PROCEEDINGS

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

July 13, 2011

One Choke Cherry Road
Rockville, Maryland 20857

Table of Contents

Table of Contents 2
Call to Order 3
Welcome and Opening Remarks 4
Deliberation and Vote on Proposed Recommendations 5
Review of Request for Information Responses 7
Public Comments 8

Proceedings (10:03 a.m.)

Call to Order

Dr. Cook: Good morning. I am Janine Cook. 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 joining us remotely, Jared has emailed 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 a 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 material presented during the open sessions, we have two options for you to submit your questions to the Board. First, if you are attending on site, three-by-five cards are located 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 closed session.

The public comment period begins at noon Eastern Daylight Time today, though I anticipate that we may run ahead of schedule. Currently there are nine attendees who have registered to make public comment. If anyone else wishes to give a public comment and has not yet registered, you may register on site 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 make sure your comments are recorded accurately. We will not responding to any public comments at this time, but they will be taken under consideration during the closed session.

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

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

I would like to introduce the members of the Drug Testing Advisory Board: Bobby Bonds, Jim Bourland, Larry Bowers, Lawrence Brown, Phyllis Chandler, Laurel Farrell, Courtney Harper, Barbara Rowland, Donna Smith, Jim Swart, and 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 valuable assistance: Captain Carol Rest-Mincberg, Jennifer Fan, Ron Flegel, Gene Hayes, Giselle Hersh, Charlie LoDico, Naiara Salgado, Hyden Shen, Bill Sowers, and Elaine White.

There are a few other distinguished guests that are here with us today that I will also recognize: Marilyn Huestis from NIDA, John Mitchell from RTI International, and Yale Caplan and Mike Walsh, who are our consultants on the Oral Fluids Project.

We have scheduled the last DTAB meeting for the fiscal year. The tentative dates are September 12th and 13th. We have not yet decided which of these 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 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 that she has provided to the Division over the last year. Thank you, Carol.

Welcome and Opening Remarks

CAPT Rest-Mincberg: Thank you, Janine. I want to welcome everybody. I am beginning to know faces, and I am happy to see a lot of people here and to have this opportunity to speak with you again. I am also excited to learn new things and to learn about your perspectives and what you have to say about the many changes as we move forward rapidly.

We are within the Department of Health and Human Services, within the Substance Abuse and Mental Health Services Administration, within the Center for Substance Abuse Prevention, and within the Division of Workplace Programs. Under a delegation of authority from the Secretary of HHS, we carry out the HHS role in the Federal Drug-Free Workplace Programs

The mission of SAMHSA is to reduce the impact of substance abuse and mental illness on America's communities, and drug testing fits into that very clearly. The agency's roles in behavioral health include funding, leadership, information, communications, and improving practice. This is accomplished through eight strategic initiatives, one of which is prevention. Many people do not realize that workplace drug testing is one of the largest public health prevention programs in the country. This program impacts the public health and safety and national security of every person in the country who steps outside of their house, whether in a vehicle on the roads, on the waterways, in the air, on a bus, if you live near a nuclear facility, etc.

Because the regulated industries test for illicit drugs, lives are saved and injuries are prevented every second of every day. The Institute of Medicine refers to this as universal prevention because it benefits the general public. As with many things in universal prevention, people do not always realize that this public health measure is in place for them. This program is also a selective deterrent because, as we know in public health, that if somebody has a problem with drunk driving and is shown pictures of injured or bloodied bodies, that does not really impact their behavior as much as the threat of a huge fine or losing their license. Thus, in public health, the deterrent effect is often much more dramatic and brings much better results. That is why this deterrent program.

There are 400,000 testing designated positions in the federal workforce and 12 million workers in the regulated industries that are drug tested. Behavioral health is essential to all health. It improves health status and lowers costs of healthcare for families, businesses, governments, labor, and everybody. We know that prevention works. If someone has drug problems and his/her drug test result is positive, we can refer them to treatment and assist them with recovery.

SAMHSA has some principles, and one of the principles involves people. If we stay focused on the goal, eventually what we do has to impact people. This is a partnership that cannot be done without others. We need

labor, industry, consumers, science, and the law to work together.

Performance makes a difference. In the case of this program, we can clearly show that performance makes a difference. We have empirical evidence that shows that there has been a decline in illicit drug use since the beginning of this program.

For the last three DTAB meetings, DTAB has followed a multiple-step process to assess the scientific sufficiency of oral fluids as a potential alternative specimen for inclusion in the Mandatory Guidelines. We are moving forward on that initiative. The DTAB has assumed an enormous burden to ensure that this moves quickly. Our working group experts have done extensive literature reviews. We have issued a Federal Register Notice Request for Information. All those things went into place in a very short period of time.

Today, the DTAB will review the public responses to the Request for Information notice. They will deliberate and vote on the scientific sufficiency of the evaluation of oral fluids. Is there enough scientific information to move forward? At any time in this process, either we or the DTAB can ask for more information. There are three options, depending on the evaluation of the data and the scientific information. The first one is the data do not support oral fluid testing. The second is that DTAB will request additional research. The third one is that the DTAB can recommend or propose revisions for inclusion of oral fluid in the Mandatory Guidelines and for HHS to provide a notice in the Federal Register for public comment. If the third option is accepted, the DTAB will send a recommendation to the Administrator on oral fluids.

I want to thank everyone for coming. I want to thank the DWP staff for all the work that they have done, the DTAB who travels here to help us with this, and all of our federal partners. Again, thank you.

Deliberation and Vote on Proposed Recommendations

Dr. Cook: Hi. I am Janine Cook. I will be discussing the proposed recommendations that Carol has just alluded to. To begin, I will review some of the key aspects of the charter under which DTAB operates. The DTAB provides advice to the Administrator of SAMHSA on specific science areas on new drugs of abuse, recommended areas for emphasis or de-emphasis, new or changed directions, and mechanisms and approaches for implementing those recommendations.

We sought advice from our Office of General Counsel at SAMHSA. Our counsel recommended that DTAB should provide advice to the SAMHSA Administrator in the form of an official written recommendation. Based on her advice, as well as the FACA rules under which the Drug Testing Advisory Board operates, we decided to utilize the recommendation process. First, any recommendation must come from a voting member of the DTAB or from the Chair. Secondly, the language of that recommendation must be clearly proposed in writing. Next, the Board will deliberate on that recommendation in the open session. A quorum of the Board members must be present, and they will vote by closed ballot in the open session on that recommendation. A majority is needed for that recommendation to be approved. The ballot will be private, but we will present the tally of that vote at this meeting before the public comment period. If passed, we will draft a letter to the SAMHSA Administrator that includes the recommendations. Each member of the Board will sign that letter. That letter will then be forwarded to the Administrator for her approval or disapproval of the recommendation.

Since January 2011, the DTAB has been evaluating the science of oral fluid to determine if the science supports its inclusion as a potential alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

The Board has two recommendations in front of them today. The first recommendation that the Board will now deliberate upon in open session is this: Based on the review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. I invite DTAB members to begin deliberation and provide comments to this recommendation.

Dr. Brown: First of all, good morning everyone. Second of all, I believe that recommendation number one has been a long time in coming. With the many things that occur in industry, progress is one thing that you look for, to the extent to which it can help identify shortcomings in the present system and offer opportunities to explore ways to address the challenges that we currently have. With respect to that, having another matrix makes sense from the standpoint of those same objectives that were articulated earlier from the public health perspective and prevention of substance abuse and its complications. In that respect, I believe that this recommendation fully represents where we are in terms of scientific development and public health needs throughout this country. So I certainly am one who would support this recommendation.

Mr. Bonds: Good morning. My name is Bobby Bonds. I want to thank the Chair for your continued leadership. Not being a chemist myself, I did find compelling evidence presented by the experts on the panel that has persuaded me to go forward based on their expertise and research. Although I know that we will have further examination and input to the process, at this juncture I feel that it is a good recommendation to provide the Administrator.

Dr. Cook: We have a second recommendation that addresses emerging drug threats. The Board recognized that the misuse and abuse of psychotherapeutic prescription drugs, specifically opiate pain relievers, tranquilizers, sedatives, and stimulants, is increasing. The pharmaceutical classes with the greatest misuse/abuse potential are the narcotic analgesics, especially the opioid pain relievers, because of their addiction potential and the euphoria they induce. The workplace, healthcare, judicial, and environmental costs associated with prescription opioid abuse were estimated at $9.5 billion alone in the U.S. in 2005. Current data on prescription medication misuse and abuse support the testing of additional Schedule II prescription medications to address this emerging threat to public health and safety, as well as to national security. Therefore, DTAB recognizes this emerging drug threat and is proposing this recommendation: DTAB recommends the inclusion of additional Schedule II prescription medications (e.g., oxycodone, oxymorphone, hydrocodone, and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. I encourage the members of the Drug Testing Advisory Board to deliberate on recommendation number two now.

Dr. Bowers: Within this business of illicit drugs, things change fairly rapidly. This has been discussed at length within the committee and within the charge of DTAB. It is an important step forward, and I am fully supportive of these additional drugs for consideration.

Ms. Rowland: I agree. Like Dr. Brown said earlier, this has been a long time in coming as a way of reducing drug abuse. I am very happy to support this.

Mr. Swart: Board members, I think that in terms of serving the public in transportation-related safety issues, I don't think that there is any doubt that we need to do testing for these additional Schedule II prescription medications. So I go on record by saying that the Department of Transportation, our DOT agencies, our managers, and the folks associated with our program are absolutely unanimous in that we need to test for these additional Schedule II drugs.

Dr. Smith: I think it is important to state in the open session that the Board has spent many minutes, if not hours, discussing the potential ramifications of the inclusion of additional drugs in the Federal Drug Testing Program and whether this represents a diversion from the basic tenets of the program, which are deterrence of illicit or unauthorized use of controlled substances, and for those individuals who are not effectively deterred, being able to detect them and protect public safety. I am convinced after deliberation on this topic over the last six months that the Board does see this as a continued and an enhanced furtherance of the objectives of the original program. Dr. Walsh, Dr. Caplan, myself, and the others who have been involved in this program since its infancy in the 1980s examined the threats to public health, to public safety, and to national security, whether that was in the military program, the federal employee population, or the Department of Transportation, and identified those key drugs. As Dr. Bowers eloquently said, the threats out there today are different, and we must address them. I feel that we have effectively addressed previous threats, whether cocaine and

methamphetamine, and now we need to similarly address these new emerging drug threats. This is not a move to attack those individuals who are using prescription medications lawfully, appropriately, and through appropriate medical treatment, but rather the deterrence and detection for those that have moved over to the illicit, illegal, and unauthorized misuse area of Schedule II medications. Thank you.

Dr. Brown: I felt so moved by Dr. Smith's comments that I wanted to share some of my own that I think are really relevant here. As an addiction medicine specialist, and importantly, as a former president of the American Society of Addiction Medicine, I know very well how difficult it is to change a number of institutions in our society, particularly medical education. I see this recommendation as an opportunity to expand the database about what is actually happening with these emerging drug threats. We get some information from the private sector and from a small component of the public sector. This would provide the database that will inform policymakers, both in the public and private sectors, about how can we respond to this continuing threat to the public health. This will also change medical education and the training of healthcare professionals based on the information that comes from this. We have seen this precedence in the past. We have seen private industry formulate their policies based on what happens in the public sector. This represents an important database that we will be able to provide, not only to public policymakers, but also to private industry. And, as someone who is a physician and has this dear to my heart, this will hopefully impact the training of our healthcare providers.

Mr. Bonds: If I may add, I congratulate the Board for their recognition of the sensitive balance between legal medical use of prescription drugs versus illicit abuse during their deliberations. This important distinction was discussed in lengthy conversations and recognitions. I found the Board to be interested in, and understanding of, this complex area.

Dr. Cook: That is all the comments that we have from the Board. We have finished deliberating in open session. What remains is for each of the Board members to vote on whether they approve or disapprove the two recommendations. Every Board member has a ballot in front of them. The voting will be totally anonymous. I will read the vote tally before the public comment session.

At this time I would like to introduce our next speaker. I have to apologize because when I made the agenda, he was only a lieutenant. But since this time, he has been promoted, and so I now want to congratulate Lieutenant Commander Eugene Hayes and invite him to the podium to speak to you about the Request for Information.

Review of Request for Information Responses

LTCR Hayes: Good morning everyone. My name is Lieutenant Commander Hayes. I will talk to you about the Federal Registry Notice that we published June 10th with a 60 day public comment period. The purpose of this Federal Register Notice Request for Information is to provide to the public a transparent look at the Oral Fluid Initiative and to have questions answered for the DTAB, the subject matter experts (SME), and their working groups.

This request for information notice was proposed by our general counsel as an ideal for transparency. We sought scientific information that was peer-reviewed so that we could also reference the submitted comments for altering the Mandatory Guidelines, changing our ideas, or furthering the knowledge of the SMEs and the DTAB. We identified five categories in which we formulated questions.

The first category was analytes and cutoffs. The associated questions were: what analytes should be measured in oral fluid for the initial and confirmatory tests, what initial and confirmation cutoffs should be used for the oral fluid drug tests, and should the oral fluid drug testing panel be expanded to include Schedule II prescription medications?

The second category was specimen validity. Those questions were: are biomarkers needed to validate the oral

fluid specimen and are there appropriate biomarkers or tests for the oral fluid specimen that would reveal adulteration, substitution, and/or dilution?

The third category was collection. The included questions were how should an oral fluid specimen be collected, and as a donor, would you prefer to provide an oral fluid or urine specimen? This question in particular, reached out to any of our stakeholders, who are consumers of the process, to solicit their opinions as well.

The next category is collection devices. The question in this category was: what should be the technical requirements for an oral fluid specimen collection device?

The final category is testing, and its question was: what technologies are available to perform initial and confirmatory testing on oral fluid specimens?

The comment period initially proposed at the last open session of DTAB was 30 days. After speaking with our Office of Management and Budget representative, the comment period was expanded to a 60-day period. We are over halfway through that period at the current time. The comment period will end on August 9th, 2011 at the close of business. We offered several methods to comment, including electronic, fax, email, and regular mail. I have included for those members who are online, as well as for those members who are here on site, the website for the Federal Registry, and comments can be made via the website. To date, we have received two comments. I will caveat that by saying that we have sent to all of our major stakeholders the Federal Register Request for Information and the methods by which they can respond. At a minimum, this request has been sent to the labs, the MROs, the SMEs, and the working group members.

Does anyone have any questions about the Federal Register Notice Request for Information for oral fluids? Thank you very much

Dr. Cook: As I mentioned in my introduction, I thought that we may run ahead of the schedule. I have to apologize for that. When I initially had prepared the agenda a while ago, I was basing the time for Gene's talk on the data we received from our last comment period. At that time, we received 596 comments. Thus, I thought Gene would be up here for a very, very long time. With only having two received two comments so far, that did not happen.

Public Comments

Dr. Cook: At this time, we will commence with the public comment period. Historically, I would take the time allotted and divide it by the number of presenters. Since we are running so far ahead of schedule, I will not be as strict on the time allotment for each person. I will select the order of the comments alphabetically, beginning with those that are present on site. This will be followed alphabetically by those who are joining us remotely via webcast. For those of you on site, please sit at one of the vacated chair at the back of the U-shaped table and use the microphone to present your comments.

I invite Lindsay Cammel from Omega Laboratories to come up and provide her comments.

Ms. Cammel: First, I want to thank the members of DTAB and guests for listening to my comments today. My name is Lindsey Cammel, and I am the Regulatory Affairs Representative for Omega Laboratories, which is one of the major hair testing laboratories in the United States. Omega has over 10 years of experience in hair testing and has over 6,000 clients worldwide, including many government entities and multinational organizations. Omega and concerned regulated industries are very encouraged to see that the long-awaited and accelerated approval of alternative matrices has begun. We hope the pace of oral fluid approval will be granted to hair testing when the Board is considering their next matrix for the Federal Workplace Drug Testing Program.

In the spirit of innovative safety policy, I would like to offer my support and Omega's assistance and support to

DTAB, SAMHSA, HHS, and ODAPC in facilitating the acceptance of hair testing. We will continue to assist in gathering drug testing data to share with DTAB members and hope that the Board will give hair testing's acceptance serious consideration to the accelerated process.

There has been a want and a need by regulated industries to be given the option to use hair testing, and this is why so many have implemented hair testing programs over the last five years. They do not believe the current urine testing program is working and have statistics to prove that people are falling through the cracks. Some of these companies have documented cases of people that they did not hire because they failed a hair test but passed an HHS or DOT urine test. Some of these individuals have applied to companies that only DOT urine drug test and were hired, and some of these people caused fatalities.

We realize that DTAB is currently busy finalizing their review of oral fluid, but I hope you can take a moment to reflect on some of the new statistics that are shared with your Board today. It is critical that hair testing be accepted for addition to the Mandatory Guidelines, as every missed opportunity to begin the acceptance process allows more time for chronic drug users to dupe urine tests and work in safety-sensitive positions, jeopardizing the lives of the American public and their own. Thank you for listening to my comments.

Dr. Cook: Thank you. I want to invite Jim Ferguson of FirstLab to give his comments.

Dr. Ferguson: Thank you. I want to say that I composed my comments long before the deliberations of the Board, so some of this will be ad lib since I obviously do not need to sit here and make a plea for you to start testing for Schedule II drugs.

I am currently the Medical Director for the Professional Health Monitoring Program at FirstLab. I am a certified MRO and have been for 20 years, Course Director for the ASAM comprehensive MRO training course, a Fellow of ASAM, author of the *MRO Team Manual*, and a Director of the Medical Review Office of Certification Council. I am making these comments from me and not from any of these organizations. I will say that some of them have come from communications to me from other addiction medicine doctors, including Dr. Brown, and most importantly, perhaps, from certified addiction medicine doctors that enroll my MRO course and view both sides of the question.

First of all, we applaud the process of including oral fluid testing and Schedule II drug testing. I have reviewed and overseen the review of thousands of oral fluid drug tests. It is high time that we are doing this, but I do want to bring two things to the forefront, and I would not be surprised if you already spent some time talking about these in your deliberations. One is the need to know how much specimen we are collecting, and the other is the need for good biomarkers in oral fluid for validity testing. As we move toward expanded panel testing, the importance of the volume of specimen is obvious to all of us. Possibly a bigger issue is validity testing. The myth of an observed urine collection is well-known to MROs and even better known to those of us involved in treatment and the monitoring of patients and workers in recovery. In spite of increased attention, as well as the new DOT regulations, one can never assume that any given collection has been well observed. While open-mouth exams and 10-minute deprivation periods seem easier to perform than observed urine collections, we cannot assume they will all be done at the same level of competency each and every time a specimen is collected. In urine testing, the burden of determining that each specimen is consistent with normal human urine is borne by the laboratory, and it needs to be that in oral fluid as well. We, as MROs, hear all the time about collection issues from donors that are positive, and we hear about it from employers who are certain donors are not negative. The general topic of how to beat a drug test has over five million Google hits, while how to beat an oral fluid drug test retrieves two million Google hits. Beating drug tests is a frequent topic of discussion during work hours among workers subject to those tests. In our world, we have no business reviewing results that come to us without either complete chains of custody or evidence that the lab was testing a valid specimen.

I can skip a whole paragraph now where I plea for you to start doing Schedule II drug testing, which will shorten these comments. It is a good thing. I do want to lead into the last paragraph of the comment with a little

bit of a caveat. I think we do a much better job as laboratories testing for Schedule II drugs than we do necessarily as MROs in reviewing laboratory results for Schedule II drugs. I wanted to just put out a reminder from an MRO perspective about expanded panel drug testing. In August of 2008, Robert Swotinksy and I appeared before the Board to discuss the MRO approach to this review. Laboratories confirmed the presence of a drug that MROs verified as acceptable, legitimate medical explanations for the confirmed positive result. Neither the labs nor the MROs can address whether or not a donor is impaired, whether or not a donor is taking the medication as prescribed, whether or not a donor is taking it at work, or most importantly, whether or not a donor is fit for duty. We cannot believe that the simple addition of Schedule II drugs to a testing panel by itself will make a big difference in workplace safety because it might not. In fact, it might do the opposite since we know from a SAMHSA-funded MRO database project that 75 percent of opiate and benzodiazepine confirmed positives are reversed to negative by MROs. What I would like to see developed is a program of collaboration between employers, regulators, MROs, and occupational medicine physicians working together to craft, implement, and maintain a comprehensive fit-for-duty program. I believe that is how we will bring real change for the better in workplace safety. Thank you.

Dr. Cook: Thank you, Dr. Ferguson. I would like to welcome Abigail Potter of American Trucking Association to the podium for her comments.

Ms. Potter: Hello, my name is Abigail Potter, and I am with the American Trucking Associations. ATA is the United Federation of Motor Carriers, State Trucking Association, and National Trucking Conferences created to promote and protect the interests of the trucking industry. Directly and through its affiliate organizations, ATA encompasses every type and class of motor carrier operation. ATA is pleased that DTAB is reviewing alternative drug testing matrices, and after this Board thoroughly investigates, which hopefully you already have, oral fluid testing, we strongly recommend that DTAB examine and improve hair testing.

Highway safety is critically important to our industry. If you think about it, our nation's highways are the trucking industry's workplace, and we as an industry strive very hard to make them safe for all highway users.

Giving the trucking industry the flexibility to use alternative testing matrices, particularly hair testing during pre-employment screening, allows us to confirm that we are putting the safest drivers out on the road. Hair testing is hard to adulterate. Since collectors cut hair specimens directly from a donor's body, and hair testing looks at the metabolites stored within the hair shaft, there is little opportunity to subvert a hair test. Whereas a 2008 government accountability report found that there was a wide range of available products and other methods that make it very easy to adulterate urine tests. Hair tests, on average, have a 90-day window of detection for all drugs, whereas urine tests only detect between 48 hours to seven days.

Looking at a handful of trucking companies that are doing both urine and hair tests, between 2.35 and 10.4 percent more drivers were caught with hair tests.10 percent—that is significant.

In the last year, ATA has seen a dramatic increase in the number of trucking companies that are using hair testing in conjunction with urine testing during pre-employment. These companies are working hard to improve the safety within their own fleets but would like to make sure that the other fleets out on the road are just as safe. Approving hair testing as an additional test to urine would allow companies the ability to share their hair results when other companies inquire about former drivers, which is currently a requirement. Companies are required to inquire about former drivers at companies, and they are required to share why they were released, and particularly, they talk about the urine test.

As an industry, we are happy to see that DTAB is making a concerted effort to review alternative drug testing matrices, but we believe that hair testing in particular deserves fast-track analysis and approval since these tests are already being widely used within DOT regulated industry. Safety should always be the number one priority, and with DTAB's approval of alternative drug testing matrices, particularly hair testing, it will continue to be the top priority. Thank you.

Dr. Cook: Thank you, Abigail. I would like to welcome Mr. Ted Schultz to the podium.

Mr. Schultz: Thank you. Given the time and importance of the discussion here, I did want to chime in with a couple of additional comments. My name is Ted Schultz. I am the Chairman of the American Association of Medical Review Officers. I have been in the business probably as long as anybody here, over 30 years or so now, and I am a toxicologist and an attorney. I work day-to-day with MROs, employers, lawyers, and policymakers on the issues we have been talking about today. I have been to many of the meetings, and I have never heard the role of this agency in this public service initiative stated as articulately and elegantly as I heard this morning. I would like to expand on this process in a public health sense in terms of the Schedule II drugs. It will be more than technology. There will be some fundamental policy issues that need to be addressed in dealing with this abuse issue. There are some significant cost issues that employers are looking at in this area as well. If you look at this in a public health context and think of substance abuse as a contagion or a contagious type of disease, what you want to obtain is immunity and to reduce the points of infection.

One of the issues that will have to be addressed is the availability of the Schedule II narcotic analgesics in terms of quantities that are prescribed and the length of time for which these drugs can be used. MROs are constantly confronted with situations in areas where we have pandemic abuse of oxycodone, such as in Appalachia, Tennessee, and Kentucky. For instance, a donor has a five or ten-year-old prescription for oxycodone that he/she is waving as their pass for his/her recent illicit drug use. As a model, the Army has a rule that states that they will only allow the prescribing of a 30-day supply of these drugs, and that you cannot use a prescription drug beyond 60 days or a month after the prescription has been written.

Again, going from an illicit drug to a drug that is primarily used legally, the challenges have been the establishment of reasonable parameters without interfering in medical treatment for bona fide pain patients and other individuals. I do think you can segregate and separate the populations. I do think that people can use these drugs safely in the workplace, as articulated and seen in many fitness-for-duty programs, and identify those that have four or five-year-old prescriptions and/or drugs that are currently in their system. I will look at trying to develop some reasonable parameters based upon what the Army has done for giving guidance to non-regulated employers.

I am thrilled with the idea that we are moving forward with oral fluid testing. Again, many MROs deal with this. One of the things you will see, and I have already started to see this without even the publication of this recommendation, is a renaissance of drug testing in schools via oral fluid testing. In some ways, adopting urine drug testing in schools was an uphill battle, not only for the substitution and integrity issues, but because of the nature of the specimen itself. I have heard about a sudden burst of interest with school boards looking at oral fluid as an alternative, primarily from MROs who have contacted me. I think that is a very promising perspective.

There are tradeoffs to all these technologies. The policies and underlying rules are issues that must be considered. It may involve broader involvement with the medical community and other federal agencies as well to establish prescription standards.

With that, I thank you. I want to commend SAMHSA on its transparency and efficacy as seen over the last 12 months or so. Thank you.

Dr. Cook: We will move on to the public commenters that are joining us via webcast. Will those that are joining us remotely that would like to give public comment please type your phone number in the chat pod so that Jared can call you and link you in. If Jared does not have your phone number, he will not be able to call you for your public comment. We will not proceed alphabetically in this group but rather by availability. I will start with Ellen Voie, who is from Women in Trucking.

Ms. Voie: Thank you for allowing me to make my comments today. My name is Ellen Voie, and I am the President of the Women in Trucking Association. We represent the interest of women in the trucking industry,

but our membership is comprised of both men and women who believe in our mission, which is to encourage the employment of women in the trucking industry, promote their confidence, and minimize obstacles faced by women working in the trucking industry.

I am addressing the Board today to share an obstacle that is significant to our driver population that concerns drug testing specimen options. Upon first evaluation, urine testing is especially burdensome, and even discriminatory, to women due to anatomical differences and the challenges faced in the urine collection process for females. For those who experience difficulty in producing a specimen, they are punished by officers who then cite them for non-compliance. Collection is difficult, but the problems of urine testing go further. Urine specimens have only a two to seven day drug detection window that drug users usually know how to bypass, and anyone with Internet access can purchase one of the thousands of adulterants manufactured to thwart the urine test.

The issue goes beyond urine having an inconvenient collection process to being one of the most critical public safety policies that drivers currently face. We hear stories about drivers who fail the hair test but move onto another company and pass a urine test and later cause a fatality. For this reason, trucking companies have taken safety into their own hands by implementing a hair testing program. The Women in Trucking Association believes in safe drivers, safe carriers, and safe policies, and adding hair testing to the Mandatory Guidelines advances the safety of these areas.

I am not the first person to ask to add hair testing to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. I come to your Board because Public Law 100-171 from July 11, 1987 states “the Mandatory Guidelines must establish comprehensive standards, including standards which require the use of the best available technology.” This has clearly not been the case in the last 10 years, and it has been made more evident by the number of carriers that are now implementing hair testing programs, despite having to continue performing the DOT mandated urine test.

Continuous band aids on the current urine testing programs have forced truck drivers to take their issues to the Secretary of Transportation and numerous congressmen and senators. You are the experts in drug testing, and when we are asked why hair testing is not accepted, we let them know that the HHS and ODAPC are still quoting studies that were heavily criticized by their peers, while shifting the blame back and forth between the two agencies.

Again, I ask the DTAB, HHS, and ODAPC to put their biases down and give the industry the option to use hair testing for pre-employment drug testing and random drug testing. If the goal of these departments is to keep drug users out of safety-sensitive positions, adding hair testing to the Mandatory Guidelines is the best way to ensure that this is done. Thank you again to the Board for allowing me to submit my comment.

Dr. Cook: I want to invite David Whiteside of J.B. Hunt Transport, Incorporated to give his public comment.

Mr. Whiteside: I want to thank you for letting me have the opportunity to comment before the Drug Test Advisory Board. I commented previously, and so some of the things I say will be affected by the members.

But I do want to say that I am pleased to hear that oral fluid is coming to a vote and will be possibly approved. This will allow us an opportunity to look at other alternative matrices for testing, including hair, because oral fluid, while it may be useful for officers on the roadside to detect current status of drug use, does provide a shorten window of detection. For pre-employment purposes, this drug test would not create the result that is needed to deter people from entering the truck driving field that are using illegal drugs or using illegally obtained drugs.

We now have 50,000 hair test results, and they still indicate that hair testing is far superior to urine in pre-employment tests for detecting the use of illegal or illegally obtained drugs. From May 2006 through March 2011, we had more than 2,700 drug-using drivers that were identified on the hair test, while passing their urine

test. At the same time, the J.B. Hunt and DOT positive urine rates have declined by more than 79 percent. That goes right in line with some of the opening comments about performance standards that show that we are able to make a difference. For identifying drug-using drivers using hair tests, random rates right after being hired have declined by more than 79 percent. More and more truck companies are using hair tests. We, as a large truck company, are being questioned because we are one of the first adopters of hair testing. Why are the regulatory bodies that control driver drug tests not adopting procedures for hair testing for DOT-accepted purposes? It is difficult for many to adopt that technology and move to hair testing because of the fact that they would then have to do two tests for employment, and they are asking us why that happens. We really are at a loss to understand why there has not been more investigation, research, and movement towards the use of hair tests.

As I pointed out earlier, the effort that is put into oral fluids is not something that the trucking industry believes will be of great benefit to us as an employer. If the goal of SAMHSA, DTAB, ODAPC, and local safety administration is to prevent drug-using drivers from operating large vehicles, then they should be actively working to adopt testing methodology to best achieve that goal. We believe that that is a hair test.

I do want to thank you again for the opportunity to comment before the Drug Test Advisory Board. I am David Whiteside, Senior Director of Compliance, J.B. Hunt Transport. Thank you very much.

Dr. Cook: I welcome Nate Butlin from Biophore Diagnostics, Incorporated to give his public comment.

Mr. Butlin: My name is Nathaniel Butlin. I am the Director of Operations for Biophore Diagnostics in Redwood City, California. I would like to thank the Drug Testing Advisory Board for the opportunity to provide comments on oral fluid drug testing on behalf of Biophore Diagnostics.
(Webcast audio is unclear. No written statement submitted.)

Dr. Cook: Thank you, Nate. Each of the Board members should have a copy of the letter that Nate was referring to in front of them.

I would like to welcome Jenny Hoffmann of Roehl Transport to give her public comment.

Ms. Hoffmann: My name is Jenny Hoffmann. I am from Roehl Transport. I am the Plant Supervisor and the DER for Roehl Transport. We are a provider of truckload services and logistics services. We drive in all 48 states and Canada.

We have just started hair follicle testing as a non-DOT program and would encourage the Drug Testing Advisory Board to accept and allow us to use hair follicle testing only in place of the urine drug testing as currently required by the DOT. Our drivers have been very supportive of our use of hair follicle testing. We are a company that values safety and see this as another tool in keeping, not only our fleet safe, but the general public safe as well. Hair follicle testing has been already proven and considered acceptable for use by regulated and non-regulated industries, as well as federal, state, and local governments; the FBI; the FDA; and the DoD. We believe that hair testing will bring the federal drug testing program into the 20th century, and we hope that you will consider moving hair follicle testing up in your list of items you consider.

Dr. Cook: Thank you, Jenny. I welcome Marie Lin of Lin-Zhi International to give her public comment.

Ms. Lin: Thank you Dr. Cook and DTAB for allowing us to present our findings. My name is Marie Lin.
(Webcast audio is unclear. No written statement submitted.)

Dr. Cook: Thank you, Marie. Carl Salavka, please go ahead with your public comment.

Mr. Salavka: Thank you very much. I am very impressed and honored by the fact that the DTAB has taken on an accelerated process for reviewing alternative matrices for toxicological testing to reach the goals through

available technology of your overall edict.

I wanted to make for the record, just in case some of the newbies to DTAB don't remember, as well as those of us who were present, available, and working on it at the time, that from 1999-2001 DTAB formed a hair testing working group comprised of dozens of individuals from all of the major testing labs at that time, as well as industry naysayers and many others from academia, military, and working laboratories who were not performing hair drug testing at that time, for the process of developing consensus standards that could be used and implement laboratory guidelines for appropriate testing of hair drug testing matrices within both regulated populations and those that fell within non-regulated populations but knew they would be subject to the testing of regulatory process because the labs that do regulatory testing have such great oversight through the federal government, who thought it would be a good process, to develop those standards, that ultimately led to the non-proposed rulemaking that came out in 2004.

That two years of effort was, we think, well spent teaching us how to look at consensus standards. Since that time, the lack of incorporation of those guidelines into the overall process ultimately led to no changes in the current regulatory standards. The international community globally has gone forward in its consensus process on hair testing to develop cutoff guidelines, proficiency testing, and the infrastructure that a good laboratory program needs to do their job right. For those who need the answers to come in that are complimentary and provide the appropriate information that are probative for the issues being addressed by agencies or companies or a particular incident, hair testing continued to provide intensive standards oversight every two years, doing a relook at consensus standards to bring them up to speed to the newest research.

If any of this is foreign to DTAB members, I will be very surprised. However, the luxury of this is that SOHT is not supplanting what the DTAB has to do under its edict, but it is augmenting your available information and standard-setting infrastructure availability. That is the one point I wanted to make sure you all completely understood, that they are in support of and not supplanting all of the efforts that you have made that are so critical to the overall safety and security of our country.

On the second recommendation that was discussed today involving opioids, for the most part, I will be interested to see what happens to thresholds and cutoffs that would be applied in oral fluids, as well as urine-based testing, to see if there is good consensus on what should and should not be tracked from a level endpoint. Given the huge burden that will now fall to MROs, I am positive that will an interesting discussion point as well.

I do realize both recommendations one and two were for DTAB to give a blessing to going forward with public comment, which then will be addressed as they are received to provide ultimate changes in standards governing the current regulatory process. I am grateful that the two-step process of first making sure you even want to do it all, followed by now that we are doing it, let us take the public comments and see if they change how we want to move forward—doing that separately. I think that is a very great change in the overall process.

Thank you for providing me with the opportunity to say thank you for how you are improving the integrity of the process and in the complementary nature of (?) which made probative different kinds of situations through your hands.

Dr. Cook: Thank you, Carl.

I was amiss in not announcing the tally of the recommendations vote before the public comment period, so I will do that at this time.

Regarding recommendation number one, based on the review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative assessment in the Mandatory Guidelines of the Federal Workplace Drug Testing Programs. The vote was unanimous to approve this recommendation.

For recommendation number two, DTAB recommends the inclusion of additional Schedule II prescription drugs, e.g. oxycodone, oxymorphone, hydrocodone, and hydromorphone, in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Again, the vote by the members of the DTAB was unanimous.

Now we will prepare a letter addressed to the SAMHSA Administrator that will be signed by all members of the Board recommending that she approve these recommendations.

The meeting is adjourned, and the open session is over. I will give the DTAB members a little break before we reconvene in closed session. Thank you.

(Whereupon, the open session adjourned at 11:28 p.m.)