. Logistically, from my standpoint, I first thought that this was a great solution. I quickly realized that with all of the collection sites and the variety of laser printers that they have, this would be a nightmare because paper feeding varies by printer. Some printers take the paper first sheet bottom or first sheet top; some are face down, some are face up. The types of forms that need to be stocked exponentially grow. Not only that, a collector would need to know how to place the paper in the laser printer to make sure that it prints it out correctly. These complications make it less attractive. But, if you want carbon through and information capture, this would be a wonderful way to do that. The software coaching would be helpful, and that cost, as well, would be transferred to the collection site from the laboratories. The digital laser carbonless sets are quite expensive, about seven cents a sheet. Take that times five and the costs is already up to 35 cents in addition to the toner and the printer maintenance costs. The only benefit here is if somebody really needs something to carbon through, this could potentially be an answer. The implementation of it would be, quite frankly, difficult with the variety of laser printers that are out there.

What are the pitfalls of electronic forms with paper output? From a supply cost standpoint, toner versus printing on an impact printer is significantly different. Impact printers are much more cost-effective to use. Although it is a five-part form, rather than printing each individual form out at one single time, it is much more cost-effective to use a lithographic or a flexographic process to produce those forms. The same thing applies with ribbons versus toner. An impact printer ribbon is much more cost-effective than toner. Toner becomes a significant cost especially when multiplying what you print by five times. We would also lose the use of highlight color. The labs highlight a form item in yellow or pink to make people aware of what must be filled in. It would really be very difficult to print that highlight color along with some recognition factors, such as the lab logo. Although color laser printing is available, I highly doubt that collection sites have color laser printers; I would say that the majority have black and white printers. Then there is the time investment of printing five times at the collection site versus printing one time at the laboratory. At the collection site, the paper tray is loaded with five sheets for every donor versus now where a case of the five-part form is loaded once. Some additional pitfalls would be from a security standpoint, and while I am certainly not an expert on this, I would encourage the group to further investigate this. With the responsibility at the collection site, there is always the question, is it a true original? If Fortune 500 companies can be hacked that have large financial and technology resources, what is to stop an individual at a collection site? This is a concern of mine, and I think there are ways to build in security to ensure it is a true original. We have all heard the stories of the 50 dollar bill under the table or trying to help out a buddy. We do not want to encourage those things, but the opportunity for tampering is much greater when printing occurs at a laser printer at the collection site. We should also take into consideration the life of printing equipment. Impact printers are workhorses; they last two to four times longer than the laser printer. While there are very few of them in the field, they are built to last. In contrast, a laser printer is as close to disposable as you can get.

For electronic forms with paper or paperless output, less paper is used. This is a green ecologically friendly solution, whether the return ratio is 1.5 to 1 or 7 to 1, because there would be less paper used. Efficiencies are gained for the laboratories because they do not need to procure, overprint, and send out the forms. The collection sites would save time because they do not have to receive the printed forms form the labs. All of the answers would be immediately available to them on the computer screen. This could potentially drive, but probably not eliminate, collection site errors with the use of coaching software which would not allow the collector to go beyond this spot until the appropriate box is checked. This is really a benefit to the electronic systems. There would be a reduction in lost or missing information. Electronic databases allow for easy data retrieval. Even from a laboratory standpoint, results would be delivered faster.

Paperless is even less expensive, ecologically progressive, and allows us to still mirror those efficiencies, including less time for the labs and collection sites and reduction in errors. I think the benefits are there whether it is paper or paperless.

What are the pitfalls associated with this? There is no hard copy and no wet ink signature. Those two are concerning to me. Certainly, the legal community could better address those situations if there was no signature and it was challenged. But the fact that nothing has been challenged at this point is a concern to me.

The next concern is around security standards for data. The highest level of security should protect against any kind of breach. But there are major companies, such as insurance, bank, credit card, etc., that have experienced breaches in their systems. There must be a way to lock that down tighter. Hopefully some of you, with your connections with DoD and DOT, might have an opportunity to seek advice from those people who are technology-wise to advise this group well. From an organizational standpoint, retrieval is easy, which in some ways is a benefit but also a disadvantage. Is it too easy? Is it too easy for people to obtain that information? We need to be careful with security. There are also legal enforcement challenges. Though I am not aware of any, at some point, will there be a concern about having no hard copy and no wet ink signature?

The conclusions that I bring to the group today are that it is important to continue to provide a paper methodology, especially for the small and the medium-sized laboratories, so there is a transition period for them. It would be very difficult for some of them, especially the smaller labs, to go "cold turkey. The larger labs are already well on their way. There are about 15-16 million specimens that have performed well using the form/ label combination instead of a five-part form. These have paved the way to move forward with the technology to convert from paper to paperless.

I would caution that if we use that transition step, which makes sense if we use an electronic solution with paper output, I am not sure what we are really gaining because we are still producing paper. I would really encourage the group, if possible, to either shorten or eliminate that step in the path towards paperless; in my mind, that is a one part form/label combination and some type of a cut sheet version.

I would recommend a deeper investigation of legal enforceability and data security. Those are the areas where I see potential problems for this process. And lastly, I want to congratulate you. What you are doing here will change the face of drug testing. I am glad to be a part of it and glad that you are moving forward.

May I take any questions from the Board?

Mr. Harris: We at the NRC would not be supportive of that interim step. There are too many problems transitioning from paper to electronic. We implemented our voluntary electronic reporting requirements, and every licensee was doing their own thing. Some were printing out the forms for electronic reporting, entering the data manually onto the forms, and then mailing them to us with a letter saying here are the data you wanted. This process does us absolutely no good from a tracking perspective, and it adds additional cost to the regulator to assess that type of data. Thus, I would strongly recommend that we do not do the interim step.

Ms. Petrick: I would agree that a transitional step might be an easier way to proceed, but that is not the goal of this process. Thank you for the comment. Anyone else?

Dr. Cook: Thank you, Kathy. Our next speaker is Charlie LoDico, who will review for you the Office of Management and Budget approval process.

OMB Approval Process

Mr. LoDico: Thank you Janine. Good afternoon. Thank you for committing your time to participate in this board meeting. This afternoon, two individuals provided information to the Board and the audience on what is a Federal custody and control form and whether it can be provided as an electronic or paper form.

The reason why it is critical and timely that we address this issue is because the current form, which was part of the October 1, 2010 Mandatory Guidelines implementation, has an expiration date and an OMB control number. That expiration date was set by the Office of Management and Budget in their 2010 Notice of Action and is three years from the initial approval date. The time that it takes to complete the process of OMB approval is between 18 months to two years. Based on the CCF expiration date of 8/31/2013, we are about 26 to 28 months from that expiration date. It is not advisable for us to take the position that this expiration date is

so far down the road that we do not have to worry about it. For this reason, it is important that we again commit to this process and examine alternatives to a paper form. The reason why we have to consider alternative forms is because of the condition that OMB placed on the approval of the current CCF form, which was that prior to the next approval of this CCF package, SAMHSA shall provide a progress update on adoption of electronic forms in an effort to reduce burden. SAMHSA is encouraged to explore ways to convert the Federal Drug Testing Custody and Control Form into an electronic form, and this remains in effort. So basically what OMB is saying is that this is your last shot, you must do it now, and you cannot justify not pursuing it because this is a forensic procedure. All of us paid our taxes a couple of weeks ago. Historically, I did my taxes traditionally, where I printed every document, myself and my wife signed on the bottom of the form, and then sent a check and our W2 forms to the IRS. For the first time, we filed our taxes on line, hit the button, and our taxes were gone. I was terrified that I maybe did something wrong with this electronic filing procedure because I was not convinced that the IRS would accept my tax forms without my or my wife's signatures. The IRS will receive our money, but did they really accept my authorization saying that I did, in fact, willingly send this out. The caveat of this story is that we take it for granted that the old process is the only way to do things, and as Kathy showed with her video, progress proceeds. If we do not follow progress, we will always be behind the 8-ball. Only through OMB's prodding will we go through this formal change from a paper document to a much more seamless electronic form.

This is not just SAMHSA's task; this is a partnership between SAMHSA and ODACP. I will be working with Mark Snider, a member of Jim Swart's ODACP staff, to develop an electronic form for OMB approval that includes all the information that is the best of the current form and complies with the OMB mandate.

OMB clearance is the process an agency follows to ensure compliance with the 1995 Public Law Paperwork Reduction Act, which implements regulations 5 CFR Part 1320. The objective of the Paperwork Reduction Act is first to minimize burden on the respondents, to minimize cost to the Federal government, to maximize the quality and utility of information, to ensure that all applicable laws on privacy and confidentiality are followed, and finally to allow the maximum opportunity for public comment. There are four major reasons why information requires OMB approval. The two most important are listed at the bottom and include reporting, which refers to the use of the Federal CCF, and the guidance document. Because of the National Laboratory Certification Program, our OMB submission package includes four documents that meet the criteria for OMB approval, including a survey that asks the same question of ten or more people. So these documents must be OMB approved and have an associated OMB number.

Neil discussed the Government Paperwork Elimination Act (GPEA), which was implemented in 1998. The most important item of these points regarding the GPEA is the third bullet, which states that the Act specifically requires that electronic records, and their related electronic signatures, are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. This goes to the heart of the forensic approach of the form. It is an electronic record, and thus, it could have an electronic signature. It is yet to be determined whether that signature is a digitized signature or the type that Neil described earlier, which is the signing of a pad by the donor.

This is all preliminary. We will develop the framework for how we will make this change in partnership with ODACP to address the needs of both agencies.

As indicated previously, two policies exist now in HHS. One is FDA's 21 CFR Part 11, which provides the criteria under which FDA would consider electronic signature to be equivalent to full handwritten signatures. The other one is the Office of Secretary for HHS' 45 CFR Parts 160, 162, and 164, which adopt the national standards for safeguards to protect the confidentiality, integrity, and the availability of electronically protected health information. I am a firm believer that you do not need to reinvent the wheel. If we already have documents and regulatory rules that have been finalized, then we should adopt those and build from them. So these are the two documents that I believe would support our change from a paper to an easier electronic document.

The characteristics of a trustworthy record include reliability, authenticity, integrity, and usability. These are SAMHSA's objectives as we change from a paper document to electronic form. We will investigate the electronic signature, a non-repudiation agreement for a digital signature, and third-party software for managing Federal CCF information. The software is critical because if we create a database that can be mined by a third party and potentially exploited, we want to ensure that there is some protection of that data from exploitation. We will also investigate unique specimen identification numbers. There were examples that both Kathy and Neil showed that that are already in use. For instance, sixteen million unique specimen ID numbers were generated using the electronic CCF, so I do not believe that will be a problem. We are researching the legally-binding equivalent of traditional handwritten signature in a forensic arena. For most of us, we are accustomed to seeing a document that has a wet signature on it. We need to remove ourselves from that mindset to accept that maybe an electronic signature in a form that has a digitized certificate will be the equivalent to a wet signature.

The most important thing is, from my standpoint, is the security of the data transmission. Can that information be hacked, can it be compromised, or can it be corrupted? These things are critical and need answering before a decision is made.

The last characteristic is the integrity of the document content. Can anybody corrupt it, can anybody hack into it, or can anyone compromise the result? How secure is the content and how sure can we be that document was not tampered with?

What is the OMB clearance process at SAMHSA? First, as the project officer, I contact the SAMHSA Reports Clearance Office nine months before OMB approval. Currently, we are about 27 months from the expiration date. The document must be completed and approved prior to beginning the nine month process of OMB approval. The project officer and the SAMHSA Records Clearance Offices work together to develop a Federal Register Notice giving the public 60 days to comment on the proposed data collection instruments. This first FR Notice instructs the public of our intentions with this new CCF, including how it will be utilized, how it will be set up, and the elements of the CCF which will enhance the process. We include a preamble, which provides a description of why it is necessary. We also provide data instruments, such as the form itself that will be converted to an electronic document. We also include a supporting statement. Lastly, we obtain the Administrator's approval to publish the FRN. Any document written by office must go through a vetting and a review process through the level of the SAMHAS Administrator. Upon her approval, the FRN can be published. After the 60-day comment period, we submit the OMB package, including the previously mentioned documents, to SAMHSA's Clearance Officer. Concurrent with the 60-day period, we start preparing a 30-day Federal Register notice, which must also have the Administrators' approval. In that 30-day comment, the SAMHSA Reports Clearance Officer notifies the public of the publication of the OMB package that will be submitted to HHS. For the HHS review, the package is sent to the main HHS office in D.C. HHS reviews, approves, and submits the OMB package to OMB. This HHS review could take up to two weeks. Once OMB receives the package, they have 60 days to act on our request. Once it has been logged into their system, OMB can send questions, comments, and/or clarifications back to SAMHSA for explanation or further information. So within that 60-day period, there is communication back and forth for clarity. OMB can pursue one of four actions upon their receiving of this package. They can review and approve it for a three-year period. If this is a fast-track emergency, they can approve it for only six months, giving six more months to finalize the additional information they requested. They could disapprove it. They can request that it be withdrawn and resubmitted. When a package is submitted to OMB, it is not a guarantee that it will be a completed task. OMB may have concerns, especially if you are not meeting the burden hour specifics of the PRA, the Paperwork Reduction Act. There may be a host of reasons why they might return the package to us.

In a tabular form is shown the timeline starting from nine months before OMB approval forward. At two months, the package is cleared through HHS to OMB. In the end, we receive a Notice of Action which permits the chain of custody form to be used as intended, whether it is a paperless form, one page with two labels, etc.

I wanted to share with the public this process and to apprise them of the task in front of us. Hopefully, at the

end of the day, we will have the approval from OMB that satisfies both the forensic element and the technology aspect, which is to utilize the tools that are available to the laboratory, the collectors, the donors, and the program. Ultimately, the desire is to maintain the same standards and to ensure that the integrity of the collection, testing, and review process has not been diminished, but altered, for the purposes of efficiency.

Thank you. Questions? Yes, sir.

Mr. Swart: Charlie, I hesitate to ask a question, but you have now talked about the electronic CCF and our office's involvement. I wish I would have heard both Neil and Kathy say that they have had some legal challenges to the forensic suitability of non-wet signatures, electronic signatures, or digitalized signatures, but they have not had any. As you know, any collected Federal evidence, which this would be considered, could result in court cases. The DOT has administrative law judges who rule on positive results, and we have arbitrators trying to overturn the administrative actions that might be taken against an employee. Are there any other Federal programs that collect evidence that do not use a wet signature? Though you submitted your taxes electronically, your wet signature was on the check.

Mr. LoDico: Yes.

Mr. Swart: So for us, the forensic issues associated with this would be pretty critical.

Mr. LoDico: Yes. Jim, those are very valid concerns, and those are the concerns that I have expressed for years since becoming the lead in maintaining of the Federal CCF and its OMB approval. There has always been that hesitation in converting this into electronic document. I have asked this before, but has anybody challenged this electronic document? No one has raised their hand and said yes, we had a challenge, we have experience in a court case, or that an administrative law judge refused to admit that result because it was not in a paper form. To answer your question, I am not aware of any.

When we collaborate through structured meetings to work on the Federal CCF, just like we did when we revised the current Federal CCF to meet the revised Guidelines implementation date, the model we will use involves searching for those individuals who are experienced and can share with us their experience, involvement, and information to prepare the document before we submit our final package to OMB.

There are still the many questions, including the one that Hyden brought up earlier about the non-repudiation of a digitized signature. We will examine some of the more critical elements of concern to determine if they can be eliminated. If we can and have the justification, support, and documentation, then we will move forward with it.

Yes, Dr. Brown?

Dr. Brown: As a physician, I try to practice consistent with clinical guidelines. Though I know very little about the law or legal issues, I am confident that someone will challenge it. Having said that, it is not a good reason for not moving forward. We will always have individuals in our society who raise valid concerns, but whether those valid concerns reach the point that they will be the issue that changes policy, is another matter. In light of the talks that we had earlier today, it makes sense, for the good of what we are doing, to move forward. I salute you and the agency for taking the step, however bold people may perceive it to be.

I do, though, want to also add the point that I think it is important for us to talk to other units within SAMHSA. One of the issues in addiction medicine that we have is with follow-up testing and its frequency. For example, if I am treating someone for diabetes, there are tests for diabetes, such a hemoglobin A1c. There is a prescribed frequency of testing that is driven by clinical evidence to support that certain frequency will achieve certain a clinical outcome.

CAPT Rest-Mincberg: In this particular program, we are not looking at clinical outcomes. The drug tests that

are given under this program are not considered diagnostic, and the records associated with them are not medical records. Thus, the schedule of how frequently somebody is tested is not set by clinical concerns because the purpose is to identify, on the Federal side, illicit use of drugs. That is it. It is not for clinical purposes. For some of the industries, illicit use of drugs and impairment are the issue. The testing used in a clinical practice and the standards applied, including the testing frequency, have a different objective than what our authorization under law is for this program.

Dr. Brown: I appreciate that distinction. When Mr. Harris answered the question about the frequency of the testing and the follow-up, and he said that it was really within the discretion of the providers with oversight for those employees. It would be useful if there was some body of evidence that could be utilized to help those clinicians also meet the additional needs that we are talking about. I do understand that there is a distinction between the two, but when we discuss what is driving the frequency of testing, it would seem to me that there needs to be some scientific evidence that under-rides the basis.

CAPT Rest-Mincberg: I think you are talking about two different areas of testing here. One is the testing that is done under this program to identify illicit use of drugs. If the donor works for an employer that sends him/her to a clinical program, a different standard is applied at that point for how often you would be tested and the purpose of those tests. Under those clinical circumstances, then they do become medical records which we do not have access to if the donor is seen and directed by a clinician for the purpose of treatment.

Mr. LoDico: One other comment that I will share is that when you asked for the frequency of testing, Jim Swart indicated that the testing volume has increased only because it is tied to economic strength of the company and/or the industry that dictates its testing rate. If a company has a 40 or 50 percent random rate and the number of company employees dropped from 100 down to 50 individuals because of layoffs, the frequency and testing volume have decreased. For the last 2-3 years, testing volume dropped from 7 to 5 million for the DOT-regulated industry; now it is creeping back up. This change reflects the tide of the economic world and depends on how viable and strong the U.S. economy is. Okay? Thank you.

Dr. Smith: I would just like to follow on to Mr. Swart's comments. I presume that those of you in the Division of Workplace Programs or other places have looked at whether or not electronic or paperless chain of custody documents have been used, whether at the FBI lab, the State Police laboratories, or other settings. Mr. Swart made a well-taken point that what we are really having to document here is the transfer and the handling of potential evidence as violation of a Federal law or regulation. There are many other circumstances where that is the case, whether in criminal prosecution or in other types of evidence transfer, especially body fluids. Are electronic, paperless chain of custody documents being used by law enforcement, Departments of Justice, and others?

Mr. LoDico: Dr. Smith, that is yet to be discovered. One of the goals of ODAPC and SAMHSA is first to find what models that use electronic CCFs already exist in the forensic field. If we do not find one, then we have to develop one for ourselves. Again, it is not a question of whether we want to convert to a paperless or electronic document. We are mandated by OMB who has let us know that they want to see this completed.

Dr. Smith: Perhaps I misread or misunderstood the language of the OMB directive. I am not opposed to doing a very thorough job of determining whether we can adopt an electronic or paperless chain of custody from the standpoint of the donor, the collector, the workplace, and the laboratories to reduce the multiple pieces of paper, internal chain of custody documents, etc.

CAPT Rest-Mincberg: That is the purpose of this discussion, and that is where we are going.

Dr. Smith: I thought that the OMB language says that what we have to do is thoroughly explore. I did not take from that that they are saying you have to figure out how to do this paperless.

Mr. LoDico: Right. I apologize if I did not communicate that. We will do thorough research and produce a

format or process that satisfies OMB's Paperwork Reduction Act.

Dr. Smith: I just wanted to make sure.

Mr. LoDico: Without question, we will. That is why it is important that we start this process early, even though we might feel that we have time on our side, being that the form does not have an expiration date until 2013. From my timeline that I showed, it really is critical that we start acting today and begin to formulate some of the conceptual issues and resolve them, so that it satisfies the standard that we have already established in the program. Does that satisfy you, Dr. Smith?

Dr. Smith: Yes.

Dr. Cook: I will not entertain any more questions because we are running a little bit behind schedule. It is time for a break, and we will reconvene at 3:10.

(Break)

DTAB's Process for Evaluating the Scientific Sufficiency of the Oral Fluid Specimen for Federal Workplace Drug Testing

Dr. Cook: Good afternoon. I am Janine Cook, and I will be giving the last presentation of today. I will be talking about DTAB's process for evaluating the scientific sufficiency of the oral fluid specimen for Federal workplace drug testing.

The slide reviews the process that Hyden had spoken about earlier this morning, in which HHS, in the preamble for the 2008 Mandatory Guidelines, had proposed a staggered timeline for evaluating the scientific sufficiency of alternate specimens for use in the Federal workplace drug testing program.

Because of the scientific information on oral fluid that we uncovered, we decided to start that timeline with the oral fluid specimen. I will outline the series of ten steps that we are currently following in the evaluation of oral fluid. At the end of every step, we will evaluate that scientific evidence to ensure that it is sufficient before we proceed on with the next step in the process.

Step one begins with the Drug Testing Advisory Board that was charged with assessing the state of the science of oral fluid as an alternative specimen at the January meeting. In the preamble to the 2008 Mandatory Guidelines, a statement was given saying that the scientific, legal, and public policy information for drug testing of oral fluid specimens was not as complete as it was for urine, and this is referring to the science as it existed in 2004. As we know from the information that Kathy just presented us, science and technology have changed dramatically since that time. Thus, we felt it was time to re-evaluate oral fluid.

Step two involves the daunting process of sifting through all the science that currently exists for oral fluid. To help both of the Division of Workplace Programs and the Drug Testing Advisory Board, we identified four lead scientific experts. These experts are Dr. Yale Caplan, Dr. Ed Cone, Dennis Crouch, and Dr. Michael Walsh.

Step three was to review the current state of the science as we know it, and this was done on day two of that January DTAB meeting. We began with Dr. Mike Walsh presenting the history of oral fluid in the drug testing program, as well as the entire history of the drug testing program. Dennis Crouch reviewed oral fluid as a specimen; Dr. Marilyn Huestis discussed drug analytes and cutoffs; Dr. Frank Esposito reviewed testing methodologies, including initial, confirmatory, and validity testing; and Dr. Courtney Harper presented the FDA approval process for oral fluid specimens. Dr. Frank Esposito spoke about proficiency testing for oral fluid. Barbara Rowland relayed her best practices oral fluid experiences in a reference lab, and Dr. Barry Sample provided actual oral fluid specimen laboratory data.

Step four includes performing an exhaustive literature search on oral fluid drug testing. To date, we have found about 620 peer-reviewed references that are published in the scientific literature. We are in the process of cataloging all those references. We will be doing something that we have never done before. After we review all of the scientific literature, and if there is enough scientific evidence to proceed at DTAB's recommendation, in the preamble of the Federal Register proposed revisions to the Mandatory Guidelines, we will support every statement that we make with a reference from the scientific literature. We are excited about doing that, as are our legal councils.

For step five, we have created a template from which to work. We began the original 2004 proposed revisions that included all the alternate matrices. We stripped everything out except for the oral fluid references. We then harmonized that document with how the Mandatory Guidelines were written in 2008 in a question-answer format. What we had left was a document pertaining only to oral fluid with all the pertinent questions identified. With this template, we could easily identify what we knew and what we did not know. We identified the topic areas in which the answers were known, and that was what we called our preliminary consensus statements. I have listed a few of them here. The consensus statements are not yet carved in stone. They are still under discussion, but we have an initial agreement that these are starting points for us to proceed.

Step seven was to identify areas that needed further research because there just was not enough literature there to support a statement. The five topic areas that we identified needing further research include analytes and cutoffs, specimen validity testing, collection, collection devices, and testing. For each one of those five areas, we drafted a generic question that we wanted to resolve. For analyses and cutoffs, what are the appropriate analyses and cutoff concentrations for the initial and confirmatory tests? For specimen validity testing, are there appropriate markers or tests for oral fluid that would reveal adulteration, substitution, and/or dilution? For collection, what are the requirements for collecting an oral fluid specimen? For collection devices, what are the requirements for an oral fluid collection and device? For testing, are LC/MS/MS or other methodologies a viable alternative to immunoassay as an initial screening test? If you examine the way the Guidelines are written, within the question-answer format for each one of these five topic areas, certain subsections fall within those. We have gone through the Guidelines and placed those different questions within each of these five categories. This is a daunting task. We have our scientific leads, but we realized we needed more expertise in order to mine through all of this data to uncover the best science. We have identified other scientific experts who will serve on working groups, with a working group dedicated to one of those five topic areas. We are in the process of forming these working groups; the working group concept is being approved through our SAMHSA Ethics Office as well as our Office of General Counsel. Besides these five topic areas that I have just shown you, we have identified other areas that are of concern. These areas of concern have been forwarded to the different Federal agencies for their input. An example, for instance, is FDA. As we develop criteria for the different collection devices, we want FDA involved in that process and to guide us as we will guide them on the criteria for approval of these devices. There are some legal issues that have been submitted to our Office of General Counsel as well as our Department of Justice JAG attorney to help us and offer advice on those areas.

Step eight involves something new. We will publish a request for information in the Federal Register, in which we will be asking the public and stakeholders a series of specific questions about oral fluid and request that they provide responses back to us. During the closed session tomorrow, DTAB will be discussing what should be included in this request for information, including what questions should we ask the public to ensure that we have all the necessary information to proceed forward.

For step nine, the information that we receive back from the public will be discussed at the next July meeting on the 12th and the 13th.

And finally, for step 10, at the September meeting, the DTAB will deliberate on the state of the science of oral fluid, and at that point decide whether they should recommend oral fluid as an alternative specimen. The DTAB, based on the state of the science research that we are in the process of evaluating right now and after addressing those significant science, legal, and policy concerns that Hyden discussed earlier this morning that

were raised by the public commenters and Federal agencies in response to the 2004 proposed revisions, will, or will not, recommend proposed revisions to the Mandatory Guidelines to include oral fluid as an alternate specimen type. If they recommend this, the proposed revisions will be published in the Federal Register, and we will seek public comment on those proposed revisions. This concludes my presentation. Any questions?

Public Comments

Dr. Cook: We have now officially entered the public comment period. There are three people who have indicated their desire to give public comment. Going alphabetically, I want to invite Bill Corl up to the microphone to provide his public comment.

Mr. Corl: First of all, I would like to thank members of DTAB and guests for listening to my comments and questions. My name is Bill Corl, and I am the 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 drug testing.

I am sure the question you are all asking yourselves is why is this bald guy up here talking about hair testing? The fact of the matter is, I am here by the request of members of regulated industries, industry associations, and some members of Congress. I am here to question the misinformation about hair testing that seems to keep circulating around some Federal agencies.

The advancements in hair testing over the last five years have placed it as one of the most accurate and reliable drug abuse testing methods available. Hair testing acceptance is evidenced by the variety of accreditations available to hair testing laboratories, such as the Clinical Laboratory Improvement Amendments, New York State Department of Health, ISO/IEC 17025 laboratory accreditation programs, and the College of American Pathologists, which now has a hair testing-specific accreditation.

The German Society of Toxicological and Forensic Chemistry currently has over 50 hair testing laboratories worldwide that are participating in a quarterly proficiency testing program. Members of the Society would be happy to come and present the last ten years of their proficiency data to this Board. The participant laboratories perform hair drug testing for organizations around the world, including corporations, military entities, court systems, and basically anything that would be considered regulated and/or non-regulated industries by HHS.

I, like most, understand that DTAB, HHS, and ODAPC all have very limited resources, including time to review advanced technologies. I am happy, like most in the drug testing industry, to see progress being made for the HHS acceptance of alternative matrices and for the electronic chain of custody systems. What is concerning to the global drug testing industry and some of its members and regulated industries is the amount of misinformation that has come from some individuals within U.S. Federal agencies over the years, like the “the technology is not scientifically sound”, and “it is not admissible in court”, when this is clearly not the case.

Federally-regulated industries need to be given the option to use the best available technology to fight illegal drug use and abuse in the workplace. Urine, hair, and oral fluid all have their place in the overall scope of testing and should be held to parallel standards when being considered for the Federal Drug Testing Program. Hair testing has been shown to improve the success of drug testing programs because it increases the time period over which drugs can be detected, as compared to urine. It is easily collected, transported, and stored, and it is less likely to transmit bio-organisms than urine and is more difficult to adulterate.

Given the fact that hair testing is widely accepted and scientifically proven, why has it not been brought to the forefront and fast-tracked like oral fluid testing? At the request of Federally-regulated industries we serve, what can Omega help to do to facilitate this process? I have some binders here that have statistics from three major trucking firms that will show how their pre-employment testing programs work and that their random urine test

rates dropped significantly after they implemented hair testing programs for pre-employment. Thank you for your time.

Dr. Cook: Thank you, Bill. Next, I welcome David Martin, of the Drug and Alcohol Testing Industry Association, to provide his public comment.

Mr. Martin: Thank you Dr. Cook. Members of the Drug Testing Advisory Board, I am the Chairman of the Drug and Alcohol Testing Industry Association, commonly known as DATIA. DATIA is the largest drug and alcohol testing industry association, and it is the oldest in the country. We represent literally thousands of MROs, TPAs, laboratories, and collection sites.

DATIA applauds the work of what is going on today. It is historic, and the vision that you have right here today with ONDCP, SAMHSA, the Division of Workplace Programs, the NRC, and the DOT is by no means anything less than historic. And I am here to say that DATIA is here to support you one hundred percent of the way.

Sometimes, theory precedes technology, but right now we have the technology, and digital signatures are used in electronic documents internationally, from banking to stock transactions to your local grocery store. So it is very common in our life these days to see electronic signatures. So it is necessary in our time of economic strife to control costs. This will help that, and it will save time, increase efficiency, and make the overall system of drug testing more consistent within the global digital age that we are in right now. Anything DATIA can do, we are there to help you. Congratulations on this historic time.

Dr. Cook: Thank you, David. Next, I welcome Eric Quilter, of Compliance Information Systems, to provide his public comment.

Mr. Quilter: Thank you Dr. Cook and the DTAB. My name is Eric Quilter; I am the CEO of Compliance Information Systems. We are a provider of information management solutions for the substance abuse prevention industry. Our customers include employers, laboratories, third party administration firms, MROs, and collection sites. FormFox, which was mentioned earlier today as an example of an electronic CCF solution, is authored by my company. I would like to thank the DTAB and SAMHSA for this opportunity to provide comments, as well as voice my strong support for SAMHSA's efforts to allow electronic alternatives to the current five-part custody and control form.

Electronic chain of custody, which I prefer to call software-assisted chain of custody, is no longer a theory, but rather a well-established and widely used tool in the drug testing industry. Many of the laboratories that participate in the National Laboratory Certification Program, and more importantly, thousands of collection sites, utilize software-assisted chain of custody for millions of drug testing transactions every year. These systems have been implemented due to three motives. They improve and enhance process, quality, and reliability; it means they are better. They improve turnaround time of the entire process, which means they are faster. Three, they reduce the overall cost of drug testing to all parties concerned, which means they are cheaper.

Our experience with several laboratories, as well as thousands of collection sites, MROs, service providers and employers, has generated ample supporting evidence that these motives can be satisfied. Since many of the benefits of electronic chain of custody have already been presented today, I would like to focus my comments on two issues that will be important to SAMHSA's success in formulating a strategy, and ultimately, requirements, for allowing the use of this technology for Federal testing programs.

The first issue is the use of digitized signatures, which is not the same as an electronically signed document or data. The current wet ink signatures on Federal CCFs are an important part of the defensibility of the document. A drug test is not the same as a credit card transaction. It will be important for SAMHSA to be specific about minimum standards for the use of digitized signatures, to ensure that digitized signatures improve the ability to defend the integrity of the collection event rather than diminish it. Many commercially

available devices and their associated software have the ability to reliably capture not just the image or the shape of a signer's signature, but unlike paper forms, some devices also capture the pressure and tempo of the signature, providing biometric data about the signer that can later be reproduced. These biometrics are a real critical component in differentiating the types of digitized signatures that are available to any solutions that might be admissible or a replacement, a very key distinguishing factor. They are not all the same.

Next is information security. There is no doubt that electronic information and process has provided huge benefits to their users, in this case, workplace drug testing participants. However, protecting electronic information arguably requires more sophisticated tools and techniques than information captured on paper. It follows that compromising such information also requires more sophistication. As such, care should be taken to ensure that electronic CCF processes allow for Federal testing and adhere to appropriate data security standards.

Examples of such standards already exist within Federal agencies today, including Health and Human Services. Again, CIS encourages SAMHSA to allow industry participants the option of utilizing electronic chain of custody technology. The heavy lifting has already been done, with a solid foundation laid down by the many labs and thousands of collection sites already using electronic CCF systems. Models exist in the industry that address the concerns with information security and use of digitized signatures, and resources exist within the industry to assist SAMHSA and regulators of workplace programs with establishing guidelines for implementing the technology for Federal testing.

Thank you again for this opportunity to provide comments for the DTAB.

Dr. Cook: Thank you Eric.

I adjourn this open session of the Drug Testing Advisory Board. The Board will convene tomorrow by closed session because it is time for them to roll up their sleeves and get a lot of work done. I want to thank everyone for attending.

(Whereupon, the meeting adjourned at 3:40 p.m.)