

Drug Testing Advisory Board

Open Session

December 7, 2004

Agenda Item: Welcome, Opening Remarks, HHS Update

MR. STEPHENSON (Chairman): Out of respect for everyone's busy schedule today, we'd like to start on time. I have been advised by our technical support group that you need to press the green button, to get a red light, so that you could hear me, and more importantly, so that it could be properly recorded. If you want to talk, look for a red light in front of you. That way, we will make sure that it gets equally into the transcript.

Donna, you want to go ahead and open up the meeting?

DR. BUSH (HHS): Good morning. I'd like to open up the meeting and as a first order of business, want to acknowledge that we have some new Board members.

I would like to introduce the new members of the Drug Testing Advisory Board, acknowledge -- Dr. Alberto Gutierrez isn't here yet, but he is from FDA, and a new member on our Drug Testing Advisory Board. He works in the Division of Chemistry and Toxicology Devices, at the FDA. He has extensive experience in reviewing highly complex data packs, for different types of testing devices that are submitted to FDA for clearance. And his expertise and experience and knowledge in this area will be invaluable to the Board, as we develop the technical requirements and final guidelines for drug testing hair, sweat, oral fluid, as well as for on-site drug testing. And he will be with us shortly, I'm sure.

Our second new Board member is Ms. Ann Marie Gordon. She is currently the laboratory manager for the Washington State Toxicology Laboratory. She is very familiar with many different types of analytical tests, and has served as director of quality assurance in a previous life, and a hair testing laboratory, a nationally known hair testing laboratory, and she has experience in urine drug testing in the military drug testing program.

Dr. Dave Kuntz is the Laboratory Director at Northwest Toxicology, now part of LabOne. He is a Responsible Person. He is an inspector for the HHS National Laboratory Certification Program, and he has been an industry representative when the working groups that were established to assist us and the Drug Testing Advisory Board in developing the proposed guidelines for testing hair, sweat, and oral fluid. His experience and knowledge in testing in these areas is extensive and will be a benefit to us, as we come to grips with a lot of the issues in formulating the final guidelines.

Our fourth new Board member is Ms. Pat Pizzo. She has extensive experience in forensic testing, as evidenced by her being a Responsible Person at the Kroll Laboratory Specialists laboratory since 1995. She is an inspector in the National Lab Certification Program. And we are confident that she is going to bring an awful lot of extensive information to us in helping us write these final guidelines.

All right, that's the first part of the HHS update for the day, and I'd like to now focus on a presentation, a PowerPoint presentation that I prepared, with our latest, biggest project. That was the implementation of the revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, which now includes specimen validity testing. The revised Guidelines went into effect on November 1, 2004.

A hardcopy of the presentation is available.

POWERPOINT PRESENTATION (Attached - End of Transcript)

Many of you sitting at the table and visitors in the audience, we recognize that you know about the April 13, 2004, Federal Register notice that we published, but I tried to make this very complete, so that if someone goes to the transcript, they can see all of this contained in one presentation. It has been a long story: from the development of this Federal Register notice and its publication in the Federal Register, and then following that -- the journey to get an effective date, November 1, and to get all the laboratories up and running with specimen validity testing as a requirement for Federal employee drug tests.

Slide 2. The notice was published in the Federal Register on April 13. The cite is there. Volume 69 of the Federal Register, page 19644, and a few after that. Final specimen validity testing requirements for Federal employee drug testing were defined with an effective date of November 1. Creatinine concentration criterion defining a substituted specimen was proposed as less than 2 milligrams per deciliter.

This was the only issue open for public comment for 60 days. Thirteen comments were received, but not all of those comments were on the one item that was open for comment - the creatinine criterion.

Slide 3. Federal agencies have always had flexibility for specimen validity testing. They have always been able to look at creatinine and specific gravity, pH, and either endogenous substances -- or substances that may be used to adulterate a urine specimen; things that one might normally find in a urine but then might be added to try to confound a urine drug test -- or even certainly exogenous chemicals could have been added to adulterate that urine specimen. They have always had flexibility but we went forward with a proscribed, prescribed kind of testing protocol.

Slide 4. We defined creatinine and specific gravity to be: Determined on every specimen; the creatinine to be determined on every specimen, and when that creatinine is less than 20 milligrams per deciliter, then specific gravity would be determined. And if reporting a specimen as a substituted or as invalid, based on this pair of creatinine and specific gravity criteria, specific gravity had to be measured to four decimal places. Additionally, we are going to determine the pH on every specimen, and perform one or more validity tests for oxidizing adulterants on every specimen.

Slide 5. In addition, the laboratories are allowed to perform additional validity tests when the following conditions are observed: Abnormal physical characteristics; reactions or responses characteristic of an adulterant during the drug testing process; and possible unidentified interfering substances or adulterants.

It may be chosen to send the specimen to a second lab if the first lab who

was performing the testing is unable to confirm the adulterant. And in each decision making process, the lab and the medical review officer will decide what is best, because this likely will depend -- it's going to be an irregular kind of situation specific to a particular donor specimen, and then will have to be handled on an individual technical and medical review officer based decision.

New adulterants, if a laboratory identifies it, we must have a reporting of that new adulterant to the Department of Transportation and HHS, and a complete testing for the drugs regardless of what else is in the specimen.

Finally, always conserve that specimen for future testing.

Slide 6. What was on our "front burner" from April 13th until November 1st was in fact implementing the requirements for specimen validity testing. Yes, we had another Federal Register notice that was proposing using hair, oral fluid, and sweat for alternative biological specimens for drug testing, and using initial test facilities and on-site devices, but that was a proposal that had a 90-day public comment period. We were in an implementation mode, with a required implementation date for most of this rule, for November 1st, so we had to put that on our technical front burner, both at HHS/SAMHSA, and at RTI International.

The final SVT requirements defined in the revised Mandatory Guidelines with that effective date and NLCP focus was on firmly implementing these SVT requirements with the creatinine, the specific gravity criterion, and testing for one or more oxidants, as we described before.

Slide 7. In the revised Mandatory Guidelines, we added definitions specifically associated with specimen validity testing, so it would be clear to our Federal agencies, as the employer, and also to the specimen donors. We have initial validity tests now. Not just initial drug test, but initial validity test, and we defined it. We have not just a confirmatory drug test, but we have a confirmatory validity test, and we defined it. We define dilute specimen, adulterated specimen, and required a donor empty their pockets and display the contents of those pockets for the collector, so that could become part of the collection procedure.

We included all the reporting requirements to report a specimen adulterated, substituted, dilute, or as an invalid result. And the requirement to report the actual numerical values, such as concentrations, for the adulterated results, and the confirmatory creatinine concentration, and confirmatory specific gravity for a substituted specimen.

Slide 8. We spoke to and addressed specimen retention requirements at the laboratory. We listed fatal flaws, the list of correctable flaws, expanded retest requirements for drugs, told the agencies that they must have blind quality control materials that are adulterated or substituted to challenge that testing capability at laboratories, and expanded the MRO functions to include handling and speaking with a donor about adulterated and substituted specimen reports and results reported from the laboratories and guided the MROs on how to report those results.

Slide 9. This revision to the Guidelines requires that labs conduct drug and validity testing at the same facility, and clearly distinguish between performance testing samples that contain drugs and those that challenge specimen validity testing

requirements. There were some other changes that were added. Several reflect policies or procedures that have been previously implemented, but are not directly spoken to in the text of the Federal Register notice.

Slide 10. Here are the definitions for substituted as published in April Mandatory Guidelines. Creatinine is less than 2 milligrams per deciliter and specific gravity is less than or equal to 1.0010, or creatinine less than 2 milligrams per deciliter and a specific gravity greater than or equal to 1.0200. Note that the specific gravity is measured to four decimal places. Then we define dilute with creatinine in a range of 2 to 20; specific gravity in the range of 1.0010 to 1.0030.

Slide 11. Laboratories are expected to have a limit of detection for creatinine of less than 1 milligram per deciliter. And we have directed laboratories to have controls at that lower detection level.

Slide 12. We define an invalid specimen. These types of specimens include inconsistent creatinine concentration and specific gravity results. And the definitions are there. Creatinine is less than 2 milligrams per deciliter on both the initial and confirmatory creatinine tests and specific gravity is greater than 1.0010 but less than 1.0200 on either or both the initial and confirmatory specific gravity tests. And then and the corollary to that, or the second type of invalid, we define your creatinine greater than or equal to 2 milligrams per deciliter on either or both the initial or confirmatory creatinine tests and the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests.

Slide 13. When the laboratory reports a result as invalid, it's going to have certain criteria as we discussed. The medical review officer is going to discuss the result with the donor. If there is no explanation -- there is going to be an immediate direct observed collection of another specimen from the donor. If there is an alternative medical explanation that can explain the result, no observed collection is required.

Slide 14. We are shifting now to when a specimen is reported as adulterated by the lab. That's when the pH is less than 3, when the pH is greater than or equal to 11, when the nitrite concentration is greater than or equal to 500 micrograms per milliliter using two different tests. Chromium (VI) concentration is greater than or equal to 50 micrograms per milliliter using two different tests. More detail to follow in the actual document itself, and we will let that stand on its own.

Slide 15. Continuing on with laboratories reporting a specimen as adulterated. A halogen is detected and confirmed with the specific concentration greater than or equal to the limits of detection of the confirmatory tests on the second aliquot, and this requires two tests. Glutaraldehyde is detected and confirmed with a concentration greater than or equal to the limits of detection of the confirmatory test on the second aliquot it. Again, this test for glutaraldehyde requires two tests. More detail in section 2.4.

Slide 16. Pyridine. When pyridine is detected and confirmed with the concentration greater than or equal to the limit of detection of the confirmatory test on the second aliquot. It requires two tests, more detail in section 2.4. Surfactant is detected or confirmed with a greater than or equal to 100 microgram per milliliter dodecylbenzene sulfonate-equivalent cutoff concentration on the second aliquot. This also requires two

tests.

Slide 17. A specimen is reported as adulterated when the presence of any other adulterants not specified in subsection 4.4(iii) through 4(viii) of section 2.4 is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Slide 18. It's not enough just to revise the Guidelines. There are additional documents that comprise guidance from the Secretary to Federal agencies on collecting a specimen, and then also to medical review officers who are reviewing Federal employee drug tests. We have to revise that additional information to reflect the new requirements in the Guidelines. And we did. We revised the urine specimen collection handbook and the medical review officer manual, incorporated the changes for the required specimen validity testing. And these are posted on our Division of Workplace Programs website.

Slide 19. In the specimen collection handbook, we incorporated the Guideline changes, stating the Federal agency blind QC samples should now include approximately 10 percent that are adulterated or substituted, so that they can challenge the specimen validity testing now required on Federal employee specimens. And we added to the list of reasons for directly observed collections that the donor's previous drug test result was reported by an MRO as drug positive, dilute, adulterated, substituted, or invalid. We also changed the format of the specimen collection handbook to facilitate its use as a reference manual.

Slide 20. We revised the HHS Medical Review Officer Manual. It is also posted on our workplace website.

Slide 21. In that manual, we discussed the revised SVT cutoffs. We also advised the medical review officer about the quality control sample requirements to challenge the cutoffs and/or invalid decision points that we ask the agencies to submit to the labs.

Slide 22. Again, this is additional testing requirements for specimen validity testing that are included and incorporated into the medical review officer manual. Many of these are the same that I discussed before, that are indeed originally first published in the Federal Register notice.

Slide 23. We ask the medical review officer to inform the donor that he or she can request a retest for a specimen that was reported as substituted or adulterated. This is the same procedure that is provided when a specimen is reported positive for one of our illegal drugs. And then we talk about the MRO actions in response to a retest of a single specimen bottle or a split specimen bottle. The manual described automatic quantitation reports from the lab, where there's no medical review officer request needed, that the lab is going to report certain results to them directly on their initial report to the MRO.

Slide 24. We added new, expanded information on dilute results, talked more about the pharmacology of drugs, added some references, some peer reviewed references on the pharmacology of drugs, talked about compounds that we know are used as adulterants, and discussed effects of some current adulterants on drug tests, and talk to the medical review officers about drug testing technologies that are used.

Slide 25. We have had a full plate in implementing these required specimen validity tests. Following the publication on April 13th, we needed to notify the manufacturers of the revised Guideline requirements. Labs don't stand on their own. If they are the final implementor of a system of tests, and manufacturers support this, so the manufacturers needed to be notified. And so we did, and everybody worked together. Sometimes a lot of phone calls, a lot of discussions, but we all worked together and then, with a little bit of time to implement the changes, in a trial mode and in the evaluation mode, that laboratories do always, by the time July, August, and September came around, we were all in a position to put out some performance testing specimens that were augmented with specimen validity testing samples that addressed all the SVT changes.

Slide 26. The successful implementation was achieved by all laboratories, and in November 2004, as part of our routine maintenance performance testing, specimens that go out to labs every quarter on November 9th, the 72nd occasion of the maintenance PT program, it included specimen validity testing samples. And the monthly Federal Register list of certified laboratories now includes a reference to those Guidelines published on April 13th, and indeed it acknowledges in that way that laboratories, all laboratories on that list, can perform specimen validity testing, with the required accuracy, and reliability, and confidence stated in that Federal Register notice. Success was achieved.

Slide 27. Summary. The program worked with the manufacturers to ensure the validation of the new specimen validity technology that was implemented. The program extensively prepared laboratories and inspectors for the implementation of the SVT changes. Implementation successfully occurred on November 1st. Finally, specimen validity tests from the November PT occasion met the revised Guideline requirements.

Long story, happy ending.

MR. STEPHENSON: In this process that we have gone through this is both a demonstration of scientific competency and administrative will in accomplishing this seemingly daunting process, seemingly almost endless process. The revisions to the Mandatory Guidelines that are now in place is a commendable achievement, and I want to recognize the hard work of the staff, our contractors at RTI, the members of the Board, and all of the other stakeholders that have participated, and lived through this process. It would not have happened if we all had not stayed the course and worked hard to make it happen.

We had a demonstration of this in our last Board meeting, and we actually went through a process with the members of the Board that were there at the time to actually discuss exactly where each individual stood on actual implementation dates and the ability to move forward. We have done it, it is working, and it is a process that will repeat again, in the broader work that is still ahead of us, and that will be the work of this meeting of the Board later on today, and through tomorrow.

It is unfortunate, but necessary, that the changes that we have made and implemented for the urine testing procedures were required to address the willful attempts by a very small percentage of those that are subject to a mandatory Federal

workplace drug test, all for the purpose of masking current drug use and avoiding detection, instead of dealing with the problem that they have with the substance abuse issue.

The vast majority of our Federal employees do not use illicit drugs, and do not have a problem with any of these issues. But the point is that if we do not continue to stay in front of this, the cat and mouse chase will not be successful. I want to say publicly that our cat, today, has improved senses. It has sharper vision, faster reaction time, and putting the mice on notice out there that this is not going to go undetected or un-caught in the future.

I think it is really important that we think about these things as we begin to address the issues around alternative specimens, because if we do not solve the problem systematically with urine, we will replicate to the same identical business approach to providing a marketplace for products, processes, and ways for folks to escape dealing and confronting their own problems with substance abuse.

I hope that this is something that we can use as just a temporary pat on the back. I think it is something that is a demonstration that periodically you have to go back to the weight pile and start lifting the heavy weights, and go through the intellectual process and the exercise that goes through every element of our administrative procedures activity that we have in the federal bureaucracy, to make something like this happen. And to say that it is a demonstration of yet things to come, I would like to see a follow-up in the next public session of the Drug Testing Advisory Board minutes to look at the implementation statistics, to see what it is we are actually identifying, what the implementation problems and successes are, and that will be something we will look forward to.

DR. BUSH: That sums up our HHS update. Some people may find this just a little dry, everything we have been through. It is never a dull moment. It never is, trying to make a systems change in analytical testing, that is so very important to every specimen donor, and to public health and safety. Sorry it is dry, but that is just the flavor we have, that is how we live. A little bit of dry science goes a long way.

Agenda Item: DOT Update

MR. ELLIS (DOT): I am a senior policy adviser with the Office of Drug and Alcohol Policy and Compliance, Office of the Secretary of Transportation. I am here representing the Department of Transportation. Our office is usually known as ODAPC, and I'll probably use that abbreviation a couple times through my remarks.

I've been asked on behalf of our relatively new director, Mr. John Bobo, to give you greetings on behalf of the department. And also, I've been asked to give you greetings on behalf of Secretary Minetta. Actually, our normal representative, Mr. Jim Swart, who has been recently appointed deputy director in our office, is unable to attend.

Our office, ODAPC, as I indicated, in the Secretary of Transportation's office, we are one of HHS's largest customers as far as the laboratory process is concerned. Our sister agency, HHS, we have relied on for many years to provide the

certification of laboratories, to assist us with establishing the cutoffs and drugs that we are testing for, and to provide its advice on the scientific and technical issues associated with our rather large testing programs.

Congress has given to our various agencies regulatory authority for safety. And among the safety issues we find most important, is the issue of drug and alcohol testing. So we have a number of agencies directing approximately 600,000 employers, and almost 12 million regulated employees, to test under the authority of the U.S. Department of Transportation. Our office provides the overview as far as 49 CFR Part 40, which, in fact, is the regulation which says "When the agencies direct you to test, employer, this is how you are going to collect specimens. This is how the laboratory process is to work, the medical review officer, the substance abuse professional, etcetera."

All of the DOT agencies rely on 49 CFR Part 40 for that consistency. But our office does other things. We are also responsible for advising the Secretary, regarding both domestic and international issues regarding drug and alcohol. Also, providing guidance and work, and partnership, with the various DOT agencies who regulate our employers, and also provide liaison with both HHS, our colleagues here, but also with the White House, and other Federal agencies.

We have a series of projects going on at ODAPC. We are intending to publish in the upcoming months, an employee guide, for use by our operating administrations, and also our employers. In other words, kind of an overview of the DNC testing process for employees. We are also preparing to publish in the upcoming months an employer's guide, kind of an overview of the process, and our expectations as far as safety and the implementation of the DOT regulations.

And then finally, a third publication we are looking forward to publishing in the upcoming months is a medical review officer guide. Our last version, as many in the audience already know, was 1990 or 1992. It is probably time for us to update that a little bit, given the fact that we have published significant new revisions of our regulations, effective in August, and upcoming. Because HHS provides guidelines principally for Federal agencies, we have kind of a different task. We have regulations for our employers, and our MRO, and employer and employee requirements may differ some in material ways with HHS's requirements that are useful to the Federal agencies.

We have a couple of other action items going on, but first let me mention before I get too much further, that many of you may know -- and some of you may not -- that one of our regulatory agencies, RSPA, or the Research and Special Programs Administration, is being broken into two, effective the 30th of November. As you are well aware, one of the areas that we regulate, which is pipeline safety, was part of RSPA, for reasons I'm not aware of, or why, or what the history of it is. However, the decision has been made by the current administration to split off RSPA into two a separate entities. The first will be known as the research and innovative technologies administration, or RITA. That agency will take over the research elements of that formerly resided in RSPA, and may well also incorporate other research requirements and programs in the other DOT agencies. The second agency that will be created from what was formerly RSPA, will be the Pipeline and Hazardous Materials Safety

Administration, and that's abbreviated -- PHMSA. Our expectation is that the drug and alcohol testing requirements formerly residing in RSPA for the pipeline communities will in fact migrate to the Pipeline and Hazardous Materials Safety Administration. Although the legislation made this change effective November 30th, our expectation is, it will happen over the next 90 days or so. So you may not hear RSPA any more. You may well hear PHMSA, or however it may well be pronounced.

Finally, the last part of my remarks will just be to remind you of a couple of items that Jim talked about in the last meeting. We just issued, on November 9th, an IF, or Interim Final Rule, to link ourselves with HHS as far as the urine specimen validity issues. This new interim final rule was effective November 9, and because we are a customer of the laboratory certification process, we did not want to confuse laboratories any more than they were having to be under the new implementation requirements.

We established several criteria for our use, and to make our requirements consistent with HHS requirements. First of all, for us, a urine specimen validity testing remained authorized but not mandatory. But if you do, for employers to decide to do a urine specimen validity test, they must adhere to the HHS Guidelines. For laboratories, we removed any inconsistent reporting procedure established by our May 2003 rule, making it consistent with HHS test reporting requirements. So the laboratories, rather than having to report differently for DOT clients than HHS clients, they were able to report in the same manner. However, we did require laboratories to report all values for creatinine and specific gravity on dilute specimens -- again, using the new HHS criteria -- to our medical review officers, to ensure that they can continue to implement our requirements for MROs in a correct and timely manner.

Our Interim Final Rule, or IF, was implemented, pending our new upcoming notice of proposed rulemaking, where we will formally review and look to implement DOT's urine specimen validity guidelines. We are very grateful for all the hard work from our friends at HHS to identify and establish and implement a lot of the scientific and technical issues. We are required by law to go to our own rulemaking process when implementing something of this magnitude. It is a cost item for our employers. It is also a rather significant scientific and technical issue. And therefore, we are required by law to go through our own rulemaking process.

Agenda Item: NRC Update

MR. MCCUNE (NRC): Like my friend at DOT, George Ellis, we also are very appreciative of the work that HHS and SAMHSA has done, and follow very closely the work, because like the DOT, we are also independently responsible for publishing our own regulations and incorporating the appropriate guidelines into requirements for our licensees.

A couple of updates on where we are with our policy. Part 26, which is our section of 10 CFR, is currently in the formulation stage. The current status is that it will go out for office concurrence internally in the NRC on the fifth of January. We hope by the month of June of next calendar year to have the complete package forwarded to the commissioners for their review. It typically takes about a year after that period to

come up with a public notice, that will go out for public comment.

We did incorporate a specimen validity testing. We followed very closely the HHS Guidelines in that regard, so you can expect to see that. We also, as I mentioned in the last meeting, have incorporated a fatigue aspect, primarily from the perspective of security, but also our reactor operators. As you can imagine, after the events of 9/11, security was greatly increased in the NRC, and you can't do that immediately, from the human perspective. And what we found, and what we expected, was a large amount of overtime for our protective forces, which caused us some concern due to the increased likelihood of fatigue on the part of those employees.

And so part of Part 26, and one of the reasons why it has been delayed somewhat, are some prescriptions for fatigue, from a critical group perspective. And again, our perspective is at the NRC that fitness for duty also means that employees must report to work in a status that they can achieve their job from an adequate sleep perspective.

We have gotten some new administrative staff in the last three months. We do have semiannual reports from all of our licensees. Primarily, the reactors, 188 reactors around the nation, but we haven't had enough staff to do much with the data we have collected. And so, I have implemented a database from all of the reactors. What we hope to do in the future is to be able to do some trending by licensee, by geographical area, by job specialty, to help us localize and discern whether or not we have any patterns, if you will, of issues that we can address separately.

The other initiative that we have is to take the data that has been reported in past years, integrate it into the database, and make it available to other customers like our HHS friends, so that they can be knowledgeable of some current trends, if you will, at least in the nuclear industry. I know that they've been very helpful in the past, of receiving reports. We have had incident reports, in other words, from some of the licensees, where we've had issues with HHS-certified laboratories, and our friends at SAMHSA have been very responsive to our needs in that area.

The second rulemaking initiative I'd like to speak about this morning is a separate rulemaking that will address non-reactor licensees. Part 26 is only going to cover licensees that are operating nuclear reactors. We have a second major class of licensees for fuel production facilities, primarily, that make fuel for our reactors, as well as cores for the Office of Naval Reactors in the Department of Defense. We have just started that process. We do not envision the requirements will be any different from those requirements of the current Part 26, but we are dealing with a completely different organization in the NRC, and so we'll keep you informed at subsequent meetings on the process, and a currency of those regulations.

MR. STEPHENSON: I'd like to see if there are any questions from the members of the Board about any of the presentations that were made, any comments that the members of the Board would like to make in the public session, and also to see if there are any individuals here in the public who feel that they want to make a public comment.

We have one person who desires to -- two people -- to make public

comment. All right, taking that in mind, are there any members of the Board who wish to make any comments at this time? (No audible response.)

We'll ask that you try to keep your remarks under 10 minutes, and that you go to the front of the room, and that you speak into the microphone with the red light on, pressing the green button.

Agenda Item: Public Comments

MR. SOIFER: Good morning, I'm Steven Soifer. I'm a professor of social work at the University of Maryland, and also the Executive Director of the International Paruresis Association, and I thank the Board for allowing me to make these remarks.

In July of 2004, the International Paruresis Association wrote a 44-page document, and 135 of our members submitted comments to SAMHSA's notice of proposed revisions to the mandatory guidelines for Federal workplace drug testing programs. Those comments identify the changes that we felt were needed to implement alternatives to urine drug testing, since it was discriminating against people with disabilities, in probable violation of the Americans With Disabilities Act.

People who have paruresis, a social phobia otherwise known as "shy bladders syndrome," are unable to provide the requisite urine samples. Over 900 members don't like to think of themselves as people with disabilities, because we're quite capable and professionally trained. We count among our members doctors, lawyers, psychiatrists, psychologists, airline pilots, a marine helicopter pilot,, other members of the Armed Services, including those serving in Iraq, policeman, engineers, and others -- including university professors.

When they can't provide a urine specimen for pre-employment or random testing, the regulations label them as a refusal to test, and therefore unable, or not hired, and then fired from their career jobs. In self-defense, one doctor filed a lawsuit against the hospital in Mexico and won a quarter of a million dollars settlement. A professor and captain in the merchant marines has filed a lawsuit against the city of New York and the Department of Homeland Security. And finally, an engineer has filed an ABA suit against Caterpillar Corporation.

We have been told that it could take one to four years to get a new drug testing policy issued and approved, under the HHS regulations procedures. This is unacceptable. People with paruresis cannot be expected to put their jobs and careers on hold for one to four years, while alternative drug testing is investigated. SAMHSA has known about paruresis for over 20 years, and IPA has provided an extensive bibliography of research papers on shy bladder disorder that goes back 60 years, in our formal comments.

We need alternative drug-testing options such as hair, saliva, patch, or even blood, available to all employees, as soon as possible. We demand an interim rule to be issued to this effect by January 2005, so that all employers and drug testing companies be required to follow it.

Let me make it clear, our organization does not oppose reasonable drug testing. Moreover, we do support alternative drug testing, whether here, saliva, patch, or

lead. However, we will not -- I repeat, will not -- tolerate discrimination against someone simply because barbaric drug testing procedures are still being used in the workplace and elsewhere. Simply put, we are asking for one thing: That alternative tests granted to anyone who claims he or she has a shy bladder; that is it, no proof needed. If a person is clean of drugs, a reliable drug test will pick that up. And if they're not, a shy bladder defense will do them no good. Thank you for listening to my testimony.

Mr. Kunsman (OraSure): Our thanks and appreciation to the Board for all the work that's been done, for having these meetings and giving us an opportunity to come down, get a little bit of insight of what's happening, and it to that point, I was hoping that someone could elaborate on the processes that you're going through now, as the format has changed a little that from the early days, when we were used to coming down and the working group, the industry working groups were providing a lot of input. The deliberations and debate by this esteemed group were open and transparent, and we kind of understood what some of the issues were, and tried to help in the discovery of scientific information to advance answers. So, if I could just -- if it's appropriate -- to have an idea of what the closed sessions are bringing, what your mechanism is for addressing some of the questions I know were raised to you in the public comment. Thank you.

MR. STEPHENSON: Well, this is a public comment period. Normally, we don't get into a question-and-answer kind of response, but it's a reasonable request, and if it's one that we haven't amplified properly in other parts of this process, when we went through an earlier phase in looking at alternative specimens and technology, we really needed to reformulate our thinking process. We established a matrix to look at the factors required for accurate and reliable drug testing, regardless of the specimen. We identified a number of issues that needed to be successfully addressed in order to fill in the various cells within that matrix. And then, to develop language that would establish a framework for a reasonable and fair to complete solicitation to the public for response.

We had used the industry working groups as our leadership and participants in providing insight to areas that from the industry's perspective were better known to them, than perhaps to each and all of the members of the Board, and to the various members of the Federal staff and our contractors that were working on these processes. It was a sharing, and a development process.

What we got from this was enough of a framework that we were able to propose a formal request to the public for comment on our proposed revisions to the Mandatory Guidelines, to include alternate specimens. That came out at the same time that our other proposed revision for urine testing had come out, and what we learned -- and again had repeated to us -- has a demonstrated lesson in the legal procedures that we needed to follow. Once the public comment period ended, it became the duty and responsibility of the government to develop the proposed revisions that would be published as a final rule, and vetted through all of the various Federal, legal, and administrative channels that are necessary. It was not up to us at that time to engage in additional fact finding, or to have a creeping change in regulation that would come

through having ongoing public comments. It is our responsibility to deliberate with the members of the Board, to develop a proposed final set of guidelines revisions, and then once those are approved, then they will be made public. It is both a legal and a procedural issue that we must follow, and it includes all the steps that are now in our closed sessions of the Drug Testing Advisory Board.

The caution that goes to the members of the Board is that what we talk about in a closed session stays in the closed session. It does not leak to the press. It does not go to anyone else. It does not provide an inside opportunity for somebody to change a technology approach, or to have their own particular project or perspectives implemented, without having an opportunity for everyone to weigh in on it equally, which is what the public comment period was about, and which we had used our website to actually put up all those public comments, so that everyone was able to see what in fact had come in during that time period.

The length of time that it takes to implement a change is a function of the number of comments received. The time that it takes to go through 285 commentors, 2000 comments, is now in an advanced state of analysis. We have developed our work products and will begin that mechanism of detailed examination by subject group, by comment type, as they are clustered across the entire document. And that is where we will be spending our time from this point on in the closed sessions until the work is done. We understand there are pressures from a number of public interest and commercial interests to see these alternative specimens come out. But one thing you have learned, through looking at the exercise we have just gone through, with specimen validity for urine testing, it is not going to get done until it is done right, and until we have the capacity to perform the test accurately and reliably and report the results consistently.

DR. BUSH: And interpret them.

MR. STEPHENSON: And interpret them correctly, the three part mantra.

A motion to close the open session was made and seconded. The open session of the Drug Testing Advisory Board was adjourned at 8:50 a.m.

Attachment:

PowerPoint Presentation: Implementation of Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, which now include Specimen Validity Testing (SVT) Requirements - November 2004

Implementation of SVT

Implementation of Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, which now include Specimen Validity Testing (SVT) Requirements November 2004

ROCKVILLE, MARYLAND AND RESEARCH TRIANGLE PARK, NORTH CAROLINA

Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing

1. 69 Fed Reg 19644, April 13, 2004
2. Final SVT requirements defined
3. Effective date November 1, 2004
4. Creatinine concentration criterion defining a Substituted Specimen was proposed as <2 mg/dL
5. This was the only issue open for public comment; 60 days
6. 13 comments received, not all on the creatinine criterion

Federal Agencies Have Always Had Flexibility for Specimen Validity Testing.....

1. Creatinine and specific gravity
2. pH
3. Substances that may be used to adulterate urine
 - ◆ Endogenous
 - ◆ Exogenous

Now There Are SVT Requirements for Federal Employee Drug Tests...They Are:

1. Creatinine and specific gravity
 - ◆ Determine the creatinine on every specimen
 - ◆ Determine the SG if Creatinine <20 mg/dL
 - ◆ SG to 4 decimal places if reporting a specimen as substituted or as invalid based on creatinine and SG
2. Determine the pH on every specimen
3. Perform one or more validity tests for oxidizing adulterants on every specimen

Now There Are SVT Requirements for Federal Employee Drug Tests...They Are

(continued):

1. Perform additional validity tests when the following conditions are observed:
 - ◆ Abnormal physical characteristics
 - ◆ Reactions or responses characteristic of an adulterant during testing
 - ◆ Possible unidentified interfering substance or adulterant
2. May send to second lab if unable to confirm adulterant (Lab and MRO decide)
3. New adulterant, report to DOT and HHS — complete testing for drugs
4. Conserve specimen

Front Burner.....

1. Final SVT requirements defined in the Revised Mandatory Guidelines published on April 13, 2004 with effective date November 1, 2004
2. NLCP focus was on firmly implementing SVT requirements by November 1, 2004
 - ◆ Creatinine < 2 mg/dL
 - ◆ SG analysis with 4 decimal places to report as substituted or as invalid based on creatinine and SG
 - ◆ Testing for one or more oxidants

Implementation of SVT

Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing (69 FR 19644), April 13, 2004

1. Added definitions specifically associated with SVT
 - ◆ Initial drug test, initial validity test
 - ◆ Confirmatory drug test, confirmatory validity test
 - ◆ Dilute specimen, adulterated specimen
 - ◆ Donor empties pockets and displays for collector
2. Included all the reporting requirements to report a specimen adulterated, substituted, diluted, or as an invalid result
3. Requirement to report the actual numerical values (concentrations) for adulterated results, and the confirmatory creatinine concentration and confirmatory specific gravity for a substituted specimen



Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing (69 FR 19644), April 13, 2004

1. Specimen retention requirements at the lab
2. List of fatal flaws, list of correctable flaws
3. Expanded retest requirements for drugs
4. Agencies must have BQC that are adulterated or substituted
5. MRO review expanded to include adulterated and substituted specimens; reporting



Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs, Specimen Validity Testing (69 FR 19644), April 13, 2004

1. Requires labs to conduct drugs and validity testing at the same facility
2. Clearly distinguish between PTs that contain drugs and those that challenge SVT
3. Other Changes...several reflect policies or procedures that have been previously implemented



According to Mandatory Guidelines Effective November 1, 2004:

Substituted

Creatinine < 2 mg/dL & SG ≤ 1.0010, or
Creatinine < 2 mg/dL & SG ≥ 1.0200
SG measured to 4 decimal places

Dilute

Creatinine 2 – 20 mg/dL
SG 1.0010 – 1.0030



Laboratory Testing:

- ◆ Expected to have LOD < 1.00 mg/dL for creatinine
- ◆ Directed to have controls at lower detection level



According to Mandatory Guidelines Effective November 1, 2004:

Invalid:

Inconsistent creatinine concentration and specific gravity results are obtained, (i.e.):

- ◆ Creatinine less than 2 mg/dL on both the initial and confirmatory creatinine tests and specific gravity greater than 1.0010 but less than 1.0200 on either or both the initial and confirmatory specific gravity tests
- ◆ Creatinine greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests and specific gravity less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests



**According to Mandatory Guidelines
Effective November 1, 2004:**

1. Laboratory result = Invalid
2. MRO Review:

No Explanation -

- Immediate Direct Observed Collection

Explanation -

- No Observed Collection



**According to Mandatory Guidelines
Effective November 1, 2004:**

1. A urine specimen is reported adulterated when:
2. pH < 3
3. pH > or = 11
4. Nitrite concentration > or = 500 mcg/mL
 - ◆ two different tests required; see Sec 2.4
5. Chromium (VI) concentration > or = 50 mcg/mL
 - ◆ two different tests required; see Sec 2.4



**According to Mandatory Guidelines
Effective November 1, 2004 (con't):**

1. A urine specimen is reported adulterated when:
2. Halogen is detected and confirmed, with a specific concentration > or = the LOD of the confirmatory test on the second aliquot; requires two tests; see Sec 2.4
3. Glutaraldehyde is detected and confirmed, with a concentration > or = the LOD of the confirmatory test on the second aliquot; requires two tests; see Sec 2.4



**According to Mandatory Guidelines
Effective November 1, 2004 (con't):**

1. A urine specimen is reported adulterated when:
2. Pyridine is detected and confirmed, with a concentration > or = the LOD of the confirmatory test on the second aliquot; requires 2 tests; see Sec 2.4
3. Surfactant is detected and confirmed, with a > or = 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff concentration on the second aliquot; requires 2 tests; see Sec 2.4



**According to Mandatory Guidelines
Effective November 1, 2004 (con't):**

1. A urine specimen is reported adulterated when:
2. The presence of any other adulterant not specified in 4(iii) through 4(vii) of section 2.4 is verified using an initial test on the first aliquot and a different confirmatory tests on the second aliquot.



**Revised Urine Specimen Collection
Handbook and Medical Review Officer
Manual**

- Incorporated changes for required SVT
- Posted on the DWP website:
 - www.drugfreeworkplace.gov or
 - workplace.samhsa.gov



Implementation of SVT

HHS Urine Specimen Collection Handbook: Changes for SVT

1. Incorporated Guidelines changes
 - ◆ Federal Agency blind QC samples: approximately 10% must be "adulterated" or "substituted"
 - ◆ Added to list of reasons for directly observed collections: "because a donor's previous drug test result was reported by an MRO as drug positive, *dilute*, *adulterated*, *substituted*, or *invalid*;"
2. Changed format to facilitate use as a reference manual



NLCP Inspection Activities: Changes for SVT

- Revised the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs
- Posted on the DWP web site



HHS Medical Review Officer Manual: Changes for SVT

1. Revised SVT cutoffs
 - ◆ Substitution cutoff for creatinine changed from ≤ 5 mg/dL to < 2.0 mg/dL
 - ◆ "Dilute" result defined as having creatinine ≥ 2.0 and < 20.0 mg/dL
 - ◆ Lower pH cutoff to report a specimen as adulterated changed from ≤ 3.0 to < 3.0
 - ◆ Cutoffs specified for some adulterants (50 mcg/mL for chromium VI, 100 mcg/mL dodecylbenzene sulfonate for surfactants)
2. Revised QC sample requirements to challenge the revised cutoffs and/or "invalid" decision points



HHS Medical Review Officer Manual: Changes for SVT

3. Added testing requirements for SVT
 - ◆ Different methods for initial and confirmatory adulterant tests
 - ◆ 4-decimal place refractometer for specific gravity determination
 - ◆ Initial and confirmatory tests for specific gravity to be performed on 2 aliquots
 - ◆ SVT to be performed when 2nd lab fails to reconfirm drug in a retest/split specimen
4. Added criteria for "Invalid Result"



HHS Medical Review Officer Manual: Changes for SVT

5. Allowed donor to request retest for specimens reported as "Substituted" or "Adulterated"
 - ◆ MRO actions in response to retest/split results
6. Described automatic quantitative reports from lab (no MRO request needed)
 - ◆ Substituted specimens (creatinine and specific gravity confirmatory test values)
 - ◆ Adulterated specimens (confirmatory adulterant value)



HHS Medical Review Officer Manual: Changes for SVT

7. Added new or expanded information
 - ◆ "Dilute" results
 - ◆ Pharmacology of drugs
 - ◆ Compounds used as adulterants
 - ◆ Effects of some current adulterants on drug tests
 - ◆ Testing technologies used



Implementation of SVT

NLCP PT Activities: Implementing Required SVT

- **April 2004** - Manufacturers notified of revised Guideline requirements
- **July, August, and September 2004** - Maintenance PT Occasion augmented with SVT samples that addressed all changes



NLCP PT Activities: Implementing Required SVT

- **November 2004**
 - ◆ 72nd Occasion of Maintenance PT; Nov 9, 2004
 - ◆ SVT PTs included
 - ◆ Monthly Federal Register List of Certified Laboratories now includes reference to Guidelines published on April 13, 2004



Summary

1. Program worked with manufacturers to ensure validation of new technology
2. Program extensively prepared laboratories and inspectors for the implementation of SVT changes
3. Implementation successfully occurred on November 1, 2004
4. SVT results from the Nov PT occasion met revised Guideline requirements

