

**Substance Abuse and Mental Health Services
Administration (SAMHSA)
Division of Workplace Programs (DWP)**

**Meeting of the
Drug Testing Advisory Board (DTAB)**

OPEN SESSION

December 4, 2018

**Hilton Hotel Rockville
Executive Meeting Center
1750 Rockville Pike
Rockville, Maryland**

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PROCEEDINGS 9:00 A.M.

Agenda Item: Call to Order, CAPT Sean Belouin

CAPT BELOUIN: Good morning, everyone. I'd like to welcome you to the December quarterly DTAB meeting. I'm CAPT Sean Belouin. I'm the designated federal officer for the Direct Testing Advisory Board, and I officially call this meeting to order.

I would like to take a moment to welcome everybody. First, the staff of the Division of Workplace Programs, our federal partners, contractors, invited guests, members of the public, and finally to our board members. During today's open session, we will discuss proposed mandatory guidelines for federal workplace drug testing programs and specimens, with updates from the Department of Transportation, Nuclear Regulatory Commission, and the Department of Defense.

There will be additional presentations from the division of workplace programs staff on urine, oral fluid, hair mandatory guidelines, and future direction, updates on electronic chain of custody and standard variables, and emerging issues surrounding marijuana legalization.

If you are participating by way of our teleconference, you are in listen-only mode. We do have a public comment period scheduled following the last presentation in the afternoon, prior to adjourning at 3:30 p.m. If anybody would like to register a comment, they will be able to do so at that time. Please make sure that if you providing any commentary over the teleconference, please mute any computer speakers and minimize your background noise during your comments.

All the information from today's meeting will ultimately be posted on the DTAB website. The open session meeting summary, as well as the presentations being provided today, will be posted, and any questions or public comments will also be posted. That information should be posted approximately six to eight weeks from today.

Today's open session is scheduled from 9 a.m. to 12 p.m. We'll have a lunch break at 12 p.m. for an hour and a half, and then start again at 1:30 p.m. We adjourn at 3:30 p.m. following the public comment period. After the public session closes at 3:30 p.m., we will reconvene with a closed session DTAB tomorrow from 9 to 4 p.m., but we're still waiting on whether or not our senior leadership, based on tomorrow's day of mourning will make the closed session not happen. We'll know before the end of the day whether or not we're going to actually have the closed session.

I'll say to all presenters, please inform when you wish the slides to be advanced forward, since we only have a separate computer that I'm operating. Before we continue, before I turn it over to Ron Flegel, our chair of the Drug Testing Advisory Board, it would be great to go around the room, and get everybody to state their name and where they're from.

We'll start with board members, please.

DR. GREEN: David Green, New Orleans, Louisiana.

MR. FERGUSON: Jim Ferguson, Chalfont, Pennsylvania.

MS. CALDWELL: Faye Caldwell, Houston, Texas.

DR. SCHAFFER: Michael Schaffer, Psychemedics.

MR. FLEGEL: Ron Flegel.

MR. CLOUETTE: Randy Clouette, Clinical Reference Laboratory, Lenexa, Kansas.

MS. KELLY: Patrice Kelly, ex officio member from the U.S. Department of Transportation.

MR. HARRIS: Paul Harris, ex officio member, United State Nuclear Regulatory Commission.

DR. WELSH: Eric Welsh, ex officio member, Department of Defense.

DR. COLLINS: Jennifer Collins, MedTox Laboratories, St. Paul, Minnesota.

DR. MOORE: Christine Moore, Immunalysis, California.

CAPT. BELOUIN: Once again, thank you everyone for attending, and I'm now turning it over to Ron Flegel, who is the chairman of the Drug Testing Advisory Board, and also the director of the Division of Workplace Programs, for his opening remarks. Here is Mr. Flegel.

Agenda Item: Welcome and Introductory Remarks, Mr. Ron Flegel

MR. FLEGEL: Thank you, everyone, for attending today. I would like to thank the board members, ex officios, industry leaders, and representatives sitting around the table, as well as at the side, for taking time out of their schedules today to attend the Drug Testing Advisory Board meeting.

Please allow me to update you on the progress of the implementation of the mandatory guidelines for urine, the proposed oral fluid mandatory guidelines, and the development of the proposed hair mandatory guidelines for federal workplace drug testing. I would also like to take a few minutes to update you on program initiatives.

Later, we'll have a presentation that I and Charlie will share, on the programmatic information we have gained through the HHS certified laboratories, federal agencies, and other drug testing industries. I hope that everyone, including the public, will find this information informative and useful.

We do have a number of presentations today, as Sean has mentioned, from federal agencies, the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense. We will also have updates from the Division of Workplace Programs on the mandatory guidelines, and updates to the electronic chain of custody forms, and the standardization of variables, which I'll speak about.

DTAB member Faye Caldwell will present on emerging issues, with the marijuana legalization. On another note, we had also planned to present the most current data on the pharmacokinetics and pharmacodynamics of the studies for CBD, both ingestion and vaporized, but we are currently still analyzing the data, and it will be available over the next several months. Hopefully we'll be able to present that at the next DTAB meeting.

As mandated by executive order 12564 and section 503 of Public Law 100-71, the Division of Workplace Programs develops and revises mandatory guidelines for federal workplace drug testing programs, with the best available technology. The Drug Testing Advisory Board was created with the intention of utilizing experts in all fields of drug testing, including biochemistry, toxicology, laboratory operations, and alternative specimen testing, such as oral fluid and hair.

DTAB members advise the assistant secretary for mental health and substance use on the development and revisions of the mandatory guidelines for federal workplace drug testing. We do have Dr. McCance-Katz' name here. She may be able to come to the meeting later in the day. We're hopeful.

SAMHSA continues to improve the quality of the services for forensic workplace drug testing, in the regulated sector and the private sector testing, by assessing the science and technology used in the drug analysis, by improving the quality of related laboratory services, and the systems for drug testing, and to set standards for laboratory

certifications of the federal workplace drug-testing programs. We hope this helps to guide national policy in many of these areas.

The SAMHSA DTAB provides advice through recommendations to the assistant secretary for mental health and substance use, based on the ongoing review of the direction, balance, scope, and emphasis of the agency's drug-testing activities, and the drug-testing laboratory certification program.

Regarding the DWP status updates, the revised mandatory guidelines for federal workplace drug testing for urine had an effective date of October 1, 2017, for implementation, and that was almost 13 months ago. We have now been testing for almost 13 months, and we'll be showing some data on the opioids later in the meeting. The major change to the mandatory guidelines, again, to reiterate, was the inclusion of the semisynthetic opioids, and increasing the lower pH cutoff range for indicating adulteration. Again, we have some data that we'll show later.

Additionally, DWP continues to streamline what we call the annual survey report for federal agencies, and have pushed the reporting period back from 2017 to earlier mid-2018, to accommodate these changes that we're making. Mostly, it's around collecting synthetic opioid data. Agencies have been also apprised of these changes.

Now, some updates on the proposed final oral fluid mandatory guidelines. They have been referred to the Office of Management and Budget for review, and when finalized will serve to enhance the federal program's ability to use an alternate specimen other than urine. While the focus of the oral fluid guidelines was to develop federal standards for workplace drug testing using oral fluid, these guidelines will also help promote standards for laboratories, private employer testing, states, and public sectors, in standardizing oral fluid collection devices, cutoffs, confirmation levels, collection processes, as well as many other items within the guidelines.

We hope that these federal standards will help to strengthen standards for state agencies, law enforcement, and other programs that use oral fluid currently as a testing matrix, including roadside testing.

Currently an internal draft of the hair mandatory guidelines is in the latter stages of review at the Department of Health and Human Services, prior to undergoing review by the Office of Management and Budget. Once approved by HHS, the proposed draft will be referred to OMB for review, which will include distribution to all federal agencies for comment and review. As recommended by DTAB several years ago, the draft hair mandatory guidelines being developed will attempt to address decontamination of hair specimens and hair color impact. The draft proposed hair mandatory guidelines addresses these two specific issues for the use of hair as a drug-testing specimen, along with many other items, including type of testing, the collection processes, collection containers, location, et cetera.

DWP and the MRO working group was updated. The medical review officer guidance manual to include a review of workplace prescription drug testing, and their final revisions were posted on DWP's website on November 2017. That was revision two. I believe currently we're working on a revision three. Staff will continue to work on the new case studies surrounding opioid testing and further revising this MRO guidance manual to provide clarification for a few of these key issues. We anticipate any updates will be posted in early 2019.

In addition, the MRO guidance manual for oral fluid is currently being developed, and is scheduled to be published prior to the implementation date for the oral fluid mandatory guidelines.

We have continued, again, to work with HHS certified laboratories in implementing the current 2017 federal custody and control form, both paper copy and the electronic version. The 2014 CCF expired on June 1, 2018. The use of these forms are no longer approved after this date. The newly approved chain of custody form, which includes the synthetic opioids, is now in use by federal agencies, the federally regulated drug-testing sectors, and DWP continues to help laboratories to move to electronic chain of custody forms in the future.

I would also like to draw your attention to relevant provisions in the Fighting Opioid Abuse in the Transportation Act, including the support for Patients and Communities Act, which is Public Law 115-271, which directs the secretary to certain actions regarding the mandatory guidelines and drug testing. This legislation was enacted on October 24, 2018. The sections I'll refer to in my presentation are in sections 8105 and 8108 of the public law, and I encourage board members to read that and review that act. We will send that out after this meeting.

My next discussion, just to mention because this has been on the forefront, specifically, lately, is the discussion around Epidiolex, which is an FDA-approved CBD product. FDA approved Epidiolex in June 2018 for the treatment of young patients -- over two years old -- with seizures associated with Lennox-Gastaut syndrome and Dravet syndrome. Epidiolex is sold as an oral solution for ingestion. Epidiolex is the first FDA-approved drug that contains purified drug substance derived from marijuana, which is CBD, and is the first treatment of Dravet syndrome.

I mention this because we also have a notification out to federal agencies regarding CBD and CBD products, but there does seem to be some confusion around other CBD products, such as oils and extracts. CBD is a schedule 1 drug, but just to note, FDA has rescheduled the Epidiolex to a schedule 5, and I believe that Faye will have part of that in her presentation today.

The CBD study that we are currently underway with RTI and in collaboration with the behavioral pharmacology research unit at Johns Hopkins University School of Medicine, is looking at the ingested and vaporized CBD oils and drug-testing results in urine, oral fluid, blood, and hair, and again, unfortunately we were not able to give that data.

DWP continues to focus on other special projects to complete the extensive studies we have undertaken, in conjunction with the National Laboratory Certification Program and the behavioral pharmacology research unit at Johns Hopkins School of Medicine and several subject matter experts in these fields, which were notably Dr. Ed Cone and Dr. Ryan Vandrey. Some of these special projects data will be presented at the next Drug Testing Advisory Board meeting.

Finally, DWP's prevention of prescription drug misuse in the workplace initiative that I spoke about, actually several years ago, is in developing a new toolkit titled Substance Use and Emerging Issues in the Workplace, along with the marijuana toolkit. The toolkit will provide an engaging online suite of materials designed to help employees, large to small, federal, nonfederal, prevent and identify and address the opioid misuse and other emerging substance use issues, including marijuana. The new toolkit revisions have been completed and should be available, we're hoping, in early 2019.

I would also like to acknowledge, we went around and identified ourselves, but I would like to acknowledge and say thank you to Dr. Madeline Montgomery. She was the FBI supervisor forensic chemist examiner and forensic toxicologist, and Dr. Buddha Paul, who recently retired, and both have rotated off the Drug Testing Advisory Board in September, so unfortunately they're not at this meeting. But we did print a certificate of appreciation for them, and we have both of those here. We'll make sure that they get that certificate.

In addition, I would also like to acknowledge Giselle Hersh. As everyone knows, and everyone is very aware, she did all of our travel. I do have a certificate of appreciation for her. I also wanted to announce Jeannette Talavera is doing a detail in Giselle's position. But I did want to address and if she was going to be available today, I was going to give her a certificate also.

I also would like to have Dr. John Mitchell step forward. I did want to acknowledge John. He is retiring from the NLCP. I would like to read what we put on the certificate for John, because I think it is very important in this program.

For his 15 years of service, steadfastly committed to protecting the integrity of the drug testing for federal and federally regulated workplace programs, through proficiency testing, inspections, and accreditation of forensic drug-testing laboratories, in partnership with the Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, and creating the gold standard for regulated testing. Your exemplary professional performance and commitment reflects greatly upon yourself and in keeping with the highest standards of the Department of Health and Human Services.

I want to thank John for everything that he has done for this program.

(Applause.)

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Lastly, I would like to announce the acknowledgement of Dr. Barry Sample. He is the senior director of science and technology at Quest Diagnostics and Jason Schaaf. He is the chemist forensic examiner for the FBI. Barry could not be here today, but Jason is here today. They will be joining the Drug Testing Advisory Board as members, and I would like to welcome both board members, and say thanks for the time and contributions they will make over the next four years.

In closing, I would like to thank everyone for attending the Drug Testing Advisory Board meeting. I hope you find the presentations informative. Thank you.

CAPT BELOUIN: We are going to go to our first presentation, which will be the Department of Transportation. That will be given by Patrice Kelly, director of the Office of Drug and Alcohol Compliance.

Agenda Item: Department of Transportation, Ms. Patrice Kelly

MS. KELLY: Thank you very much, Sean. And thank you, Ron.

This is basically how we're structured. The Office of the Secretary of Transportation has regulation 49 CFR part 40. It is the department's procedures for how drug testing is done, what the roles of the collector, the laboratory, the medical review officer, the substance abuse professional, et cetera. Anything dealing procedurally.

The actual designation of which employers and which employees fall under the safety sensitive categories, are determined in each of the modal regulations, and I have them listed there. Motor carriers, railroads, pipelines, transit, FAA, and the United States Coast Guard. Though the United States Coast Guard is part of Homeland Security, at the time we came out with Part 40 back in 1988 and forward, United States Coast Guard was part of the Department of Transportation. So the United States Coast Guard continues to follow 49 CFR Part 40, and the Department of Transportation acknowledges and is grateful for the support and enthusiastic work of the United States Coast Guard.

Here are horizon issues. We have the marijuana issues. I think there are going to be quite a few presentations that dabble in the marijuana issues. Faye Caldwell and others will address this, so I won't go too deeply into it, except to say we absolutely do not have an impairment standard. We all know that. In the states where there are impairment standards, those are very successfully challenged in courts of law. So we are very much hopeful that there will be additional research that eventually can bring us to an impairment standard.

In the meantime, marijuana remains a schedule 1 drug, and is absolutely prohibited from use by anyone regulated under the Department of Transportation. Additionally, with marijuana issues, as most of the people in this room would know, the Department of Transportation in 2009 and 2012 put out guidance to medical review officers saying that in no circumstances, regardless of state medical marijuana laws or recreational marijuana laws, regardless of those, that would not be a legitimate medical explanation for a DOT-regulated test. No explanation for marijuana other than Marinol, and Epidiolex is a whole other issue, as Ron said.

The opioids act. I will go into that in great detail. The support act that Ron was talking about at the beginning of his presentation. The most immediate piece for us at the Department of Transportation is to create transparency for our management information system data. That's that the data that we get from transportation employers. So we have a deadline of March for that, and we're on track to accomplish it.

The driver clearinghouse database, that's a Federal Motor Carrier Safety Administration initiative, I know a lot of people are watching that with great interest, and we are on track to have that in place on schedule in January of 2020. If we don't, Congress reminded us in the opioids act, that we will be providing reports to update them as to the status.

Electronic reporting records, again, there's a lot going on there, through the opioids act. We remain eager for a fully electronic chain of custody form so that we can modify Part 40 through rulemaking process to address the idea of going electronic with all of our records, drug and alcohol. But again, we are waiting for and working with HHS to accomplish a fully electronic form first.

Public interest exclusions, the PIEs, as we call them. Those are decisions that are rendered by the Department of Transportation with me as the director of ODAPC actually writing the decisions. Those are cases brought to my attention where there's serious noncompliance that has strong safety repercussions.

Alternative specimen testing methodologies, oral fluids and hair, hot on our horizon. We'll go into a little more detail.

Our random drug testing rates -- this is kind of a reminder to everybody -- the minimum and annual random testing rates, the FTA has already announced that they will raise the annual minimum random drug testing rate from 25 to 50 percent for 2019. Pipelines and hazardous materials safety administration went up last year to 50 percent. The other modes have not announced yet. Remember, for those of you, again, who are familiar with the DOT regs, this is a refresher, for the rest of you it may be news, but when our random positive testing rate as reported by employers goes above 1 percent, for one year, we go up from 25 to 50 percent. If we want to lower it back down to 25 percent we need to have two or more consecutive years. When you hit 1 percent or above, it goes up to 50 percent. For FTA and for pipelines, it went up.

Just to give you an idea, our office is small but mighty. In the Office of Drug and Alcohol Policy and Compliance, we had 15,662 emails, phone calls, in person contacts, assistants to the modal administrators, assistants to the modal program managers, field inspectors, what have you. When we pick up the phone it could be anybody from an administrator of a federal agency to somebody who has been using drugs and needs to find a substance abuse professional, or somebody who wants to challenge his or her drug test results or alcohol results.

It's always a challenge, it's always exciting, and we definitely put a strong emphasis on medical review officers, on collectors who are in the middle of a collection. There are actually emergency calls that come into our office, and we pride ourselves on trying to get back to people immediately if we don't catch the call on the first ring.

We have more than double the contacts we had in 2012. I took over as the acting director in 2013. Business is good. There were 64,882 listserv subscribers as of November 1, 2018, making us the largest listserv of our kind in the world, dealing with antidrug audiences. We have trade associations. We have medical review officers, collectors, employees, unions, other federal agencies, all who subscribe to the listserv.

We've been working very closely with the Drug Enforcement Administration and we have put out a lot of their information through our listserv. One of the greatest feedback

we had gotten was several years ago, the then DEA administrator came up and said, we started Take Back the Drug Day, and our very first day people came to our offices from all over the country and said the Department of Transportation sent me. We really can get the word out there for other federal agencies and in our own program, and we rely on that.

As of January 1 of this year, anyone who's required to be qualified under our regulations and to stay current, that's specifically medical review officers, collectors, breath alcohol testing technicians, the STTs, the substance abuse professionals, all of those personnel must subscribe to the listserv, with the idea being otherwise how do you stay current? How do you know that the Federal Register has changed? I take it most of the people in this room, maybe one or two exceptions, don't read the Federal Register every day. But most of the people don't.

So we want to make sure we get that word to there and we keep people informed as to any program changes that are going to impact their work for us and the quality of our program. Our website is one of the department's most viewed websites, with 1.9, almost 2 million subpages viewed last year.

Outreach about opioids. In the first several months of this year, we spoke to more than 2,000 people about opioids at industry conferences, union meetings, and in other venues. Our union contacts have greatly increased, and we are very grateful to the AFL-CIO. They called a special meeting at the end of last year, just before we implemented opioids, and they brought together 22 transportation-related unions to hear about opioids, and to hear what we had to say about opioids and opioids testing. That was tremendous for us.

It was the first time in the history of ODAPC's more than 30 years as a program that we had an honor like that, and I think ultimately it really helps the transportation employers when we can remind employees that it's their duty, first and foremost, to be aware of what they're taking and what the impact is on safety. Before the test is given, before the MRO is involved. For the employee to take responsibility and really own what their prescriptions are and understand them, and realize the impact on safety. We sent listserv notices to our more than 64,000 subscribers.

I'll just hit this quickly. There are five notices that we put out to the public through that 64,000-plus listserv. We had a summary of changes, we reminded about the CCF, which Ron had talked about earlier, where the old one was going out, the new one was coming in. Public notice for employers, the employee notice, again, following on from -- I actually, we released that the day that my deputy and I had gone to meet with the AFL-CIO members. And the five-panel notice, to remind people that even though we've added the oxys and hydros, it is still a five-panel test.

The employee notice. We educated safety-sensitive employees about the potential opioids addiction issues. It wasn't just, hey, world, the rule changed. It was, understand that there's a reason why we're all concerned about addiction in opioids. We reminded

employees to have continuing dialogue with their treating physicians about using opioids before performing safety-sensitive functions. And we educated employees that a medical review officer has the discretion to report to a third party about a safety concern.

That is under the DOT program, not under the HHS internal federal employees' program, but under the DOT program that is an important component. You may have a legitimate medical explanation, you may have a prescription. But does the medical review officer see this as a threat to safety?

We're also working on a new employee notice, so stay tuned for that. I think after a year it's time for us to remind people again.

Fighting the Opioids in Transportation Act. The larger act is the support act, which Ron had mentioned. The transportation piece of it is called Fighting Opioids in Transportation Act. It's part of Public Law 115-271. I believe all of you will see that, Ron was mentioning he's going to provide that as a handout to DTAB. For the Federal Railroad Administration, the FRA is going to be required to designate rail mechanical employees as railroad employees responsible for safety-sensitive functions, meaning that will add a whole new class of employees through a notice and comment rulemaking conducted by the Federal Railroad Administration.

For us, at DOT, in the office of the secretary, we are being required to publicly make available on our website a database of drug and alcohol testing data reported by employers for each mode of transportation. I mentioned that on the horizon slide, where that's the data we collect annually from medical review officers. The act is very clear. We're not going to be releasing it by employer. There will be no identifying information in that.

It's just purely what does the raw data look like? Members of Congress felt that it was very important for them and for their constituencies to be able to see and sort that data, so it'll be the total number of drug and alcohol tests done, by type of substance tested, the drug and alcohol test results by type of substance tested, the reason for the drug and alcohol test -- meaning preemployment, random, et cetera. By the type of substance tested and the number of individuals who refused testing.

Again, we will not release and must not release commercially sensitive data. That's an important point. I know the employers have always been sensitive over the last 30 years to being identified as an employer who has drug users. It's not the employers' fault. It is the result of a test. This is not a judgment. This is purely a data issue. Therefore, it's dissociated from the names of the employers.

The comptroller general. They're going to send the comptroller general after ODAPC to take a look at our data. They're going to send them in to take a look and provide a report back, which is actually going to be great. I think we're going to get a lot of insight about where we are using our data well, where we could expand, where we should be

collecting more data from labs, from employers, et cetera. I actually am excited about this provision, and I think it's going to end up being a very productive exchange of information.

Fentanyl. I don't know how much of the presentation from HHS -- do you have this covered in yours, too?

MR. FLEGEL: No, I was going to say I apologize. We're relinquishing control of the slides. We're trying to -- Sean's not moving them, it's from outside. Sorry -- what was your question?

MS. KELLY: I was going to say, did you want to cover anything on fentanyl, or is it okay if I keep going through the fentanyl?

For fentanyl, HHS are the scientists that DOT must rely upon by Congressional mandate through the Omnibus Transportation Employee Testing Act of 1991, but also the scientists we want to be able to rely upon. Congress recognized that HHS has great expertise, so therefore they wanted HHS to look at whether, not mandate that there be a revision, but look at whether or not there should be a revision to include fentanyl.

As most of us know, fentanyl has morphed into many different chemical compositions. Adding fentanyl may or may not be a good idea for the federal program. It could increase employer and federal agency costs tremendously, or it may be doable. But it was really important to all of us that that science be left within the hands of HHS, relying on the DTAB, relying on their own SMEs, so I think that that was a really important way that HHS raised that.

Then if fentanyl is added then the Department of Transportation, my office, must include fentanyl in the panel. Again, once the scientists have acted, we will follow, and you'll see that's a theme.

Hair testing. HHS was given two requirements. One is that not later than 30 days after the enactment, and every 180 days afterwards, they will provide information to Congress on the status of hair testing. Ron covered in his opening statement that hair testing, a draft is underway.

The second requirement is regarding passive exposure, and this is important because you're going to basically see a similar thing regarding oral fluids. That is, to the extent practicable, and consistent with the objective of the hair testing -- and it goes on, hair testing provision, blah-blah -- the final notice of scientific and technical guidelines, and again, I skipped a little bit of the language, shall eliminate the risk of positive test results of the individual being tested caused solely by the drug use of others, and not caused by the drug use of the individual being tested. So an important distinction.

By the way, as HHS progresses into hair testing and oral fluids, we'll talk a little bit more about this, but I just wanted to remind everybody that we cannot move science forward at the Department of Transportation without our scientists. However, we will seriously

consider the new sciences that are proposed, the new alternative testing, we want to see alternative testing. But we also need to make sure that the forms of alternative testing fit within the four corners of the Omnibus Transportation Employee Testing Act. There's a bit of balancing that goes on here.

With the oral fluids testing, not later than the end of this month, HHS has the pressure on to publish a final notice of the oral fluids requirements. Again, you'll see that passive exposure language. To the extent practicable, and consistent with the objective of testing, the scientific and technical guidelines under that subsection shall eliminate the risk of positive test results of the individual being tested caused solely by the drug use of others and not caused by the drug use of the individual being tested.

Congress also wants DOT to be able to use oral fluids and hair testing. Our statute, the Omnibus Transportation Employee Testing Act of 1991, requires that we test for use. There is no provision that would allow us to test for the exposure of the person being tested to other people's drugs. So again, it's kind of a deal breaker for us, and that's right in the legislation.

Paperless electronic chain of custody forms. Again, this is something initially on HHS, but it's got a component for DOT, too. Requires HHS to ensure that each certified laboratory that requests approval for the use of completely paperless federal drug testing custody and control forms from the National Laboratory Certification Programs electronic custody and control form systems receives approval for those completely paperless electronic forms instead of forms that include any combination of electronic, traditional, handwritten, signatures and executed on paper forms.

Does that mean we are eliminating the paper forms at HHS or DOT? Absolutely not. Paper forms will always exist for the foreseeable future as an option. But I think we're all eager to see things move to another option for completely paperless, because once we get to that level and we have the standards in place for signatures for authentication of those signatures, for storage of the documents, for security of the storage of those documents, and on down the list, then I think we need to move this. It's going to be a huge cost savings to employers.

So then comes the DOT component. Electronic records under Part 40 requires that 18 months after HHS approves the paperless CCFs, the DOT, my office, for Part 40, will revise part 40 to authorize to the extent practicable the use of electronic signatures or digital signatures executed to electronic forms instead of traditional handwritten signatures executed on paper forms. Again, our goal is not just signatures. Our goal is also electronic storage of records, and making sure that the security protocols are in place, et cetera, but the times of file cabinets and buildings full of file cabinets, I think is gone. We don't need those anymore. That's not the way you run an effective program. So again, we're eager to finally move into this century, though 18 years late. We are eager to all move into this century.

FMCSA CDL drug and alcohol clearinghouse, as I mentioned at the beginning, it is on track to go into effect in January 2020, and I offer, I challenge, I encourage, anyone in this room, anyone listening, and others who you may work with, to let us know if you need a briefing on this. It's very interesting, I found that in industry conferences last year, a lot of people were coming up with sessions on what they thought the FMCSA clearinghouse was going to include, because the final rule was published. It was published last year.

So people sort of started trying to fill that gap of what information did they need to know, as employers, as medical review officers, as unions, as substance abuse professionals. What do I need to know? If you're putting together a group where you want to brief on subjects including that, if you're putting together conferences or whatever, again, I want to reach out to you and encourage you to let me know, and I will coordinate with the Federal Motor Carrier Safety Administration to either provide a joint ODAPC-FMCSA briefing for you, or an FMCSA-only briefing for you. But we really do what to get this information out, because we feel we are going to be ready on time. Will you? We'll do what we can to help you get there.

The refresher on the relationship, as I said, the OTETA has us follow HHS for the science.

So we have to follow on certain things. The comprehensive standards for laboratory controlled substance testing, the minimum list of controlled substances for which individuals may be tested, and appropriate standards for certifying and reviewing labs.

So there are examples of times when we differ, and a good example is on negative dilutes. In the interests of time, I won't go into this too much further, except to say that there is a difference. This will be in the public record. So if you want to see this slide further, I would encourage you to take a look at that in the public record for DTAB. Again, just want to keep us on schedule.

As I said, we can't follow HHS when the Omnibus Act prohibits us. One example of that was the IITFs, because the Omnibus Act explicitly states that the initial test and the confirmation test must both be done at the same laboratory. That also knocks us out of the ballpark for any form of onsite testing, in the Omnibus Act as it is today. It's been that way since 1991. So remember, when Congress wrote that statute, things were in a very, very different place. It was almost 30 years ago.

So as far as the Omnibus Act goes, we must follow what the act requires and, as I said, right now for hair testing and oral fluids, the pertinent part of that is use. We can only test for use.

Our ODAPC staff. I have with me today Cindy Ingrao, senior policy advisor, and Sue Lenhard, our newest policy advisor, and that's the rest of our staff. As I said, we handle over 15,600 inquiries, and it's a very energetic staff. I'm grateful to have the people I have.

The final note and the final slide is on our website. Next slide, final slide, thank you. Our mailing list, our listserv, is found on our webpage, which is www.transportation.gov/odapc, and that's the bottom of that slide. Our listserv button is on the righthand side.

We have where you see the balloon in the upper righthand corner, literally the hot air balloon, that is a resource we put together that links federal programs on prevention and substance abuse. So that was a project we did working with the prevention internal working group, or interagency working group, of the Office of National Drug Control Policy. So ONDCP supported us in spirit, but my deputy Bohdan Baczara was the one who actually pulled all of that together, authored it, worked with our computer folks, and created the site. But our federal partners are represented well there.

Again, I hope that you'll find our webpage to be very user-friendly, a good resource, if you haven't already used it and please know what we stand ready to support. Thank you.

CAPT BELOUIN: The next presentation will be by the Nuclear Regulatory Commission, Paul Harris, senior program manager, fitness for duty programs, drugs and alcohol.

Agenda Item: Nuclear Regulatory Commission, Mr. Paul Harris

MR. HARRIS: Thank you, Sean. I am Paul Harris from the United States Nuclear Regulatory Commission. I'm the senior program manager for 10 CFR Part 26, which is the fitness for duty program requirements established for the commercial nuclear industry and other licensees that the Nuclear Regulatory Commission has regulatory oversight of.

To my left I have Brian Zaleski. Brian is the fitness for duty program specialist. He is our technical expert for drugs and alcohol, and you might hear Brian chime in during my presentation at times that he feels necessary to do that, and that's fine.

During my presentation, I'm open to any questions from the DTAB board, as you might see fit at the time of the slide. It will not upset our presentation one bit.

Before I get started, I'd like to give a special thank you to HHS, namely Ron Flegel and his staff, for always inviting us as the ex officio member to the board. I'd also like to parrot what Ron said about John Mitchell. It's really important to put on the record that HHS and the John Mitchell National Laboratory Certification Program provides a foundational layer of defense in assuring that individuals who perform safety or security-significant activities within the public arena are fit for duty and free from the presence and effects of illegal drugs and illicit drugs. So a special thank you to both those organizations.

This is just a typical routine disclaimer slide for the audience. Basically we don't make any decisions for the commission, and we do the best we can to accurately communicate our data and personal opinions and NRC staff positions.

Discussion topics for today. We're going to talk really quickly over a number of slides, because the last presentation made to the Drug Testing Advisory Board was in March 2018. During that presentation, we made a number of these slide presentations. So for most of you, this will be all repeat of March. But for the public's perspective and for the new members who haven't seen this presentation, I provide them here.

So we are going to talk about the program objectives, the individuals covered by our program, some of the program elements and how we assure safety and security through a defense in depth strategy. Drug and alcohol testing is only one element of the commission's defense in depth strategy to ensure the safety and security of our nation's nuclear infrastructure, and that's why we're here today.

We are going to talk a little bit about FFD performance in the commercial nuclear industry, with some data, and we are going to talk a little bit about industry activities and initiatives.

The fundamental program objective is to provide reasonable assurance that nuclear power plant personnel are trustworthy and reliable and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause which in

any way affects their ability to safely and competently perform their assigned duties and responsibilities inside the nuclear power plants. We also provide regulatory oversight of facilities called category one fuel cycle facilities. These are the facilities that actually manufacture the commercial nuclear industry fuel and they also do work for the United States Department of Defense through the Nuclear Power Program. Overall purpose of the program is to ensure that we create an environment that is free from drugs and alcohol and the effects of such substances.

Individuals covered by our program are very important individuals in the power plants. They include security officers, control room operators, health physicists, individuals who direct and construct our nation's nuclear power plants, and other people who have unescorted access to these facilities. In addition, the FFD program personnel, which includes individuals such as managers, technicians, collectors, medical review officers, and substance abuse experts who are all part of the drug testing program are also required under our program to be fit for duty and to be drug tested and under a behavioral observation program, which I'll cover next.

This is important, because these individuals, the NRC is notified when the preponderance of these individuals are impaired or test positive on a drug test. For example, if a control room operator tests positive for a drug that's on a panel or a drug that's implemented by the licensee under the voluntary testing program, the NRC is informed within 24 hours of that occurrence. That same notification requirement is for FFD program personnel. So if we have collectors or managers who are under the influence of a substance, we get informed of that within 24 hours of that.

What do we do with that information? At every nuclear power plant in the United States that's licensed by the NRC, we have two residence inspectors at least that will provide regulatory oversight of the licensee's corrective actions to ensure that adverse conditions don't result.

What's also important under the 24-hour notification requirement is that we get informed of any programmatic weaknesses or vulnerabilities that have been identified by the licensee, such as if they have adverse trends, we get informed of that. If they have managerial issues or procedural issues that represent a programmatic weakness or a vulnerability, we get informed of that as well. So we have a number of elements in which the NRC is informed on a timely manner.

A particular provision under the notification requirements under FFD program personnel is important to mention to the Drug Testing Advisory Board, and that is for medical review officers. If the licensee has determined that the medical review officer for the facility has made an error in technical or assessments such that the medical review officer has to go back and change his original determination on a positive confirmed drug testing result, that is notified to the NRC within 30 days, required in writing.

So how does fitness for duty contribute to the overall safety and security of the power plant? Well, first of all, it's the people. The people are educated, experienced, training,

and qualified. We implement drug and alcohol testing. We implement what's called a behavioral observation program such that when an individual appears to be impaired or makes a mistake on the job that results in a cognitive error of omission or another error while performing his duties and responsibilities, that individual is for-cause tested or a test is conducted under post-event.

We also do fatigue management. So we monitor individuals and the number of work hours that they perform. Layered on top of that are very stringent access control requirements, physical protection requirements, in the form of blast walls, bullet resistant enclosures. That's the picture on the lower right. The picture on the lower left is the blast wall and a part of the protected area boundary to prevent people from entering the power plants.

We also have other additional programs in which part 26 in the drug testing provisions are an essential element of, namely the insider mitigation program. Individuals who have unescorted access to the power plant are in different category. We consider these individuals critical, and they are under a higher level of scrutiny and access control requirements to ensure that these individuals do not result in conditions adverse to public health and safety.

Overall industry performance. This is a slide that Brian Zaleski does the data analysis and computations for. Typically we test about 150,000 people every year in the commercial nuclear industry, and that's a 50 percent random testing rates. Out of that 150,000, about 1,100 of them tested positive for drugs, alcohol, or they refused to test.

Some individuals as you'll see on some additional slides, do test for more than one substance, and I'll get to that in a second. The overall random positive testing rate is .44 percent. The overall positive rate for the industry is .77 percent. Those two numbers are important, because .44 percent represents those individuals who are inside protected area of the nation's commercial nuclear power plants, and therefore, it's more than likely that they are being tested for positive substance and they could be impaired.

I list three observations here. First one is that contractor/vendors are testing three to four times higher than licensee employees. Contractor/vendors in the nuclear industry are those individuals who typically are short-term highly skilled, highly technical individuals who go from power plant to power plant conducting maintenance and surveillance activities. They're only on site for a short period of time.

Why is that important? Well, if they're under a 50 percent random testing rate and they're in a short period of time on the site, the odds of them being screened for a positive -- pardon me, being tested under the random testing rate is small, because they are on site for a short period of time. I'll talk to why that's important in a second.

The second observation is subversions. This is a very important element as well, which I have another slide for. Subversions are occurring in the commercial nuclear industry.

That indicates to me that subversions are occurring in society, and if they are occurring in society, they are occurring in other federal workplace drug testing programs, and we have some data indicating that in our program.

Last one is the FFD program personnel remain the silent heroes in the program. These are the collectors, the medical review officers, the managers at the power plants who provide that first line defense in assessing the individual when they show up for tests, ensure they are not subverting the drug testing process, ensuring that the specimen is collected properly and sealed properly and sent to the laboratory for testing, and that the medical review officer evaluates those results accurately.

I already mentioned the National Laboratory Certification Program. Clearly they can be part of the silent heroes for the drug testing arena. Ron Flegel also mentioned during his opening remarks, he mentioned the medical review officer manual. I would also parrot on top of that the substantial input provided into the medical review officer manual by members of the Drug Testing Advisory Board and other technical organizations that may be or possibly provide a comment to that manual.

I would like to specifically note that there are two nationally certifying programs for medical review officers, and if they weren't doing their job as well as they are, the medical review officers in the industry would not be performing as well as they are.

I apologize for the size of the fonts. Our slides will be posted publicly available on the NRC's website and of course the Drug Testing Advisory Board has a hard copy of these. What's important on this slide is to note really two things. In the first row, under pre-access, you can see the three to four times difference between licensee employees testing positive at a rate of .42 percent and if you go to the right of that under contractor/vendors, they are testing at a rate of .97 percent. So that's a three to four times higher.

Now the contractor/vendors again are the short-term employees on site. That's under pre-access. That's actually good. We are actually screening individuals prior, catching these individuals, prior them entering the protected area of nuclear power plants.

The problem is if they get inside the power plant, we also see increases in the random testing rates or the for-cause testing rate or post-event testing rate. If you could take a look to the bottom of the slide, the bottom block, the small print there says where were most drug and alcohol test violations identified in 2017? Under the left-hand column there, you'll see pre-access at 32 percent and random testing at 42 percent. Not much difference there. That demonstrates the validity of random testing.

There are individuals who are getting into the nation's commercial nuclear power plants that are not being tested or not being identified on pre-access testing. There's a number of reasons why this might be happening. One, the individual knows he's shown up for a pre-access test. So that's a predictable test. The individual self-abstains from

his drug use or his alcohol use to pass the drug test prior to employment or access to the nuclear power plant.

The second item is it's a urine test. So the individual knows that there's a lot of open-sourced products on the market to subvert a drug test. This is why a collector in the MRO are vitally necessary for an effective program to identify subverters.

If we take a look at the contractor/vendors on the righthand column, you'll see that the contractor/vendor pre-access testing rate is almost 67 percent. It's above 67 percent. That again is good; we're identifying individuals on pre-access. However, the random rates, the 20 percents. So this data helps inform NRC inspection of the nation's nuclear power plants to help focus our inspectors on areas in the power plant which might represent a vulnerability such as pre-access testing, which is why the NRC technical staff is very supportive of HHS and Drug Testing Advisory Board efforts on oral fluid testing and hair testing.

This slide is a historical perspective of the total positives by substance tested. The top line is marijuana. It is in color blue. It's about 50 percent. The next slide will show more granularity to the data. Notice alcohol is in red. Alcohol is an easy choice of drug for individuals at the power plants. It's well engaged in society. The green line next to that is cocaine. That has shown a marked decrease since about the year 2006. Notice in the last few years from about 2014 to 2017, cocaine has increased a little bit. Amphetamines has been showing a slight increase over the course of a number of years.

Opiates, the NRC -- the current drug testing panel is not the expanded panel for the four semisynthetic opiates yet. So we still only test for morphine, codeine, and 6-acetylmorphine. The last one is PCP. That is the yellow on the very bottom.

What I wanted to note here in the green box in the small print, because we're seeing a number of subversions in the nuclear power plants, the data is not aggregated into the graft data here. So if an individual subverts a drug test, we may not identify what subset of persons taking because that specimen might not be tested at an HHS-certified laboratory.

This is the slide that provides a little bit more granularity on what we're seeing in the nuclear power plants. Under licensee employees you might see 111 individuals tested positive, and then you'll see the N equals 119. That difference is due to individuals using multiple substances, and that's not reflected on this graph here.

The pie chart proportions are relatively the same from year to year. Alcohol is always predominant, with marijuana being predominant for licensee employees. Brian has identified that marijuana use is increasing a little bit from the previous years to 2017. You can't see that of course by the pie chart.

Under contractor/vendors, the typical pie chart proportions are pretty typical. Alcohol being less than marijuana, marijuana being highly prevalent in society.

I mentioned earlier in the presentation that we're getting a number of additional substances being tested. This is a layout of the years that we're identifying with a substance being identified on the left-hand column. In 2017, you notice that we identified four additional substances, hydrocodone, hydromorphone, and -- someone who has to be smarter than me has to say that word.

(Off mic comment.)

So we are not seeing a lot of additional substances being identified in the power plant. That's additional 31 -- the 31 test results reflect positive result for 24 individuals. So a number of the individuals tested for more than one substance.

I want to point out at this point that the 10 CFR Part 26 regulations enable NRC licensees to voluntarily expand their drug testing panel beyond that established by HHS, and there's a number of facilities that have done that. However, a number of facilities have not done that, due to logistical problems that they might face.

Again, apologize for the size of the font here. What this is important for is this identifies the drugs that are being identified, but where are the drugs being identified inside the power plant? The columns here at the farthest column to the right is the total number of positive tests, but two columns to the left is another column full of number ones. Those are the for-cause tests, and this is important because these are the individuals who are inside the power plant, have unescorted access, who are being identified as being potentially impaired and undergoing a for-cause test, and these individuals are being tested for substances that are not parts of the drug panel, either established by HHS or the Nuclear Regulatory Commission.

If I can, on the left-hand column, there's some of the substances are methadone, fentanyl, benzodiazepine, and those are some of the examples which are substances that are outside the panel.

This is a subversion trend. So subversion is defined in our requirements as any willful act or attempted act to cheat on a required test. So if the individual self-announces that he cheats, well, he's cheating. If the individual is caught cheating with a subversion product, as illustrated in the picture, that individual is identified as subverting the drug test as well. That individual is permanently denied under requirements from ever gaining access to the nuclear power plant again, under that FFD program.

In the typed font, you can see 2012, we had approximately 15.8 percent subversions out of all tests conducted as resulting in a subversion attempt. In 2017 and 2016, we see the value at 26.1 percent. So that indicates to me an increasing trend and it indicates to me that individuals are trying to subvert a federally mandated drug test. This is important for the public to understand and for the Drug Testing Advisory Board to understand, that even in an industry which there's highly trained, highly educated skilled individuals, individuals are still trying to seek employment and maintain employment who are purposely subverting a drug test.

This is why it's so important that collectors and the testing programs that we establish are robust and they provide confidence to the public that these individuals and others are fit for duty.

CAPT WELSH: Paul, I have a question. This is Eric Welsh from the DoD sitting to your right. What is the basis for determining subversion? Is that based on observation, or is that based on specimen validity testing?

MR. HARRIS: There's actually a number of ways. We define what a subversion is in the part 26 regulations, and it could be based upon an individual's activities that he is doing. It could be based upon the paraphernalia that the individual brings into the collector, collector room, and it's also based upon laboratory results being substituted or adulterated. So it is a broad spectrum, and we provide a number of -- a lot of flexibility for the licensees to make this determination.

MR. ZALESKI: The majority of the subversion attempts that we identify are based on temperature issues at the collection site where there's two specimens collected and one not observed and one observed and differences in those results. That's primarily where we are getting our subversion determinations, although we do identify paraphernalia that is on the physical presence of an individual. It's rare that we have a substitute or adulterated test result, a handful out of the 150,000 tests we do a year. Very, very limited that way.

MR. HARRIS: A lot of licensees have implemented very robust collection facilities at their sites to prevent the subversion trend at their sites. They have installed mirrors. They have installed doors that provide privacy, but not too much privacy. They have interviewing techniques in which they review and discuss with the individual prior to the drug test to see if the individual is indicating any sort of impairment or mental nervousness, sweaty hands, fidgeting. We make them empty all their pockets, like the requirements require, but a lot of licensees go above and beyond that. They make them take off a number of their outerwear, anything that they're wearing on their hats. A lot of them look into their boots and make sure their boots are turned down. So a lot of the industry is really focusing on the collection process to try to make this trend go away.

This is also important, because these are the people we are catching. It would be really interesting to find out what the value is of the people we're not catching and how many of the drug tests are going through the laboratories that are not being identified as being substituted or adulterated.

That's why I continue to focus on the collectors and the FFD program managers, because as Brian mentioned, we're not getting a lot of adulterated substituted products coming out of the labs indicating subversion results, but we are catching these individuals during the collection process.

The third bullet under subversion attempts, which is the bottom bullet, I want to just point out that 98 percent of all the subversion attempts are contractor/vendors. There's a lot of speculation on why this is. Contractor/vendors are more representative of the actual workforce in society. They might have a lower expectation of being -- a higher expectation of not being caught, because they think they're good at doing this. They might have a product that they think will get them out of jail, you might say.

In addition, licensee employees are highly educated and qualified and they're well-paid. So they might better appreciate the fact that if they are caught subverting a drug test that they're going to be fired from the licensees because their unescorted access authorization to the power plant is going to be denied by the Nuclear Regulatory Commission.

This last slide I just want to point out some of the industry initiatives and activities, and the reason why I'm doing this is to share information. The industry is interested in oral fluid testing. We have communication with the Nuclear Energy Institute and a number of licensees who own and operate nuclear power plants, and there is interest in oral fluid testing, so they look forward to the publication in the oral fluid guidelines.

Second bullet is there are a number of licensees who want to expand their drug testing panel. I mentioned before that they have some difficulty expanding their panel. However, with HHS expanding their opioid panel, that tends to provide additional validity to the industry on additional substances that they could test.

Auditing of HHS-certified laboratories. I know that there's a number of laboratories on the drug testing advisory panel. You might see a shift in how the nuclear industry audits your laboratories. Brian and I would both be interested in hearing some of your observations based upon those audits on their effectiveness and how much burden they're resulting in.

The last bullet there is background checks and true identity determinations. This is important because on pre-access testing, as I already mentioned, that is probably the most important test to keep the individuals out of the power plants, and it's just one of the layers of defense in depth that we have established to ensure that the people going into these sites are trustworthy and reliable.

The last slide here is how to contact Brian and I. And our emails and phone numbers are here, and if you have any questions or want to discuss any items with us, feel free to give us a call or an email. Thank you very much.

CAPT BELOUIN: Thank you, Paul, for that presentation. I'm going to turn this over to Ron Flegel.

MR. FLEGEL: I know we are ahead of schedule. I want to thank both DOT Patrice Kelley and NRC Paul Harris for giving presentations today. It's the one time that the regulated sectors as well as the federally-regulated sector can come together, give their information, et cetera.

I did want to expand just a little bit on what Paul and Patrice said. I think to be an effective program, which I think that's what the board is striving to do is to have alternate matrices, again, with oral fluid being an addition and hair hopefully being an addition later on. So that is one of the issues that I think with subversion, adulteration, all of those combined, that to be an effective program we need to see all of those matrices.

I also -- since we're ahead of schedule, we had another presentation in here that we took out, and that's why we are so far ahead of schedule, but I did want to mention one of the things; because of the day of mourning tomorrow for former President Bush, it is still being decided if we will have a meeting tomorrow. So I am waiting to hear from senior leadership from HHS as to if we're going to have a meeting. That has not been decided tentatively.

I say that because tentatively right now, board members and ex officios as board members, you are federal employees for the day. So there's some complications to that if we actually work on a day off basically for the government. So that is being decided what we will have to do.

Then again, with federal agencies and again there are board members that are federal positions here that they will have to decide from their own federal agency as to if they can attend tomorrow. That's going to have to be a federal agency decision, not necessarily a board decision in that regard.

So I did want to mention that. I hopefully will know much more later this afternoon, and we can give an update. The intent was to continue on to have a closed session tomorrow and have discussions that we have put in closed session around the agenda. Hopefully that will occur, but we will see. But we will keep -- by the time the day is out, we will know more as to if we can actually hold that meeting tomorrow.

So with that, what I'll say is since we are ahead of schedule, and I don't -- because there's public that calls in and listens to that, I don't want to come back after 15 minutes. So what I think we'll do, because of Department of Defense update at 11:15, is we'll have a little longer break. So we will probably try to come back a little bit early, say 11, 5 after 11, and we'll get started right at 11:15 with Department of Defense presentation. Is that okay?

So with that, I'll turn it back over to Sean for the break, and then we'll go from there.

CAPT BELOUIN: All right, operator, what we're going to do is we're going to take a break from now until 11 o'clock. So we will reconvene, operator, at 11:05 a.m. and we'll pick up from there the Department of Defense presentation.

(Brief recess.)

CAPT BELOUIN: Again, this is Captain Sean Belouin, Designated Federal Officer with the Drug Testing Advisory Board. Before we get started with the next presentation by the Department of Defense, Ron Flegel has a couple quick comments to make.

**DTAB Open Session Meeting Transcript
December 04, 2018**

MR. FLEGEL: Just a couple of comments and a clarification of the agenda. We know we had a time difference at 2:30. There will be a presentation by DWP, and then there's also going to be a presentation under the data that RTI will be presenting before 2:30. So again at 2:30 it will be Faye Caldwell's presentation. And with that, I just wanted to mention that because that was drawn to our attention. And just for the public, if there's any public comment be sure to notify us or the recorder so that we make sure that you can have public comment, I think it's at 3:00.

CAPT BELOUIN: We're just waiting for the Department of Defense presentation to be brought up here online, and then we'll get started.

MR. FLEGEL: Tentatively, while we are waiting for the presentation to be brought up, I have not heard anything as of yet, but if it were to be cancelled tomorrow, the meeting, I was informed that any travel from DTAB members would have to go through our travel agent. So we will again let you know. But since tomorrow will be considered a holiday we will have to make any changes for DTAB members today while the individual is working. So again shortly we will hear something as to what is going to happen then.

Agenda Item: Department of Defense, CDR Eric Welsh

CAPT WELSH: Good morning. My name is Captain Eric Welsh, I am stationed at the Pentagon. I'm now convinced this morning after driving up here that it would be easier to travel across country to get here than it would to drive up. So I'll be back online next time. I work for the Office of Drug Demand Reduction at the Pentagon, and I'll explain the chain of command and the overall structure. But I am the director, I replaced Colonel Tom Martin who retired in March, if you know Tom. So he still works with me as a contractor. So he's probably one of those you're concerned about with the higher positive rate. That's a joke.

The mission of the Office of Drug Demand Reduction, and I hope, please interrupt me if I use jargon that's too specific to the Department of Defense, I'll try to explain what we mean by some of these terms, and I've tried to remove a lot of the vernacular, but please interrupt if you have any questions about what I'm saying.

The overall objective of Drug Demand Reduction is to have a safe and ready force, and by ready we mean not just ready to do their jobs, but ultimately the readiness that we act of members of the armed forces is to prosecute war and to be warfighters, or to be directly in support of those warfighters. I think we would all agree the use of drugs undermines safety, it undermines good order and discipline, it undermines a person's ability to be ready when they're called to be ready and respond to whatever they need to do, regardless of what their specific job is.

So when we talk about the total force we're talking about not only people in uniform like myself in the Army, Navy, Air Force and Marines, but we're also talking about civilian personnel and contractors, although what I'm going to talk about today doesn't necessarily impact contractors.

We also in addition to doing drug demand reduction, which is mainly achieved through a robust drug testing program, we do find prevention education and outreach efforts. We also pay for collections, and we do dedicate a significant amount of time and effort to developing new testing procedures and doing surveillance, which is what I'm going to talk about right now, to make sure that we are leading the target when it comes to emerging drug threats.

The scope includes all DOD components. By components I mean not only Army, Navy, Air Force and Marines, but I mean the active components. So people like me who it's their fulltime job to be in uniform, and that's what we do for more than 40 hours a week. I mean reservists, people who work one weekend a month and are recalled as needed to active component, and we're talking about guardsmen. We're also talking about Department of Defense civilians who are in testing designated positions.

Our policy is promulgated through three different instructions. They're cited there as DODI, that means Department of Defense Instructions. The first one is general overriding guidance about the drug abuse testing program. The second is specific to our federal employees, our civilian employees that are subject to the Drug Free Workplace

Program. And the third one is probably one of the longest instructions in the Department of Defense, it's similar to the NLCP manual, but it provides the technical procedures for drug testing. And all of those are publicly available if you'd like to take a look at them.

The four main focus areas as I just alluded to was principally testing and collections. We spend most of our budget on robust testing. The principle means to deter drug use in the Department of Defense is through testing and to have punitive consequences associated with testing, and I'll talk about that a little bit more in the future.

We also do minor funding for prevention education and outreach. We're trying to as I think a lot of other federal agencies, we're trying to coalesce those efforts into a single one rather than having the respective services, and by service I mean Army, Navy, Air Force and Marines, do their own prevention education and outreach.

Finally we have a very centralized governance structure where we buy jointly for all of our drug labs the exact same equipment, we do centrally procure not only the equipment so that we're standardized, but we buy all of our reagents so that we do things in a very standardized way such that our policies make sense and can be implemented. We also partner with the lower right, there's a picture of the Armed Forces Medical Examiner System in Dover Delaware, that's our forensic toxicology lab for probable cause, investigative testing, and for quality assurance functions.

I think this is a mandatory part of a Department of Defense Presentation, it's the chain of command or the organizational structure. And the reason I bring this up is, there are two reasons. One is Secretary Mattis is the Secretary of Defense. I work within his office, the Office of Secretary of Defense. One of his subordinates is the Undersecretary for Personnel and Readiness, that's Mr. Stewart. My boss works directly for him.

So if you want to look at it one way I'm just three away from the Secretary of Defense, but I think the more important way to look at that is that I can get in trouble at any time. But in reality our mission aligns very well with the Secretary of Defense's mission. He has three focus areas of readiness which I've talked about, forging partnerships, and to become efficient and adopt the very best business case practices such that we're efficient in prosecuting war.

And his idea of readiness isn't just to be ready, but once you're called to action that you maximize lethality, which is something he talks about. So the senior policy maker for the Department of Defense is the Secretary of Defense, and all policies that are developed have to be signed and socialized at the level of the Undersecretary. And they're all very interested in the Drug Demand Reduction mission as an enabling mission to make sure that our service members are ready to go and are drug free and are safe as they can be.

The dotted line there between policy, where we write the policy, is execution. And there are two branches of execution. One is to the respective services, Army, Navy, and Air

Force. Some might ask why aren't the Marines there, the Marines are part of the Department of the Navy.

So when it comes to personnel issues, the hiring, the retention, the wellness programs, the other readiness programs, basically the suitability for ongoing deployment as an active duty service member, reservist or guardsman, is up to the respective services. So part of that execution in policy is the human resources side of things, and I've represented that there by showing these services secretaries.

The other side is the technical side. Again this shows the chain of command if you will, with the Undersecretary, Mr. Stewart, my boss, and myself, where we write the policy. And this is a very iterative process. We just don't write the policy, so it's very similar to what happens in this program, the federal program.

There is back and forth with these policies, it's not that I get to write them and they're written in stone and I come down from the hillside and give them to people and tell them they have to follow them and then mandate compliance, it is a very iterative process, it's an interactive process, the services are able to socialize and coordinate and comment, and even not concur on some of the things that are proposed, and so there's a lot of back and forth in developing policies.

On a technical side though what's missing is a yellow box in the middle, which should be the Biochemical Testing Advisory Board. I don't know where that went, Sean scrubbed that out I guess. Great, that makes it a little bit clearer, I'm not going to have to draw it. How I get advice mainly rather than just inventing what we should do is we have a Biochemical Testing Advisory Board which functionally is very equivalent to the Drug Testing Advisory Board for the Federal Workplace Program.

And we seek advice from and have two way discussions with the technical program managers, and their names are listed there, you probably know some of those people. For the Army it's Lieutenant Colonel Nickels, Commander Jameson for the Navy, Dr. Mike Laubach for the Air Force, and again we involve the Armed Forces Medical Examiner System, because they are our forensic toxicology subject matter experts. They also advise and work with the five Department of Defense drug testing laboratories to make sure that we're not proposing something that's outside the scope of our capabilities. So I'll talk a little bit more about their functions.

I'm not going to go into this in great detail because it's very analogous to the way that the DTAB works. Essentially the BTAB, the Biochemical Testing Advisory Board advises me in two different areas, technical issues with respect to drug testing, and policy issues. So we have two different versions of our advisory board. One is assembled to only talk about technical matters regarding drug testing, and the other for policy.

They're made up of representatives from the Armed Forces, so none of these decisions are made in a vacuum, they're always made in concert with all of the respective

services, so that there's no monopolization of ideas. They're also comprised of not only people in uniform but also federal employees. Typically the chairs of those two embodiments are not voting members. We are given the ultimate vote from the respective bodies so that we can then make decisions.

Some of the things that they advise on, and these again are similar, and there's analogies between the DTAB and BTAB, make proposals about methodologies and new technologies that we can use from a technical perspective. We talk about proficiency testing, the frequency, the kinds of things that we'll look for, the results, the consequences and outcomes, quality assurance procedures including inspections, each one of our labs is subject to three inspections annually with a group of about eight to ten inspectors. We also have external proficiency testing, just like the NLCP program mandates, both blind program and an open program.

The BTAB advises on certification and decertification and recertification of those drug labs on a by drug basis if they have a serious failure or the entire lab itself. They make recommendations frequently on adding or taking away drugs from the testing panel, other policy changes, and increasingly research projects you'll find in the area when you're doing forensic drug testing that sometimes scientists who have good ideas and want to investigate things, that that needs to be sometimes run past lawyers because the outcomes of those investigations can have consequences in legal proceedings.

And then of course one area that's of interest to this group is prevalence testing. We continually test our service members, that same population, for other drugs and emerging drugs to assess whether they should be added to the panel.

This one again is a little redundant, but we try to make data driven decisions based not only on surveillance data, and there's two populations that we use for surveillance. We will routinely subject some of our specimens, and I'll talk about this more in the future, to a very rigorous panel. It's a 202 drug panel, which will be most of the end of my presentation. Those are routine specimens from our population. We also collaborate with the United States Army Criminal Investigations Lab, and they do testing on seized materials pursuant to criminal investigations.

So whether it's the Army's Criminal investigations Division, the Air Force's Office of Special Investigations, or the Navy's Navy Criminal Investigation Service, when they seize a material during a bust, any kind of an arrest, those materials are sent to the United States Army Criminal Investigations Lab, and they give us those data on a quarterly basis so that we can see what's being consumed by service members, and then we also test collected urine samples from our routine drug testing, and use those as two indicators about the prevalence of drugs and emerging drugs. We also rely on literature, but we have found that the military population is somewhat different than other populations in drugs of abuse.

Sometimes it's Congress or the services themselves that will give us the impetus to test for a new drug. That was certainly true for synthetic cannabinoids. It was the Navy in

2009 and '10 and the Pacific Command that noted there was an issue in the submarine community in Hawaii that was using these synthetic cannabinoids, and largely through the efforts of one admiral pushed our entire program to add synthetic cannabinoid, even at the time when it was difficult to do so. Also news media can drive that and inform what we should test for, just the popular press.

That whole series of indicators gives us the should we, should we test for new drugs, should we add them to the panel. And sometimes the answer to that is yes, but then the answer becomes can we, and that's where we have to do an assessment of the capability, are we able to, do we have the right analytical equipment, and the capacity, even if we have the right equipment, how much of that testing can we do, and at what cost.

And so those are the kinds of deliberations that I think a lot of labs make. It's basically the business case analysis that backs up whether we should or should not add a drug to the panel. And of course the deterrent effect. Our ultimate goal was to deter use. And so even if it costs a lot we are willing to add new drugs to the panel if there's some deterrent value.

These decisions inform policy changes. The Undersecretary as I said has to approve all of the policy changes. And then we make sure that those policies that are implemented, we have a feedback loop through our Department of Defense Quality Assurance Oversight Mechanisms to make sure that when we put a policy in place we track it to see that it has the desired effect. And so this is really an iterative process where we continually, we repeat this, this is repeat and rinse kind of methodology. We see what's out there, we modify our methods, we modify our panel, we then put measures in place to assess whether that's effective or not, and then we correct course as needed.

So these are some examples of where this process has been applied, using some of the inputs or decision points. Prescription drug abuse, of course opioids and benzodiazepines were two things in the press and 2010 and 2011, Captain Kevin Cleat who many of you know, he's an NLCP inspector still involved in the program, based on responses from and concerns from leadership and the popular press really pushed to have our opioid panel expanded, have the addition of benzodiazepines to our panel.

We also looked at emerging drugs. There are a number of different inputs that are of interest. Spice was certainly in the popular press. There were indications it was being consumed. There were incidents of seizures and incidence of people admitting that they were using synthetic cannabinoids. We have also continued to look at bath salts on an ongoing basis and other novel psychoactive substances.

And an emerging area that's increasingly of concern is that of supplements. So we are aware that service members use a lot of supplements to try to stay in shape, try to meet their operational requirements, but a lot of those supplements it's really a buyer beware kind of a scenario, and we're getting increasingly concerned about those.

So we do prevalence testing and surveillance data, which I'm going to present to you in just a few minutes to show some of the decision points, some of the data that leads to decisions. But in the past some of those outcomes were that ecstasy and oxycodone, this is a little bit dated, they were added to the panel back in the past, a long time ago, based on these kinds of inputs. But more recently hydrocodone or hydromorphone, these opioids were added in 2012 to our program, Benzodiazepines were added in 2013, five drugs.

And synthetic cannabinoids in 2014 were formally added to our drug testing panel. We currently test for seven synthetic cannabinoids, and I'll provide data that shows exactly what our panel is in a few minutes. But those were all in a response to these types of inputs. Similarly we saw the prevalence of LSD, MDEA, and barbiturates completely disappear, so we felt that there was no benefit. However, PCP those are maintained on what we call a relegated panel, and if at any time a commander suspects that a person is using LSD or any of these drugs, we can have the armed forces medical examiner test for those drugs, and there can be punitive consequences.

The next slide provides a little bit of a historical perspective. As many of you are aware from Hollywood, one of the things they got right is that in Vietnam there was a lot of drug abuse, principally heroin and marijuana. A survey done in 1971 of service members returning from Vietnam revealed that 42 percent of those service members had used drugs while in theater, and half of those, so roughly 21 percent of our deployed individuals in that theater felt that they were addicted to drugs at some point during their tour. So President Nixon in response to those data gave people a chance to receive treatment.

They also began clinical testing, clinical based testing with no punitive consequences all through the 70s. In 1980 a similar survey was done and we found that we've gone from 42 percent of people admitting to using drugs to 38 percent of people admitting they were using drugs. So again that didn't really change the will, we saw that there was no corrective behavior when there were no punitive consequences when the only consequence was offering rehabilitation or treatment, we didn't see the needle move very much.

And then this incident helped to change the will of Congress if you will. In 1981 there was an incident aboard the Nimitz, it was off the shore of Jacksonville Florida. There was a plane called an EA-6B Prowler who had made several attempts to land, eventually when it landed it careened off the flight path into some parked planes, there was a massive fire, and a number of people were killed. Six people had detectable levels of marijuana.

While the report didn't conclude that marijuana was a contributing factor in this incident, it raised this idea that we had people aboard ships in an operational status where safety was an ongoing concern, that there was drug use. So largely based on that the Deputy

Secretary of Defense in 1981 authorized the drug testing results to be used in a punitive way, for either jail time or for separational, loss of a job, separating from the military.

So unfortunately at that point, the drug testing program, they continued to test in a clinical setting, a hospital setting, strict chain of custody procedures were not followed, so in 1983 a gentleman named Major General Einsel did a study based on some information that came from legal proceedings, and found out that the drug testing program in the DOD did not follow forensic standards and maintaining chain of custody specifically, and at that point in 1983 the Secretary of Defense, the equivalent of my boss now had to announce up to nine to 10,000 service members who had been separated that the records could be expunged and they could be made whole and brought back into the service.

So that was a very bad day, but it solidified this idea of having the forensic nature and the legal defensibility of all of the drug results, and that really was the basis for and a foundation for the federal drug testing program which was codified by executive order in 1986.

So here we show, there's actually some data, this only goes back to 1987. When the drug testing program started in a punitive way in the early 80s the positive rate as almost at seven percent. A survey revealed that like I said between 30 and 38 percent said that they were using drugs, and we caught about seven percent that year, and the positive rate has plummeted, especially with the punitive consequences, through the '80s, to what is essentially a baseline.

There was a little bit of an uptick in 2000, that's when we deployed people. Zero tolerance has had various interpretations over the years depending on whether we're in a state of war or not. It turns out that some people are very good at their jobs, and the fact that they use drugs doesn't always lead to an immediate separation. It eventually does down the line however. And in 2017 we're down to one of our lowest years of 0.88 percent positive rate, which is pretty good.

So the DOD has five drug testing laboratories. Two Navy, there used to be three Navy, actually there used to be five Navy, but now we're down to two. We closed a lab in San Diego, it was in an old building, that was just a cost analysis, it was not worth repairing. There's a brand new building at the drug lab at Great Lakes, a dedicated 30,000 square foot facility that's able to accommodate the extra work load. So the lab at Great Lakes tests about 1.4 million specimens a year.

The lab at Jacksonville Florida, the other Navy lab does about 1.1 million specimens. The Army lab out at Tripler does around 800,000. The lab at Fort Mead which also does civilian testing, about 150,000 samples a year, civilian does another about 350,000 Department of Defense samples. And then the lab down at Lackland Air Force Base, does around 800,000. So all together, right around 4.6 million samples a year. The bulk of those are military samples, about 150,000 are federal employees.

And this is a joint program, it doesn't matter to which of these labs any sample goes, they're all handled the exact same way at all of the labs. These are all subject to inspection, they're all subject to quality assurance oversight. And again all of these sites use the same equipment, the same quality control standards. So this is our equivalent of the 29 or so certified ALCP labs, these are the five DOD certified labs that do all the testing.

I just want to share some data from our 2017 report. This actually goes back a ways, but just to show you the general trends. Typically the guard and reserve, these are people who are not on active status.

So for all intents and purposes these are people who are in their civilian lives, and these trends have held for many, many years that guardsmen and reservists have higher positive rates, they act more like civilians. So similar to the data we saw for NRC, employees who are vested, it's their 24/7 job, have lower positive rates. By military applicants we mean anyone who tries to join the Army, Navy, Air Force, or Marines. Anywhere across the country they are subject to a pre-employment drug test at the military entrance processing station.

So every one of their recruiters will take every kid to run through a battery of tests, physical, mental, and otherwise, psychological, including a drug test. Those are all sent to the lab at great lakes. The positive rate is actually lower than it has been. In the early 2000s it was high as three percent. So these trends as I've said have held for quite a while, but active duty has the lowest positive. In the next few slides I'm going to break each one of those down a little bit more.

We talk about the active component. These are people like me who it's our 24/7 job, it's our career to be in uniform every day. The Army continues to lead the way at the highest positive rate. Marine Corps next. Navy is trying to beat the Air Force for some reason, but the Air Force has the lowest positive rate. And again these trends have held over a number of years.

Reservists, very similar trends, the Army and Marines again lead the way, followed by Navy, our Air Force and Navy, but you see the positive rates are fairly low. Now as far as the guard goes, only the Army and the Air Force have a national guard, there is no Navy National Guard Marine National Guard, it's just Army and Air, and there's quite a difference between the Army National Guard and Air National Guard, and that may have a lot to do with the fact that many guardsmen, many reservists in the Air Force also are commercial pilots or work in the airline industry, and they're subject to pretty rigorous workplace drug testing in their own respective day jobs, and that may not be the case for the army, so that may lead to the difference, but nonetheless it's one that is longstanding.

So on the left this is our drug testing panel, it's half of it. This is split into two slides, and these are roughly ranked. Some of them, we have data from 2012 to 2007, these data are normalized by 100,000 unique service members tested. So these aren't, you look

for example at marijuana in 2017, the number is 649.3, that's per 100,000 unique service members tested across the entire Department of Defense. That's active, that's reserve, that's guard. And you can see what those trends are roughly, but I'll show you, I want to point out a few that are good news, and some that are a little more disturbing.

First in the green box, you can see that our opioid panel includes not only codeine, morphine, oxycodone, oxymorphone, and the two hydros, but initially, prior to 2012 we only tested those at about 20 percent of all specimens that came in. So part of expanding opioid testing was not only increasing the panel, the number of drugs on the panel, but the testing rate to 100 percent of all specimens that came into the door. So good news on the opioids, especially the prescription opioids, as we've had a 70 percent decrease since 2013. Heroin, we've had a decrease over that same period of time of 54 percent.

However during that same interval, back to 2013, and the reason I picked 2013 is that was the first year we tested for all of these drugs at 100 percent rate. We've had a 58 percent increase in positive rates. And it seems like that's consistent with the data that was just presented by the NRC, at least it's a very similar trend, and we're seeing an increase in ecstasy as well in the popularity. I don't know if that tracks other workplace testing, but we're definitely seeing it in the Department of Defense.

In the blue box I point out the fact that the old standbys, marijuana and cocaine, represent 78.2 percent of all of our positives, and the next highest is amphetamines at five percent. So again that parallels very well what the NRC just presented, with marijuana being 50 percent, alcohol 20 percent, and I think we had cocaine and amphetamines in that order. So we don't test for alcohol. So I think those were your data.

So one thing I would like to point out is an enabling, what enabled us to add these to the panel, which is different from the challenges that the federal workplace programs, is that we have a captive audience in the Department of Defense, which means we have access to healthcare data. And so when we started testing for these expanded drugs, many of them prescription drugs, we also could leverage the fact that we had access to their prescription information.

So during the testing process, during the screening process we do an in situ check of their prescription history, and for example if a person has a prescription for oxycodone, and during screening we find oxycodone, and they've had a dispensing event for that drug, they've picked it up from the pharmacy in the last 180 days, we wash that out and call it negative. So it's like an in situ MRO process that happens automatically.

And for oxycodones that washes out over 80 percent of those specimens from going to confirmatory testing and adjudication after the fact. So for that very reason whenever we're asked about federal policies, laws, and regulations, we weigh in that we are in favor of a national prescription database for this very purpose, and for all other purposes that I think we understand when it comes to doctor shopping and diversion

activities. So it's very useful for us in drug testing. We do that also for some of the opioids, it's a little more difficult because of their metabolic pathways, and we do it for benzodiazepines as well. So we're able to wash out a number of those.

The other thing that we've learned since we added prescription drugs that may be of interest to this group is that we try to define what illicit prescription drug use was by saying that a person was using too much of their medication, they were using it for a purpose other than which it was given, so maybe they had a broken arm and they were given vicodin and later they were using it on their ankle, they were using it in excess of the prescribed amount, which is difficult to determine through routine drug tests, or it was not their prescription. Through four or five years of testing for prescription drugs we only have one illicit basis for prescription drugs right now, and that is that it was never their prescription.

So the concern we have is that people get one prescription ever in the Department of Defense and they continually bring that out of their back pocket to show that oh, five years ago I got this prescription, I accidentally took it. So that is an ongoing concern. So we are actually going to try to put policy in place that gives a reasonable window that's consistent with prescribing timelines for consumption of a drug.

Currently there's no federal prohibition against using schedule substances for any period of time as long as they were used by the person to whom they were prescribed. But we do have cases where a person will pull out a temazepam prescription from nine years ago and say they must have actually taken that three days before urinalysis. So we're going to try to put in a policy that says you have 180 days to use a prescriptions drug. So stand by to see how that goes.

This is the other half of our panel. It's mostly the synthetic cannabinoids and benzodiazepines. So we have seven synthetic cannabinoids on our panel. As you can see the not tested is we've slowly modified our panel. Initially we started with three of the most common ones, we've added some others. This is a moving target. I don't think that the decrease has anything to do with decrease in user prevalence, I think it more has to do with we're probably not testing for the right drugs anymore. So I think there are just new versions. There are hundreds of these compounds, and this is an ongoing area of concern, something we're continually trying to widen our aperture so that we can wrap our hands around this.

The good news is though that as with the opioids we have seen a 67 percent decrease in benzodiazepines since we started testing for those in 2013. And we have looked at, again as I've said we have a captive audience, we can get prescription data from these individuals. We have seen a decrease in opioids being prescribed across the Department of Defense in response to concerns about addiction and its association with suicide, suicide ideations, and just overall addiction concerns.

We've also seen a decrease in prescription of benzodiazepines over that same period of time. Much of this is not attributed solely to having punitive consequences in the drug

testing realm, but has been in partnership with the providers and the medical treatment facilities and responsible practitioners and their practices. And so we coordinate with Defense Health Agency and we present these data when we talk about these kinds of things. So it's good to control the supply side and the drug demand reduction side, and together we've seen a significant decrease in these drugs that are of concern.

Another area that, this parallels I think data we see in college aged students. The high risk population in the Department of Defense has been and continues to be 18 to 25 year old enlisted males. They represent only 37 percent of the individuals tested. However they account for two thirds of all drug positive results.

We thought we might see a shift in this as we transition to more prescription drugs, thinking that maybe the more mature group of people would use and abuse prescription drugs at a higher rate, but this trend continues, and this data have, there have been maybe plus or minus three percent if you look at these data back year over year over year. So it turns out that the younger population not only abuses illicit drugs but they also abuse prescription drugs at a rate that's proportional to the illicit drugs.

This is an area of concern that we heard Mr. Flegel raise this and some of the other agencies, that the popularity, the legalization of marijuana is a concern for us. We continually as I'm sure you do in your agencies and your MROs deal with this topic, it's the I didn't know I couldn't do that defense.

We have service members in places where marijuana is legal, thinking that it's legal they get prescriptions and think it's legal, we've had to put out amplifying guidance to both our military service members and our federal employees to tell them that marijuana is a schedule one substance, so are extracts in all versions, unless it's Marinol, and now Epidiolex. Of course now we have a number of healthy adults thinking that they have seizures.

So we're dealing with that as well. The marijuana does account for 73.4 percent. So if you look at these data you say if we wanted to get the most juice for the squeeze if you will, we would test younger people at a higher frequency, and we'd only focus on marijuana and cocaine, and that would be true, but we are trying to have a comprehensive Drug Demand Reduction initiative.

Again marijuana counted for 96 percent of all applicants. So this is a concern. We have a decreasing application who is eligible to join the military, only 30 percent of high school graduates meet the standards to join the military today. With the competitive job market it's harder and harder to get people to join the forces. The fact that a large number of them now use marijuana on a recreational basis causes problems when they've prohibitive to do so. So some of the services are offering waivers, if a person admits to using marijuana they could be waived for that, but if they test positive no services in our policy does not allow them to come in.

They can one time be re-tested after a 90 day grace period, if they test positive that second time for marijuana or any other drug they are barred from enlistment or commission for the rest of their lives. So it's increasingly a problem in not only maintaining the manning of the Department of Defense but in recruiting as well. The positive rate after decreasing for a number of years is starting to see an uptick.

We don't know if that's in parity with the legalization efforts, but many of those started in 2013. California was many years ago, but a lot of other states and jurisdictions have started to legalize recreationally and medicinally in 2013. And so we are going to overlay our data onto state data and see if we see any sort of correlation with those jurisdictions. But it is a concern as I'm sure it is with a lot of people in the audience.

These are the data from our about 150,000 civilians who are tested, in testing designated positions. The top line there for 2017 shows just those who are tested during routine tests, with 391 positives for a rate of 0.33 percent. Applicants, those who are subject to pre-employment screens, 110 were positive with a rate that's very similar to that for those in an ongoing basis. For combined positive rate similar to what has been historically of around 0.32 percent, fairly similar to what I think NRC presented as 0.44 percent.

So we anticipate with a new panel that this is going to increase, but so standby for data from next year, there's a picture of the lab at Fort Mead to remind me to tell you that we only do civilian testing at the lab at Fort Mead, for those of you who have potentially inspected there.

So surveillance testing, I'm going to go through this fairly quickly. We do these in groups of 2000 for each round or each reporting period. This is not a random population of individuals. These are specimens that screened positive at one of our drug labs but then upon confirmation were not just negative but dead negative for the analyte of interest.

So they may have screened for amphetamines, but there was no indications of amphetamines, by that I mean amphetamine or methamphetamine, in the confirmatory test. So those are identified only on the top as to what they screened for, so they may say amphetamine or methamphetamine, and otherwise they're completely deidentified so there's no other demographic information or certainly any personal identifiers for this kind of testing.

There's also a sample, whenever there is a law enforcement case or a mishap investigation, including those involved in the airlines or flight incidents, the crews, not only the air crews, but anyone involved in a flight has to be subject to a drug test. They'll take those specimens, once they're done with their initial testing, when they're deidentified, either aliquots or the entire specimen are subject to our surveillance panel.

And the panel down below, it says 202, the plus 27 just indicates that we have recently added 27 since the last round of testing. So that includes 45 stimulants and hallucinogens, 75 total designer type drugs, 46 synthetic cannabinoids, and 36

benzodiazepines. And we subject these groups of 2000 to that full panel. So I'll share some of the data here in the next few slides.

The first group are the stimulants and hallucinogens. To remind you, there are 45 total. They're only shown here if we have detected one of these drugs. So there are 13 of the 45 we've detected in the seven sets of data that we've looked at. We've looked at a total of 14,000 specimens. Again out of 101 total positives 26 came from the drug labs, the rest of them came from probable cause and investigational testing. The one that has been enduring is ketamine and norketamine. We see a little bit of escaline, but these things come and they go. So far the prevalence, we don't see really any indications here that we would add these to an ongoing panel, but we continue to monitor these, we continue to change our panel. But ketamine and norketamine would be the ones of primary concern from this panel.

The next one, these are considered. This testing is all done by a lab, it's called our Special Forensics Toxicology Testing Lab, it's at the Armed Forces Medical Examiner System, it's actually a separate lab within that one where we send these specimens and they do this testing. These are our designer drugs, they're 75 total, we have detected 16 different drugs. The ones that initially there was a D2PM stimulant that was initially very popular, again it has completely disappeared. As we see with a lot of these they come on scene and then they disappear. Fentanyl and norfentanyl have become very prevalent in this panel.

I will caution that we did not scrub any of these because they are deidentified, we have no demographic information, these have not been scrubbed for legitimate prescriptions. So some of those could have been legitimate prescriptions, not necessarily illicit use. And we see, so again these things come and they go. Fentanyl, mophedrones, those kinds of things, some of the designers, the novel psychoactive substances, we see them from time to time but not persisting in our population.

This is the area that's really causing us a lot of, we get a lot of pressure from the services and just from people picking up the paper, whether it's a group of folks in Connecticut that all vape something and they find this synthetic cannabinoid, or we have service members who buy vaping product that's supposed to have CBD which has problems in and of itself, and they find out that it wasn't CBD but it was synthetic cannabinoid, we receive a lot of calls and pressure to expand our panel.

So these are the synthetic cannabinoids. We test for 46 now, we surveil for 46, but the one that came on the scene in the recent past is this 5F-ADB metabolite, 5F-ADB PINACA. We found eight of those in surveillance. This is very consistent with what our partners in the Army at the Criminal Investigations Lab are finding in seized material. In general with synthetic cannabinoids, when they were originally popular in 2009 and 2010, and we've seen a change in those panels, both in seized material and in surveillance, we've seen in some of the old compounds now that used to be distributed

on organic carriers to be smoked are now making a comeback as vaping oils. So we are keeping an eye on that.

The limitation on adding these and expanding these is just getting reliable reference standards, which I'm sure is a challenge for some of the other people here. But our current proposal and what we're working toward is to make every synthetic cannabinoid that has been put out on emergency schedule or scheduled by the DEA is to essentially make those prohibited.

So should we, the answer is yes. Can we, we're working toward that. And it may require a new paradigm that doesn't have the exact same quality assurance standards and quality controls because of the reliability of some of the reference standards. But that's something we're working through but there's definitely interest in doing that.

Benzodiazepines, as a class we've found 10 of 36. Again these are not scrubbed for prescriptions, so the ones that have been persistent are midazolam. Most of those are probably, midazolam and alpha-hydroxymidazolam, likely from legitimate prescriptions. We see the metabolites of valium prevalent again, restoril and valium are popular drugs not only in the civilian world but in the Department of Defense as well, but we continue to monitor these.

Of specific interests are other stimulants. The dimethylamylamine, which is apparently not from geraniums, and kratom and phentermine are things that we're continually looking at. Dimethylamylamine is still in a large number of over the counter products, they still disclose it, they use synonyms, but it's still out there, and again with service members' tendency to use a lot of supplements we have ongoing concerns about dimethylamylamine. Kratom does not seem to be an issue, even with the DEA scheduling it temporarily they're deciding not to schedule it on their emergency schedule. We just don't see abuse of that widely in the Department of Defense like we hear about in the public sector.

Regarding phentermine though, phentermine is extremely popular among service members. It continues to be the number one drug we find in surveillance testing. You look at those numbers over on the left, we're talking 600 or 700. Any of those other charts that I showed you which were hard to read, the cumulative totals there were like in the hundreds, just 100 or so, maybe as high as 200, maybe 500 for the benzodiazepines, but phentermine is by far the most popular and prevalent drug that we find in our surveillance panel. Why is that? It's an anorexiant. People in the military have to maintain weight standards, so you might get fired if you're overweight for two consecutive cycles.

So phentermine is not banned, we can't distribute it in the military, you can't get a prescription for it from a medical treatment facility, it's not paid for by insurance, our version of insurance, but that doesn't prevent a person from going out in town to a private doctor and getting a prescription for phentermine to help to boost their metabolism, and they do. So we present these data to the services.

So far the policy people don't feel like this is something that we should prohibit or ban, we're just continuing to monitor it. So again these are the kinds of data that we present to the policy makers to see whether they feel like these are a concern or not.

Just to summarize some of our initiatives, we talk about expanding synthetic cannabinoids, opiates, and benzodiazepines. We're not only talking about the testing rates which we've now tried to ramp up to 100 percent of all specimens being tested for those drugs, but we're also talking continually about expanding the panel. We have gone since 2012 from 13 drugs on our panel to now around 25. So we've had quite an expansion already, we're continuing to open the aperture as I say based on surveillance to add more and more drugs.

We also for applicants to the military, I don't know where we lost the visibility on this, but they were only tested for four drugs, cocaine, marijuana, and amphetamines. And that's also the designer amphetamines. We tested for those four drugs for years for people coming into the service.

We changed that such that they are tested applicants for the exact same panel of drugs so that we can identify other issues associated with prescription drug use and abuse in applicants. And so far after one year of expanding that panel for them we did identify some individuals who are using drugs that they did not disclose to their recruiters that needed to be addressed. Again the big goal is that third bullet, the near real-time emerging drug surveillance testing.

We are planning on implementing a model which is a little bit like analogous to the IITF model used in the NLCP or the Federal Workplace Program, in that based on surveillance when we identify a drug that we want to add to our panel we would use a centralized method development at one site that would be deployed to the five labs and then those five labs would do a screening function even if it's mass spec based screening, and then send that small number of specimens to the special testing laboratory at the Armed Forces Medical Examiner System to do the confirmatory work.

So rather than have all five labs get certified for all of those new analytes, the idea would be to have decentralized screening and centralized confirmatory testing so that only one lab has to be certified. Of course that requires consideration of a partner lab to make sure that there is some interaction with an outside certification entity, but that's a fairly easy fix.

We did close the lab at San Diego, so that has allowed us to recapitalize quite a bit of money to dedicate to these surveillance and to new equipment. We're continuing to look at robotic technologies, liquid handling, rapid mass spec types of technologies that allow us to look for more drugs instead of just classes of drugs, but specific analytes so that we can take advantage of the prescription database that we have access to.

We continually, when we take a drug off the panel and we relegate it to a relegated panel if you will, like LSD, PCP, some of the other drugs, we will with some frequency,

every two or three years, do prevalence testing and specifically look at those to make sure that those haven't become new drugs of abuse. So far even though we've heard anecdotally that we think people are using LSD, the testing doesn't indicate it's LSD, it's often synthetic cannabinoids, and PCP as well.

We are considering, I was glad to hear that the civilian testing for some of the other partner federal agencies is at 50 percent. I don't know about 25 percent, but that's not my call. But we are considering increasing that in response to the abuse of opioids and legalization of marijuana, increasing that to 75 percent of the testing designated positions. For us it's just a matter of throwing more money at it, and we seem to have that, at least this year.

The biggest challenges, this is just a summary. These are high risk population, 18 to 25 year olds. They tend to be higher risk in their behaviors, they experiment with drugs, they tend to be polypharmacy abusers. So the good news or bad news is when they try one it tends to be a gate way for many others. It's not uncommon for us to see people who are positive for five drugs unfortunately.

We are concerned about prescription drug abuse and misuse, even though the trends are in a positive direction, we're continually concerned about prescription drug abuse and misuse, even though the trends are in a positive direction we're continually concerned about people getting one prescription ever in their military life and then using that as an excuse to cover ongoing abuse of those drugs. And again that cuts across all ages in the military, the young and older people, they tend to have issues with prescription drugs.

Our guardsmen and reservists, who are more like just regular civilians, tend to use drugs at a higher rate, which is again consistent with what we see in the contractor/vendor realm of the NRC for the day it was presented. it's always a concern for us that we're not as agile as we want when it comes to synthetic cannabinoids, even though they were identified as a threat and an emerging issue in 2009 and 2010, it took us until 2014 to make them a routine part of our panel, we just didn't have the equipment, unlike we tend to have fairly robust budgets, but to implement new technology can take much longer than it can in the private sector.

So we now have those technologies in place, including LCMSMS, rapid fire MSMS, we have automated liquid handling equipment, and we are now implementing that, coming up with validation protocols, and starting to implement those into our routine drug testing. And all of those things will expand both our capability, what we can do, what we can test for, and our capacity, the how much.

But it's our intent, even if we only can test at 10 or 20 percent of those samples, to expand our drugs to address the emerging targets. And then just staffing is an issue. We have a hard time hiring and retaining people in these very, in these process oriented jobs that tend to be high risk low reward for people that process millions of urine samples a year.

So these are our bottom line goals. I have talked about a lot of these, but at the end of the day our entire program is to really make sure that we have a ready and safe force in the Department of Defense such that when we're needed to do our jobs we're not impaired by any drugs or the consequences of drugs.

That also extends to the communities and the other people that support us in our mission, including our civilians who work alongside us. The number one way to do that is through a frequent random drug testing program. Again we have just over a million, 1.7 million people in the military, we do about 4.5 million tests. So some individuals like myself are tested three to four times a year on a random basis.

We do some education and prevention initiatives, and the last thing I want to point out is that last bullet there, and this is an opportunity I hope to take advantage of the interagency process. Even within the Department of Defense we are concerned about a person who gets fired from one agency within the Department of Defense, say Defense Logistics Agency, for drug use. Currently there is not a way to share that information with other agencies that may inherit that person.

So this is a concern not only within the DOD but it's certainly even a greater concern across other agencies in the federal government that we need to have a government wide clearinghouse or way to achieve reciprocity such that if we're truly concerned about the consequences of drug use, if it's bad for an NRC employee it's bad for a DOD employee, it's bad for a Department of Transportation employee, we would fully support some reciprocity to make sure that that information is shared in a legally supportable way. So with that I'll turn the time over for any questions.

DR. MOORE: I have question. Why do they not test for alcohol?

CAPT. WELSH: Alcohol is a separate program, that's considered a wellness program under the medical realm. And they do fitness for duty testing for alcohol. If a person appears to be impaired when they show up to work they actually will do a breathalyzer, but it's completely separate from drug demand reduction. That has to do with our funding.

Our funding comes from a dedicated account that not only focuses on drug demand reduction, but drug interdiction. So that's the supply side and the demand side. And quite frankly the funding has to be, it's specific for those types of functions, and it doesn't include alcohol. So a separate agency, and we turn that over to the defense health agency to do alcohol testing, but it's based purely on fitness for duty.

MR. LO DICO: Thank you for your presentation. I have a question. Does the BTAB have any discussion on expanding your alternative specimen to oral fluid or hair?

CAPT. WELSH: That is a great question. Part of the budget that we distribute is for collections, and obviously in the Department of Defense one of the big separators, distinguishing features if you will between that and the federal program is we do direct observation, which means we observe the urine leave the body and go into the

container. Obviously that is a gender specific type of a function, and so where we pay for people to do that, even people in uniform to be stationed at different sites to do those kinds of things, there's significant costs in that gender specific collection.

So we are very interested in looking at an alternate matrix which is gender neutral, because frankly we have to pay for half as many people, and so it makes collections in a lot of ways easier and there's a lot of benefits, and so yes we're interested in that. Not so much hair, because I personally don't have any, and so I'm a little angry at that, but I think oral fluids, I'm looking very much forward to the guidelines to come out on oral fluids and for you guys to lead the way so that we can beg, borrow, and steal those standards for the DOD. I can see us within five years doing oral fluids ideally.

MR. FLEGEL: Are there any other questions for Captain Eric Welsh? I personally want to thank Eric for his presentation. The prevalence data is very informative. It's something that I think as a whole problem that's really informative on what is actually outside of the drugs that we currently test for to look at.

I want to also thank all federal partners for this. It's sort of a complex issue sometimes because within the Department of Defense, within DOT and with NRC you also have federal civilian employees that are testing under the HHS guidelines, but you also have their own programs tested under part 26 or 49 CFR part 40.

So it is sort of complex, that's why I'd like to have everyone here as federal partners to have their own drug testing programs, so we get to hear a little bit about everything. So again I think we reconvene at 1:30, and so we'll reconvene a little bit before that and we'll start back up with the HHS presentation to WP, and I'll turn it over to Sean.

CAPT BELOUIN: If there's no further questions, operator, if we can stop the recording and then we'll pick up promptly at 1:30 PM.

(Luncheon recess)

A F T E R N O O N 1:30 PM

CAPT BELOUIN: Good afternoon, everyone. This is Capt. Sean Belouin, with the Drug Testing Advisory Board. We're going to begin the afternoon session, and at this time I'm going to turn it over to Ron Flegel for his presentation.

Agenda Item: Updates by DWP (Urine, Oral Fluid, Hair Mandatory Guidelines, Future Directions), DWP Staff

MR. FLEGEL: Thank you, Sean. I'm going to present from here. One of the issues around this is I wanted to present, also to show some data on-screen, for DTAB members. This morning was mostly opening remarks. I wanted to get that on record as to the information, but some of the same information I'll cover here. We also added some additional slides. Charlie will be giving a short presentation within this one, as well as what we call standard variables. We wanted the public to understand some of the certified labs, et cetera.

I'll go ahead and get started, and once they bring this up on screen. Again, feel free, if there's any questions, comments from the board, feel free. Don't worry about interruptions or anything like that, so if there are questions on any of that, please do ask your question.

To start off, I want to thank everyone that's on this page from the Division of Workplace Programs. I don't think we could obviously do it without any one of us. We all have very specific position of what we do. It's been a long year, long couple of years, and I feel we're in a great place right now with where we are. Not only with oral fluid, with the urine program, but also with the proposed hair mandatory guidelines. Again, I just want to thank staff there, because we all rely on each other.

Regulation and policy, sometimes, often it sort of intertwines, and especially I think with the upcoming presentation from Faye Caldwell, is it's very difficult to tease that out, especially around the emerging issues of marijuana, but this is one of the slides that again, we, as far as policy and/or regulatory oversight of where it actually goes to the pyramid of the donor test results are the most important. I think that also applies, not only in urine program, obviously, but looking forward to oral and/or hair.

Just to reiterate, when it comes to the employer drug testing policy, really federal programs have oversight of all their federally regulated or federal and federally regulated when it comes to the HHS mandatory guidelines, but again, there's a lot of intertwining of state laws, legal issues, testing issues. I think the prevalence testing was, for me, some of the most important thing that, and looking for, is all the other analytes that are out there that we may not necessarily be detecting, and then of course, federal laws.

Some of the DWP objectives, and that's the Division of Workplace Program, objectives and goals, one of the goals is to establish an implementation date for the mandatory guidelines using oral fluid. Establish the proposed final mandatory guidelines on using hair and refer the proposed to the Office of Management and Budget for review. Some of the present things are receive final approval for the mandatory guidelines using oral fluid as an alternate specimen to enhance the federal workplace drug testing program. As I mentioned earlier, I think it's important to have a comprehensive program, or at

least an effective program, especially around invalids of what we've seen, adulteration, substitution products that are out there.

Future issues are referral of the proposed draft hair mandatory guidelines to the Office of Management and Budget for distribution to all federal agencies for comments and review. I think that's important, that we receive all comments and recommendations from other federal agencies.

To reiterate, on the urine mandatory guidelines, the Federal Register was 82 FR 7920, the implementation date was October 1. The most prevalent changes were around the synthetic opioids. We removed MDEA. We also added MDA as an initial testing analyte. We raised the lower cutoff from 3 to 4, which has had an impact on the program when it comes to adulterated specimens. Then there were many wording changes to address alternate specimens when authorized. Again, that carries over to the oral fluid, so it's pretty accessible going back and forth between mandatory guidelines, whether it's urine, oral fluid, and/or hair. We're trying to keep all that information the same in the sections.

Just the drug-testing panel. I showed essentially what we have with opioids. I put in the emerging drugs just as a -- I should have an emerging drugs with question marks, and I think the prevalence data is so informative on what's actually out there in different emerging issues. One of the ones that Captain Eric Welsh identified was in the synthetic cannabinoids, and I think that was one that DEA had seen a while ago and that wasn't identified at the time. Now it is actually being identified, it's not one of the LR compounds or the JWH compounds.

I think those are issues that within our group, Dr. Deborah Galvin looks at emerging issues, not only in the workplace, but we're also trying to look at those under the drug-testing guidelines.

Effective date was October 1, 2017, and DWP continues to follow up with federal agency drug program coordinators that oversee the agency's drug free workplace programs, and that is consistent with the requirements of the mandatory guidelines, specifically around testing for the synthetic opioids. The HHS secretary's priority was to continue around the opioid crisis. This testing for synthetic opioids will help and has deterred illicit drug use of prescription opioids, and provides treatment for employees in federal agencies.

Charlie will speak a little bit about the new federal chain of custody form, the effective date around when in the regulated testing area, and then the use of the previous 2014 CCF was extended until June 1, 2018, but is no longer an approved CCF, and therefore for that reason you would need a memorandum of understanding, MOU -- not MOU -- anyway, you would need that, if you used the 2014 chain in order to process it within one of the HHS-certified labs.

Patrice had mentioned some of the Patients and Communities Act, or some of the regulatory information within that, and that is in Public Law 115-271, and it's coined the Fighting Opioid Abuse in the Transportation Act. It was enacted on October 24. Again, not to reiterate some of these. Some of the things I wanted to bring out was the mandatory guidelines for federal workplace drug testing programs using oral fluid. It gave a date no later than December 31, 2018, which is very fast approaching.

One of the requirements, again, I also put in there, as Patrice did, to the extent practicable and consistent with the objective of testing is to eliminate the risk of positive test results, and that's what I think we've done within the mandatory guidelines, within all mandatory guidelines.

Just to update, again, on the marijuana studies. We just published in JAMA a technical and scientific peer-reviewed journal article from the subject-matter experts as well as other SMEs that have written the article. It's a very good article on vaping, along with all the other studies that we've completed. We continue to update this list of referenced articles. We have quite a few now. Again, a thank you to Dr. Ed Cone and Ryan Vandrey as principal investigators, as well as the other individuals on this study, especially around the cognitive functions of these studies when they look at this. Studies around CBD and data for marijuana analytes are still under review. Again, that's something that we wanted to share as soon as it's available.

Within oral fluid, are we looking at a Federal Register notice in 2018? We're hoping so. Possibly 2019. But we hope to get this out as soon as possible. Inclusion of the oral fluid as a new matrix in the federal program will enhance the drug-free workplace program. We are currently developing the MRO guidance manual for oral fluid, which will accompany the MRO guidance manual for urine. The oral fluid collection procedures and collection manuals, we're currently working on those. And developing the NLCP program documents outside of the actual public documents that you see here.

Within the oral fluid mandatory guidelines, again, laboratories could use an alternate method, other than immunoassay, for initial test. Again, I'm a believer that let the technology lead you, not necessarily you lead the technology. So within the mandatory guidelines we've tried to open that up so that technology can lead, not necessarily just around immunoassay, but also other alternative testing instrumentation. Testing for parent drugs, specifically THC, the psychoactive component of cannabis, we know that it's very important for other uses including driving under the influence of drugs, which, again, there are several pilot studies around the United States going on right now.

The primary one that I'm familiar with is the one in Michigan, at testing at the roadside using oral fluids, so I think that's going to be important, especially going forward. Then establish an implementation date for the HHS certification of laboratories, specifically around oral fluid.

Under the hair mandatory guidelines, as mentioned in my opening remarks, an internal draft of the proposed mandatory guidelines for federal workplace drug testing using hair has been developed. Unique metabolites continue to be studied, as was mentioned. We've had presentations here within DTAB of the effectiveness of the decontamination procedures are also being studied. Comments and recommendations have been received from HHS operational divisions within HHS, so, again, we're looking at all those comments and recommendations. The scientific and technical issues are being addressed through literature or have been addressed through literature, or specific studies that we've looked at going forward in the future. Other issues will be addressed, we hope through public comment or questions that we've proposed in the preamble.

Again, the proposed mandatory guidelines using hair, the DTAB recommendation from two years ago was one, to look at the decontamination of hair specimen, and secondly, hair color impact. I wanted to bring this out, because that was part of the DTAB recommendation. As recommended by DTAB, the development of the proposed mandatory guidelines using hair has attempted to address the specific scientific issues for the use of hair as a drug-testing specimen. Again, we're receiving comments now, so we're looking at those comments. The proposed mandatory guidelines using hair is currently under review based on the recommendations and comments that we've received.

As far as a status report on the hair testing, one of the -- within the Patients and Communities Act -- it does state that it requires the secretary of HHS to report to Congress on the status of the final notice of the statutory requirement, both the scientific and technical guidelines for hair testing, within 60 days. Again, we've been looking at this as what to report to Congress when this timeframe comes up.

Some of the advantages, I think we all are aware of with hair testing is it's a directly observed specimen collection, not unlike oral fluid, which is a directly observed specimen collection. But unlike hair, which is not necessarily a direct observed collection in most cases. It is noninvasive, in most cases, I think. With specimen collection it is difficult to adulterate or substitute, and it's readily available, depending on the length of hair, of course. With me that is also an issue, and also with Eric. Also, the drug metabolites are present in the hair as early as one week after most recent use. You have to look at the type of testing, would post-accident, reasonable suspicion, et cetera, be one of those testings you would want to do? Not necessarily with hair. But if you have an effective program and you have all matrices, it does make a difference, having urine, oral fluid, and/or hair.

With that, this is just a routing process that I've shown before. Essentially we are at the end of the routing process, as you can see, if you could see that. It is a pretty lengthy process. The proposed hair mandatory guidelines is relatively in the beginning of this process. The oral fluid is really at the end of this process. Again, we hope to move those along as quickly as possible.

MRO guidance manual, as I mentioned, we had some updates to those. We had some updates to the case studies. We sort of looked at specifically addressing the addition of the prescription opioids. We looked at it in length. That has now been posted, the changes, 2.0. We looked at some additional case studies that we're going to update here shortly, so those will go in. Again, we'll notify the industry of those, specifically MROs, when those happen.

As mentioned before, fentanyl is one which requires the secretary of HHS to determine within 180 days, is it pertinent to include fentanyl in the drug testing program, specifically the federal drug testing program? Again, we have to look at those, as far as prevalence. Is there enough to determine that it would be beneficial to include fentanyl in the program?

Ongoing studies, as mentioned, we have the cannabidiol, or the CBD study, that started I believe it was June of 2018. Again, we finished up most of that, looking at the data now. It is a pharmacokinetics and pharmacodynamics study. Specifically around oral, what we looked at is smoked, CBD vaped, et cetera. Again, disposition of CBD or cannabinoids in oral fluid and whole blood after vaporization, along with a pharmacodynamic comparison of CBD and cannabinoid following oral, smoked, and vaped administration. I think that's all three.

We're continuing to gather opioid data, which Marquita will be giving a presentation after this on what we've established as far as with urine, when it comes to the data around pH changes, invalid results, and substitution and adulteration.

As mentioned in my opening remarks, Epidiolex. This is fundamentally -- I'm not going to steal, because Faye's going to give I think a more extensive presentation on this -- but it is the one where I think there's a little bit of confusion because FDA rescheduled this as a schedule 5. CBD products in general are still schedule 1. I guess, as we were discussing, it is sort of a buyer-beware, because of the contamination potential of the CBD oils that are out there on the market. Again, we've put out information to federal agencies, please be careful when it comes to CBD products, because there could be some contamination potential within those products because they are made from the plant products.

Then again, emerging issues, primarily one is the synthetic marijuana, which was discussed earlier. The DUID and marijuana laws that are being, that are going on the books as states move forward with their own laws around marijuana and decriminalization. The CBD studies that we've looked at with marijuana emerging issues, and I think that really we have a pretty robust cadre of different things that we've done with studies around marijuana, and this really is finishing up some of the last ones, I feel, that we really needed to do as a program.

Other potential problems with synthetic drugs and the lack of rapid and cost-effective means of identifying the substance. I think that's a big issue within the laboratories, makes it more difficult. I think that also applies a little bit to fentanyl, although we have

some screening assays out there. The cutoff seems to not really be established as one standard cutoff, so it's something that we'll have to look at.

With that I'm going to turn it over to Charles, who will talk.

Agenda Item: Updates on Electronic Chain of Custody and Standard Variables, DWP Staff

MR. LO DICO: This next few slides that I will present is concerning electronic federal custody and control forms. For a recap, for those people that might not be aware, the ECCF has been approved by OMB since the summer of 2014. Even though we have 26 labs that are certified currently, as you can see, this is a table that indicates how many labs are actually approved by NLCP to have ECCF services provided to the collection site and to their client. What I've done is I've broken them down into the laboratory category. For those who might not be aware, laboratories are categorized as category 1, or actually zero, to 6. So depending on the volume of work you do, that's how you get your categorized number.

To the next column is the percentage of that particular lab that does in terms of total ECCFs, and you can see that there are three types of services, software packages. There's a FormFox. There's a eScreen. And then there's a LabCorp. And you can also see that in certain laboratories, the software is multiple. You might have a lab that has both a FormFox and a LabCorp system in place. Again, what I'm trying to share here is that the laboratory is not uniformly dedicated to one system, but it could be multisystem.

This is a very hard table to look at, but the most important thing is that at the bottom line of this table are two important numbers. In terms of the 12 laboratories that have validated ECCF systems, the total number of samples that they do annually is 5.2 million. The number of that 5.2 million that is translated into electronic custody and control forms is 919,000, which represent only 17 percent. Those 12 laboratories have an 83 percent total market share.

So when we're looking at trying to speed up the clearinghouses and the ASR, it all starts with capturing electronic data, and if the laboratories did not fulfill their part of the technology revolution, then it becomes very undoable on our part to complete what has been tasked by Congress. That's one of the things that I wanted to share with everybody here.

This is another way of looking at this, in terms of, as I said, we started -- the OMB-approved ECCF in the summer of 2014. The first year, in 2015, the total system of the laboratories only did about 3,000 ECCFs. In 2016 it ramped up to 110,000, in 2017 it ramped up to 400,000, and in 2018, as of August of 2018, only 730,000 ECCFs have been performed in the total laboratory system.

I think what I'm trying to reiterate here is that the system is in place, and right now the laboratories are underutilizing the ability of converting their paper forms into electronic forms. I might add that the OMB-approved ECCF has an expiration date. It expires every three years. The next expiration date for this current ECCF is in 2020, and at that point we need to reassess and reevaluate whether paper forms are still allowable in terms of trying to achieve our goal, which is to capture the data that is given by the electronic format.

Which goes to the next questions regarding what is an approved ECCF. The approved ECCF, by definition, requires that the use of federal ECCF are in the NLCP manual in the urine laboratories and urine IITFs. The definition is that the system is inclusive in the ECCF form. The form itself is only part of the completion of that laboratory use. So one of the things in 2014 that was critical that OMB must and agreed to, or allow us to use an ECCF, is that the system has a security element component so that the privacy information that the donor provides in completing that ECCF has been maintained and the security element is non-compromised. Therefore, when a laboratory is approved to use an ECCF, it also includes that system, which we review it, and inspect the components of their security elements.

Here is an example of what came to our attention most recently, where a system was an unapproved ECCF, and this was only discovered by chance when an MRO called in questioning some of the result. From this particular example, we see that there are sections in part 2 and part 4 where that information has been pre-included, or is pre-marked, before the form has ever even been printed, and the reason why we can say that is because there is a date and stamp time there that was duplicate to the one from the error ECCF.

Once we saw that, we contacted the laboratory, and the laboratory explained that this is not part of their system. Therefore, that collection site was using an unauthorized system, where they generated the ECCF and then submitted them to the laboratory. What happened from that point on is that we had to send out NLCP alerts to the laboratory warning them and giving them guidance on how to identify their system as either being part of their system, or whether these are like rogue collection sites that pulled out software. Again, the system, which includes the security of capturing that information, has not been validated.

That brings up to the next topic, which is standard variables. Again, back in February 6, 2018, we sent out an alert to laboratories regarding standard variables, and it really reflected on one particular issue where the electronic reporting indicated -- could not differentiate between a scientific technician versus a certifying scientist. In our guidelines they're very different roles, so what we sent out an alert was really to make the laboratories be aware that we need to have standard terminology that reflects the action of that particular individual, whether it be a certifying technician versus a certifying scientist. Which then led us to the next phase.

Then we started talking about electronic reporting. We followed it up in August, where we decided that we need to do standardization of variables, and these variables are such information that would be found in an electronic report. What we did was, we contacted, and Dr. Barry Sample at Quest Laboratories, and he agreed to be a chair of the working group, and from that working group what we're trying to do is to create standard variables that would be adopted and be uniform across all the laboratories. We're going to be asking what is a standard variable? How do standard variables cross between matrices, such as oral fluid, urine, and hair? What standard variables are

going to be captured on the federal custody and control form? How does this benefit the HHS-certified laboratories and reporting methods?

The first two that come to mind is the ASR, which is the annual survey report that we capture from the federal program, but also the clearinghouse database that is going to be needed by the Department of Transportation for their purposes. And lastly, how does this benefit the regulatory industry in reporting standard information? Again, the clearinghouse comes to mind as an indicator. Plus, what DoD had indicated is that they would like to see some sort of information-sharing among their group. Again, if we create a standardized uniform reporting system, then that goes to the heart of it being used across many platforms.

Some of these standard variables that are listed here are probably taken, borrowed, from Quest Laboratories, and these have been offered to us as examples. This standard variable table right here really reflects some of the fields and some of the descriptions, and I won't go through any of these, but you see that they really are very varied and specific to what should be captured. This is only focused on the specimen. This is one of the standard variables.

The next standard variable, as you can see, is this table is focused on the employer.

Then this one is a standard variable that is focused on the collection site and the collectors.

And the next table is just the lab's variables. Again, it just addresses a lot of the fields that are probably have to be captured. If it's not captured, how valuable is that information?

The last one is focused on the MRO, and then the specimen ID. This next one is on the reporting analytes.

This brings us to the next two tables. The next two tables is again is an effort to begin with something that is uniform. These are some of the standardization of analytes. Specifically this table looks at the analytes across all specimens. You can see there's a column for the urine, there's a column for oral fluid, and there's a column for hair, and then you see the far right is the abbreviations of those particular analytes. Again, this is the type of redundancy of information that we want all the laboratories to understand is the accepted and proper designation.

The next table is now just focused on standardization of analytes for just oral fluid and hair, which are the two new matrices. That ends my presentation. Really, again, the focus of this short discussion was to just give you sort of what direction the NLCP and DWP and RTI are going forward in trying to capture information. We're collecting the data regarding the usage of the ECCF among all the laboratories, and as I said, it's in my belief it's underutilized, and we need to somehow get the laboratories to buy in that this is very important. If they're not going to buy in on a voluntary basis, then in 2020, when the ECCF goes up for renewal through OMB process, there might be a

suggestion that it has to be an ECCF. But that's just my suggestion, not just something that I would recommend.

That's it, thank you. Are there any questions?

MS. KELLY: This is Patrice Kelly, from DOT, just to add to what Charles is saying. We fully support the idea of fully electronic chain of custody form. In DOT, as I mentioned during my presentation, we will always contemplate some degree of paper forms, because there are certain collections that occur in places where there is no internet. For the reasonably foreseeable future, for example, pipelines out in an oil field somewhere. Out on an oil platform in the Gulf. Those are places where we don't necessarily have internet reception. There'll still be an allowance for that on the DOT side, but I completely understand the rationale for why HHS wants to go in that direction, and we applaud it.

MR. DO LICO: Thank you, Patrice. Like I said, the thing that I want the board to understand and to have the impression is that when we were all demanding the use of an electronic CCF, it was probably felt like it was going to happen with the total embracement and total usage, and what I've come to find out is it's a very slow, methodical process, and again, if we want to have both the ASR and the clearinghouse be effective and be efficient, then it has to be through the use of an electronic custody and control form, and a reporting format that is going to be uniform across all the laboratories, so that data field, that data mine, is not going to be ambiguous.

CAPT BELOUIN: Just to remind everybody, people listening in are having a really difficult time hearing, so try to speak in as close to the mike as you possibly can.

MR. FLEGEL: Thank you, Charles, for that. I think it is important to note we're trying to move this forward. I know within laboratories, as we bring on other matrices, we don't want to complicate the problem, so we want to start looking at it now, so as IT changes occur in the future, those IT changes can occur across the band of different matrices. Again, depending on analyte you test or analyte you report, and also to add to what Charlie had there as examples, when you also look at the confirmation or quantitative levels, there's other additional fields that are variables that are reporting. We're trying to establish it right up front, and I want to thank Dr. Barry Sample, who is now online, for leading this charge within the working group of what we'll try to get going.

Agenda Item: Opioids and pH

MR. FLEGEL: Also, I wanted to -- Marquita, are you online? What we had planned to do is putting this presentation within DWP's. It's just an update on what DTAB had originally seen before on really where we are with the opioids, adulterations, et cetera.

Marquita, if you want to go ahead.

(No response.)

MR. FLEGEL: I am going to go through and just sort of update the board members, the public, as to where we are with the opioids and what we see specifically around opioids. It's the synthetics as well as pH. Marquita, if you come on, if you could just let me know.

Just to reiterate, the effective date was October 2017, and again, we've had about 13 months of now testing and updating the opioids.

The revised mandatory guidelines, as reiterated in our presentation, the biggest two things were around the synthetic opioids and also changing the pH level from 3 to 4 for identifying specimens as adulterated. The revised pH cutoffs for federal agency specimens and DOT-regulated specimens were captured in here. We discontinued testing federal agency specimens for MDEA. For DOT that was continued for a certain period of time. We delayed testing for federal agency specimens for the added opioids until the effective date, which was October 1. DOT federally regulated specimens came on on January 1, 2018.

Some federal agencies, as we identified, and that's why we are following up with federal agencies as we've moved forward in the last 13 months to see if federal agency, again, the proposed or the --

MS. BROGDON: This is Marquita. Can you hear me?

CAPT BELOUIN: Yes, we can hear you. Do you want to take over?

MS. BROGDON: Sure. I apologize for that, technical difficulties. As Ron was saying, I'm Marquita Brogdon, and I'm from the National Laboratory Certification Program. This here is a brief update for the opioids and pH presentation that was actually given during the Drug Testing and Advisory Board meeting held this past March. I'll pick up with the slide Ron was on.

As you guys know, the revised guidelines went into effect on October 1. We already know that DOT revised part 40 on November 13 and implemented testing for the four additional opioids as well as removed MDEA from its drug testing panel, which became effective January 1 of this year. Also, on the October 1 implementation date of the revised guidelines, some federal agencies were not prepared to add those additional analytes, and they were instructed by the Substance Abuse and Mental Health Services Administration to notify their service providers of the date that they will begin testing their workplace specimens for these drugs.

Right now, even at this time, more than a year later after implementation, it is actually still possible that all federal agencies still have not implemented testing for the added opioids.

Here we looked at the number of non-negative results, that is, results including those specimens reported drug positive, adulterated, substituted, and/or invalid, that we've seen since 2014. Many of you have seen this graph before. You can see that the number of non-negative results had remained pretty consistent month by month over this time period.

Though, with the implementation of the revised guidelines you can kind of see the noticeable gap that started beginning between the fourth quarter of 2017 and all the other years represented here, and you can see how beginning in October and then becoming more pronounced in November and December, the brown line representing 2017 deviates from what had been typical of past years. We know that has been due in part to the addition of the semisynthetic opioids.

The blue line represents the first several months of this year as compared to the same time in previous years. The gap between years -- the gap between the lines on the graph -- for monthly comparison has definitely been much more pronounced for all of 2018 thus far. Again, the difference has been due in part to the addition of the semisynthetic opioids, along with DOT January 1, 2018 implementation of the added opioids to its drug testing panel.

With regard to the revised guidelines, I'll now focus on and give an update on the opioids. Here we have the drug positivity rate by drug class for January to October of this year. Again, I'm beginning with January of this year, for it wasn't until this time that DOT, which conducts the majority of federally regulated drug testing, began testing for the four additional opioids. As stated previously, even at this time, all federal agencies have not begun testing for the additional analytes. Therefore our N value for those specimens tested for these opioids so far in 2018 is approximately 5.29 million, which actually only deviates from the total regulated testing by about 3 percent.

Hydrocodone/hydromorphone and oxycodone/oxymorphone have seen positivity rates at levels only behind THCA and amphetamines, and what we've seen so far, that as a percent of those specimens tested, hydrocodone/hydromorphone and oxycodone/oxymorphone have a .513 percent and .363 positive rate respectively.

Here we have the monthly breakdown for this year, January to October, between hydrocodone/hydromorphone and oxycodone/oxymorphone. It appears that we're seeing more specimens reported positive by the labs for hydrocodone/hydromorphone as compared to its oxy counterparts for each month of the year, though their positivity does appear to be moderately positively correlated right now. As you can see on the chart, it just breaks down the monthly positive as a percent of total tested for each of the two categories, between hydrocodone and oxycodone.

Moving on, I also want to give an update on how the revised pH cutoff has impacted MRO reports for adulterated specimens. Prior to October 1 of last year, specimens with a pH between 3 and 4 were included in the invalid range, though the revised guidelines, it raised the lower pH cutoff to 4 for specimens reported adulterated due to pH. So we just want to look at how this revision impacted the number of specimens that have been reported adulterated over the past year.

On average, we've seen about 23 additional specimens per month with a pH between 3 and 4 that has been reported adulterated since the October 1 implementation date, as represented by the red numbers in the chart. Without revisions to the guidelines regarding the lower pH cutoff, if you focus on October and November of 2017, we would have only seen 82 and 96 specimens reported adulterated due to pH as opposed to the 106 and 119 that were actually reported, as now mandated by the revised guidelines.

I will also use this chart, though, to point out the significant drop in the number of specimens being reported adulterated overall. This, I believe, was also a result of DOT's revisions to Part 40, which became effective January 1, 2018, where employers and/or third party administrators are no longer required to submit blind specimens to laboratories. So that, in and of itself, removed a lot of the adulterated specimens that we were seeing. What we've seen this year is that by raising the pH cutoff to report adulterated specimens, those reports have basically doubled what we would have seen prior to the revised guidelines.

Essentially, a specimen with a pH greater than or equal to 3 and less than 4 is no longer being reported as invalid but rather adulterated, and for specimens reported as adulterated, if there is no legitimate medical explanation, the MRO now reports a refusal to test to the federal agency, which may have adverse consequences for the donor.

Again, just to recap, the revised mandatory guidelines went into effect October 1, 2017. As per Ron, again, and you guys have heard several times before, the revisions added hydrocodone/hydromorphone, oxycodone/oxymorphone to the federally regulated drug testing panel. It raised the lower pH cutoff, removed MDEA, and revised MRO requalification requirements. It's been over a year, and we feel that revision to the pH cutoff has helped to detect more donors trying to subvert the drug test, while the overall effects of adding the four opioids is somewhat still to be determined, though it appears that their addition to the drug testing panel has generated an approximate 1 percent increase in the laboratory reported drug positive results. I will reiterate that these are the laboratory reported and not MRO verified results.

And this 1 percent increase is roughly a 50 percent increase in drug positive reporting. Although it can be assumed that many of these lab reported drug positives for the added opioids may be overturned by the MRO due to valid donor prescriptions, prevention of prescription drug abuse is still paramount and the NLCP will continue to monitor.

I also will make note here that all information presented here is provided by RTI through the NLCP contract. RTI only provides information and makes recommendations to the Division of Workplace Programs under SAMHSA and SAMHSA is the entity that will make the final decision for any and all actions taken.

And that's it.

CAPT BELOUIN: Thank you, Marquita.

Next up for our last presentation will be by Faye Caldwell on emerging issues with marijuana legalization.

Agenda Item: Emerging Issues with Marijuana Legalization, Ms. Faye Caldwell

MS. CALDWELL: Thank you all. Probably the biggest question I am asked sort of every day, day in and day out, is what's going on with marijuana. So we are going to give a brief overview. Ron has asked me to sort of do it.

This is my disclaimer. Yes, I'm a lawyer. Don't hold it against me. I'll try to make it palatable. But this is not legal advice. My malpractice carriers make us say these sorts of things.

I know these slides are going to be very dense. Those of you that are with Adobe Connect I know can probably see it better. The first question, and this is a little bit of for me and for the other lawyers in the room a trip down memory lane of what is the law, and I'm going to start very much, because we hear about marijuana is illegal federally. Marijuana is not illegal in some states. Let me break that down, because it will provide some context of why differences.

What that means when something is a schedule I drug, which is what we talk about is that you can face -- it's a crime; it's a crime to have marijuana under federal law. That's federal law. We also have in this country state law. So sometimes we have federal law and state law for the same event. So let's use cocaine as an example to stay in our bailiwick.

You can be charged for federally, by the federal government, for cocaine possession. You can also under a completely different set of law be charged under an individual state's law. So when we're talking about what is illegal, we're talking does the federal government call it illegal? Does an individual state call it illegal? And we are talking about criminal penalties here.

So I promise I'll get off of this. The first issue is certain crimes are only federal. You can't be charged in your state. The most obvious example of that is treason. Treason is a federal crime. You can't ever be charged under a state for treason. In the same way under a state law, typically driving infractions and crimes are state laws, and there's comparable federal law. When it comes to drugs, historically there have been both, with different penalties and different amounts. This diverges when we talk about marijuana.

So, what I'm talking about federally, and we have heard a lot of talk about that marijuana remains illegal federally. So a federal law enforcement can arrest an individual for possession of marijuana. When states talk about medical marijuana or recreational marijuana, what they have basically done is make it so that at the state level under certain circumstances, it's no longer a crime for which you can be charged in the state. So a state patrol officer can't arrest you under certain circumstances.

So we have two schemes going on here, and we are going to intersect them, but keep that in mind: treason and car accidents. Two different systems.

Okay. Back to marijuana. We are going to get to sort of what's happening at the federal level, although I have a lot of subject matter experts sitting in this room, but let's talk about what states have done. As of last week, and I make no representation about today -- it changes almost every day -- 33 states plus D.C. plus two U.S. territories have passed what I'm going to call comprehensive medical marijuana laws. The laws vary widely, and we're going to talk about that. There's no uniformity here, unlike a federal law. Every state can do it their own way.

Thirteen other states have passed what we're going to call low THC high CBD laws. So that adds up, because every state that has a comprehensive medical marijuana, they may or may not have a CBD, but it's covered. So that means 46 states have some sort of either medical marijuana or CBD. Ten states, plus D.C., plus one U.S. territory, Commonwealth of the Northern Marianas Islands, if you're interested, have recreational marijuana where they have now not decriminalized it, a state hasn't decriminalized it, just for medical purposes, but in general for all purposes.

Now are there still limits on how much marijuana you can have in your possession? Absolutely. Just like under alcohol. Believe it or not, there are limits on how much alcohol an individual might be able to possess versus having a distributor's license. So there are limits.

That leaves four states at this moment which prohibit marijuana in all forms. Idaho, Kansas, Nebraska, and South Dakota have nothing.

So that's the overview of what we are going to talk about. Now, the laws are dramatically different, and that's what we are going to get into. Additionally, just so you know, our neighbors to the south in Mexico, they have a medical marijuana law that passed, and most people who know that north of us there is not only been a longstanding medical marijuana law, but they recently passed recreational. Okay.

I have now been trusted to forward the slides. Don't trust me. You're making a big mistake.

(Laughter.)

Okay, so here are the states. The ones in red are the ones that passed in 2018, 33 states plus D.C. You're going to see -- I have the dates on it, when you guys get this, and I understand they'll be made available, and you're going to see that if you get some trends down of how it happened, there's some very longstanding ones, basically on the west coast in the late 1990s, going up to literally last month.

They're inconsistent. No two laws are the same. Program requirements are different. Physician requirements. Qualifying conditions. Reciprocity. Lots of things that are different. Possession limits. Distribution, potency, method of ingestion, protections, which we'll talk about quite a bit, workplace protections and other civil protections.

So the fact that they have something, don't assume that you can assume what happens in Colorado is anything similar to what happens in Arkansas. They're just not.

We have ten states with recreational marijuana law. These have all been relatively new. All of these states also have comprehensive medical marijuana laws. Now, one of the biggest questions I get is why do you need medical marijuana if you have recreational marijuana? Well, a couple of differences. Possession amounts can vary, but probably one of the largest ones I see is the taxation rates can massively vary between them. So there are some reasons of why in all of these states medical marijuana law is alive and well in the ten recreational states. They are different schemes.

Sort of politically, if you're interested; almost all of them were passed by voter initiative, with the exception of Vermont, which passed by legislation. But there's also very differences

We're going to come to each of these, but the next is the low THC high CBD laws, which I guarantee you is going to be difficult to read on this, but what's important about it is each of these laws not only have different qualifying conditions for how much, but most importantly, how much by percentage of THC is allowed in the state. Not at all the same.

So many states are less than or equal to 0.3 percent. A lot of them are 0.5 percent, by percentage of volume. But you can go up to Georgia or Virginia, you can have 5 percent of it be THC. So they are massively different as far as potency of what you're buying or what -- more importantly is probably what is authorized by a state, and it varies all over the board.

I will leave it to the scientists to tell us whether you test positive, because that's the next question, at these levels, and obviously as Dr. Cone and I had a discussion earlier, it kind of depends not only of the percentage, but how much you ingest. So that's not the purpose of this.

Florida passed, Missouri, and Utah are all in these categories. So these would be examples -- and you're not going to see them on this list, because they in 2018 passed and now have medical marijuana. So just because it doesn't eliminate it, there is more.

Here's a map for you. You're going to see a little hole in the center of the country. That's where three of the four states that are in white. But all of them form a patchwork of what's allowed. Again, we're going to get over here and we're going to take it to the individual, but that sort of sets the stage for some of what are going to be fairly surprising to you some of the requirements in each state. Everyone always thinks California is the most liberal. Not at all. Probably one of the most rock solid for the employers. Don't go to Oklahoma. Different story.

But this is very, very active. In 2018, last month, plus Oklahoma was earlier, we had three additional states come up with medical marijuana. Interestingly, it was introduced

in another 12. Now what does this mean? It means it is also typical. We have been watching this for a couple of years, and they typically it fails in state legislatures, and gains some traction, and then tends to improve. That is the trend. Obviously some states still haven't passed. So we'll see what happens.

Recreational marijuana has passed in two states, one U.S. territory, Vermont, Michigan, Northern Marianas Islands, all started in 2018. Introduced in additional 20 states. Okay? Right now, most people are sort of looking at New York and New Jersey as the most likely ones, but my crystal ball doesn't work very well. So that's just sort of what talk is. But it's not there yet.

Some of them -- and you are going to see in states -- that they have outstanding -- maybe they didn't pass, but we have nonbinding referendums or advisory committees going on. Lots of them get working groups going on. So over time, at any moment, you could be talking about a state, and each one of them is on a different method of where it's at.

Now, so that's the overview of the states, and now we're going to come to what is federal law? Remember, treason and car accidents. Nothing I've just talked about changes anything about the fact that marijuana remains illegal under federal law. You can be charged with a crime, and that's what it means. We often talk in terms of testing positive in drugs, but fundamentally these are criminal statutes, and as you heard both Patrice and Ron talk about, it is the fact that someone has a medical marijuana card or they're in a state that has it, we heard from the Department of Defense getting lots of questions, none of that changes anything about the fact that it is federally illegal. But immense amount of confusion and most people think -- I'll tell you, donors that if it's legal in my state, then it's okay by me. They have no concept of federal law being preemptive, and we're going to talk about that when it gets to it. We talked a little bit about the fact that we have our first CBD product, again for severe childhood epilepsy. Obviously brand-new stuff out there.

What else is happening in the federal law, and there are some trends. I'm not here to tell you where it's going. I'm here to tell you these are things that my law firm tracks. The question always comes, and this is the craziness of our system right now, or the discrepancy, because the question is how are we out there assigning medical marijuana in Arkansas when it's a crime under federal law? How does that work? Why do we have systems that do all that?

Simple answer. Economics and enforcement. Is it legally possible for the federal government, a federal agent to go in and arrest someone who has a medical marijuana card? Absolutely. Now let's talk about will they? Absolutely not. There is something currently called the Rohrabacher Blumenauer rider, it's now an amendment. What is that all about?

For years now, budget controls whether or not the Department of Justice at the federal level can go out and arrest people for having marijuana if it would be legal under their

own state law. There is zero money given to that, and there are court decisions that say, since you can't spend any money of it, we can't hold a trial about that. So this is absolutely federal inaction, not acting, to support what is currently on the books. How does this work and what does that mean? It's a never-ending world, because this amendment travels with the federal budget.

How long do we have right now before this expires? I do not know if the President has yet signed a two-week extension before we're going to shut down the government. But assuming he has not signed it yet, that would be this Friday.

Every single time, theoretically, this could not go forward in the budget, and our world would change. I am not here to tell you whether it will or whether it won't. I am here to tell you that is the situation. I can tell you that we have had many, many budget extensions, and it has always gone forward.

Additionally, and this is always sort of what are you going -- what's the agenda, what's going to be pushed, as compared to the law? We don't really know what's going to happen. We do know public statements made by many senators from marijuana states that derive significant revenue have asked that it not be enforced, but I have no information that it won't.

There are currently right now more than a dozen bills that have been introduced regarding marijuana. I'll give you some examples. Proposed legislation. I have no opinion about where it goes. There is currently some public statements about it, about, again, whether they allow it for certain purposes, whether they reschedule it. I don't have insight on that. Right now I can tell you it remains federally illegal, with a lot of talk, sort of is the summary of what I have, and anyone can look at that. So that is the trend at the federal government. It's not that the laws really has changed. It's that they're not acting on the current law when it comes to -- as far as criminal enforcement. I'm certainly not talking about the DOT or HHS drug testing programs. I'm talking about criminal enforcement.

So that's the dichotomy, because remember, we have what's called preemption. Back to law school 101. Federal law trumps state law, as long as the federal law, they want to do something. So it's not -- it exists in this odd world, which is at least in my law school career, this is the only one I've seen this much of this go on. It's quite a unique circumstance in the history of my understanding of federal preemption, and I kind of do it all the time. It's quite unique.

So that's the trend at the federal government. So let's do some trends, and then we'll dive deep into this. What are the trends? What are we seeing? What can you sort of, if you read the tea leaves, think about?

The trends -- and this is important in our safety world and safety-sensitive world, again, nonfederal testing -- is states are moving towards providing explicit employment protections. We are going to go through some of those antidiscrimination positive drug

test language, we'll explain what those mean. Providing other protections. What does that look like? Housing? Custody. So for example, if you have a medical marijuana card in many states, and you're in a custody dispute, that can't be used against you by a judge. Things like that.

Medical care. You can't be discriminated against. They can't say you're not going to get your liver transplant because you're a medical marijuana card holder. These are all sorts of protections that come up.

Other sorts of things are program expansion, increasing access, easing restrictions. These are the trends, both with current ones that then institute new regulation or legislation, and also old programs that look to change the law to make it easier. Qualifying conditions, we're going to talk about this, many interesting changes in the life of the opioids in this country, what's happening with this. Adding conditions, PTSD is adding. Veterans are a big push to add that in many states. Who can recommend it? It is not a prescription. Prescriptions are those drugs that are regulated by the federal government. It is a recommendation. And other program requirements.

So that's the trends in medical marijuana. What are the trends in sort of state recreational marijuana? So first off, first off, as I said before, if you have recreational, you're going to have a medical marijuana that's probably predated it. There's only one territory that does not have a comprehensive medical marijuana that allows recreational.

Frequently, they are different. Possession limits, potency, taxes. Impairment, driving under the influence, how does that look? Most states prohibit driving under the influence or being impaired, but very, very little guidance. At the very end of this, we'll show you which states have some per se limits in blood. But no consensus. You're going to see them all over the board.

The current trend on recreational, unlike medical, is to provide no employment protection. One state -- it's wide open for discussion -- may provide employment protection for off-duty use. I will tell you that state is Maine. The reason I'm a little hesitant on this, it was in the law and it seems to imply it. The Department of Labor took it off their website. That's going to take some court interpretation. You're going to hear me say that a lot today about we're waiting for guidance from the courts, Maine being the one where it passed February of this year, that we have some issues of what does that mean and where are we going to go? Currently, I'm unaware of any lawsuit where an employee has challenged that for an employer.

Some of the new ones that passed last month, it's just unclear. We'll go through those.

So what type of laws, and we talk about -- I'm going to focus now on employment, because particularly in the safety sensitive world, that's the real key. Looking at the state marijuana law is not enough. We're starting to get some case law. How is law made? Back to law school 101. Legislatures pass laws, statutes we call them. Regulators make regulations. That's law. And judges make case law.

That performs generally the bolus of information that you're going to have to take into account. How this happens, in almost every area of developing law, drug testing was an excellent example 25 years or 30 years ago, of judges sorted out what was constitutional, what wasn't, after the regulators and after the legislatures did their part. That still goes on today.

You're going to hear that 2017 was a watershed moment where we started to get more, but we don't have a lot. But it's not everything. So we have the state medical marijuana laws. So we'll go through them, and they're remarkably vague at times. But that's not the only state law that matters, and I put down here some of the ones that may impact. Workers comp. Does workers compensation insurance have to pay for medical marijuana? I can tell you in New Mexico they do. Lawful activities, if you use marijuana off duty and are not impaired, what does the state law say about that? It's called off duty use laws having to do with -- typically it's nicotine, where can you smoke, can an employer fire you for smoking a cigarette when you're not at work? Everyone agrees you can control the workplace. Some states they can't. Yet the ADA and FMLA, which have not really been impacted, because federal law hasn't changed, but state disability and discrimination laws are making some high cases of what it is.

And other drug, there could be other drug testing laws. So this is just an example of sort of all of the things you have to look at. It is not enough to look at what we have got. So employment protections really fall in three categories. I'm trying to sort of put these into buckets, because it's easier. One is 13 of the 33 states have explicit statutory employment protections. This is definitely the trend for the newer states. Ten of these 13 have come out since 2010, and they have antidiscrimination provisions. Now, the laws vary, and the extent of protections are not clear, but they're in the, yeah, something is protected there. The question is how much.

Seven states have no employment protection. Either the law is explicit, but the state supreme court has found no protection. So if you're in California, which we typically think of as very progressive, I can tell you at this moment in time, there's absolutely zero employment protection in California for medical marijuana or recreational usage. Footnote, California is busy trying to change that law, and there are some other states that have had. But until today, and for those historians in the group, the reason is it was the first one to go with medical marijuana, and they were much more interested in having it decriminalized than worrying about employees.

Then there's another 13 states and D.C. that don't know. No cases, they are silent or it is vague, a court has found possible protections but it's not the top court. Some states have department of labor rules. So there may be some addition, but it's not really clear. We can get you if you want them states that actually have all these, but this is a summary of what they are. We are going to end up talking about the explicit ones and sort of talking about how they vary, but that's how they fall out right now.

So let's talk a little bit about explicit protections, and these are ones that we want to look at, but they have what's called positive drug test language. As we all know, a positive workplace test, and I'm really talking about urine, oral fluid, or hair, are not going to give definitive impairment. There's no evidence by having a positive test or a test for metabolites that in fact that person was impaired at the time the specimen was collected, and they put that into statutes saying they cannot -- the employer can't discriminate based on a patient's positive drug test for marijuana components or metabolites.

Four states currently have that, and two want to add it. Some states treat it as a disability. So if you're in Nevada or New York, it's treated as a disability and you're going to go at least like in Nevada, you're going to go through an ADA analysis of can you reasonably accommodate it. Two states, interestingly, have safety sensitive positions that actually have per se limits in blood, which is obviously not a typical workplace matrix, but it very much varies.

Getting more into it, employers can vary, may have to have them and here's the one exception. So don't think it's completely the wild, wild west, but science may think it is, is none of the states do you have to -- does an employer have to allow the use of marijuana in the workplace or have them work while impaired. That is a universal. So we're really talking about -- here, when I'm talking about explicit protections, I'm talking about off-duty use of marijuana. Nobody has to allow it in the workplace. Now, of course the difficulty is determining impairment. That is really the sticky point at this moment of what would be an impairment standard. We don't have anything yet.

But generally, as lawsuits come up in the context of somebody has tested positive on a drug test or has disclosed to their employer or potential employer that that they have a medical marijuana card or they use marijuana, and some adverse action has happened.

The next category is explicitly no protection. It might surprise you. California, Colorado, Florida, Montana, Ohio, Oregon, and Washington. A lot of these, as you point out, as you'll notice are states that have fairly old medical marijuana standards, and these are generally supreme court decisions that over the years have found that there is no duty to accommodate off-duty medical use.

Some states have moved to change that. Nevada changed it in 2014. California, Oregon, and Washington have all made some attempts. None have passed at this stage, but that is a likely trend in the addition with states that have recently gone to medical marijuana, of states that have historical medical marijuana laws of changing the legislation to add it. I think that is a trend, and it's likely to continue. But that will make a difference when it comes to that.

Probably the most difficult one for employers is what I'm going to call the maybe category. We have analyzed that 13 states at this point, either they just don't address it, which also means they have no case law, no one has sued over it and gone to a final decision on it, but there's troubling things. So example in Maine, the supreme court has

found possible protections under other state law, disability law. Some states have issued guidance documents, a New Jersey or Vermont, to look at this. Decisions, quite a few have pending lawsuits.

It takes a long time for cases to make their way through the courts. For those in this room who have dealt with this back when drug testing came about, it was a lot of years before there was a determination that for example DOT drug testing was constitutional. It had to make its way through the courts, and for marijuana, this is all happening. Could take another five to ten years. Most states simply haven't looked at it, let alone looking at it.

A lot of states are looking at working groups to figure out, but it's simply not clear, and the language, so you look at -- let's take a state that's brand-new, Missouri, which had a constitutional amendment that passed and what it talks about is that absolutely -- you could take any employment action you want against someone who is at work or you can discipline somebody for working or attempting to work under the influence, and it is absolutely silent on the issue of what about off-duty use?

Hard to say, but it's likely that they may be employment protection, because they wouldn't have to say it -- it's kind of like if you bring it up in one context, it means they probably didn't intend to regulate it, but some court someday will determine what Missouri wanted. But for me right now, it's a definite unknown of whether someone has to accommodate this, and this is true for almost all of them. So it's difficult. There's not a definitive answer when it comes to employment protection in a lot of them, but you're going to see the trend is definitely to add it, which means absent impairment, absent signs and symptoms, that employers will have an increasingly difficult time.

So we're going to get proposed legislation where we are looking to change existing ones, change unclear, they're looking to clear it up, and some like Rhode Island and New York are looking to add what I'm going to call positive test language. The idea that a drug test, a workplace drug test, is no evidence, because of course everyone wants to talk about blood, and even that's not a standard. But workplace tests just don't give much information about impairment at work.

These are failing. So New York it failed this year. Rhode Island it failed, but they recommended further study. So all of these things like many types of law are making their way through it.

I mentioned 2017 for me was a watershed year when it comes to looking at cases. We track cases that we find all over the country. So prior to 2017, there was -- the courts found consistently no duty to accommodate medical marijuana usage, and I know there was a lot of my colleagues who are sort of doing a bit of hoopla as some of those decisions came out. They were all in states that did not have an explicit employment protection, every single one of them. 2017 comes along and they started getting cases, not all of them are final. So I'm just talking trends here. Two decisions with explicit,

both courts found implied rights of action and let the cases go forward. Some of the other ones that go forward, so let's look about the pre-17.

These are all the ones that you are going to be able to get these, of all the ones that say, yeah, we're good, employers can do what they want. But they're historical ones that all the courts have found no explicit protection.

These are the three cases that in 2017, Connecticut, Rhode Island and Massachusetts, and the American Bar Association now calls these an emerging trend. You never know. I don't like to declare a trend in three instances. But it's clearly moving that way. One of the most interesting -- and some of these cases, if you want to sort of an understanding of why they are, they have done some really good work in this, some of these judges. You don't have to agree with them, but the legal analysis is quite good.

The question I get is how can a court find employment protection when it's illegal? It's federally illegal. I'm going to do -- because it's true that there's preemption, and most of these have language that says that if you would face problems because of losing federal contracts or something, that you don't have to do that, and a lot of employers, because they want to do the safety thing, would like to do that.

The problem is there is no federal law that mandates you can't hire someone who uses marijuana. The federal drugfree workplace, and we're going to look at that, doesn't even mandate drug testing. You don't have to do drug testing to have a federal drugfree workplace. So the court found in this one circumstance that, okay, well, that can't be the basis, because if you don't have to do the testing at all, you certainly can't be forced to fire someone for it.

Some of them looked at, you know, you're also getting issues across state lines. What do you do if you hire someone who's a Connecticut resident, but works across the state line somewhere else? Who what applies? We're looking at New Jersey has one that looks okay, and Montana. Montana doesn't have explicit protection. That's a very -- I put it for completeness, but it's a very odd case because it was recently affirmed where the court found there was no explicit employment protection.

What is happening over time is that they are going differently. So courts have interpreted similar provisions differently, which is why I'm hesitant to declare it too much of a trend. But what you're going to find is the more recent cases have tended to find explicit protection. The other ones are quite a bit older cases with the exception of a Montana case. So the trend appears to be changing with favoritism going towards the employee.

We have some pending lawsuits that we are watching, and I think in the next year we may have a little bit clearer, but I can tell you in reading the preliminary courts' decisions, I think the trend is continuing. But until the decisions come out, until they become final, you can't say for sure. Both Arizona, Florida, Massachusetts, New Jersey, and New Mexico we're just watching.

That's the trend. We are also going to see a switching away from employment, medical marijuana put program expansions are. So in New Jersey, they have expanded access, and they're adding 1,000 -- 100 new patients are added every day in New Jersey for medical marijuana. They want to eliminate physician registry requirements. They want to remove limits on the amounts and expands access to forms.

Mostly every state, with the exception of California, requires an application with what I'm going to call cardholder status and historically has been available for a year, and the card itself has an expiration date on it. Some of those are getting expanded. So New York is doubling licensees, expanding qualifying conditions; we'll talk about that. Pennsylvania is a mere example, expanding to include plant material. Pennsylvania has smoking illegal, by the way, which it doesn't really help in drug testing, but it certainly does sort of out in the community. They want to start involving some of the medical people in research.

The biggest area I think for people to understand about medical marijuana that's changing dramatically is what I'm going to call qualifying conditions and how that is changing. Typically, as particularly those in the room who are physicians know, that physicians' medical judgment would apply whenever a drug is prescribed. There are certainly approved, FDA-approved reasons for it, but the immense amount is left up to a physician.

Historically, medical marijuana has not been -- put an asterisk by California -- this system. It has been a legislated set of conditions. So in some states the conditions for what you must have a diagnosis, Crohn's disease, AIDS, severe cancer, have been determined by the legislature, and so one of the trends is that's first off not only are we adding to the number of types of qualifying conditions, but we are also just eliminating the requirement of all.

In 2018, four states have passed what I'm going to call just physician recommendations, including Oklahoma, which was always seen as a fairly conservative state, and three additional states are looking to the -- of which New Jersey, New York, and Pennsylvania are the current ones, which would eliminate, allow any physician or perhaps let's just say any qualified person to recommend, we'll get to that in a minute, for whatever they thought.

Now there's been concern raised that this would allow a much more expansive view of medical marijuana, because it's not limited, that that is the trend. Additionally there is quite an explosion of additional conditions that are going on. So you see Connecticut added eight, Louisiana five, Michigan added 11. They considered 22 of them, and New Jersey and Pennsylvania added them.

What do those look like? How broad-based are we going on medical marijuana? Qualifying conditions, common conditions, would include chronic intractable pain, autism or any sort of that, Tourette's syndrome, PTSD, a real hot mover on this list,

arthritis, sleep apnea, migraines, anxiety, and lupus. This is just some examples. They are by no means exhaustive on this.

One of the most interesting changes and late-breaking news in our world, the legal world, in literally 2018, the opioids. I hinted at this earlier. Prior to 2018, opioid abuse disorder I don't believe was for anyone that had specific condition, it was not on the list. Most of these are in the last four to five months. Illinois, Pennsylvania, New Jersey, New York, and Utah, and right now proposed in Colorado, have all come about to say that if you have an opioid disorder, we will convert you to a medical marijuana patient.

What's that based on? I've read some of the legislation. I certainly haven't -- and again, I'm not here to approve or disapprove. I'm just here to tell you what it is, is that in some of the early statistics are that in states that have medical marijuana, opioid deaths have gone down and opioid prescriptions have gone down. I don't know that those are all correlated, but that's often the evidence, in air quotes, that is cited for adding these conditions.

There's another six or seven that they either failed or vetoed. This is one that is continually on the list. This is likely to be a bigger deal, and it really came out of nowhere. Illinois was the first one to go, and it was like, really? That was signed in August. So when I say late breaking, I mean this is mighty new. New Jersey went, they visited in May, New York, there are some others. But it is interesting, in addition to those states that don't require a condition-based.

So this is probably one of the trends that's moving the biggest is the opioids. Some commentators have suggested it's in response to states taking action on the opioid crisis. I'll leave it to everyone to determine how beneficial that is.

The other way that medical marijuana is changing is increasing access. So one of the issues is who may recommend? It used to be basically physicians. That's no longer true. So we have New York where it's nurse practitioners can now. Who can administer it is changing. There are easing physician requirements. This is also a trend fairly recently that are going to be there.

Other ways that access is now being increased across the country is who can obtain it. There's what's now called a support person. We used to call them historically, they've been called caregivers, those who get the marijuana for the person who is the patient. Just so we are clear under the law, the caregiver gets all the protections a user does. Not asking you to understand why, I'm just saying that's the way the law is written. So if you test positive and you are a caregiver, even though you say that you're not using it, you get all the protections in a state that would have explicit employment protections, generally.

They are doing telehealth is more -- certification length. So it used to be every year you had to go in and get your medical marijuana card. They are going to two and three years now. So for right now, Hawaii for example just went to three years. After an initial

visit you can visit with your physician or recommender by telehealth. They have out of state reciprocity, and they for certain products they'll increase it.

The next thing and probably the last thing I want to talk about and I've mentioned is impairment. So there are a few -- and these are typically old. These are not new laws of usually meant for DUI. These are meant for criminal impairment standards. Some of these apply in the workplace, but they haven't really been tested too much. So you're going to see that there are five, two, one, nanograms per ml, all of these in blood, of course, which is obviously not a typical workplace matrix. There are two states that have per se limits for certain safety sensitive positions. If you want to use this, please, I urge you to look at the statute carefully. It's not that clear.

But if you can't test over in Pennsylvania over 10 nanograms for ml in blood or in West Virginia 3, for certain types of positions. That's assuming that testing is done in blood. But there is not a lot of movement that I've seen so far for adding per se limits in current legislation. There's a lot of -- I know that among the professionals they talk a lot about, I'm not seeing it put into those sorts of things.

With that, I have gone through everything. I'm happy to talk about any of the topics that anyone has questions about on any of these.

MR. FLEGEL: Faye, this is Ron. I would like to ask one question on your last slide. Have you seen any of the states move towards oral fluid at roadside instead of blood?

MS. CALDWELL: There are currently -- there's talk, Ron, and there's certainly some use with the idea that you're getting closer. I have not seen any legislation that would impose per se limits, if that's what you mean. I have not seen that yet.

DR. SCHAEFFER: Faye, I enjoyed your presentation, good as always. I did have one question about your state, Texas. I don't know if it was an oversight or if it's just something special with the Texas law, it was on the low THC high CBD list of 13 I think states, but it wasn't on the 33 states that had medical marijuana. Is there something special with that?

MS. CALDWELL: Sure. The states that have -- the 13 states that I talked about for low THC high CBD, all of those by definition do not have comprehensive medical marijuana. So that's the first issue, and you are correct; Texas does not. My home state of Texas indeed has probably one of the most restrictive CBD low THC laws in the country. It's for infants who have failed on I think two other regimens of opiates that they will allow them to have CBD low THC with I believe it's 0.5 percent THC. It's extremely limited, but it has a smidgen, and that's very recent. But it is correct. There is no comprehensive medical marijuana law in Texas. There's only 33 states that have comprehensive medical marijuana law. The other ones may have something else.

MR. MCGREW: Hi, I'm John McGrew, one of the interns with DWP. I have a quick question for you. It's on your caregiver. You stated if they tested positive they would get the same protection as one of the clients. How do they get around, let's say if it was

the marijuana, and Ron may be able to touch on this a little bit more, but how do they get around the passive inhalation?

MS. CALDWELL: There is no passive inhalation issue. Let's walk through a caregiver and give an example. This means that when someone applies in a state that has caregiver protection, there are two people eligible for a card, a registration card, the person who is going to use it and basically the person who is going to transport it. They cannot work typically under the influence, and they can't use marijuana at work. But there is simply no distinction or explanation or discussion under state law of the idea of what the heck are they doing testing positive? There's just no discussion of that. They are entitled; they cannot be fired from their job, where there is caregiver protection, for testing positive or the fact that they have a card. I agree with you it seems unusual. That's fairly typical. Not every state is slightly different, but that's sort of a generality if there is caregiver protection.

Obviously it was originally designed for the idea of they could transport it. They could -- and remember, that's what typically these medical marijuana laws are for is to allow people to not be charged with a crime of possession. They just drafted in these employment protections without any real distinction between the classes of people, is the typical way they're drafted. Again, not here to justify it, here to just say what it is.

MR. LO DICO: This is Charlie. I have a couple of questions. Are you familiar with the 2014 Department of Agriculture Farm Bill?

MS. CALDWELL: A bit.

MR. LO DICO: What do you know about it that addresses some of the high CBD low THC content?

MS. CALDWELL: Charlie, to be fair, I'd be guessing. I don't know enough about it to really talk about that.

DR. LO DICO: The reason why I ask is that if you read the Farm Bill itself, it addresses - - and this was in 2014 -- it addresses what a state can -- if a state issues a permit to grow hemp, you can as a farmer produce hemp that contains up to .3 percent THC in dry volume, and an isomer of the THC plant or the marijuana plant. So when you saw those high CBD and THC states, you saw this pattern of a .3 or a 3 percent, and you also look at the dates that those were initiated. It was like in 2014, 2015. So when I saw that, it brought me as that's a possibility that from that particular statute, that regulation, by the Department of Agriculture, that's where the states adopted their high CBD THC.

MS. CALDWELL: The answer to that is yes and no. remember we're talking federal law and the Farm Bill, and the federal law can do whatever it wants. If you look at the history of state CBD law, I will tell you that when I watched it develop, I did not see it developing particularly from the Farm Bill. I saw the impetus was, I believe, the first state was 2013, was media. There was a CNN, Sanjay Gupta, who issued and had the

story of infants with epilepsy, and if you look at the dates of the passing, almost all of the legislative history that you started looking at was looking at sort of that type of condition and moving it forward, at least in the stuff I read, Charlie, and I'm not saying I've read it all.

The idea that the federal government was allowing it in the hemp bill didn't really seem to be the mover. Most of them took some studies into account. So some of them, part of the question is, I believe, and I'll let the scientists defer to that, is getting below 0.3 percent THC is extraordinarily difficult for purity in CBD oil, which some people say it's sort of the lower limit of what you can scientifically get pure. Which sort of provided those states which wanted the least possible to provide it, and some are much, much more.

There. At least in what I've read I've not seen it tied immensely to the federal Farm Bill, but it could be. I mean, it was more really scientists and sort of legislative committees that came after the 2013 media blitz.

MR. LO DICO: Again, the reason I am bringing up the Farm Bill is because from one example of a product that had CBD in its back of its content, descriptor, it cited specifically section whatever of that law as exempting them from containing any THC. So therefore, the FTC or the Federal Trade Commission, which is the oversight to pulling out products that are fraudulent or -- that's how they are sort of the loophole. That's what I'm suggesting is that these commercial products are now available using that sort of guise.

MS. CALDWELL: So there's two issues going on here. One is transporting product across state lines, which of course very much influences and requires federal law, which is kind of different from use, in an individual state, which is much what most of the individual law is. But I do agree with you the practice of why they would refer to that is to allow them to move across. One of the problems in the CBD law, and I think Ron alluded to it earlier, is this idea of contamination. It's very much right now a buyer beware scenario. I will tell a war story. This is reality. This is not judgment.

Federal truck driver wants to use CBD for back pain. He also clearly understands that he can't use THC. He goes on the internet and orders 100 percent THC-free CBD oil guaranteed. Guaranteed. And he ordered it and he used it. He then had a random drug test and he tested positive and he lost his job. He was like how can that be? I really did everything I could. The case, he then had a second unopened bottle of this 100 percent guaranteed THC-free CBD oil, and he sent it off to a lab for testing for his own money. They impounded it and called the DEA on him because it's an illegal substance.

He then turned around and there's a current lawsuit going on with this truckdriver and the manufacturers of this CBD oil. It's very much a buyer beware. There are currently, because it is not handled for potency, contamination, frankly pollutants and other chemicals, we don't know what you're getting.

So when I hear, as I understand it, and I'll leave it to the scientists, that generally of the normal CBD oil at .3 percent, you are unlikely to test positive for THC at current cutoffs. I'll leave that to the scientists, but the idea is CBD itself is not intoxicating or impairing. But right now no one knows what they're buying, so it is not impossible that whatever these people thought they were buying that was CBD oil in fact was not. So it is quite a scary world out there in the CBD. The law is not so much of the problem, frankly, is that just like in marijuana, impairment in the science hasn't caught up to the law; in CBD I don't think the products have caught up to the law.

But yes, to transport across state lines, you're definitely going to want to have federal coverage or else you can't move it across. Does that help?

Any other questions?

DR. COLLINS: Just a comment, and that's on the front page of the Minneapolis Star Tribune this morning, Minnesota added Alzheimer's as a condition that could be included.

MS. CALDWELL: Almost any end of life stage disease is generally eligible for medical marijuana, very much so, in addition to -- that's a fairly obvious one, but yet, states are doing this all the time.

Agenda Item: Public Comment

CAPT BELOUIN: If there are no additional comments, we are now convening the public comment period. If you have a registered public comment, the operator will now open the line for you to make your comment for the record.

OPERATOR: We will now begin our question and answer session. If you'd like to ask a question, please press star then 1, and record your name clearly when prompted. If you need to withdraw that question, you may do so by pressing star then 2. One moment as we wait for the first question.

CAPT BELOUIN: While we're waiting, I'll just thank Faye for her presentation. Great presentation.

Operator, just as a clarification, this is for everybody on the line. The comment period is for making a comment. It's not actually asking a question for any board members. It's just for comment only.

OPERATOR: At this time, there are no comments on the phone.

CAPT BELOUIN: Okay, thank you so much, operator. Does anybody here in the room have a comment that they would like to make? This is your opportunity.

All right, since we don't have anybody here that wants to make a comment, I'm actually going to turn it over to Ron Flegel. We have a couple of announcements to make regarding the closed session for tomorrow.

MR. FLEGEL: I appreciate everyone's candor, and I apologize for the little busting around up here, but it was decided and guided that we do have to close tomorrow's closed session meeting. So we are going to cancel that meeting tomorrow based on guidance, and after we close this meeting, I will give board members guidance as to how to rearrange travel, et cetera. So that was given to me from our travel person.

So with that, again, any federal employees again would have their own guidance, but due to the guidance of HHS, we are going to cancel tomorrow's meeting, and I do apologize, because we did have some things that we want to discuss. So we had looked at possibly closing and opening as a closed session today, but unfortunately that is not in the federal register notice, which was given to the public, and therefore that we cannot do either.

So I will turn it back over to Sean to close this meeting, and then I'll give guidance to board members.

CAPT BELOUIN: Again, this is Captain Sean Belouin. Thank you, everybody, again, for attending today's open session. If there are no other issues, I'm going to adjourn this open session of the Drug Testing Advisory Board. Operator, you can now stop recording.

(Whereupon, at 3:30 p.m., the open session was adjourned.)