Drug Testing Advisory Board

Open Session

June 1, 2005

Agenda Item: Welcome/Opening Remarks

MR. STEPHENSON: Good morning. Thank you very much for being here. This is the open session of the Drug Testing Advisory Board. This morning, we will go through an abbreviated open session, but we will provide some updates on some important issues. We also will invite public comment for that purpose. Please make sure that we are aware if you are interested in making a public comment, we will divide the time for those comments up equally among those who let us know they wish to make public comment.

I want to welcome you to our building. The only advice I have for you is that the restrooms are just down the hall here, this way. This is a good room, it is a good day, and it is going to be a good meeting. I want to acknowledge the members of our Board that are here, and the staff from RTI International, and the public that have come. Thank you all very much for being here.

We know that this is not as long and as much of an open a session as some of you would wish for, but trust me, due diligence and process are at play, and we are doing what we need to be doing for the Mandatory Guidelines.

I want to ask a question before we go into our HHS update. How many members of the Board were aware that we had a Congressional committee hearing on specimen validity and adulteration, and so forth? How about the members of the public back there?

When we did that hearing, we had gone down the week before to scope out the conference room. We were going to be using the committee room, and we happened to be in the Rayburn Building on the morning that they evacuated Capitol Hill. It is something we can smile a little bit about now, but I want to tell you, it brought back the reality of everything that is out there that we are facing, and the vulnerability. It was the only time that I have ever seen the Capitol Hill police saying, run, don't walk. You have 3 minutes to get totally clear of this building. It reminds me of the role that we play, that the workplace program plays in the national security issues and the roles that are important for all of us to remember in the environment that we are in. This is deadly serious business. It has great implications for those in our environment that deal with public safety and national security, but it also deals with a lot of other work forces and issues that are out there. It is in that context that I mentioned the evacuation.

Agenda Item: HHS Update

DR. BUSH: Between yesterday and today, I discovered something. My old e-mail address no longer works. If you send something to that address, I won't get it and you won't get an undeliverable. You need to use our new e-mail addresses. The format is for me, donna.bush@samhsa.hhs.gov. This is the convention that pretty much all of HHS is moving toward, so your colleagues in FDA have e-mails similar to that, with FDA

attribution and gating, but those new e-mail addresses are on our website. The important thing is for all of us who use address books to update them. I am finding now that a lot of communication has been sent to me that I never got and you don't know that I didn't get it. We have a sheet back there, should you wish to pick one up with our new e-mail addresses.

If you go to workplace.samhsa.gov or www.drugfreeworkplace.gov, you will find it has been redesigned. When you enter the site, all of our current information is going to be there. A lot of the older stuff is in an archive, so go to our website, navigate through the documents. I think you will really like it.

So far, I am aware that six individuals in the audience would like to make public comments.

MR. STEPHENSON: What I am going to do is give you the website information for the house hearing. It was http://energycommerce.house.gov, then it was 108 -- for the 108th Congress -- slash-hearings, and that was 05172005. On that site, they have archived the hearings. They are going to keep the record open for about another 17 days. There are some additional questions that have come in and we are responded to them, beyond those that were presented during the hearing.

I was very pleased to be a part of a panel of 9 individuals who presented information. When we were finished, I found out later that it had actually been presented on National Public Radio. We have a Power Point presentation that was presented. We did provide written testimony, as did almost everyone else who was there, except for a couple of guys who took the fifth.

For the purposes of today, I am not going to go through what we presented, because enough of the public are aware of it. I will make sure that this is available to the members of the Board separately. It is now public domain information, what we presented, so we can certainly make sure it gets in the hands of all those who are here.

Agenda Item: Department of Transportation Update

MR. ELLIS: I am here representing the Office of Drug and Alcohol Policy and Compliance in the Office of the Secretary of Transportation. We are in fact the stewards of 49 CFR Part 40, which are those regulations which govern the collection, testing, medical review and substance abuse professional CTPA rules and some employer rules which govern the testing of approximately ten to 12 million regulated transportation workers, and approximately 600,000 regulated employers.

Besides being the stewards of Part 40, we also provide technical assistance to the five federal agencies who were conducting testing under their own authority, Federal Aviation Administration, Federal Railroad Administration, Federal Transit Administration, Federal Motor Carrier Safety Administration and the new agency, PHMSA, Pipeline and Hazardous Materials Safety Administration. PHMSA of course used to be the role RSPA, which was broken up into two agencies. We also provide technical assistance as require to the Coast Guard who, although they are now under the Department of Homeland Security, do in fact continue to use 49 CFR Part 40 as it supports their testing of the merchant mariners. We also provide some responsibilities

for liaison with foreign governments and other Federal agencies, and the ever-popular other duties as assigned.

I do have on behalf of our office a number of updates.

First item. We are in the process, as we told you at the last meeting, of finishing our urine specimen validity testing notice of proposed rulemaking. It is on schedule. We certainly have a lot more to do, because of course we have to run it through our own systems as well as the agencies that this will affect, but we are on schedule. We hope to have it released this summer or at the very latest, early fall.

Second item. We are increasingly happy about the feedback we are getting from our website, which is becoming very popular. We do have a new feature for you, that is, a signup opportunity for anyone -- the public, other agencies, individuals -- to get automatic e-mail notification of any changes, updates, interpretations that we provide. I recommend, for those of you who have not already done so, sign up on our website. It is www.dot.gov/ost/dapc, one more slash and you are good to go. Sign up and you will be notified as soon as we release information on the NPRM, et cetera.

Among the things you will receive are a pretty new item we have, something we call ODAPC dispatches, which is being released as needed. It is a newsletter format. It lets you in on recent interpretations and news from our office and news that may affect you if you are under our testing regulations or are just interested in them.

Third item. A few months ago, the Mexican government contacted the Department of Transportation, interested in reopening the dialogue that had taken place a few years ago regarding, as once the border reopens from Mexico, their interest in being ready to comply with DOT alcohol and testing regulations.

Obviously none of us have control over when the border will reopen, but there was a meeting a couple of weeks ago in Mexico City, representatives from the Mexican government as well as our office, to talk about their progress in the laboratory area, medical review area, and issues that may affect, once the border opens, the testing of Mexican citizens as they cross the border into our country.

In addition to that, the Federal Railroad Administration, consistent with its new rules, are dealing with more and more cross-border issues from Canada and from Mexico. The challenges they face are much like those faced by federal motor carriers when they started dealing with the issue of cross-border operations.

Finally, just a reminder on the RSPA change. That is up and going. Our testing regulations do reside in one of the two entities that were created out of RSPA, which is the Pipeline and Hazardous Materials Safety Administration. Everybody is trying to get the regulations renamed with the new agency, but you will probably see for awhile, at least as far as testing is concerned, both RSPA as well as PHMSA, which is where their testing regulations reside and the regulation of pipeline safety resides.

Agenda Item: Nuclear Regulatory Commission Update

MR. MC CUNE: I work for the Office of Nuclear Security and Incident Response at the NRC. I'd like to give you a brief update of our actions on 10 CFR Part 26. But first, let me say that the scope of the responsibilities in our office are to provide fitness for duty requirements as a regulator for the nuclear industry, primarily our licensees and other

entities that support the peaceful use of nuclear energy.

In that regard, 10 CFR Part 26, as I have mentioned in previous meetings, encompasses not only drug and alcohol testing, but for the first time, work hour controls both on an individual and group level. To our knowledge, it is the first time that any government agency has attempted to regulate group work hour controls. We feel this is necessary to address the long term impacts of fatigue management.

With respect to the status of Part 26, I can tell you that a year ago, when I joined the NRC, I had an action that was waiting for me. That was to get the rule to the Commission by December of this year. Last year at this time, that milestone was changed to June 1, which is today obviously. We were ahead of schedule in delivering 10 CFR Part 26, the proposed rule, to the Commission about three weeks ago. While we can't control the schedule of the Commission, we would expect that 10 CFR Part 26 would be out for public comment within the foreseeable future, hopefully sometime in the early fall.

There is a redline strikeout version of the current proposed rule on the NRC website at www.nrc.gov. I welcome you to take a look at that, to review it, and also feel free to make any public comments on the version as it sits now or during the formal comment period. We also have a requirement to publish fitness for duty performance indicators. We require the licensees to report on a semiannual basis positive drug and alcohol tests, cutoff levels by plant, by licensee, by program. We are preparing to issue an information notice within the near future that will encompass the last few fiscal years. We were somewhat behind in our publishing of that. But I can tell you, with respect to the rates by licensee and by capita, the rates are relatively static. We don't see any spurious activity that would suggest that we have a drastic increase in any of the testing positives for drugs or alcohol. We are running somewhat less than one percent with our licensee personnel that we have identified for drug testing.

We have made an inroad to alleviate the backlog of the FFD performance, which as you might realize is quite extensive. We are going to a trusted system reporting process that should be in place sometime within the next year. That will streamline the issuing of the fitness for duty performance data. That is also on the fitness for duty website at a separate link, and you can reach that through the link that I previously mentioned.

MR. STEPHENSON: I think I was a little remiss in not saying in our update that we are now in what I would call an advance state of internal review on the Mandatory Guidelines that would include alternative specimens and testing technologies. We have shared with and are in the process of internal reviews that go to the Office of General Counsel and Legislative Affairs. Once that has been completed, it will make its way to a number of other entities. That will be determined both by the Department and then subsequently by Office of Management and Budget, and perhaps by ONDCP. They will certainly be a part of the briefing process on this.

As you understand, and I am saying this at this time, because in the public comments process, the information that has been received during the public comment period has been factored into our discussions and to the decision processes. Information that is presented in public statements here today are not a part of that process. That process is closed. Although it will be good to have a sharing of information and updates,

the other processes that will need to be used will be through the peer reviewed literature, the process issues that are out there, and the other mechanisms for sharing scientific information and new discoveries or findings through the scientists that are in the various Federal agencies, that may in fact still have some comment process they will be dealing with us. That could be NIDA, it could be other entities that are out there.

I am just saying that just so that you understand clearly that we are about a process that is very firmly directed by established regulation and legal counsel, and that we are well on the way in that process at this time.

For purposes of fairness, limit your comments to about five minutes per person? We have 7 individuals that are identified.

Agenda Item: Public Comments

DR. NIEDBALA: To the Drug Testing Advisory Board, thank you for allowing me to comment on the use of oral fluid for the detection of drugs of abuse in the workplace. In particular, most of my thoughts are directed towards the recent draft of proposed guidelines published on April 13, 2004.

My name is Sam Niedbala. I am currently a professor in the chemistry department at LeHigh University. I was formerly the chief science officer and a founder of Orasure Technologies, Incorporated. During my tenure with the company, I also led the industry working group that assisted DTAB in developing earlier drafts of the proposed regulations that would allow oral fluid testing.

A key point that I would like to make initially is that my approach to the development and use of oral fluid testing devices has always been science based, with the goal of providing accurate, reliable results that ultimately withstand legal challenge.

Specifically, I would like to comment on the concept of specimen collection of oral fluids. As far back as 1998, when the first presentations on alternative matrices were made to the DTAB Board, diluted oral fluid samples have been collected using some sort of device.

This was consistently the position of those involved in the industry working groups that met regularly for months to gather information and to suggest the first set of draft regulations. Only one company was planning to develop an instrumented platform that directly collected and analyzed whole saliva. That one company, Life Point, Incorporated, has been delisted from the stock exchange, and is currently selling its assets.

I point this out to the Board, not to isolate this company, but rather to contrast it with the success of those who have used the alternative technical approach that includes the use of an oral fluid collection device that dilutes the sample. In my opinion, specimen collection by a device is the only logical scientific approach.

We have shown repeatedly that observed oral fluid collection with a device overcomes many of the problems inherent in urine collection of substitution and adulteration. Further, the use of a device is minimally invasive, hygienic and simple in nature. You will likely hear from private industry of other advantages that save substantial time and cost through the use of such a device.

The scientific basis of oral fluid testing has been clearly established as evidence by the many publications and peer reviewed journals. The equivalency of oral

fluid testing to urine testing has been established in positive prevalence rate studies of oral fluid compared to urine, including THC.

Our database now contains over 1.5 million specimens, with data from multiple laboratories, and the outcome has not changed. Oral fluids provide similar positivity rates to urine testing. These data are available to the DTAB Board and have been publicly discussed in various scientific venues.

Several key points are worth stressing.

One. Large population studies show that the use of oral fluid testing involving collection devices and a diluted sample, not expectorated saliva, provides evidence of drug use similar to urine analysis.

Two. Multiple laboratories have set up testing procedures and quality systems that have demonstrated assurance of proper specimen collection and population on a large scale.

Three. These labs collect diluted oral fluid samples with a device and complete their analysis with volumes less than 0.5 milliliters, demonstrating analytical advances in specimen handling and analysis techniques made over the last decade.

The current proposed draft regulations contain several concepts that do not agree with the early working group recommendations or data from the existing results in non-regulated commercial laboratories. Specifically, it has been proposed that oral fluid collected must be accomplished by expectoration. This does not agree with existing or anticipated future technologies or hygienic standards or human physiology.

For example, on average a person will produce 0.5 milliliters of saliva per minute in the mouth. Assuming 25 percent of this could be collected, the collection time could easily range from five to ten minutes to reach one milliliter. Additionally, those who work in this field know that whole oral fluid can be difficult and impractical to work with on a routine basis. For these and other reasons, developers long ago made the decision that oral fluid must be collected with a device.

These collectors should be qualified for performance by FDA clearance. To date, there have been several companies that have done this for oral fluids drugs of abuse. None of these devices would meet the current suggestions in the April 2004 draft regulations.

My comments to the Board ask that it consider the body of evidence available in oral fluids testing. Since the early meetings on the potential use of alternative matrices, those involved in oral fluids collection and the test kit development have answered many questions that necessarily arise in regulated testing. Clearly, testing by oral fluids must be accurate, reliable and defensible.

I believe that oral fluids collectors and tests have proven to be adequate in these roles. I ask the Board not to impose definitions of sample volume size or collector performance that would negate all that has been gathered from years of scientific studies and practical use in the private sector. Instead, construct regulations that utilize the unique strengths and attributes of oral fluid testing as demonstrated in the many peer reviewed scientific publications that are now available. I think we all share the same common goals of providing accurate diagnostic tests for use in a deterrence based workplace program.

Respectfully. Thank you.

DR. CONE: I am Ed Cone, ConeChem Research, Severna Park. I am here to speak on the issue of passive contamination of oral fluid by marijuana smoke. In the proposed guidelines published in the Federal Register on April 13, 2004, SAMHSA indicated that further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination.

I would like to submit to SAMHSA and DTAB that such information has now been published or accepted for publication in peer reviewed scientific journals that clearly show that passive marijuana smoke inhalation does not produce positive oral fluid tests.

I have worked with Orasure on four separate studies designed to evaluate if passive inhalation of marijuana smoke would result in positive oral fluid tests. The first two studies were published in 2001 and 2004 in the Journal of Analytical Toxicology. The last two studies were combined into a single report that has been accepted for publication in the 2005 SOFT special issue of JAT.

In our latest article, of which I have copies of the abstract that I will share with you, we designed the most extreme passive inhalation study possible. We exposed four passive drug-free subjects to smoke from four active marijuana smokers, who were smoking high potency marijuana.

One group, we call it study number one, was exposed to 5.4 percent THC marijuana mixed with tobacco. Each passive subject was seated alongside an active smoker in a closed unventilated van. Oral fluid specimens collected inside the van contained up to seven and a half nanograms per ml of THC in the first oral fluid specimen following smoke exposure. Subsequent oral fluid specimens went negative within 30 to 45 minutes.

In addition to this finding, we learned something extremely important in that study: Oral fluid devices are easily contaminated from environmental smoke.

When we repeated the study, study number two, we call it, with the same design, four passive subjects seated alongside active smokers in an unventilated van, but now the active smokers consumed 10.4 percent THC marijuana cigarettes. That was pure marijuana, no tobacco. The results of that study were that there were no positive tests for THC in oral fluid specimens of passive subjects. Let me repeat that. There were no positive tests for THC in oral fluid specimens.

The differences in these two studies can be explained by the fact that the oral fluid collections were made in study two in a clean environment outside the van, where contamination of oral fluid devices was not possible. Although all specimens screened negative for THC, we performed GCMS analysis on all specimens. Only traces of THC could be found in the oral fluid specimens, with a maximum content of 1.2 nanograms per ml of THC.

We also analyzed urine specimens collected from the passive subjects, and found that contaminations of the marijuana metabolite, the carboxy acid, rose to levels near the confirmation cutoff of 15 nanograms per ml.

My conclusion from these latest studies is that passive marijuana smoke inhalation poses no greater risk and perhaps less in oral fluid tests than in urine tests.

I respectfully submit to SAMHSA and DTAB that the weight of scientific evidence shows that oral fluid testing for marijuana is a viable and accurate procedure for identifying the recent use of marijuana, and poses no risk of falsely accusing someone

who has been passively exposed to marijuana smoke.

Thank you.

MR. STEPHENSON: Again, I want to re-emphasize the value of making these contributions in a format that will also place them in the peer reviewed literature. Ultimately, as Sam had pointed out before, they need to be legally defensible. Ultimately, the presence of that kind of information in the peer reviewed journals and available for those to review at time of certifications will become very important for any of the alternative specimens. So I appreciate the work that you all have done.

DR. KARDOS: Thank you for allowing me to speak on oral fluid testing. My name is Keith Kardos, and I am vice president of research and development at Orasure Technologies.

In the proposed guidelines published in the Federal Register on April 13, 2004, SAMHSA stated that a neat oral fluid sample is to be collected instead of allowing for oral fluid collectors. Collection by expectoration carries with it the inherent problems of dealing with a viscous liquid, time delays and risk of adulteration. In contrast, device-based collection with sample dilution can be readily performed in a minimally invasive, hygienic manner without the risk of adulteration.

We now have a large body of data on oral fluid testing with the Intercept collection device. Nearly 1.5 million specimens have been collected and analyzed using our test system in non-regulated workplace settings. These data have demonstrated that oral fluid testing with the Intercept collection device is equivalent to the established urine test in detections of drugs of abuse.

We understand the guidelines for oral fluid testing must have recommended cutoff concentrations that govern reporting of results. Establishing appropriate cutoff concentrations is a complex process that involves consideration of pharmacological and analytical factors. Each type of biological specimen has unique sources of variability specific to the matrix. Although urine can be measured exactly, drug concentration urine can easily and dramatically be manipulated by the individual, as evidenced by the extreme variability in creatinine concentration that may range from a low of approximately five mgs per dl to a high of over 300. This represents a potential change in drug concentration of over 100 percent.

In contrast, the Intercept device minimizes subject to subject variability. Data from recent studies demonstrate that Intercept can collect an oral fluid specimen with a 30 percent or less variation. Furthermore, the variation in oral fluid volume is not under control of the subject.

In addition, I would like to discuss the quality control standards for oral fluid testing. Currently, the majority of oral fluid testing is performed with microplate technology, which can achieve the required analytical sensitivity for oral fluid analysis. To insure performance of the Intercept system, controls for the microplate testing were established at one half the cutoff and two times the cutoff concentration. Laboratories utilizing this system have effectively implemented these quality control standards in over 1.5 million specimens. Imposition of urine homogeneous assay control criteria to microplate technology is inappropriate.

Finally, oral fluid testing is suitable for all situations, including return to

duty and follow-up testing. Data previously submitted to SAMHSA has demonstrated comparable results between oral fluid and urine through all testing scenarios. Consequently, return to duty and follow-up testing should not be excluded as categories for oral fluid testing.

I respectfully submit to SAMHSA and DTAB that the existing scientific data show that collecting an oral fluid specimen with Intercept and assaying the samples with the microplate system provide an effective method for drug testing in the federal workplace.

Thank you.

DR. FRITCH: My name is Dean Fritch, and I am a toxicologist and oversee technical and field service operations at Orasure Technologies.

I am here today to offer a public comment in support of oral fluid testing for drugs of abuse. In the proposed guidelines published in the Federal Register on April 13, 2004, SAMHSA stated that a neat oral fluid sample is to be collected instead of allowing the use of oral fluid collectors. It is presumed that this recommendation for collection of neat oral fluid was concluded to overcome use of collection devices with diluted amounts of saliva.

Measurement of exact volume of an expectorated oral fluid specimen is not a simple matter, as pipettes are not designed to handle viscous fluids, and stability of these samples is unknown. Adoption of this recommendation would necessitate further research, since the majority of data collected to this point has used diluted oral fluid samples.

Consequently, it is my opinion that a collection of diluted oral fluid with a suitable device is the only viable method. An oral fluid collector using a specimen diluent delivers comparable drug testing results, as compared to urine.

It is important to stress that each biological specimen has unique sources of variability. Urine volume is highly variable and under the direct control of the subject undergoing the drug test. Water loading is a common practice of the drug user, and may result in extremely large variations in output. Oral fluid, on the other hand, reflects the drug concentrations of the blood and is not amenable to control.

To illustrate a point of water loading by drug users for manipulation of drug use urine drug concentration, I offer the following. Dr. Barry Sample of Quest Diagnostics in his testimony on May 17, 2005, to the Oversight Investigations Subcommittee on Energy and Commerce, U.S. House of Representatives, on products that claim to prevent detection of certain substances by drug testing programs, reported that drug positive specimens are more than two times more likely to have a low creatinine, possibly indicative of dilute sample. This observation clearly indicates that drug users are intentionally drinking increased amounts of fluids to try and physiologically dilute the drug concentration to a level below the cutoff of the assays.

In 1992, Dr. Saul Needleman reported in the Journal of Forensic Sciences, Vol. 37, pages 1125 through 1133, that the normal variation of urine specific gravity in a group of 14 volunteers had a CV of 25 percent. This same group then drank increased amounts of fluids which resulted in decreasing their specific gravity about one half, supporting what Dr. Sample reported for creatinine. In addition, by decreasing their average specific gravity, they also decreased the specific gravity CV to 95 percent, an

increase of 70 percent.

A variety of other studies reported in peer reviewed scientific literature also indicate that deliberate water loading can alter urine drug concentrations and change a positive result to negative. E.J. Cone, R. Lange, and W.D. Darwin in vivo adulteration: Excess fluid ingestion causes false negative marijuana and cocaine urine test results, in the Journal of Analytical Toxicology, Volume 22, page 460 to 473 (1998).

Therefore, even though we can accurately measure the volume of urine tested, the individual can physiologically excessively dilute their specimen. With dilution of urine, they also increase the variability of the analysis by 70 percent or more. This allows the experienced drug user to have the unfair advantage over other people, since we are applying a fixed cutoff to available fluid.

Our recent data has demonstrated that a variation of less than 30 percent in oral fluid specimen volume can be consistently achieved with the Intercept device. This variability is not under the control of the individual producing the specimen, unlike urine, which can be intentionally diluted by a factor of ten or more through excessive fluid intake.

The variability introduced by drug users who are intentionally diluting their urine specimens through increased fluid intake cannot be eliminated, and is currently tolerated. The use of oral fluid testing offers a viable, accurate alternative.

In conclusion, oral fluid collection and testing minimizes the variability that can be introduced by the donor. I respectfully ask that DTAB and SAMHSA consider these benefits of oral fluid testing when drafting its final policies and guidelines.

Thank you.

DR. KADEHJIAN: My name is Dr. Leo Kadehjian and I am an independent biomedical consultant from Palo Alto, California. I thank the Drug Testing Advisory Board for this opportunity to speak to you today about legal issues in oral fluid drug testing. Please note that I am not an attorney, I am not holding myself out to you as an attorney, nor to the public as an attorney. My comments are intended for informational use only.

I have been invited to provide a written article to the Journal of Forensic Sciences International on legal issues in oral fluid testing. This article will be published in the upcoming issue of Forensic Science International, and I provide a copy of the abstract along with my written comments. In addition, I will be serving as an expert witness in an important upcoming oral fluids workplace drug testing case in Canada, where I will be expected to demonstrate to the court the accuracy and reliability of oral fluid drug testing results and their interpretation.

If Federal workplace applicants and employees are to be subject to drug tests utilizing various technologies and specimens, it is critical for safeguarding these persons' due process rights that these methods be able to demonstrate sufficient scientific reliability in order to withstand legal scrutiny in these potentially adversarial settings. I wish to provide the Board my opinion on the admissibility and evidentiary weight which should be afforded to all fluid drug test results.

Under the 1975 federal rules of evidence, later reinforced by the U.S. Supreme Court in its decision, Daubert v. Merrell Pharmaceuticals, the requirements for admissibility of scientific evidence are simply that the evidence must be relevant and reliable. In its Daubert decision, the Supreme Court did specifically note some factors

which might be considered testing, peer reviewed or publication, known or potential rate of error, standards controlling the operation, and general acceptance. All fluid testing for drugs of abuse should have little difficulty meeting these admissibility requirements.

In contrast, at the state level most states follow the federal rules of evidence in the Daubert ruling, while others follow an older standard, the Frye Rule, requiring a general consensus within the scientific community that a method is reliable. Again, all fluid testing for drugs of abuse should have little difficulty meeting these admissibility requirements.

I have thoroughly reviewed the clinical and scientific bases for the presence of drugs in oral fluid specimens, the collection and handling and analysis of those specimens, and the interpretation of those test results. In my opinion, there is no question that ample clinical and scientific data exists in the international peer reviewed published literature to demonstrate the accuracy and reliability of all fluid drug testing.

This literature has over a 150-year history with several hundred peer reviewed publications from around the world. In fact, one of the first papers published on the detection of drugs of abuse by immunoassay technology published in the Journal of American Medical Association in 1972 in fact included saliva as a specimen.

The collection of oral fluid specimens clearly minimizes invasion of privacy issues as well as allowing for gender neutral collection. Several studies have also demonstrated the stability of drugs in oral fluid specimens. The technologies for oral fluid drug testing have collection devices and test technologies that have been cleared by the FDA, which provides a further demonstration of recognition of accuracy and reliability.

There has been international recognition of oral fluid drug testing, as evidenced by numerous peer reviewed publications from several international forensic research groups. In addition, in 2001 the United Nations published guidelines for testing drugs under international control, which included saliva as a specimen. Furthermore, an international project to address technologies for roadside drug testing, ROSITA, received a commission by the directorate-general transport and energy of the European Commission in 2002 for the continued evaluation of oral fluid drug testing.

That SAMHSA has published proposed rules on the use of oral fluid as a specimen for Federal workplace drug testing after several years of review again provides evidence of regulatory recognition that the science and technology of oral fluid drug testing has reached a sufficient level of development and scientific recognition.

From the legislative standpoint, it should also be noted that several United States states have incorporated saliva as a specimen in their statutes addressing drug driving tests, and roadside oral fluid drug testing has already begun in Victoria, Australia.

Given the above solid clinical and scientific foundation as demonstrated by the extensive international peer review literature, recognition by international regulatory agencies, as well as statutory recognition in several states drugged driving laws, it is clear that oral fluid drug testing when properly performed should have no difficulties in fulfilling legal standards for admissibility and being given appropriate evidentiary weight in any adversarial settings. It is the responsibility of toxicologists and laboratory professionals to insure that oral fluid drug testing serve society well in addressing its problems with drugs of abuse.

MR. BARNARD: My name is Don Barnard. I am with Georgia-Pacific Corporation, Corporate Relations Department.

I would like to thank the Drug Testing Advisory Board for allowing me to give this testimony here today, and offer a comment on our company's successful implementation of oral fluid drug testing.

I oversee the drug testing program at Georgia-Pacific Corporation, one of the world's leading manufacturers and marketers of tissue paper, packaging, building products and related chemicals. We have over 71,000 employees working in 600 locations worldwide. We first launched our drug testing program in the 1980s. For two decades, my company had used the conventional urine sample drug test as the means for drug testing for pre-employment, random testing post accident, or if there is reasonable suspicion for cause. In 2001, after thorough evaluation, our company switched to using oral fluid with the Intercept oral fluid drugs of abuse system, the only FDA cleared oral fluid testing system that can detect the HHS-5 drug panel. We immediately began to see the positive effects it was having on our company.

Since we initiated our program, we successfully conducted approximately 50,000 oral fluid drug tests improving the effectiveness of our drug testing program on a number of fronts. First and foremost, we have been able to keep our employees on the job. With oral fluid testing there is no need for sending employees to a collection site. We are able to administer the collection of the sample with little or no down time, reducing the economic burden of administering the drug testing program.

In addition, we can also hire new employees at a much faster pace. This has greatly increased the productivity of our employees. Secondly, oral fluid collection using the Intercept device eliminates the potential for tampering or adulteration. We are confident in the results, knowing that there is no opportunity for interference.

Our current method of oral fluid collection also has been better received from our employees, because it does not threaten their dignity and removes any potential gender collection issues. Alternatively, if we had had to spit in a cup, we would never have used oral fluid testing and as a result would be denied the benefits that we have enjoyed with oral fluid testing.

Finally, we have found oral fluid testing to be more sensitive to recent drug use than urine tests. In the past, employees took a urine test because there was reasonable suspicion for cause or post accident. Often the result will not show up because of very recent drug use.

Our company's transition from urine test to oral fluid testing, specifically the Intercept test, was seamless. The employees throughout the company supported this transition, including the 150 unions who prefer oral fluid testing because it is non-intrusive for the employee to have an observer witness the collection of the employee's sample.

Orasure Technologies sent an interactive training CD-ROM that allowed the rapid training of my human resource staff. After passing a test included on the CD-ROM, my staff members were ready to administer the test.

The clear benefits of oral fluid testing have been reflected in numerous ways throughout Georgia-Pacific, helping to make our work environment a safer place.

Thank you.

DR. SOIFER: I am Steven Soifer. I am the director of the International Paruresis Association and an associate professor of social work at the University of Maryland.

I actually just have two questions. One is, has a specific date been set or no later date been set for when the new regulations will be promulgated?

MR. STEPHENSON: This is your opportunity to make public comment. We do not engage in dialogue in this environment. It is not a part of the process that is established. If you have a comment that you would like to make, we would be more than glad to allow you the time to make that comment.

DR. SOIFER: So how would these questions be addressed, in what manner can the public ask these questions?

MR. STEPHENSON: I have already responded to you.

DR. SOIFER: Is there someone whom I may address at a later date to have questions answered?

MR. STEPHENSON: To the degree that I can, sure.

DR. SOIFER: Okay. That is all I have to say.

MR. STEPHENSON: Is there anyone else who wishes to make public comment? Are there any questions or issues that the members of the Board would like to raise in this public session at this time?

If not, then I will close the open session of the Drug Testing Advisory Board meeting.

Open session was adjourned at 9:28 a.m.