Center for Substance Abuse Prevention (CSAP)

Substance Abuse and Mental Health Services

Administration

Meeting of the Drug Testing Advisory Board
Day One – Open Session
June 11, 2019

Hilton Washington DC

Rockville Hotel & Executive Meeting Center

1750 Rockville Pike

Rockville, MD

Table of Contents

Call to Order **1**

Matthew Aumen, Designated Federal Officer

Welcome and Introductory Remarks **1**

Ron R. Flegel, BS, MT (ASCP), MS, DTAB Chair

Department of Transportation (DOT) Update **17**

Patrice Kelly, DOT

Nuclear Regulatory Commission Update **33**

Paul Harris, NRC

Department of Defense Update **58**

CAPT Eric Walsh, PhD, USN

Program Updates by DWP Staff **67**

Update on Emerging Marijuana Legalization **85**

Faye Caldwell

Drug Testing Index (DTI) Data – 2018 Update on Drug Use in the American Workforce **109**

Barry Sample, PhD, Quest Diagnostics

Emerging Issues: Fentanyl and Fentanyl Analogues **144**

Ruth Winecker, PhD, RTI International

2019 Update on Cannabidiol and Hemp Products **163**

Charles LoDico, CSAP, SAMHSA

Public Comment **186**

PROCEEDINGS (9:00 a.m.)

Agenda Item: Call to Order

Matthew Aumen, Designated Federal Officer

MR. AUMEN: Hello, everyone. My name is Matthew Aumen. I'm the acting designated federal officer for the CSAP Drug Testing Advisory Board.

Ron, we have a quorum. So I would like to now officially call the Center for Substance Abuse Prevention Drug Testing Advisory Board meeting to order. This meeting is being webcast online and it's being recorded and transcribed. So please be sure to state your name and speak clearly into the microphones to ensure accurate reproduction of the meeting. Please also, if you can, silence or put your phones on vibrate. I think that would be helpful for the group.

So what I'll do now is turn the meeting over to our DTAB chair, Mr. Ron Flegel. Ron?

Agenda Item: Welcome and Introductory Remarks

Ron R. Flegel, BS, MT(ASCP), MS, DTAB Chair

MR. FLEGEL: Thank you, Matt. I would like to thank everybody, board members, ex officios, industry leaders, and representatives and members of the public for taking time out of their schedules today to attend the Drug Testing Advisory Board. It's a beautiful day here in

Rockville, and I think it's going to be a great meeting today.

So with that, before I turn it over to some of the individuals that I would like to have make remarks, I was going to read -- since we do have some new members, through the list of members and new members of the board so that the public is aware of who is here. So the first is Costantino Iannone; I believe he is online. Randal Clouette, if you can just sort of identify yourself. Faye Caldwell. She's there. Dr. David Green, Dr. Michael Schaffer, Dr. Jason Schaff, Dr. Barry Sample, Kristen Burke, nice to meet you. Kristen is a new member, and I will have a little bit more to say about that in the presentation later. Deborah Motika, hi, Deborah, and Stephen Taylor is not with us today; he was unable to make the meeting, but we still do have a quorum.

So I thought as some background before I introduce Dr. Roneet Lev is just one of the things that we're trying to coordinate is what's called the ICGEC, and so with that, I wanted to read a little bit about what is the role of the Interagency Coordinating Group Executive Committee. Executive Order 12564, Federal Drug-Free Workplace Program, and section 503 of Public Law 100-71 set out a series of discrete and collaborative roles for the

Department of Health and Human Services, Department of Justice, and the Office of Personnel Management. In general, the Department of Health and Human Services is responsible for the scientific and technical guidelines for the drug testing programs and for the certification of agency plans and programs.

DOJ provides legal advice on the implementation and OPM is responsible for appropriate benefits coverage, model employee assistance programs, and in cooperating with DHHS, supervisor training and employee education. All three of these agencies work together closely on the implementation of the executive order and the development of the Model Plan for a Comprehensive Drug-Free Workplace Program, which is the standard for the agency plans and programs. In 1991, the Office of National Drug Control Policy was named as the lead agency for the implementation of the executive order and has since chaired the Interagency Coordinating Group Executive Committee.

I thought that was a little bit of background that I wanted to share and with that, I'm going to introduce Dr. Roneet Lev. She is the first chief medical officer of the White House National Office on Drug Control Policy. She is charged with providing medical leadership and coordinating drug policy across the federal government.

Dr. Lev brings 25 years of experience as an emergency physician treating the frontline cases of addiction. In 2012, she established and chaired the San Diego Prescription Drug Abuse Medical Taskforce, the first of its kind in California, that integrates physicians of various specialties and practice settings, along with hospitals, dentists, law enforcement, DEA, hospital administration, medical assistant treatment programs, and public health for decreasing deaths and mortality from the prescription drugs.

Dr. Lev's medical publications, known as the Death Diaries, studied the deaths and prescription patterns of people who died from accidental prescription drug overdoses, giving insight to the causes of overdose and directing prevention efforts.

With that, I want to thank Dr. Lev for being here today, and I turn it over for her welcoming remarks.

DR. LEV: Thank you, Ron. On behalf of Jim Carroll, the director of the Office of National Drug Control Policy, we thank the members of the Drug Testing Advisory Group for their science, research, and expertise in providing drug testing standards for the federal workforce and across the United States.

The Office of National Drug Control Policy,

ONDCP, is part of the Executive Office of the President and coordinates drug policy across 16 federal drug control program agencies, including the Department of Health and Human Services, Justice, Defense, Homeland Security, Transportation, Labor, and others. Our office develops a national drug control strategy that defines the President's drug policy. The President's fiscal year 2020 budget includes $34.6 billion to address every aspect of the addiction crisis, more funding than ever to support this critical mission.

As the chief medical officer of ONDCP, my role is to provide medical expertise and strengthen coordination between public health, law enforcement, and community prevention programs across our nation. It is estimated that over 20 million Americans over the age 12 require treatment each year for a substance use disorder that includes alcohol or drugs.

We consider addiction a chronic relapsing disease, like diabetes or high blood pressure. We advocate for treatment with compassion and without stigma. But at the same time, we operate under Presidential executive order dating back to 1986 requiring all federal employees to refrain from using illegal drugs on or off duty.

The executive order recognized that illegal drugs

use can seriously impair the national workforce, resulting in the loss of billions of dollars each year, as well as serious safety concerns. As an emergency physician still in practice for over 25 years, I witness the impact of drugs on our society. I served as expert witness in drug driving cases, treated traffic accidents of impaired patients, and ordered drug tests on a daily basis.

Being new to federal government, I was subjected to my very first employment mandated drug test. I studied for the test all night, and I passed.

(Laughter.)

ONDCP works closely with the staff from the Division of Workplace Programs and on the Drug-Free Workplace Program to establish up-to-date and evidence-based drug testing policy. We very much appreciate the diligence, science, and national impact of the program, and today ONDCP looks forward to hearing from you and engaging with you, the experts, on Drug Testing Advisory Board.

Thank you.

MR. FLEGEL: Thank you very much.

Since the last Drug Testing Advisory Board meeting, there have been a number of changes within CSAP, Center for Substance Abuse Prevention, and we now have a permanent CSAP Deputy Director, which I will introduce, and

also a Center Director.

Mr. Richard Carmi, he is the CSAP Deputy Director, and I apologize, he's back there. Richard has over 20 years of government and private sector experience in business operations, administrative policies, program management, organizational development, public health, human resources, and financial management.

For the last 13 years, Mr. Carmi has held several high-level positions within SAMHSA. I also want to introduce our new CSAP Director sitting to the right of me, Mrs. Johnnetta Davis-Joyce. Mrs. Joyce has 25 years of experience in the public health field prior to coming to CSAP. She has served as a senior director for Research and Evaluation of the National Association of County and City Health Officials. She has been director of the health programs at Econometrica. She also has been the center director of public health improvement and innovation at the Pacific Institute for Research and Evaluation, or PIRE, where she provided strategic leadership to a staff of over 200 employees, consultants, and volunteers in implementing policies, practices, and training to prevent underaged drinking.

She also has been the Deputy Director of the Office of Alcohol and Other Drug Abuse at the American

Medical Association, and she has been a board member of PIRE. She has been in these various leadership positions with the American Public Health Association and with that said, I want to turn it over to her for some remarks.

MS. DAVIS-JOYCE: Good morning. I am just honored to be here with you all today, and just thank this advisory board for the work that you have done and are doing, and Ron has been a great leader in this work, but I just want you to know all the work that you do really does inform the work that we do at the center. So I just want to thank you for your dedication and for your support, and I look forward to working with you. Thank you.

MR. FLEGEL: Thank you very much. With that, I would also like to share some of the updates from the Division of Workplace Programs in SAMHSA. I want to read these so we officially get these correct and then later on, I will also be doing a presentation with slides just to talk a little bit more in depth about some of the things I mention in this.

So with that, I will go ahead and begin. I wanted to update everyone 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 the program initiatives, program information we have gained through the HHS certified labs, federal agencies, and other drug testing industries. I hope that everyone will find this information both informative and useful for the drug testing industry.

We do have a number of presentations today, as you can see from the agenda, the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense, plus the HHS updates. Again, I will be presenting after the morning break.

We will also have updates from the Division of Workplace Programs on the proposed mandatory guidelines and brief updates on the electronic federal custody and control form and the standardization of laboratory reports, which we will discuss tomorrow morning. CBD and hemp products from Charles LoDico later on today, I believe, and standardization of variables on the second day with the discussion regarding the drug testing panels.

DTAB member Faye Caldwell will present on an update on emerging issues with the marijuana legalization, if we have time. We did not necessarily -- we didn't have that in the agenda, but I think we will have some time to

present. I think that's essential.

Dr. Barry Sample will be presenting data from the drug testing index on drug use in the American workforce, and Dr. Ruth Winecker will be presenting on emerging issues from fentanyl and fentanyl analogues.

On another note, I would also like to introduce Dr. Winecker as the new director for RTI over the National Laboratory Certification Program, or NLCP. Thank you, Ruth, and welcome. She's back there. She's sort of been thrown in the fire of everything that's going on, but she's doing great. She's doing a great job.

As mandated by Executive Order 12564 and section 503 that I read earlier of Public Law 100-71, the Division of Workplace Programs develops and revises the Mandatory Guidelines for Federal Workplace Drug Testing Programs. SAMHSA continues to improve the quality of services on the workplace drug testing in regulated testing and also on private sector testing by assessing the science and technology. You'll see some of those presentations later today.

We hope this helps to guide national policy in many of these areas, including many areas of the nonregulated testing sector. SAMHSA/DTAB, since there are new members, I thought this was a little bit important to

read, provides advice through the recommendations to the Assistant Secretary for Mental Health and Substance Use based on the ongoing review of the direction, scope, balance, and emphasis of the agencies' drug testing activities and drug testing laboratory certification program. Much of this ongoing review of current federal guidelines encompasses the science, technology, and emerging issues in the United States.

Regarding the DWP status updates, the revised Mandatory Guidelines for Federal Workplace Drug Testing Programs for Urine had an effective date of October 1, 2017. I mention that because now we have about 20 months of testing underway, I guess, within the synthetic opiate realm, and we're also going to -- I'll show later -- the evaluation around fentanyl, one of the things we're charged with.

The proposed final oral fluid Mandatory Guidelines is undergoing review at the Office of Management and Budget. Once approved, oral fluid will serve as a complementary alternative specimen to urine. While the focus of the oral fluid Mandatory Guidelines was to develop federal standards for workplace drug testing using oral fluids, the guidelines will also help promote standardization for laboratories, private employer testing,

states, and public sectors in standardizing oral fluid collection devices, the cutoffs, the confirmation levels, the collaboration process, as well as many other items. We hope that these federal standards will help to strengthen standards for state agencies, law enforcement specifically around roadside testing, and other programs that use oral fluid as a testing matrix.

Real briefly, the hair Mandatory Guidelines has currently been logged in as a proposed rule at OMB, I know if you have looked at that rule, it actually says final stage. That is inaccurate. It is a proposed rule. I just wanted to clarify that.

As part of the OMB review process, the proposed draft of the hair Mandatory Guidelines will be distributed to all federal agencies for comment and review. The length of time for review will be determined by OMB, usually it's 60 to 90 days, just to make everyone aware, since this is a significant rule.

As recommended by DTAB, the proposed hair Mandatory Guidelines will include questions for public in very specific areas. The proposed hair Mandatory Guidelines also address many other items, including test, the type of testing, the collection process in itself, the collection containers, location, a number of other issues

within those.

DWP staff, or Division of Workplace Programs staff, and the MRO working group have also updated the Medical Review Officer Guidance Manual to include the review of workplace prescription drug testing. The final version was posted on DWP's website along with case studies surrounding opioid testing. In addition, the MRO Guidance Manual for oral fluid is currently being developed and will be posted after the publication of the final oral fluid Mandatory Guidelines.

The 2017 federal custody and control form, which includes the synthetic opioids, is now in use by most federal agencies, I believe, and also Department of Transportation, and other federally regulated drug testing programs. But it will expire on August 31, 2019.

DWP is currently forming a working group to include these chain of custody forms for alternate matrices. DWP will continue to help laboratories move to these electronic forms, both now and in the future. I would also like to add an update as mentioned at the last Drug Testing Advisory Board meeting concerning the Fighting Opioid Abuse in the Transportation Act included in the 2018 Support for Patients and Communities Act, which requires the HHS Secretary to determine whether it is justified

based on the reliability and cost-effectiveness of testing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include testing for fentanyl, and to consider whether to include any other drugs or other substances listed in Schedule I and Schedule II of Section 202 of the Controlled Substance Act.

SAMHSA is evaluating this proposal to revise the guidelines and is moving through the process necessary to reach a determination. As I mentioned, later today Dr. Ruth Winecker will present some background information on fentanyl and results of the pilot study with the federal drug testing specimens.

My next item for discussion is CBD. If you haven't heard of that, I am sure everybody has. We still continue to do studies currently underway with RTI and in collaboration with the Behavioral Pharmacology Research Unit at Johns Hopkins University School of Medicine. This is an expansion of the 2018 pilot study, the pilot CBD dosing study. We are looking at ingested and vaporized CBD, along with edibles or oils and drug testing results in all matrices, including urine, oral fluid, blood, and hair. I was really hoping at this time to be able to give an update of that presentation or give the presentation to open, but we're still currently working through the

progress of continuing that study.

DWP continues to focus on other special projects to complete the extensive studies that we have undertaken in conjunction with RTI and Johns Hopkins under the National Laboratory Certification Program. It seems like emerging issues are definitely on all fronts that we're looking at now.

Just to note, many of these items will be discussed by DTAB in addressing the emerging issues such as marijuana, the opioids, synthetic drugs, legislation and state laws that are changing dramatically, and the revisions to the Mandatory Guidelines including the fentanyl analogues that we're looking at.

In summary, I would like to acknowledge and say thank you. I know Dr. Jennifer Collins is not with us. She was a prior board member. She is Lab Director of Medtox Laboratories. Dr. James Ferguson, who also has went off the board, he was the Medical Director of Recovery Management Services, and Dr. Christine Moore, she is Vice President of Toxicology Research and Development at Immunalysis Corporations. All three have rotated off the Drug Testing Advisory Board in December.

Their contributions over the last four years have been truly appreciated and I would like to acknowledge them

with certificate of appreciation from SAMHSA, and we have a certificate that we will unfortunately have to mail to them, but it's a certificate, just so the board members can see. It's very nice.

Again, I want to thank them. It was an extraordinary four years. I think the new board members have an extraordinary four years coming up with that, and I would like to also acknowledge Kristen Burke, who is Laboratory Director at California Department of Justice. Deborah Motika; Deborah is Senior Vice President Toxicologist at DrugScan, and again Dr. Stephen Taylor, who is Chief Medical Officer at Pathway Healthcare, LLC, who will joining the Drug Testing Advisory Board.

We would like to welcome the new board members, and also say thank you for the time and contributions you will make over the next four years being on the board. I think you will find it extremely interesting. I do every day. After 25-plus years of the drug testing, there never seems to be anything that doesn't surprise me anymore, with the questions we have.

So with that, I would also like to thank everyone for again attending the Drug Testing Advisory Board and the meeting today. I hope you find the presentations coming up both informative and also interesting in the drug testing

world that we see right now.

Okay, with that, I'm going to turn it back over to Matt, who will introduce the next speaker.

MR. AUMEN: Okay, folks. So next up on the agenda we have a presentation on the Department of Transportation update by Patrice Kelly. Patrice is the Director of the Office of Drug, Alcohol and Compliance with the U.S. Department of Transportation.

Patrice?

Agenda Item: Department of Transportation (DOT) Update

Patrice Kelly, DOT

MS. KELLY: Thank you very much. Good morning, everyone, and thank you, Ron, for including DOT in this presentation.

I started with our technical assistance, because our outreach as the Department of Transportation is pretty significant, but we're looking at a regulated audience of millions. Last year, we had over 6 million tests. So last year, we also covered more than 16,000 phone calls, emails, in-person appearances, and consultations within the government. That was more than double what we saw in 2012.

As of the end of last year, we had more than 64,000 listserv subscribers. That's now up to 72,000 as of

May 7, 2019, and the Department of Transportation's listserv also serves as a vehicle for SAMHSA, DEA, and others to put out information about their own programs to antidrug audiences. Our website is one of the department's most viewed websites, with more than 903,000 sessions last year.

So the way our program is structured, my office is in charge of 49 CFR Part 40. We write it. We modify it. We provide guidance regarding it. It's the overall procedures for workplace drug testing, and underneath Part 40, each of the modes of transportation you see the sixth picture. FMCSA is motor carriers, federal rails, pipelines and hazardous materials safety administration, transit, aviation, and the United States Coast Guard, which is part of the Department of Homeland Security, but at the time Part 40 and the drug testing regs were originally created, Coast Guard was under the Department of Transportation. So they have remained very much a member of our roundtable. They ascribe to Part 40 and we have regular communications with them.

So we set the procedures. Each of them sets who is subject to testing; in other words, who are the safety sensitive employees? Who are the people who are going to impact safety, and therefore need to be drug and alcohol

free? They also set which employers are required to test. The program is aimed at commercial entities, but also commercial entities who are participating in a way that each of those modes of transportation thinks is significant. So for example, in motor carriers they've got school bus operators as well as large tractor trailer and commercial motor vehicle operators. With federal transit, you have a much broader spectrum of types of transportation employees, as well as in aviation, because an awful lot of people in aviation can impact the actual safety of operations.

These are our horizon issues, and this is basically going to be the focus of where we go during this brief presentation; in the interests of time, I'm going to try to run it a little bit more quickly so that we can get back on schedule.

The marijuana issues as everyone here knows are pretty complicated. We're not anywhere near reaching an impairment standard, and so we're really continuing to look for the presence of marijuana, and we hope in the future continue to look for the presence of marijuana regardless of its scheduling.

Ron mentioned briefly the Fighting Opioids in Transportation Act, which is part of the Support act. I'll

go into that in more depth during my presentation today. Under that is an area that's near and dear to most of our hearts, if we're involved in this teleconference or in-person session, and that is alternative specimen testing methodologies, oral fluids and hair. While we recognize the fairness and effectiveness and accuracy of urine, we also all realize that there is a tremendous cheating problem out there, and oral fluids and hair offer great promise, because both of them are observed collections and arguably in many cases are less intrusive.

Electronic reporting and records was another area we were also working on before the Support act and the Fighting Opioids in Transportation Act came along. That's something that we had been working with HHS with for many years on the electronic chain of custody forms, and now where we want to go eventually with Part 40, and I'll talk about that some more.

The driver clearinghouse database. Federal Motor Carrier Safety Administration is moving forward under congressional mandate with this database that will track people with positive drug test results and refusals, and FMCSA was kind enough to share several slides with me that I want to present to all of you, because not only is it extremely relevant to commercial operations, but any

federal agency who has internal federal employees who are driving vehicles that fall under the FMCSA regulations in these agencies are already testing under the FMCSA rules, but they will also be required to enter these test results into the clearinghouse database. So stay tuned for that.

Public interest exclusions. That is something that our office takes, moves forward with, involving serious noncompliance by service agents. So if laboratories, collectors, Medical Review Officers, are in serious noncompliance with the regulations, those cases are investigated by our inspectors, auditors, investigators, sometimes by the Office of the Inspector General, and the U.S. Attorneys often take them forward as criminal actions. We then see them referred to our office for final decision in terms of rendering a public interest exclusion which prohibits those bad actors from working with DOT-regulated employers for up to five years.

Finally, medical review officer onsite reviews, that's another on our horizon this year. We're currently in the process of going out and visiting several of the large Medical Review Officer practices to take a look specifically into nonnegative test results. It's not so much a compliance review for looking at enforcement purposes, though obviously if we found anything seriously

out of compliance, we could take action. It's more guided toward figuring out exactly what is going on with non-negatives, what's going on with safety concerns, and I'll touch on those briefly later, but just to remind everybody, Department of Health and Human Services does not have a provision like we have for safety concerns, so that on a DOT test, if a Medical Review Officer changes a laboratory confirmed positive to a negative because of the existence of prescription, that MRO also has the option to refer that back to the employer as a safety concern, something that would need addressing in order to ensure safety.

It's not a provision on Ron's side of the house, but it's a provision on ours, and that is something that we recognize that we don't have full grasp on what is actually being done by MROs, and so we're taking a further look at that, and perhaps will address that in future rulemaking, depending on what we find in the way of data this time.

The Fighting Opioids in Transportation Act, the Federal Railroad Administration is being required to add another category of employees. They have just added maintenance of way employees, about a year ago, and that's significant because for almost 30 years, none of the DOT agencies added a significant group of new employees, but FRA added maintenance of way, and now they will add,

through rulemaking, they must propose to designate rail mechanical employees as safety-sensitive subject to testing.

Also a requirement specifically for our office, ODAPC, is that we must establish and make publicly available on our website a database of the drug and alcohol testing data reported by the employers for each mode of transportation. The deadline for that was March 31, 2019, and we met that deadline.

Fentanyl, as Ron mentioned, the Secretary of Health and Human Services is tasked with determining whether to expand the category of opiates to include fentanyl. Again, it's within SAMHSA's discretion. Should SAMHSA add it, then there's a requirement in the Fighting Opioids in Transportation Act for ODAPC, for DOT, to add fentanyl to our drug testing panel. Again, that would be a notice and comment rulemaking also, but we will be working very closely with SAMHSA to first determine whether or not they are going to add fentanyl. But we were particularly pleased that Congress left that to the discretion of the scientists. HHS is of course our scientific base, and we appreciate the discretion that they were afforded in that Act.

Hair testing. In the Fighting Opioids in

Transportation Act HHS was required to provide a report to Congress every six months until hair testing Mandatory Guideline go forward. There's also a requirement that is for both hair testing and a similar requirement for oral fluids, to remove to the extent practicable external exposure. The passive exposure issue. The language of the statute is there, that will be part of the public docket for this, but basically eliminating 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. Again, the common vernacular for that is passive exposure, but this is the way Congress phrased it.

For oral fluids testing, again HHS is working on that, and trying to make sure that, though we didn't meet the December 31 deadline, I can assure you that DOT is continuing to work in support of HHS on this, and we're hopeful for further resolution of this, and the same issue about passive exposure. That has to be resolved to the extent practicable.

Paperless, electronic chain of custody forms. It's interesting the way that Congress phrased this. They wanted HHS to ensure that each certified laboratory that requests approval for the use of completely paperless

electronic federal drug testing custody and control forms from the NLCP's ECCF systems receives approval for these completely paperless forms, instead of forms that include any combination of electronic, traditional handwritten signatures executed on paper forms. Again, this would take us to a new level. No more authoritative copies, no more wet signatures. This would take us to a new level, and this is someplace that DOT is eager to move also.

For us, Congress required that 18 months after HHS approves the paperless ECCFs we will issue a final rule. We'll go out with a notice for public comment, and then we'll establish a final rule to authorize to the extent practicable the use of electronic signatures or digital signatures executed to electronic forms. What I try to explain to people is it's pretty difficult for DOT to move the rest of Part 40 forward into electronic signatures, and say that applies to everything except the drug testing part of this. That is of course ridiculous.

So we're hoping to, again, work closely with HHS, see these forms move forward, paperless, and then we'll be able to ascribe to the same standards. If that's not the case, I know we will have further pressure to accept things with electronic signatures regardless, so that's why it's important that we each have a component in the statute and

that we continue to work together.

The FMCSA's drug and alcohol clearinghouse, I have those slides for you on this. Congress reminded FMCSA that they were very serious about this, and that they want a report 180 days after the enactment of the statute, which incidentally was signed by the President in October. FMCSA already did their report, their 180-day report, saying they we are on target, we are moving forward, we are going to have this database in place for January 6, which was the original final date for this, the effective date. They're on track, and I'm very impressed by the people at FMCSA who are working on this, the brainpower that is going into this, and I do fully believe they are going to meet their goal.

The Omnibus Transportation Employee Testing Act basically codified the relationship we had already set up with the HHS as our scientists. Back in the late 1980s, in 1988 and 1989, DOT did a rulemaking where we said we would proceed with drug testing, and at that time we said it made sense to follow what HHS sets up in the Mandatory Guidelines. Congress agreed with us in this statute, and they further said, okay, from this point forward, you will unequivocally follow HHS for this.

So we need to follow HHS for laboratory and

testing procedures for the controlled substances, the comprehensive standards for laboratory-controlled substances testing, the minimum list of controlled substances. So the drugs for which we test come from HHS, and the appropriate standards for certifying and reviewing labs.

But we can tailor other aspects of our regulation -- collection procedures, MRO procedures. We talk in here, I put specifically in this slide the idea of reporting the significant safety risk to third parties which I mentioned earlier, reporting about medical qualification issues. We are a deterrence program. We are not a medical qualification program. However, if a Medical Review Officer, during the course of verification, finds out that somebody is using a substance that would disqualify them medically under FMCSA, FAA, or the United States Coast Guard -- those are our three agencies with medical standards -- then the Medical Review Officer needs to report out that this is something that applies to the medical qualifications. And also, we differ as to the return to duty process, from what HHS does. So there are various aspects, but these are three examples of where we differ.

We cannot follow HHS when the Omnibus Act

prohibits it. IITF, the Initial Instrumented Testing Facilities, we got knocked out of the ballpark on those as well as point-of-collection testing because the Omnibus Act requires us to have the initial screening test and the confirmation test done at the same laboratory. So that takes us away from point of collection testing, and away from IITF. So even though HHS has successfully implemented IITFs as an option, we cannot follow those.

Our DOT regulated drug testing data. This is our data through the end of last year. A little different from HHS, who implemented the opioids testing on October 1, 2017. By final rule, we implemented it January 1, 2018. You will see our data as it concluded in December 2017. Our opiates level, positivity level, was low. In January through June, it goes all the way up to 1.01 percent, and again, because the Secretary knew and we all knew, opioids are a problem out there. However, we're greatly encouraged by the fact that the line is now on the decline for the second half of 2018.

For us that was significant data. It was not a surprise that opioids were a problem, that the semisynthetics were a problem. That certainly was not anything that we found earth-shattering. It was right in line with what the President had told the nation right

before we issued that final rule. Again, we have this data. We've shared it with the Office of National Drug Control Policy, shared it with Ron and others within the federal government earlier than this, but just, again, I want to show that we are encouraged by that and it actually has come down to touch where the marijuana level is -- which, incidentally, you can see, even though states have been legalizing marijuana, we are not finding a huge problem in it, and I do attribute that to the fact that we are very clear in our policy statements that Medical Review Officers will not downgrade a positive test result on the basis of state use of quote-unquote medical marijuana. They will not do that.

So I think that that also has gotten the word out through the industries, and the unions have been tremendously helpful for us in spreading those statement and getting that information out, as have employers and associations. We're grateful for the outreach that others have helped us do. But it's making a difference.

The Drug and Alcohol Clearinghouse, this is the FMCSA clearinghouse. Importantly, the final rule went out December 5, 2016. It said January 6, 2020 was going to be implementation date. Starting in March of 2019, FMCSA sent out its information phase and I will have a slide in a

couple of slides from now to show you exactly where you can go to sign up for information about it, or where you can go to just take a look at what they've got up there so far. They've been tremendously effective, and they've been going out and doing public speaking along with us in ODAPC, and the DOT agencies, to get the information out on there. They're on schedule for that implementation date, so stay tuned. Then there are postimplementation aspects of that go into effect January 6, 2023. But registration's going to open this fall for the clearinghouse. Medical Review Officers and others who are covered by this, including employers, are going to want to start registering earlier rather than later.

Who is going to be in the clearinghouse? Drivers who hold commercial driver's licenses or commercial learner's permits, employers of CDL drivers who operate commercial motor vehicles, CMVs. Again, remember, the federal agencies, a lot of them, have CDL operators who are operating CMVs that fall within the weight limits, and consortium third party administrators will need to register, because many of those stand in the shoes of the employer when it comes to owner-operators. There are an awful lot of small trucking companies out there who are required to use CTPAs. Medical Review Officers must

register. Substance abuse professionals must register, and state driver's licensing agencies.

Coming in the fall, people can register their company and/or themselves. People can set up assistants, so it doesn't mean the Medical Review Officer has to actually key in the data. It means that they must invite their staff, specifically Patrice Kelly needs to be invited, then I can go in and sign up to enter that data for my MRO. Then we and they are encouraging drivers to register.

Here's what I promised you. The website, and for those on the phone, is https://clearinghouse.fmcsa.dot.gov. That's a very good one-stop shop, and we also have a banner on our web page for ODAPC that will lead you directly there. You can subscribe for email updates, and I strongly recommend anyone with even a passing interest in this to subscribe for those email updates.

Please, because it's very important to keep you in the information loop. There are frequently asked questions already. They're gathering more people ask those questions, as they go out and do public speaking. This is a very live source for information on this. There's a clearinghouse fact sheet, and then there's also an email address that they monitor pretty constantly. It's not

unusual for me to get emails from this after hours, because somebody's asking a Part 40 question. So again, I encourage you to use this as your resource.

Finally, that is our webpage, and as you can see there's the clearinghouse banner. The banner above that, the "Preventing substance abuse begins with knowledge," that was a task we took on, my Deputy Bohdan Baczara specifically took it on working with ONDCP, and it is a resource of what the federal agencies prevention resources are. So I always strongly encourage employers and others to take a look at that.

There's a lot of good information to put in your employer policies and to share with your staff. It's not scientific, it really speaks to people who are running their programs and people who are subject to testing and people who need help. Again, those are federal government resources in that first and the FMSCA, other than that, and our listserv is the fourth bullet down on the right-hand side to subscribe to ODAPC's listserv, and I do encourage people to subscribe to that, too. It's a very quick and easy way to get the information you need. We send our listservs with limited frequency so that we're not spamming anybody, but when you need to know we're going to put it out there.

I believe that is my last slide. Thank you very much, and I appreciate this opportunity, Ron. Back to you.

MR. FLEGEL: Thank you, Patrice. I should have introduced the Ex Officios, too, when I did the board members, so as you are aware, you just heard from Patrice Kelly. There is also James Mullally, who is from FDA, sitting with us today. There is Eric Welsh, from Department of Defense, who is sitting with us today.

And also, I will turn it over to Paul Harris from Nuclear Regulatory Commission, who is going to present next.

Agenda Item: Nuclear Regulatory Commission Update

Paul Harris, NRC

MR. HARRIS: Good morning. I am Paul Harris. I'm the United States Nuclear Regulatory Commission's Senior Program Manager for 10 CFR Part 26 fitness-for-duty programs, drug and alcohol testing.

With me today I have Brian Zaleski, to my left. Brian is the NRC's Fitness-For-Duty Program Specialist, and will be performing and sharing part of my presentation.

I agree with Ron Flegel that it looks as though it will be a gorgeous day outside and I wish I was outside golfing. However, nonetheless, the DTAB agenda and resulting discussions are very important to us to help

ensure public health and safety and contributes to the common defense and security by helping ensure individuals are fit for duty.

Here I'd like to thank Ron and staff again for the invitation to present to DTAB and to the public, and to be an Ex Officio member on the Drug Testing Advisory Board. I thank the HHS staff for all the hard work they did to orchestrate this public meeting.

Brian and I are here today to present two key objectives. First objective is to present and describe the NRC's fitness-for-duty program elements that directly contribute to public health and safety and the common defense and security. And second, to present and describe the result FFD performance at our nation's commercial nuclear power industry, which includes two nuclear fuel fabrication facilities and the commercial power reactors that are operating and being constructed. Brian Zaleski of the NRC staff will make this portion of the presentation.

From our presentation, I ask that the Drug Testing Advisory Board members and members of the public to be assured of the importance of federal drug testing programs for individuals in safety sensitive positions and the challenges we are facing. This is why Brian and I are here, and why the NRC commission has established fitness-

for-duty regulations.

What are these challenges? I have three to present. One, subversion of the drug testing process. My counterpart Patrice of the Department of Transportation has already mentioned this. Subversion of the drug testing process using either urine or oral fluid as a test matrix. I think market economies will make companies develop products that are going to try to subvert oral fluid testing. I think we need to be ready for that. We need oral fluid testing for effectiveness and efficiency improvements, and have for years desired hair testing for pre-access screening and possibly random and follow-up testing.

The second challenge, dispositioning the adverse effects of prescription drug use and multiple drug use on the conduct of safety or security duties and responsibilities by employees in safety or security sensitive positions. It is unacceptable to have NRC licensed operators, NRC-required security officers, and other individuals in the so-called critical group of individuals within the commercial nuclear industry, which operate, maintain, and construct these facilities, to be under the influence of alcohol or legal or illegal drugs. If this were the case, we would lose public confidence, and

this could be adverse to our nation's electrical infrastructure.

The third challenge is test for the right drugs, and only the right drugs. This is vitally important because we cannot drug test our way to safety and security. It has to be an integrated approach that leverages not only drug testing, but preemployment screening, behavioral observation, background checks, employee assistance programs, and trained, empowered, and professional employees.

So if I may, we must continue to protect the rights of individuals from unlawful search, we must ensure that the program is efficient and does not result in an unreasonable burden on the entities subject to federally mandated drug testing, and we must continue to test for marijuana as an impairing substance no matter what its scheduling, and strongly consider other substances, such as benzodiazepines and other families of impairing narcotics that Brian Zaleski will present.

These are tough challenges, and we at the NRC staff are very proud of the DTAB board and its deliberations. We look forward to the oral fluid guidelines and hair guidelines.

This is just a disclaimer slide. We are the NRC

staff. We don't represent positions and policies of the NRC commission. Discussion topics, this quickly shows the discussion topics we're going to be looking at. I'm not going to go through every bullet for timeliness's sake.

This represents the FFD program objective, which 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. An FFD program developed under 10 CFR Part 26 is intended to create an environment which is free of drugs and alcohol and the effects of such substances.

It's important to understand who the FFD program covers, and as Patrice, my DOT counterpart, eloquently explained, we have the same individuals being covered in safety and security-sensitive positions. I've listed them here for your information. It is vitally important that we cover the individuals that perform all these duties and responsibilities necessary for operation, maintenance, and construction of these facilities. The red dot in my little Venn diagram there is definitely safety and security. It's an integration of all three.

We assure safety and security though a defense-in-depth strategy. We use people. These people are

trained in the items listed here, such as education, experience, qualifications. We do the drug testing for a number of drug testing categories, such as pre-access, random, follow-up and post events. We do behavior observation, and we do fatigue management, all within the program.

We have access requirements for all of our facilities. These are very stringent requirements that require a number of background checks, academic checks, employment checks, fingerprinting, FBI, we coordinate with FBI on background investigations, and psychological testing of individuals.

We have physical protection, as you can tell, in our facilities. These are definitely one of the most highly protected commercial industries in the United States, by the security regulations we implement. And we have programs for insider mitigation, which are the bad actors who have access to the power plants and we don't know about them, and we would need to find them. We have cyber protection, and we also have a very robust information controls program.

The key items of interest I already mentioned. Oral fluid testing. We think there's benefit there, and we do think it will result in some efficiencies and

effectiveness improvements. We are interested in expanded panel testing. I think Brian will talk a little bit about that and why that's important. Marijuana rescheduling, I already mentioned that. Currently, the NRC staff, namely us, sitting here at the table, our view has been consistent on impairing substances. It really doesn't matter to me what schedule they are. If they're impairing it's a public health and safety issue. Auditing of certified laboratories. I think Brian is going to talk a little bit about that. That's still important. Blind performance testing.

And one of the key elements in the successes that we're pursuing right now is proposed rulemaking to better align the 10 CFR Part 26 with the HHS guidelines for urine testing.

With that, I'd like to turn it over to Brian, and discuss operating experience.

MR. ZALESKI: Good morning. I would like to mention one more about that previous slide. The proposed rule that was voted on by the Commission just a week ago, and they directed the staff to move forward with aligning with the 2008 HHS guidelines, one element that they did include was a question to the public about also including the 2017 HHS guidelines. They did modify the proposed rule

to align with the adding MDA to the initial screen to remove MDEA, because of prevalence. That's going to be out later this year in proposed rule form. We encourage everyone here, if interested, it will clearly impact the laboratories, to provide public comment on that. We will have a public comment period within the public comment timeframe for the rule. I'm the lead on that rulemaking, and Paul will be working on it, as well. If there's any questions about that, happy to discuss.

Today, what I'd like to do briefly is to highlight some of the operating experience from 2018. There's a lot of information and details on these slides. One real critical part of what we do at the NRC is make sure that the public is aware of what we are doing at our commercial nuclear power plants. Public trust is critical to confidence in what we do in generating nuclear power and energy in this country.

The first slide is just an overview of the top-level test results. We basically tested about 145,000 individuals in the past year. The number of individuals that are in our random testing program, so those are the folks beyond pre-access, we're talking about 100,000 individuals a year. It's a pretty standard, stable industry. Most of the programs have been in place for a

very long period of time. We've had two construction sites that have changed test results over the last -- started in 2009, moving forward, just because of the number of people they're screening, and also the types of individuals that are using substances, a higher percentage of individuals applying for employment at these construction sites are substance users. We had 1,185 individual that tested positive in 2018, and we provide some breakouts there where we identified these individuals.

The number one screen that we use, and the best screen, in our mind, is pre-access testing. In DOT world it's preemployment testing. We call it access, because you gain unescorted access to nuclear power plant, so it's a pre-access test. We identified in 2018 almost 70 percent of individuals that were using alcohol or drugs were identified before they gained access, which is a good thing.

Our rule is all about being risk informed. The terminology is becoming more prevalent right now at the NRC, but it's always been that way. We have defense-in-depth approaches to ensure that we have safe individual operating our power plants.

The overall positive rate for the industry is quite low. It's .8 percent, and rolls up all the different

tests that we conduct. The random positive rate is .37 percent in 2018, and if you break that down, there's data -- there are distinct differences between licensee employees. These are more likely to be permanent fulltime employees at power plants, versus contractor vendors who may be more temporary. They have much higher positive rates, three to four times in some instances, depending on the test rate.

One other thing I should mention is that all the data that you're going to see today, the end of the reporting period was the end of February this year for calendar year 2018. All the sites report annually, and all the results are MRO verified, so these are all verified results.

This slide, while busy, just breaks out the percentages of positive test results by licensee employees and contractor vendors. They're very different workforces. The contractor-vendor population is primarily servicing shorter period of time activities, outages. Nuclear power plants are in outage every several years to replace fuel and to do maintenance that they can't do when the plant is operating. So there's a continual influx of contractor vendors for short periods of time.

Licensee employees are much more stable, fulltime

employment, they're very good jobs, and they tend to have very, very low positive rates. For instance, the random testing positive rate for licensee employees was .17 percent in 2018, as compared to .68 percent for contractor vendors.

This slide presents the prevalence of substances identified since NRC started testing back in 1990 through the present time. What you can see, the top line is marijuana, so roughly 50 percent of substances identified each year since NRC's been testing has been marijuana. That hasn't changed, the numbers do bounce around a bit from year to year. That's all I'd like to say about that, other than we believe that the results have been impacted by subversions. We'll talk more about that. There's a slide that demonstrates that every year 20 to 30 percent of individuals that are violating under a drug test are identified as subverting the test, which is quite significant.

This is a breakout of the identified substances as well as those that have refused the test by worker population. The substances identified are different from licensee employees. Licensee employees tend to test positive for legal substance alcohol a lot more often than contractor vendors. The left pie chart demonstrates the

licensee employees, and the red color is alcohol. Conversely, with contractor vendors, the number one substance they use is marijuana, or at least identified in our testing program.

These substance differences have not changed over time, although you do get some year-to-year variability. Last year we reported that there was an uptick in marijuana detections with the licensee population. This year it's been stable, so last seemed more of an anomaly, in terms of marijuana use.

One other thing that I would report is that the pie -- you can't really see it very well, but there's a refusal test pie slice -- and for contractor vendors what that represents there is the individual did not provide a specimen for testing. If they provided a specimen for testing and it was determined to be subversion attempt, so the initial specimen was out of temperature -- that's likely most times we identify cheating -- the second test comes back as a positive, it's going to appear in this pie chart as a positive result, not as a refusal.

So that refusal indicates that no specimen was collected. So you can see, over 19 percent of the individuals of contractor vendors did not submit a specimen for testing, therefore we do not understand what these

individuals are using, and we don't have a complete picture of the substances in those individuals.

I did look at the slides that we presented over the last four or five years and tried to pull a couple of additional ones, just to demonstrate the specificity of the information that we collect on individuals. This slide demonstrates the substances identified by different labor categories. The first top five bar lines there are maintenance. Most of the detections that we're seeing in our workforce are coming from the maintenance category. Eighty-two percent of the observed positives in 2018 came from maintenance categories, and those are the top four to five line items there.

There are a number of labor categories in there that have many fewer hits, which is obviously a good thing. We get 24-hour event reports for individuals in a select group of categories, so supervisors, reactor operators, FFD program personnel, and anybody transporting strategic spent nuclear material, which we've never had a positive on. We'll get a 24-hour event report, and we'll be able to review that quickly. So there's a time element for some of the reports that we get.

This is an example of urine testing. It does demonstrate the effectiveness of using cutoff levels. Back

in 2008, when we modified the last major modification of Part 26, we included time-dependent alcohol cutoff levels. So if an individual is at work for at least one hour and they have a .03 BAC, they're going to test positive under our rule. If they're at work for two or more hours, and tests positive at .02, they're also positive.

This pie chart and the bar charts demonstrate that in 2018, 42 percent of individuals that tested positive, tested positive below the .04 percent level. That demonstrates we're identifying additional individuals because of more stringent cutoff levels. It also demonstrates that the effectiveness of these levels across the types of testing. We didn't have any positive alcohol tests in post-event, so that's why that line is blank there. But it does demonstrate that we have a stronger program on follow-up, for-cause and random, as well as we do for pre-access testing on all individuals for alcohol. I know there's variability amongst different federal agencies on that one. We test individuals at a 50 percent random testing rate for both drugs and alcohol every year, and that's been that way for the last 20 years, 25 years.

Last year we talked about additional substances, testing for additional substances. NRC empowers our licensees to test for any scheduled drug if they identify a

local drug use trend that's affecting their workforce. We also empower our licensees to expand the panel of drugs on follow-up, for-cause and post-event tests. Very few licensees do take advantage of these provisions, but on occasion we do see that.

In either of the cases, if they do choose to do this, they first need to get a forensic toxicologist to review the testing assays and the cutoff levels used by the laboratory. That is unless HHS currently has those substances in their panel. If our licensees right now want to test for hydromorphone, they could do that, as long as they use the cutoffs and the assays at the HHS laboratory, they could do that without forensic toxicologist review.

This is just a summary of the facilities that have used additional substance testing, and this gives us a bit of insight, and it's worth talking about briefly. We have had one reactor program, one corporate program that's been testing for many years for barbiturates, benzodiazepine, methadone, and propoxyphene -- they test all specimens for that. They have very few positives. They've been testing it since the 1990s.

The second corporate program that we have, the second bullet, has been testing at follow-up, for-cause and post-event for several benzodiazepines, as well as

hydromorphone, hydrocodone, and oxycodone. Those four facilities from one corporate program have been doing that since 2015. They've had zero reported positive for hydromorphone, hydrocodone, or oxycodone. That's one key indicator in our mind in terms of whether there is some level of prevalence of those substances in our workforce.

We do get some variability in terms of testing for individual drugs. In terms of individuals being subject to a follow-up testing plan, where they self-report as part of their hiring process they had a prior positive, they had an addiction issue or a DUI, they'll be put into a follow-up testing program that's unique to their circumstances, so therefore we may be testing for additional substances there.

This is a summary of all of the additional substances that we've identified since 2011 through 2018. It's a small number of identified positives. It's surprising, because these are not standard tests that we're doing. These are targeted primarily in for-cause testing situations as well as some follow-up testing situations. In total, over the last nine years, we've had 33 substances identified out of 25 individuals. Some individuals tested positive for more than one substance.

While busier, this also gives you an indication

at least where we're identifying these individuals. It should be of no surprise that the majority of these individuals would be identified on a for-cause, that's the third column, where 17 of 25 individuals have been identified testing positive for an additional substance.

Most of these individuals, by the way, have tested positive under credible reports, more than an impairment-based standard. To do a follow-up test in NRC you can either be observable signs of impairment or credible report of use. That does bolster our program, and we have had success in identifying individuals using, including the third line on the bottom there, oxycodone, oxymorphone, and fentanyl. That was a security officer, and it was identified in that individual.

I should make one more point. The green highlight on the bottom basically indicates that 68 percent of the individuals that were identified for-cause testing and 36 percent of the individuals tested positive for a substance in the NRC-required panel as well as an additional substance. So there is some crossover in terms of the substances individuals are using. They're tending to use a lot of different things when we're identifying them in the additional substance test results.

This is something that we've been presenting for

quite a while. Subversion attempts -- I think we're unique in one way. While there's clearly a process to identify individuals that are attempting to subvert the collection process, mostly we're identifying this with temperature. I think 60 to 70 percent of the collections where we identified possible subversion attempt, it's a specimen that's out of temperature range. This has been a significant issue for us.

After 9/11, NRC modified its regulatory framework to more firmly address trustworthy and reliability issues. Someone's attempting to cheat on test results, that's a trustworthy and reliability issue. If an individual is identified cheating, and validated as cheating under the testing process, they will be permanently denied access to a nuclear power plant in the United States.

The eye-opening piece of this, in our minds, is that each year between 20 and 33 percent of individuals that test positive on a drug test, and positive meaning a violation, were subverting, which is a huge number of individuals. In 2018 it was 219 individuals of the 1,100 that tested positive.

Subversion attempts of the urine testing process is prevalent. Seventy percent of the facilities report at least one subversion attempt. Seventy-seven percent of the

identified subversions were at pre-access testing, so it's a predictable testing event that most likely when this is going to occur, and it's going to occur by the contractor vendor, where 95 percent of them have been identified.

These trends have held up over the years we've been collecting this information, and it has not changed. If anything, it's getting worse. Part of our proposed rule that will be issued later this year will bolster the subversion attempt detection standards that we implement at the NRC.

This gives us a snapshot of what individuals who are attempting to subvert, what was identified in them. So, I said already earlier that many of the individuals who are identified subverting, they just refuse. They don't provide a specimen; they've already been caught and they just walk out.

But roughly, in 2018, 22, 23 percent did provide a second specimen, and this is what was identified in the specimens. Forty-seven of the 68 hits were for marijuana, but there's a slew of other substances that the individuals were using, so as I said, many times people that attempt to subvert are using substances we're testing for, otherwise they're not the brightest people in the world. We disclose what we're testing for, so they're clearly using things

that we're testing for.

One unique thing that the NRC does is we use limit-of-detection testing in a broader format than what typically a federal program would use, which would be only if an individual requested a split specimen, they'd be tested at a second lab and you're going to take that to the LOD. NRC permits our licensees to test dilute specimens to the limit of detection if the screening assay screens at least 50 percent of the cutoff level for any of the drug metabolites or drugs they're looking for.

Most of the sites in the industry do use this optional policy. Our proposed rule will mandate that they use this moving forward. We'll also expand the limit-of-detection testing for post-event follow-up tests -- actually, I'm sorry, we'll expand limit-of-detection testing for any indication of a subversion attempt, so hopefully we'll broaden our ability to identify more subverters in that way, and deter more people from attempting to subvert.

Every couple of years we present some information about the hits that we get on limit-of-detection testing. It's a small number of individuals, but it is notable. We are identifying a variety of drugs. Primarily we're identifying in pre-access testing, which is not surprising

because it's a predictable testing event, but we're also gaining some on random testing. Mostly for marijuana, but also other drugs.

I mentioned earlier that we get a 24-hour event report if a certain labor category individual tests positive for drugs or alcohol. We also get a 30-day event report after a licensee concludes an investigation on unsatisfactory performance of a test. These are all related to HHS-certified laboratory testing, or four of five of them are. Last year we presented similar information. I think there were five as well.

The majority of them are human performance issues. Just want to note a few of these. There's always questions about whether blind performance testing is an important element of a program, and we continue to see information that demonstrates that it is, because we have low positive rates in our industry, and therefore the challenge in the laboratory to identify in some cases our unique testing standards, blind performance testing ensures that we're getting correct results.

So in the first instance, we had a blind sample that was adulterated, formulated to be adulterated, and it was returned as negative. The result of the investigation determined the forensic processing technician did not

properly aliquot all the original specimens to the correct collection cup, and that resulted in the incorrect result.

Obviously, that's not something we would have ever discovered if it wasn't a blind specimen, and that demonstrates the value of the blind program. Second bullet, a donor specimen was reported as negative dilute. Two days later, the laboratory updated the result to negative. Their internal review identified that the screening technician did not load the specimen on the refractometer consistent with the standard operating procedure, and that resulted in incorrect specific gravity value. The second test determined that it was not dilute. Again, human performance.

Third bullet, an adulterated validity test result. This was a blind, that was submitted to an HHS-certified laboratory. Screening indicated general oxidants. That laboratory, however, did not have a functional confirmatory testing equipment. Therefore, they sent it out to a second laboratory. Unfortunately they sent it to a laboratory that was not approved by the licensee to conduct that testing. By the time that was discovered and the specimen was moved to another laboratory, the specimen had leaked in transit and it was an invalid result.

Our rule requires that the HHS-certified laboratory maintain both initial and confirmatory testing capabilities for all tests and validity tests. That's something that -- and most of these, we do alert HHS when we discover these issues to ensure that any types of other reviews that NLCP might want to do, they do do. This affected a number of our sites.

We do have a small industry. We have 71 different locations that conduct testing. Most of the corporate entities who have many different locations will use the same laboratories to conduct testing. This capability was affecting a number of our sites, and this laboratory did not have that testing capability for multiple months, and that was something that we were only informed of because of this 30-day event report.

The next bullet is a blind specimen that was formulated to test positive for marijuana, was reported back as negative. While we rarely see these anymore, we did see this. The result of the investigation determined that it related to a poor formulation by the blind performance test sample provider. It was not related to the laboratory. Generally when these occur, the licensees will send aliquots of the specimen to other laboratories to confirm the results, and in this case, all the results came

back in the same direction.

This is an interesting one, and I hadn't seen this one before. Two donor specimens were submitted to an HHS-certified laboratory for testing. They both were rejected because the bottle B specimens were switched. There were conflicting results that came back on the investigations. The laboratory said that the specimens were switched in the bags. The licensee said there was no way that was possible, because we only collect one individual at a time and we seal the bag in front of the individual.

The last slide is just some resources in terms of the program that we use to collect the information. So back in 2009, we implemented an electronic reporting system. These are individual PDF files that licensees complete. They complete one form for each individual that tests positive, as well as the summary form. We have a lot of information that we're able to drill down and to tremendous amount of detail that will benefit us in terms of more precisely risk-informing our rule moving forward. Wouldn't it be nice if we could target our program to those who are actually using the drugs and be more resource efficient? That's something that we intend to move forward with as we have the capability.

Thank you for your time. If you have any questions, please feel free to reach out to us. Our contact information is in the slides. Happy to answer any questions later on.

MR. FLEGEL: Thank you very much, Paul and Brian. It was really -- especially around the subversion. I think that's truly interesting. Barry, I think, will have more data on what we're looking at.

With that, I'm going to conclude. After we come back from break, Captain Eric Welsh will be giving a presentation. So we're going to start right at 11:20. We'll still extend a 15-minute break. Anyway, I'll let everyone go, and we'll be back in your chairs by 11:20 and we'll start again.

Thank you.

(Brief recess.)

MR. AUMEN: All right, folks. Next on the agenda is a Department of Defense update. We have Captain Eric Welsh, Director of the Office of Drug Demand Reduction, Office of the Executive Director Force Resiliency, Office of the Undersecretary of Defense Personnel and Readiness.

Eric, when you're ready.

Agenda Item: Department of Defense Update

CAPT Eric Welsh, PhD, USN

CAPT WELSH: Thank you very much. For those of you who understand or maybe want to understand -- maybe you don't want to understand -- how things work at the Pentagon, I don't have slides, because I didn't have enough time to get them through the routing and approval process, and fortunately there are not a lot of updates from the last time that I spoke. In December, I presented data through FY2017. The FY2018 data has been compiled and is in routing. So I hope when we reconvene in December or next meeting that I can present FY2018 data.

The trends in the Department of Defense are very similar to those that we've already seen presented today by NRC and Department of Transportation. Marijuana is one of our biggest drugs, followed by cocaine and amphetamines. Opioids are certainly high as well.

So I just want to highlight that our drug panel is somewhat different from what we see in the drugfree workplace program, and so our panel includes marijuana, cocaine, D-amphetamine, D-methamphetamine, MDEA, and MDMA. So nothing different so far.

We also have codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, five

benzodiazepines, which is different from the federal program, and we test for six synthetic cannabinoids. The update I want to give is to an expansion that we've recently undertaken to this panel to include fentanyl and norfentanyl to our panel. So that's the update that I'm going to give. It's just going to be verbal.

The decision process that we make within the Department of Defense is we have a biochemical testing advisory board, which is very similar in composition. It's a governing and adjudicatory body similar to the DTAB that's meeting here today. We look for various inputs, both subjective and objective, upon which we base our determination. So we did two prevalence studies that involved military specimens, specimens from our routine testing population.

The first study looked at 32,000 specimens. The second study looked at 24,000 randomized specimens. One was done in late 2017, and other one was just completed in January. What those studies showed was prevalence similar to what we see for heroin in the military population. So we met as a group, as a biochemical testing advisory board, to assess whether we should expand our panel. You already know the answer to that. We have, and I'll discuss that, but I just wanted to talk a little bit about the decision

process that we go through.

There's really two questions. The first is the should we. Should we expand our panel. That includes subjective inputs like prevalence and the prevalence rate in our military population. It also includes any sort of anecdotal information we get from the Armed Forces Medical Examiner System regarding post-accident and postmortem investigations to see whether we see prevalence in those populations of specimens, even though we know that they're very focused and biased.

We consider the notoriety and in this case the lethality of incidental or accidental exposure to a drug or purposeful exposure to that drug, and we all realized with the potency of fentanyl that that is a significant concern, even from one exposure event, unlike some other drugs that don't have the same lethality.

We also consider other databases and other inputs, including the National Forensic Laboratory Information System report that's published by the DEA, which has showed a massive proliferation and expansion of fentanyl. We also noted that fentanyl, as everyone here likely knows, is used alone, but it's also cut into many, many other drugs and in our discussions with the DEA, they are seeing fentanyl virtually in every drug that's on the

street.

We also looked at CDC mortality data to see what was happening in just the popular culture, and again, those data indicate that deaths associated with fentanyl, either purposeful or accidental, are on the rise. So there's been many -- there's been discussions about opioid crisis and other endeavors with respect to opioids. So that was the should we, and the answer that we -- the resounding answer for that was yes, we should add these to the panel.

On the other side, we consider can we, and that's more of a practical discussion about our capabilities. That speaks to not only capabilities from an equipment standpoint, do we have the right technologies to test for these specimens; are they stable in urinary solutions? Is there enough research out there that allows us to expand our methods to add these in some facile and comprehensive and accurate way? And do we have the appropriate expertise to do so? So that's part of a capabilities assessment we do.

Then we look at capacity. How much testing can we do? Should we test all specimens? Should we test only a subpopulation? So again, this goes into the calculus and the decision-making.

Then finally I think everyone here, especially if

you're in the federal government, and I alluded to this before in getting slides and data approved, there's this institutional momentum that has to be overcome. So I call that our will. We have people who say no, we shouldn't do this, in spite of all these other driving factors, and leading indicators, simply because they don't want to change. That's part of my job is to rally people to make sure and to point out that this is a priority and that losing one individual to accidental or purposeful exposure is too much and the return on investment is definitely worth the effort, even if that effort includes changing your frame of mind.

The BTAB voted unanimously to add fentanyl and norfentanyl to our testing panel at a cutoff of one nanogram per milliliter. We sent that action to the Undersecretary of Defense for Personnel and Readiness, Mr. Stewart. He enthusiastically endorsed that, that action, in a memorandum that was promulgated on the 29th of March 2019, which gave 90 days notice to start testing for fentanyl and norfentanyl.

We met that objective on the 3rd of June, so last Monday. We started testing for fentanyl and norfentanyl. All the services were made aware of this. All of the service members were made aware such that there were

medical review processes in place to ensure that individuals who were using this legitimately through medical procedures or through medical prophylaxis were not prosecuted in any way.

And initially our testing is quite limited. We're leveraging the fact that fentanyl and norfentanyl are known to be associated with other opioids on our testing panel, and with cocaine. So we are using initial tests for those opioids, and a reflex or secondary adjunct test to test for fentanyl to begin with.

And we're going to be increasing that testing as we get a contract in place, and we hope to apply this to every one of the specimens coming in the door, the 5 million or so specimens we test every year on or about the 1st of September. So we're using an IITF model where all five of our DoD drug testing labs will do the screening at their geographic locations and presumptive positive specimens will be sent to our dedicated lab at the Armed Forces Medical Examiner System for the confirmatory testing.

So again, we started with an adjunct or secondary screening model to start with to get this out there to have maximum deterrent effect, and then we will expand to the general military population starting as soon as 1

September.

So that's the main update that I have that I thought may be of interest for the group, because I see that it's a topic that many people are going to talk about. So we hope to provide data to you, but obviously a week into it I don't have any data to share with you regarding fentanyl prevalence, but we're definitely going to monitor the prevalence and see if there's been return on investment.

So pending that, I'll take any questions.

MS. BURKE: You were talking about the screening you are -- did you say that you rely on whether it cross-reacts with opiates to decide whether to take it on for a confirmatory test for fentanyl? So you don't have a screen for fentanyl?

CAPT WELSH: Yes, ma'am. We are using the initial screening results for other opioids and for cocaine to reflex to a second initial test for specific for fentanyl. If that is positive or presumptively positive, we will forward those specimens for confirmatory testing.

MS. BURKE: So if it were negative for cocaine or any other opioids, you would not necessarily detect it on the screen.

CAPT WELSH: Initially no, but we are expanding

such that starting September 1 we will randomize this testing, we'll expand to eventually encompass all 100 percent of all the specimens that come through the door. But to get it out there the fastest most agile way was to leverage the fact that fentanyl -- so it's a little bit of piling on. We understand that. Someone will be positive for cocaine and fentanyl, positive for an opioid plus another opioid being fentanyl, but we felt it was important to get to deterrent effect out there as we absorb the learning curve testing for this drug. This was the fastest way we could get it out there.

DR. SCHAFFER: Hi, this is Mike Schaffer. I commend you for going to fentanyl. I think it's tremendously important for us to really take a good look at that, because it's devastating. It's something that needs a lot of attention. But I do have one question for you, and that is the sample -- I don't know that you have very many heroin samples, but the samples that you have had in the past, have you stored those and have you gone back and looked for fentanyl in those samples?

CAPT WELSH: Our positive rate from 2017 for fentanyl was 4.9 positives per 100,000 samples. So it's a relatively low rate. We have not done a comprehensive retroactive study looking for fentanyl in any of those

specimens, no, sir. But it's troublesome to test heroin positives after the fact anyway, because many times the heroin degrades to the point where there's not a whole lot there. So we don't know if that's the case with fentanyl or not, but we did not do a retroactive search. But thank you.

MR. HARRIS: Captain, Paul Harris with the Nuclear Regulatory Commission, when you do your prevalence testing, do you do it geographically, or do you just randomly select from all areas?

CAPT WELSH: We have five drug testing labs in the Department of Defense. One is in Hawaii. One is in Texas, another one at Great Lakes, Illinois, Jacksonville, Florida, and then Fort Meade here in the D.C. area. They receive specimens from all over the world. We send each one of those labs an equal number of screening kits and have them test their subordinate populations during a specific period. So we'll say starting 1 September, test until you have extinguished these kits, or test 6,000 to 9,000 specimens and send any presumptive positives for final confirmatory analysis. So it is very geographically dispersed, but it does rely on whatever normal population is submitted to those labs during the time period of the evaluation.

MR. HARRIS: Are all of those specimens uniquely identified, or are they erased from the individual's personal record?

CAPT WELSH: They are completely deidentified. Before there are any sort of prevalence testing, we're required to deidentify them. So there's no personal identifiers, no geographical information, no service affiliation.

MR. FLEGEL: Any further questions for Eric?

(No response.)

Thank you very much. Works right into the conversation of what we're going to look at later in the day. So that's great.

Now I am actually going to give an update on the program updates.

Agenda Item: Program Updates by DWP Staff

MR. FLEGEL: If I finish in a relatively short time, we're going to also have Faye Caldwell update on the emerging issues around marijuana. If not, we're going to push that to later in the day.

Again, Division of Workplace Programs, a list of members here. I truly appreciate all these individuals here, staff members, myself. We also do have several positions over the last several months that have vacated,

so we are looking for positions.

Drug Testing Advisory Board, we did a rollcall, but I just wanted to add the new members, and I appreciate them coming on, as Kristen Burke, Deborah Motika, and also Stephen Taylor, who is not with us today. And also, Dr. Barry Sample, who is with us today who was unable to last meeting to be with us, but he is here today.

Regulation and policy. Due to the emerging issues, I think all three parts of this triangle are being stressed. There's a lot of things going on, not only around emerging issues with fentanyl, emerging issues with CBD, but a lot of other laws and requirements and things that are being set up in the states as well as the federal government.

So again, it starts with a donor, but ends up as far as a result and ultimately ends up with the Medical Review Officer. There's a number of things that we're doing there, not only around the MRO Guidance Manual, but everything in between, and what we've been working on, not only as a program for urine, but also as a program for oral fluid and also in hair in a sense, going forward.

Just the Drug-Free Workplace Program in general, we try to take into all accounts when it comes to federal law, state laws, testing issues, which has become somewhat

difficult in itself, and then contract and legal issues around employer drug testing policies that they set.

DWP's objectives and goals, one of the first goals is to establish an implementation date for the Mandatory Guidelines using oral fluid. The proposed Mandatory Guidelines using hair has been referred to the Office of Management and Budget for review. A little bit later on in these slides I'll go through the process so everybody just understands where we are in the process for that.

"Present" is receiving the final approval for the Mandatory Guidelines using oral fluid as an alternate specimen, again to enhance the federal workplace drug testing program. I think what NRC talked about with the subversion and the ongoing problem with subversion, I think with oral fluid that's one of the benefits is being able to look at direct observed collection of a specimen, specifically oral fluid in that way.

Then the "future" would be the referral of the proposed Mandatory Guidelines using hair for distribution to all federal agencies for comment or review.

Again, just to touch on the revised urine Mandatory Guidelines, again, they were published on January 23, 2017. We have essentially had about 20 months of

testing around that. I did want to mention at the time, and we'll see later in the program, but what Eric talked to you about with fentanyl, is at the time when we initially evaluated the fentanyl, there seemed to be multiple mixtures of fentanyl with other drugs. I think that is changing over time. Now you see a lot more fentanyl by itself and/or mixed in as a contamination product of other drugs. Specifically, as we try to move forward around the testing of synthetic opioids, I think that people that are illicitly using those drugs are moving in new directions and some of that is due to cost and other issues around moving to fentanyl or heroin or other issues.

Just to reiterate some of the changes, and again, I commend NRC on their changes within what they're doing in the NRC program of moving closely or more closely aligning with the HHS Mandatory Guidelines but we removed MDEA, we added MDA as an initial testing analyte, and we raised the lower pH cutoff for the adulterated specimens from 3 to 4. There have been I think significant differences in what we've been looking at, not only around invalids, but also around the adulterated specimens, et cetera, subversion, substituted. So a number of those categories in testing the urine specimens have changed.

And there were multiple wording changes to

address the alternate specimens when authorized, vice versa on that is also in addressing the oral fluid or the hair, is basically now it's addressing an alternate specimen or an authorized specimen. So once the Mandatory Guidelines go into effect, whichever authorized specimen it is, it can therefore be used throughout the program when it comes to a federal agency.

The drug testing panel, of course, is cocaine, amphetamines, marijuana, PCP, opioids, and all the additional opioids that we added in 2017, but now the question is coming around emerging issues or emerging drugs, and that would be fentanyl that we're going to talk about a little bit later today in some of the information that we have done through a pilot study to look at this and to move it forward for a decision as to whether to add fentanyl to the drug testing panel or not.

Just to update, if an agency desires to add any other drug to the drug testing panel, there's an advance written approval from the Secretary, Department of Health and Human Services, it's required. However, the agency may test at any time Schedule I, Schedule II, on a case by case basis. So we get those routinely. We have had a number of times that fentanyl has been requested on a case by case basis in order to test for that analyte.

Effective date October 1, 2017, again, DWP continued to follow up with federal agency drug program coordinators that oversee the agencies for the Drug-Free Workplace Program, and again, that's consistent with the requirements in the Mandatory Guidelines and the testing of opioids. Right now, comprehensively almost all federal agencies we feel are testing for the synthetic opioids. HHS Secretary's priority has continued to be the opioid crisis. I know it has now moved from President Trump also to the fentanyl crisis that we see with the deaths, and as Eric had also stated, they continue to climb.

Again, the testing for the synthetic opioids could help deter the illicit use of prescription opioids and provide treatment to employees and federal agencies.

And then later on today, also we'll look at the current federal custody and control form that's in effect for federal agencies and the regulated testing until June 1 of 2020, and the process for development of the new oral fluid CCF has started. We're looking at a working group to put together as we stated, and I'll just -- I won't elaborate, because Charlie will talk about this a little bit more, but the form in itself has a limited space for the real estate of what you're supposed to put on that form. So again, we're evaluating that as to how we move

that forward. Does it become separate forms? Does it become a single form, and electronically, it seems to me more a sense that you can choose what collection you're doing when you have an authorized sample. For instance, if it's a urine, you collect urine, it goes to a federal CCF for urine. Oral fluid it goes to oral fluid.

So again, that's going to all be evaluated based on or within the working group to see what is the best options that we have in order to move this forward.

I have updated last time on the marijuana studies, I do apologize for not having the data available yet. We're still -- they're ongoing studies. There's a number of ongoing studies. The initial one we did was a pilot study. We have to expand on that pilot study, which will hopefully continue here shortly. Again, there's a number of technical and scientific peer-reviewed journal articles that are on our website. We're trying to keep that up to date as best we can within weeks of the time that the publication is completed so that the public can see that.

We continue to update again these lists of reference articles. We're also looking at the approval of other articles going forward that we're writing right now or currently in the review before being published to a

scientific journal. And again, I just want to thank Dr. Ed Cone and Dr. Ryan Vandrey. Again, Dr. Ryan Vandrey is the principal investigator on these for JHU, and Dr. Ed Cone is the SME is sort of leading it for us when it comes to these pilot studies that we're doing.

Again, studies for CBD and the data for marijuana analytes are currently under review, just to note that. And under oral fluid, I put this under oral fluid, but the CBD studies not only affect urine, oral fluid, possibly hair, there's multiple things that we're looking at regarding those. The question is will we have a federal register notice in 2019 for the oral fluid guidelines. So that's yet to be determined there.

So inclusion of the oral fluid as a new matrix in the federal program will enhance, I think, the Drug-Free Workplace Program. I think it boils down to multiple issues, but the one issue is the subversion and adulteration. If an individual is going to attempt to subvert a urine collection but yet when they walk into the collection site, they're getting an oral fluid collection, it is very difficult to subvert that on that in that sense. Vice versa the other way.

Then to be developed under the National Laboratory Certification Program, under the oral fluid

program documents, specifically is the MRO Guidance Manual. We are in what I would consider as a close to final draft on that which includes the oral fluid. So the MRO Collection Manual is sort of a binder where it will have not only urine, oral fluid, eventually other authorized samples within that. So the MRO that's doing multiple reviews of authorized sample will have everything included in one manual.

The oral fluid specimen collection handbook is being worked on. The collection site checklist and manual, et cetera. So there's a number of also scientific and technical issues under the NLCP program that we're working on.

Under the oral fluid Mandatory Guidelines, the laboratories, again, I reiterated this last time, but I think it's very important. Laboratories could use an alternate method other than immunoassay for initial testing. We've tried to let the science lead us a little bit in updating and revising the Mandatory Guidelines. So we don't want to -- we want to enhance the technology and move this forward. There's an interim period when you're going from immunoassays to LC-MS-MS, let's say, and we're trying to overlap that. Very specifically in the Mandatory Guidelines we have addressed it when it comes to initial

cutoffs. When you're looking at an immunoassay cutoff as compared to a screening LC-MS-MS cutoff, they're going to be a little bit different, because it's just much more specific. So in the allowance of that, so we're moving in that direction.

Testing for parent drug, THC, the psychoactive component of cannabis, is very important for other uses, including drug driving and I think that is relevant in a lot of the things that the states are doing right now as far as pilot studies under drug driving at the roadside, that being the basic -- the psychoactive component, the marijuana itself. I think for the Office of National Drug Control Policy, and everything else having federal standards that are set under the Mandatory Guidelines is more beneficial because you can point to a federal standard under that.

Then again, establish the implementation date for the HHS certification of laboratories; this is around oral fluid.

The hair Mandatory Guidelines. I have to say on both fronts with the oral fluid and the hair Mandatory Guidelines, there's a lot of interest. I understand the interest. We are, I think, doing due diligence ourselves trying to push those forward as soon as we can under the

scientific and technical realm of that. Just to update on the hair Mandatory Guidelines. The proposed Mandatory Guidelines for Federal Workplace Drug Testing using hair has been sent to OMB. It was logged in in the OMB website. So it is there. There is no information as stated as far as reading those, but they have been logged into the OMB website.

Comments and recommendations have been received from HHS operational divisions and have been incorporated. SAMHSA is proposing to seek federal agency comment and recommendations on the proposed Mandatory Guidelines, and SAMHSA is proposing to seek public comment on the recommendations, within those guidelines under the preamble, using hair.

The proposed Mandatory Guidelines using hair: DTAB recommendations were to pursue hair as an alternate matrix. We have done that. As recommended by DTAB development of the proposed Mandatory Guidelines using hair, has attempted to address some of the scientific issue of the use of hair in the drug testing specimen in itself. The proposed Mandatory Guidelines using hair will be sent to other federal and federally-regulated agencies for recommendations and review, and as I mentioned in the briefing earlier is that will be set by OMB as far as the

amount of time given to federal agencies to return those comments.

Status report on hair requires the Secretary of HHS to report on Congress on the status of the final notice of the statutory required scientific and technical guidelines for hair testing, and again, this is within 60 days from enactment, and annually thereafter until the agency publishes a final notice of guidelines for hair testing. Again, several provisions for the federal and federally regulated entities in the Fighting Opioid Abuse in Transportation Act are in that. That was one of these that was in I believe there's eight different sections, some refer to the Department of Transportation, some are to HHS. I didn't list those necessarily, but also in that was also around the electronic chain of custody form.

Just some of the advantages I felt were prudent to put here for hair testing. Again, it's direct observed specimen. It's noninvasive, as far as what was considered invasive for specimen collection. Difficult to adulterate or substitute in that regard. It's a readily available sample, depending on the length of the hair tested, and from the 2004, there was a number on the proposed rule of what was to be not only collected, length of hair, et cetera. I think in the new guidelines we expand upon that

regarding the 2004.

Then the drug metabolites are present in hair as early as one week after the most recent use. Again, I don't think this would be good for a post-accident test, but when you have a different selection of authorized samples from oral fluid to urine to hair, as far as all comprehensive program, I think that's a great comprehensive program to have.

I know some individuals follow this very closely, the Mandatory Guideline routing process currently within oral fluid is at the end, which I believe is number 16 or close to that. So really through the entire process from when we started the oral fluid, we're relatively close to the end.

With hair, we're relatively close in the middle, about at section 8 or 9, and again, these slides will be posted so that individuals can look at those, but for the routing process of where the Mandatory Guidelines are, we've tried to assemble this so that the public can understand in the routing process. There are many steps in that routing process, not only from federal agency comment, back to HHS, but then out for public comments.

MRO Guidance Manual, I also briefly talked about that. The urine MRO Guidance Manual, we have updated that.

That has been updated. We're still looking at updating some of the case studies around this, not necessarily around the opioids, but there are some around the adulteration, subversion, et cetera, that we wanted to update. Diluted samples, we have added some more information around the actual synthetic opioids when it comes to case studies.

Then again, we're continuing and had the working group for the MRO Manual on oral fluid. I believe that's where we're getting to a final draft proposal of how we're looking at that. We should hopefully be able to conclude that in a relatively short time, and then I would like to see that posted on the website as a draft obviously prior to the oral fluid Mandatory Guidelines being implemented, so that MROs et cetera could have time to look at that manual.

The Mandatory Guidelines for Federal Workplace Drug Testing falls under Subpart N under Medical Review Officer Section 13.1 specifically.

Fentanyl. It seems to be the topic of emerging issues, especially lately. There's a number of things. This was the requirement under Section 4106 and, as Patrice had said, requires the Secretary of HHS within 180 days to determine whether revision of the Mandatory Guidelines for

Federal Workplace Drug Testing Programs to expand the opioid category on the list of authorized substance testing to include fentanyl is justified. That's based on the reliability and cost-effectiveness of the availability of the testing.

We are considering whether to include with the determination under Subpart A a separate determination on whether to revise of the Mandatory Guidelines for Federal Workplace Drug Testing to expand this list of substances authorized for testing to include any other drug or other substance. There are a lot of other emerging issues. I know that there's some interest in tramadol. That's one of the ones that I gave a presentation, I guess was a couple weeks ago, and there's always been a list of opioids as far as hierarchy of where they fall, but I think that chart is moving when it comes to not only tramadol but other parts of the testing around opioids, whether it's fentanyl or the synthetic opioids.

So again, that was to include other drugs and other substances listed in Schedule I and Schedule II of Section 202 of the Controlled Substance Act is justified based on criteria. So we are giving a two part -- not only looking at fentanyl, but looking at other drugs that we should include in the Mandatory Guidelines if they're

warranted.

Ongoing studies which are quite a few and it solves a task that we're trying to complete is the cannabidiol study, the start date was June 2018, that was the pilot study. We still have ongoing studies and studies to conclude or continue on expanding that pilot study. We have the pharmacokinetic data and pharmacodynamic data of oral, smoked, and vaporized CBD. We're looking at that disposition of CBD, cannabidiols or cannabidiol as well as cannabinoids in oral fluid and whole blood after vaporized and smoked cannabis, and then the pharmacodynamic comparison of CBD and cannabinoids following oral, smoked, and vaporized.

I think this is interesting, because I did not realize the relatively new way CBD is used currently for most people is it's vaporized seemingly. So it's a whole different process when you're vaporizing, and if the CBD or hemp product is contaminated, then that's a different issue when you're vaporizing as compared if you're eating an edible or you're smoking, or you're actually taking it as an oil. So it's a whole different route of not only the kinetics, but the pharmacodynamics of what you're looking at when this occurs.

We also gathered opioid data under the revised

Mandatory Guidelines using hair, and under the changes for pH changes, invalid results, substitution and adulteration, I hope to be able to give that presentation at the next open board meeting where we have evaluated a lot of this information and be able to show it for the public.

Epidiolex. I had this in my last presentation, but this is the secondary FDA-approved cannabinoid product. It was approved in 2018 for the treatment of young patients over two years old for the seizures. This is sold as an oral suspension. It is the first FDA-approved drug that contains a purified drug substance derived from marijuana, specifically CBD, and the first treatment for Dravet syndrome. It has been rescheduled as a Schedule V drug, and all other CBD products remain Schedule I, as far as the amount of THC within that.

Then again, as far as emerging issues, specifically around synthetic drugs that we've looked at, I mentioned DUID and the marijuana laws. I think that continues to be a problem. I think the other part to add to that would also be polydrug use within those. There's seemingly a lot of polydrug use when it comes to not only marijuana, but I think as NRC showed, just the benzos in general of all the other analytes you see within a person when you're looking at those other analytes.

The CBD studies continue, and then other potential problems with synthetic drugs are the lack of a rapid and cost-effective means to identify the substance. I think this changes a little bit specifically around oral fluid, because if you can use, for instance, LC-MS-MS and screen for those other types of substances, it's a little bit more effective, I think, than not having an immunoassay to actually be able to screen for those. So hopefully in the future, we don't want to limit technology. We want technology to move us forward.

With that, that concludes my update. I do wish I was able to give more details on certain things, but we are in the process of moving everything through for approval, it is moving through, public can be assured of that. We're hopeful that things will be logged in as things do move forward and the public can see those.

Thank you.

Any questions from board members?

(No response.)

Thank you.

I'll go ahead and turn it over to Faye Caldwell, who is going to give an update on the emerging issues section under the marijuana laws, and so I appreciate her doing this. It was not on the agenda, but I think they're

moving so fast and furious that, as you will see from her, that it's something that we wanted to update.

Agenda Item: Update on Emerging Marijuana Legalization

Faye Caldwell

MS. CALDWELL: Thank you, Ron.

For those who were at the last DTAB meeting where we covered some of this, this is going to definitely be an update. So we will refer back a little bit, but it really is focused on what's happening now and what's moving forward.

So let me sort of say in the 30-second constitutional law that you can all become experts on is the first question I'm always asked is if it's federally illegal, why are we having this conversation at all? Marijuana laws under the state, as well as the federal, are essentially criminal laws. So there are federal penalties for criminal penalties for possession of marijuana, and the same way, states have criminal penalties. So what happens is essentially all state marijuana laws are essentially decriminalization statutes originally. I.e., you no longer can be arrested and charged under a state law for possession of marijuana in certain amounts. You can still be charged federally by federal law enforcement.

So what we're going to talk about today is state laws. We all understand and everyone's given presentations, it remains -- cannabis remains federally illegal. We'll put the CBD carveout to the side. But states have taken a different standard towards it, and they then have now added on in terms of employment protections.

So think of treason and murder. Treason is traditionally a federal crime, and exclusively. Murder is typically a state crime. Cocaine possession is both. So we're really only talking about what the states have done under their laws.

As of June 5, and I'm going to make this really clear, these slides are only current through June 5. I will actually orally tell you about changes between June 5 and June 11 as we sit here today.

(Laughter.)

It changes that fast. Literally that fast. You're going to hear me say I have an update to this.

So as of June 5, we have 33 states, D.C., three U.S. territories that have passed what I'm going to call comprehensive medical marijuana laws. Let me be clear with you. They are not the same, in no way the same. Every one is unique.

Fourteen additional states have passed what we've

been calling low THC/high CBD laws. Please understand that it's different from the 2018 Farm Bill, and we're going to discuss that just a smidge. One state has only industrial hemp, i.e. under the 2014 Farm Bill they chose to expand. Coincidentally that's Nebraska.

And then 11 states, plus D.C., plus two U.S. territories, have passed recreational marijuana. All right? It's sort of saying these are layered. All but one territory that supports recreational also has medical. They're alive and well. These are two separate policies. For those who want to do the math, there are only two states that prohibit all cannabis for all purposes. That would be Idaho and South Dakota, for the ones that want to keep track of that. Okay?

We're going to first focus on state medical marijuana laws, 33 states. You'll notice what we've done is we've given you the year and the ones in green are the ones really that we're going to update you on today. So it is moving. It's by far the most prevalent. We have 50 states. You can do the math. Most states have some form of legal cannabis where they have chosen to accommodate possession/ingestion for some purposes. They are massively inconsistent.

The program requirements among these states are

not typically similar. They have different physician requirements, different qualifying conditions, reciprocity with other states. How much you can possess. Who can be a cardholder? How you distribute it. The potency, method of ingestion can vary. What type of protection, and we're going to talk a little bit -- a lot about what employment protections in particular, because our group in the workplace is quite interested in that.

Then there are some other civil protections. So one of the takeaways of today is if you have employees or in different states, do not assume they're all the same. It will vary dramatically, and everyone has to drill down individually into a state.

Let's go to the next slide. State recreational marijuana laws, as of since the time of this presentation was given to DWP, we now have 11 states, plus D.C. The trick was, and you'll note it, that Illinois which passed late last month by the legislature actually has now been signed by the governor. So it is now in effect. So that's an update from this.

All of these states also have comprehensive medical marijuana laws. There's some trivia for you. Vermont passed by legislature and it doesn't allow sales; it's cultivation. Illinois, uniquely, was the first one to

pass solely by the legislature, and I think caught a few people by surprise, some of the provisions in it. Not all of these are in effect. Illinois does not go into effect until the first of next year. But you'll see the years, and so we're going to talk a little bit about the three states and some trends that we're seeing among them. There is definitely movement.

No one, sadly to say, has moved in the other direction and eliminated recreational marijuana after passing it. It is a growth issue.

Again the overview, and I know that we have already heard today about the 2018 Farm Bill, which defines industrial hemp as the cannabis sativa L with no more than 0.3 percent of THC. This is not the law among the states at the current moment.

This is only the states that don't have medical marijuana. There are more states than this, but of the ones that do not allow medical marijuana but have low THC/high CBD laws, you will see an immense difference of allowable amounts of THC. It is not the same thing as the Farm Bill. These are two separate functions and separate programs.

So you're going to go as far as Virginia which allows 5 percent THC in their what is typically oil, though

it doesn't have to be. You look at Georgia. The same way. It is big diversity. These similar to the medical marijuana, the methodology, the who can get it, how you can get it, the conditions, all of those same factors go into the low THC/high CBD laws. They are very, very different. Some states have dispensaries. Some states you have to register. Some states you do not.

So it is a movement -- all of these laws came into effect after -- mostly in 2014 on. These are very, very broad-based, but it's also interesting for some of the high ones, Virginia and Georgia, although it's on the books; they don't have dispensaries open. So the method to get it. Texas, on the other hand, which is extremely low does have dispensaries.

So after you pass the laws in this area, each state has to develop their infrastructure. That doesn't happen -- sometimes not very quickly at all. It can be years before that happens.

We're just going to give you a map visual. You're going to see there's only three states that don't have anything, with Nebraska having 2014 industrial hemp. But there's clearly a grouping geographically. That is altering. Some people are surprised by some of the way some of the states have gone, but that is the current

status today.

So let's turn to the updates of medical marijuana before we get to recreational. It passed in three states in the last year, Oklahoma, Missouri, and Utah, U.S. Virgin Islands also. But what's interesting, if you look at legislation, it was introduced in at least 12 states. It is shocking how much marijuana legislation in general is being introduced to state legislatures. I don't know that anyone can keep up with all the aspects of it.

Most of the state legislatures for 2019 have closed, but not all. So we don't know if there will be some more changes, but we have captured all that we could find and all that have passed the legislatures. Recreational passed three states, which obviously as a percentage is moving right on up there, two U.S. territories, and I mention Canada because although it's certainly not U.S.-based, it has had a big impact in how some of the states have viewed their legalization efforts, and they're going through the throes of trying to, through legislation and regulation, deal with some of that and particularly in safety-sensitive.

So we have Vermont, Michigan, Illinois, the Northern Mariana Islands, but what's interesting, it was introduced in at least 20 additional states; it's also for

our sort of nonscientific watching that typically in state legislatures, these types of bills are introduced a number of years before they pass. It is kind of unlikely that they typically pass on the very first go round that it goes in. They tend to build support, et cetera, is what we have watched.

There's a number of other states that have -- and cities, counties -- that are also looking at sort of I'm going to call them advisories, or studies, to look into referendums on either medical or recreational marijuana. South Carolina, you know, Ohio has five that approved it, Wisconsin's looked at this. So it's happening at a more level in terms of eliminating, for example, ordinances in cities of marijuana. So it's happening really all the way down as far as you can go.

When you get to the recreational proposed, everyone, I've got to tell you, thought that New Jersey and New York were on track to pass. They did not pass. But they didn't really go to a vote. It sort of failed through the process, and they're working on it. It's anticipated. Those are two states that are being watched very, very heavily, and you'll -- we're going to talk about employment protections, and one that really doesn't match up because of it. So that's kind of where we are at from a

legislative point of view.

So I'm going to talk about general trends and I really said that every state's individual and I mean that, but as we look at trends, we can see that there are definite trends. Not 100 percent, but definitely trends. The first one is to providing some sorts of explicit employment protection. Now, how does that look? It comes out through various ways. Let me give an example.

A number of states have that if the sole evidence is metabolite present in a drug test, that is not a definition of impairment or using on the job. Every single state medical marijuana law and every single recreational says that you don't have to accommodate two things. You don't have to let people use on the job, and you don't have to let them work under the influence. It will tell you that some legislators may not understand that the difficulty of determining impairment on the job, but it's in there, and they all say you don't have to let anyone use impaired.

They also use antidiscrimination provisions, and we'll talk about those. That would be the state ADA laws where because medical marijuana connotes a medical condition, that it might be impacted. There are other protections that are going on that we are not going to

focus on with this group, but be aware. Schools, custody, housing, medical care. All of these things are being impacted, like should you be allowed to have an organ transplant if you are a medical marijuana user?

There is in some states protection against that, where illegal drug use might not be. Custody hearings. Those are all being played -- so it's really happening in all aspects of life for people in these states that wish to go down the medical pathway.

Qualifying conditions are changing. There's a movement, it's a trend toward total physician based. If you can get a physician recommendation for it, that is enough. Some states are very, very restrictive. You have to have a diagnosis of certain things, and interestingly enough, it is not a medical determination. It is a legislation. So i.e., the legislature determines whether they want to add or detract conditions to allow it, and we're going to talk about some of those.

Who can be the recommender? Is it a physician? Is it a nurse practitioner? That's changing. And all other program requirements. So almost every year, many -- they made the legislature -- this changes even in states that have medical marijuana. We're going to talk about a change that's happened since June 5, when we get to it. So

that's sort of the trends that you're going to see, but you have to delve in.

Let's talk about state recreation marijuana laws, and I will tell you, I didn't change it as of June 5, but this slide has massively changed within the last two weeks. All states as we said before, that have recreational cannabis, also have comprehensive medical. Just so we're clear, medical isn't dead when they go recreational. States are actively involved. There are differences in possession limits, potency, taxes that you pay, et cetera. So medical marijuana in a state like Colorado, which has recreational, is alive and well and being considered by legislatures when they meet. There are its uses. There are still uses.

Also, typically, it's interesting that medical marijuana tends to -- for those using it truly for medical -- tend to be in different format. They're often not smoked. They're often in tinctures or extractions that are being done.

Impairment. Driving under the influence. Of course, most states prohibit this. However, they do not provide any guidance on it. We're going to talk at the end about the two or three states that have something, but there is certainly no per se accepted limit of THC in

blood, and there is certainly no consensus on the limits of what manages impairment.

Employment protections. If you would have asked me a year ago, I would have said there was no employment protection for recreational use. We are going to talk about that, because that has changed. That has changed in the last two weeks, and we're going to talk about Illinois and Nevada in particular. It is a seismic shift in what we're seeing in what the states are doing. Maine has some. Michigan is proposing some. There's none -- and some are looking to change it. We'll go through that.

So let's look. Let's go to the next slide and let's talk about Illinois. You'll notice it says it's awaiting governor signature. That is no longer true. The governor has signed, as -- well, take that back. This is not signed. Sorry, Nevada. I'm getting them confused. This is still waiting, but the governor has indicated he will sign, was a strong supporter of it going through.

Yes, I'm right. It provides employment protections for off-duty use of recreational marijuana. It provides definitions of workplace and on call. It does not provide any safety sensitive carveout at this stage.

Now, one of the things that we are obviously going to have regulations on this, and there has been a bit

of a trend in states, and this is more medical, where even if it wasn't in the original statute, that sometimes regulation is added in. So we don't know where that will go. The governor hasn't signed it yet. But right now, it does include the signs of impairment, but this would be for both applicants and current employees. We don't know where this will go, but this is a big thing.

The second one, Nevada. By the way, Illinois and Nevada go into effect the first of January 2020. They're not in effect today. This the governor has signed. So this is now law. This is a preemployment provision. Put an asterisk by that. So for applicants, it is an unlawful employment practice for an employer to fail or refuse to hire prospective employees because they submitted to a screening test and tested positive for marijuana. There are some exceptions written in, and if you track the legislative history on this and read the committee notes, you'll see them. Firefighters, operation of a motor vehicle, and for which federal or state law requires the employee to submit to screening tests. Not sure how meaningful that is, because I'm unaware of any requirement under state Nevada law to submit to screening, drivers to submit to drug tests, and of course federal is going to be controlled by federal law.

And positions that in the determination of the employer could adversely affect the safety of others. So there is a safety sensitive carveout. It is unclear what that means, and unclear how far that will go. I'm sure that will be subject to some legal challenges and definition, and hopefully we'll get some guidance from the regulations when they come out.

Probably one of the most troublesome areas of the Nevada law is it provides that for preemployment applicants within 30 days after the positive test, the applicant can submit to an independent test and have a brand-new test. Obviously, with this one we understand that that is likely to produce a negative test within 30 days after. Now, although this legislation applies to preemployment, we have made a note here. Nevada has a very, very broad off duty use statute.

What it provides -- and I'm paraphrasing a little bit, but close -- that you cannot penalize a current employee for anything that is otherwise legal under state law. It has not been challenged yet in court with respect to marijuana. I can tell you from reading the committee notes on Nevada that the legislatures think that this would connote that there is current protection for current employees. So this is again fairly seismic shift that has

not been present before. So Nevada will be watched for. So that's sort of where we're at at this moment.

So I'm going to back to medical marijuana, and this is where it's much broader in the considerations. For a long time, people thought if they read the medical marijuana statute under a state and it didn't mention employment protections, they were good. But really now it's quite clear with case law, since we now have enough years of medical marijuana to have at least a handful of cases, that employers have to look at everything from state disability laws, drug testing drugfree workplace laws, unemployment benefits, the ADA, FMLA, legal off-duty use laws, and even worker's comp, and they all interact.

So workplace, it's not enough to just look at the law. So let's go to the next slide, and we'll talk very quickly in general. I know I'm keeping you all from lunch here. There's three sets of employment protections. States that generally provide no protections, though be aware of those legislatures are often moving to change that. States that just haven't determined it, and unclear. So every employer has to make an individual determination of what they're going to do for their workforce and their risks. If anyone wants, I can talk to any of them about what states are what. But we won't take it -- it's just

tremendously unclear.

I understand these will be available. There's 15 states -- out of 33 -- that provide some degree of explicit protection. Whether the idea of positive drug testing language, i.e., you can't tell people what to do -- merely because they have a positive drug test. You can't fire them. They have supreme court decisions, disability laws, people say, well, if you have medical marijuana, it must mean they have a claim under a state disability law.

There's a couple of states that have some safety sensitive carveouts and definitions in blood. Definitions of employer and a few exceptions. So this sort of goes back to our beginning thesis, which is you have to really look at the individual state law.

Let's go to the ones that just came. We have as we all know Oklahoma. They passed just a couple of months ago the Unity Bill, and it does add some exceptions for safety sensitive, but it's a non-exhaustive list. We'll see how far that goes. There's always when we go to safety sensitive carveouts, a lot of discretion on the part of employers and the courts I imagine will get to decide how far that goes.

Medical marijuana in New Mexico had a previous one, it's now added employment protections, but it doesn't

apply to people in safety sensitive. Be aware, safety sensitive varies in each state. That is a definition typically that's often not.

This is probably the most troublesome. This is New York City. The council has passed legislation that as of May 2020, employers cannot test for preemployment, hiring practices, for marijuana. I said earlier I was a little surprised that New York didn't have recreational. Be aware, while New York has a fairly robust medical, they don't have recreational marijuana on a statewide basis. So I'll be curious as we go through this what this means. There are some safety sensitive carveouts, but this was the first and only situation where you cannot test, which is a very different aspect than not being able to take adverse employment action. This was a very big change. We'll see where it goes.

This will be explicitly no protections. We have seven states that right now do not allow it. Most of them, the regional medical marijuana states, are on the west coast. Many are changing this, but they're still out there and they're normally by supreme court decisions that we have it. If anyone wants these slides, just let me know.

These are the ones where employers struggle with, because it's really quite frankly unclear. They have to

evaluate their individual risk and their individual employee population to determine it. These are ones that don't affirmatively address employment. It's unclear. These are some of the states where they have been found to have employment protections under disability law or other law, but the statute itself for medical marijuana does not include it, and we will have that.

To give you a sense, these are proposed legislation to add employment protections to existing medical marijuana laws, and you're going to see a number of states or that some of them are trying; they were proposed. They didn't pass. Many of the states that have explicitly no protection, there was an attempt to get through the legislature. A couple of them passed, as we talked about earlier. But it's ongoing. We'll see what happens. A couple of them are still open because the legislatures haven't closed.

This is -- we're going to cover very quickly. These are court decisions, which is really where it is being fought out. Before 2017, there was no duty to accommodate, and at 2017 is the watershed year where we're having it.

These are a variety of cases, and the cites are here for anyone who wants them who can read the ones where

this is developing. This is an emerging trend. We're going to continue to see that.

Let's go further. The employment protections, Rhode Island, Connecticut, and Massachusetts. We're starting to find employment protections.

Let's go on to the next. In the last recent year, Arizona, Delaware, and New Jersey have all had them, and they typically follow whether there's explicit protection in the state or something confirmed or whether the disability statutes move, but employers are really having to be difficult.

Let's go on further. You're going to see that the second New Jersey, these all went without it. New Jersey currently has both ways, protection and non-protection, and these cases are making their way through the courts.

This is to tell you how difficult it is. These are three states where they have interpreted differently the same exact. So the idea of Washington state versus Maine. Really similar positions, just different interpretations. So one of the things, the takeaways that I advise my clients, don't rely too much on other states. There's no guarantee that someone would go the way Colorado went, if you're sitting in another state. It's good to

know what they are, but no guarantees whatsoever.

Let's go to the next one. Okay, these are all states that are just pending cases we're watching. They're happening all the time, and more are being filed, and we're going to find out -- and there are some sort of outliers that we're watching very, very closely.

There is immense medical marijuana program expansion. They're also going to smoking. They're going to additional conditions. Each one of them are ongoing, just this year these three are going -- undergoing massive expansion, additional conditions, who can prescribe it.

Going on to the next slide, I promise you we're close, is these are qualifying conditions. There is a trend toward more access. Some of them I don't think we'd have an argument, you know, Parkinson's, spinal cord injury, those sorts of things, but there's being added PTSD, anxiety, migraine. We also have ones obviously that pure physicians -- as one good for what ails ya type of provisions that we have.

You'll see some examples of various states. Chronic intractable pain, PTSD, migraines, obstructive sleep apnea. Interesting, I am making no attempt to determine whether they're good or bad, I'm just here to tell you what is happening.

We've talked somewhat today about opioids. With the advent of the opioid, recognition of the opioid crisis was really about last July, there is now a lot of movement to add opioid use disorder as a qualifying condition for medical marijuana use. You can see this has all happened since July. This is as we turned, since this slide deck was prepared, New Mexico has added to it and they passed it a couple of days ago. So we now have that, and it's proposed in a lot more. It's one of the most common sort of answers to the opioid crisis. There's a lot of -- if you Google it, you'll find out rationales and what they see is causing studies.

It's all somewhat interesting. There's a new study out today that I've read about where one of the ideas is that driving deaths -- opioid driving deaths decrease in medical marijuana states, now sort of suggesting if you do a longer study perhaps it's not quite so true.

Increasing access. Who can recommend and certify? Some states are now going nurse practitioners, physician's assistants. That would be New York. Who could administer? Easing up physician requirements. So it's giving broad-based.

We're giving a lot more sort of increasing access. Just so we're clear, medical marijuana protection

not only applies to the person who uses medical marijuana, but to the caregiver, the person who often transports marijuana. They get this exact same employment protections. It's a cardholder status. So yes, people who don't use the medical marijuana and test positive for marijuana can get protection under these laws. I'm just here to report it.

(Laughter.)

So that means that because obviously people who are dramatically ill may not be able to go get their medical marijuana is the rationale, but they don't distinguish it. So that's sort of an example of how we're doing it. They're also increasing things like the timing. Most medical marijuana cards are good for one year. Hawaii is expanding to three years, instead of annually. How much you can have, all of that is changing.

And then as promised at the last, let's go to the next one. Impairment in the law. These are the states that have per se levels, all in blood. Now, be aware, obviously in the workplace, this is not a common sample type. But you're going to see that they have per se limits. These are typically not for the workplace. They're usually DUI statutes, and two states have safety sensitive positions, which at least in Pennsylvania are a

defined list. You have per se limits in blood. Again, you would have to test people in blood in order to allow that. So obviously it's much more of a post-accident reasonable suspicion, and a provision it can be in blood.

I know that we've gone through an immense amount. I'm happy to provide them to anyone and answer any questions we had. Ron, it took a little longer than I thought. So I apologize for your schedule.

MR. FLEGEL: Well, thank you very much. I think they're all important issues. I wanted to make sure there was an update to that.

What we'll do is we'll hold the questions, because I have one, until after we come back at 1:30, and then we'll start from there at 1:30. So I'll actually turn it over to Matt to close this section of the meeting.

MR. AUMEN: So that concludes this portion of the meeting. We'll come back at 1:30.

(Recess for lunch.)

AFTERNOON SESSION

MR. AUMEN: We are going to get started with the afternoon agenda for the Substance Abuse Prevention Drug Testing Advisory Board meeting. We will proceed with some questions that we have for our last presentation.

MR. FLEGEL: I had one question for Faye after her presentation, and this may extend over to the laboratory personnel that is here. Have we seen any trends at all of employers moving away, at least in the non-regulated sector, from testing for THC? Or are they changing their profiles? I am just curious if that is a trend that we are seeing because of these state laws.

MS. CALDWELL: I will give you my impression, but I am certainly going to defer to the labs that would actually have that data. There has been maybe a slight decrease, but I would anticipate with these very, very recent changes in the recreational, this is likely to be a subject of continuing change, much more perhaps dramatically than in the past. But I will defer to the labs that are here much more than I could say.

DR. SCHAFFER: We have had some requests to remove THC testing from panels. But it has been fairly limited at this point.

DR. SAMPLE: All I can say right now is wait for

it. You will see the slide on that shortly.

MR. FLEGEL: Are there any other questions for Faye on her presentation? If not, we are going to go ahead and start with Dr. Barry Sample on his presentation.

Agenda Item: Drug Testing Index (DTI) Data – 2018 Update on Drug Use in the American Workforce

Barry Sample, PhD, Quest Diagnostics, Inc.

DR. SAMPLE: It is a pleasure to be here and share with you our data on our workforce drug testing results. I am going to give a longitudinal look at our data, as well as call out small interesting insights, I think, particularly as we are looking at some of the newer drugs and changes in the regulations. But before I start, I will give my normal caveats about the dataset. This is all workforce drug testing data to the extent that we can identify criminal justice, rehab, really non-workforce drug testing. All of that is excluded to the extent that we can identify point of people that are sending us specimens for confirmation of point of collection tests where we don't have line of sight to those field screen negatives, and thereby able to calculate an accurate prevalence rate. That would be removed, as well.

Unlike the data that was presented earlier by the NRC, this data is laboratory positive data, prior to any

MRO reviews. So we don't know if there is any alternative medical explanation. Although, that being said, particularly for the prescription drugs, I think there will be some interesting insights that we may be able to draw from this data.

I use to say that it would include employer blinds, MRO blinds. With the recent change in the DOT regulations, that would be much less of a component in the data. Although some regulated customers, and certain some non-regulated customers, still include blinds. And generally, particularly for the higher positivity, higher prevalence rate drugs, that really wouldn't have any impact. Blinds to the extent that they would have an impact in the past might be for the very low prevalence drugs where it might have a greater impact.

There are two major groups that we look at in our data. So obviously, the overall, or what we call the combined US workforce, but we also break out the federally-mandated safety-sensitive workforce, by far, the largest component in that FMSS group would be DOT regulated testing of safety-sensitivity private sector transportation employees. And within that group, FMCSA, of course, would be the largest.

But it also includes employees covered under

Nuclear Regulatory Commission rules, again in the private sector, as well as those few people, maybe some of which are sitting around this table are in the Testing Designated Positions that are actual federal employees. But by and large, this FMSS group would be private sector employees that are covered under US government rules. And then everybody else, we call the general US workforce. You can think of that as purely company policy tests not being done pursuant to any federal requirements.

I also try and weave into this data that I present information that is derived from the National Survey on Drug Use and Health. It is an annual survey conducted by HHS, non-institutionalized, civilian population, age 12 and older, that assesses drug and alcohol and tobacco usage patterns in the US population. They survey about 67,000 or 68,000 people annually. But I think it is interesting as we look at this data to compare maybe what is happening more broadly in society with what we are seeing in our drug testing index data, as well.

I am sure everyone is familiar with this aspect. Three common matrices used in drugs of abuse testing in employment-laded drugs of abuse testing, urine and oral fluid, which detect relatively recent use. Urine, we generally think of one to three days, oral fluid, one to

two days. Even less so if we are talking about marijuana. Again, all of this has always depended upon the drug, the dose, the usage patterns, et cetera. But these are stereotypically what we think of.

And then hair testing, which detects a pattern of repetitive use. We think of up to a 90-day window based on testing of the closest inch and a half of head hair and other matter. The majority of our hair tests are our head hair. So that is the background and the caveats. What are some of the key findings? Overall positivity continues to climb. It is at its highest rate since 2004. Marijuana continues to positivity and continues to increase across almost all categories.

A potential bright note as we look at cocaine and heroin, between 2017 and 2018, we will talk more about all of these later, while positivity for opiates continue to decline in all opiate categories, we will talk about some interesting data there. Increases in post-accident positivity continues to outpace other testing reasons, including preemployment screening.

And we have seen a rise in specimens reported as invalid, which while that doesn't prove that somebody was trying to subvert the testing process, it certainly raises the level of suspicion when you see this big spike in

invalid tests. We will talk a little bit about that.

As we look at our data, let's first start with the combined US workforce. So when we first started summarizing and reporting on this data in 1989, our overall positivity rate and combined US workforce was 13.6 percent. It reached its lowest point in 2004 at 4.5 percent. And now in 2018, while we had previously been seeing those year over year declines, over recent years, we have been seeing slow but steady year over year increases. It is up to 4.4 percent in 2018, which means it is at its highest level in more than a decade, since 2005. And in fact, in addition, those slow but steady increases reflect an increase of more than 12 percent over the course of the last five years.

If we look at the various testing categories, so first of all, the federally-mandated safety sensitive workforce in 2018, it jumped, went up 28.6 percent to 2.7 percent. You might be able to guess what was probably one of the big drivers of that. There were a few changes in the federal program between 2017 and 2018 with the inclusion of the prescription opiates. We will talk more about that in a little bit.

I would also add that for the federal testing, since 2014, we have seen nearly a 59 percent increase in overall positivity. In the general workforce, we were at

5.1 percent in 2018. It is a 2 percent increase as compared with 2017. It is at its highest level in the general US workforce since 1997. That is many, many years since we have seen levels that high. And it is up 8 and a half percent over the course of the last five years since 2014. And then there is the combined US workforce again which we have already talked about.

If we look at our overall positivity in the drug-testing index and compare that with the National Survey on Drug Use and Health, looking at the general US workforce, this again is our DTI data for the general US workforce between 2000 and 2018, which we have already talked about. But when we look at the NSDUH data, National Survey on Drug Use and Health, and only look at those respondents who are employed, they are in the workforce, and break them into two categories. Those that are subject to some type of employer drug testing program. It might be preemployment, it might be random or post-accident. It may be some combination of those. But some type of employer drug testing.

We see the self-reported use of an illicit drug in the last 30 days among those respondents subject to an employer drug-testing program. Clearly, over the course of the last five years or so, we have been seeing increases.

And it is at its highest level going back to 2000 at nearly 10 percent. Self-reported use of an illicit drug among those respondents subject to an employer drug-testing program.

If we look at those respondents not subject to an employer drug-testing program, we generally see 40, 50, 60 percent higher self-reported use of an illicit drug in the previous 30 days among those respondents not subject to the drug-testing program. And we actually started detecting the increase in self-reported use among this group a couple years earlier than we did in those subject to drug testing.

I think it is somewhat of note that those subject to drug testing are also reporting an increase in self-reported use, which likely isn't very inconsistent with our data where we have been reporting for the last five years on year over year increases across a broad category of drugs, not just overall. Really looking forward to when that 2018 data will be available towards the end of this year to see how it compares with the more recent data that we have.

So marijuana dominates in the US workforce. It remains America's favorite illegal drug, as I am fond to say. We all know what America's favorite legal drug is, but maybe pretty soon I can't say it is America's favorite

illegal drug. So in our general US workforce testing, it increased nearly 8 percent, between 2018 and 2017, up almost 17 percent since 2014. It is at its highest level since 2004. So year over year increases, as you can see here, in marijuana positivity on our general US workforce. Sorry, that was federally mandated. This is the general US workforce. I gave you those numbers.

Let me start over again. General US workforce, up 8 percent, 2017 versus 2018, almost 18 percent since 2014. In the federally-mandated safety-sensitive workforce, it grew about 5 percent between 2017 and 2018, and still up 24 percent versus 2014. And in the federal group, it is at its highest level since 2007. Sorry about that confusion just a second ago.

We compare marijuana positivity in general US workforce testing between the three different specimen types. There is our urine general US workforce data again. For those of you who haven't seen this data before, you will probably find this next slide to be somewhat surprising. There is oral fluid as compared with urine. We think about urine generally one to three days for relatively casual use. Heavy use, obviously three to four weeks, sometimes more.

But oral fluid, with generally 24 to 36 hour

window detection, how is it that we have a three times higher positivity rate -- more than three times positivity rate on oral fluid than we do on urine? My answer to that at least is, at least today, it is probably a test that is very hard to study for.

By its nature, it is an observed collection. The donor isn't afforded the same opportunity to try and subvert the testing process in the privacy of the restroom as they may be with a urine drug test. To me, this speaks to the power in many ways of the observed collection. And if you think back to that National Survey on Drug Use and Health, we are almost at that same self-reported usage rate just for marijuana within that testing group.

In 2018, it went down slightly. It finished the year at 8.7 percent, so it was at about a little over 1 percent decrease. But again, three times higher than urine. It is at its highest level since 2014. And it is higher, believe it or not, than hair testing, which detects this pattern of repetitive use. That is, I think, a function of testing for acid and hair versus testing for oral fluid.

And just the nature of hair and how much it incorporates acids as compared with basic drugs. But still, hair is up 6.3 percent since 2017. Finished the

year at 6.8 percent at its highest level since 2014. But as you can see at least in our data, our positivity rate in hair for marijuana is far more volatile than what we have been seeing in the other specimen types.

So if we look at our marijuana positive data in the general workforce as compared with the NSDUH data, again there is our general US workforce and the DTI. The data for those respondents subject to an employer drug testing, relatively steady between 2002 and 2011, slight uptick within that group in 2012 and 2013. But much higher in 2014 through 2017, so probably not surprising that we have been reporting on year over year increases in marijuana positivity for those in our DTI data.

And then if you throw in the self-reported use of marijuana for those respondents who aren't subject to a drug testing program, we have been seeing slow steady increases since 2010. And it now ranks at 14 percent of those respondents.

So recreational use, we are going to go state-by-state for the recreational use states. So starting first with Colorado here, I have got to refer to my notes because there are a lot of numbers. I will try and get it right. So this is Colorado between 2011 and 2018. And what you will as we go through this, so states, the bars that are

grayed out means it has not yet achieved recreational use status.

So in 2012, Colorado permitted recreational use. So those are now solid bars. Some year over year increases, a big jump in 2018 as compared with 2017. And in fact, it is a 26 percent increase in our general workforce data in Colorado. There is Washington, so we started with the first two states with recreational use.

They track very closely together, Colorado and Washington, between 2012 and 2017. I think of note is that Washington actually went down a little bit in our data in 2018 as compared with 2017. Very different than what we saw in Colorado. And in Washington, that decline was about 5 percent in our general workforce testing data.

D.C., so here in the District, 2014, recreational use became legal. It didn't have much of an impact 2014, 2015. Some of this may relate to when the drugs were actually available for sale, so we hadn't factored that into any of this data yet. But that will be a coming attraction, shall we say. But year over year increases, 2016, 2017, 2018, for the District.

Oregon has been showing some remarkable increases. 2018, it was over 5 percent positivity rate. California, less of an impact. It is a newer state, 2016

state. But perhaps some of that may be related to the fact that, in many ways, it was all but recreational. The medical marijuana statutes were very easy to get a card and be a cardholder. So we really haven't seen much of an impact in California, perhaps as some of the other states.

Massachusetts, in our general workforce testing, it is up 9 percent. A relatively new state. What I should have mentioned, as well, and we were talking about California, it actually went up 15 percent between 2018 and 2017.

Another state with some large increases, Nevada. Nevada in our general workforce testing went up 53 percent, which followed an increase in 43 percent between 2016 and 2017, so some dramatic increases in Nevada in our general workforce testing.

Michigan, okay, technically, it is a recreational use state in 2018, but it didn't really start until 2019, this year. Maybe people were getting ready because we saw an increase in 2018. So that is general workforce. The national average is shown over light here on this graph now. You can see that certainly since 2017, all of the recreational use states are at or above the national average. We will look more closely at the differences in recreational use status.

CAPT WELSH: This is urine only? We are not seeing hair --

DR. SAMPLE: This is all urine. This is 100 percent urine, yes. We wanted as much as possible to be an apples-to-apples, same detection windows. We do not mix specimen types in this data.

We are going to do the same walk with the federally-mandated safety-sensitive workforce that we just did with general workforce. So Colorado looks very similar to what we were seeing in general workforce, even though it remains illegal at the federal level, even though employees can still be sanctioned on a DOT drug test. They are not being completely deterred, shall we say. Or at least applicants are not being completely deterred.

Washington, somewhat of a similar pattern, but lower across the board year over year than what we saw in Colorado. And just looking at those two, Colorado went up 5 percent. Sorry, in our federal testing, Colorado went up 5 percent between 2018 and 2017. And Washington went up 8 percent between those two years.

In the District, year over year increases over the course of the last three years. Oregon, a lot of up and down, so a very different pattern in the federal group testing category than in the general workforce category.

If you recall, Oregon was much higher than the other states.

California, some ups and downs, mostly down in recent years. Nevada, sorry, that was Massachusetts. This is Nevada. So in Nevada, for our federally-mandated safety-sensitive testing, it went up 39 percent in Nevada between 2017 and 2018. And there we have Michigan and the national averages overlaid. So slightly different pattern. There are some states that continually were higher than the national average. But other states that even after the passage of the recreational use statutes, they remain lower than the national average.

MS. KELLY: I have one question. So when you are reporting the state that these positives came out, is that the state where the collection was done or the state where the employer or donor was located?

DR. SAMPLE: One of these days, I will remember to give that information as a prelude. Thank you for asking me that question again. All of this is categorized based on the ZIP code of collection, not the location of the employer.

So let's look at a macro sense in the general US workforce. If we look at various groups here, the non-recreational US total, the recreational states, the medical

only states, and I say medical only because all recreational use states are also medical states, if you remember from Faye's presentation before the break. And then non-recreational, non-medical states. Then an overlay of the national data.

This is general US workforce. Surprisingly, 2017, 2018, went up. 2015 and 2016 were very comparable to one another. Not surprisingly, higher positivity in the recreational use states, although 2017 looked like it might have dipped a little bit as compared with 2016. But the overall trend is increasing. A big delta between the states. The recreational states being at 3 and a half percent. And the non-recreational states being at about 2.6, 2.7 percent in 2018.

Here is the surprise maybe for folks. Medical only, it looks very much like the non-recreational use states. So what we are seeing here, and there we have the non-recreational, non-medical, is that the impact of, shall we say, loosening or relaxing of the requirements around marijuana really is having an impact in the recreational use states on our positivity rates, not so much in those medical-only states.

And perhaps that isn't as surprising. There is a smaller group of individuals that are qualified to be a

cardholder in many of the states, not all. Just it could be that a lot of the cardholders aren't necessarily in the workforce, so there could be a lot of factors driving that we are seeing really more of an impact in the recreational use states than in the medical states. And there we have the national average.

Somebody asked the question, what about employers including marijuana in their testing panel. Obviously, they don't have a choice for the federal testing, but they do for general workforce testing.

So by again status, in the non-recreational use states, recent years, we have been seeing a slight decline. So 2015 is more than 99 percent of all of our general US workforce urine tests included marijuana in the panel. In 2018, it was a little over 98 percent. So yes, it went down in absolute numbers, 1 percent, between 2015 and 2018, but not necessarily a dramatic impact.

Recreational use states, they started a little bit lower. So over 98 percent in 2015 down to about 94.7, 94.8 percent in 2018. A large part of that could be driven by certain states. Anyone want to venture a guess at what state has shown the largest decline in the inclusion of marijuana in the testing panel? Not Colorado. Nevada, exactly. So between 2015 and 2017, Nevada has 8.2 percent.

So in 2015, 96 and a half percent of all of our urine general workforce tests included marijuana. In 2018, it was down to 88.5 percent.

Medical use only states, it very much mirrored what was happening nationally. And there are the non-recreational, non-medical states. Then overlaid with the national average.

For the most part, clearly in the non-medical, non-recreational, very little change in employer behavior. Some change in employer behavior in the recreational use states. But a big difference in the right. So in the district, between 2015 and 2018, the inclusion rate dropped 1 and a half percent. We talked about Nevada at 8.3 percent. Colorado and Washington, each dropped approximately 4 percent between 2015 and 2018. So there really is a lot of variable state by state in the continued inclusion of marijuana in the testing panel.

So onto cocaine, I think everyone still agrees cocaine is a bad drug. So we had been reporting on year over year increases in cocaine positivity and previous releases of the drug testing index. Here, we have our federally-mandated safety-sensitive data went down nearly 10 percent between 2017 and 2018.

So one year does not a trend make. But clearly,

some encouraging data, at least in the federal workforce with respect to cocaine. But it is still at its highest level. Well, I should say it is still up 12 percent since 2014. Yes, it declined, but we are still way up as compared with where we were five years ago. In the general US workforce, similar pattern, it is down 6.7 percent between 2017 and 2018, but still up 16.7 percent since 2014.

As we compare by specimen types, there is the urine general workforce data again, in oral fluid, it is down 19 percent between 2017 and 2018, but still is more than 16 percent above the 2014 level. And in hair, which is like a cocaine magnet. We have been continuing to see year over year increase. It is up 6.3 percent to finish the year overall at a positivity rate of 3.4. It is at its highest level since 2008. It is up over 30 percent since 2014. So continuing to see high positivity rates in hair for cocaine.

For 6-acetylmorphine, again some encouraging news as we look at federally-mandated safety-sensitive workforce. We have been seeing year over year declines and a drop dramatically over 31 percent between 2018 and 2017. So we are now at a rate of 13 in a 100,000. So that was good news. And is it much higher than it was when we first

started testing.

For heroin, in our general US workforce testing, a similar pattern. Not quite as a dramatic decline, but it is still down 16 percent since its peak. This clearly, I think, is encouraging news. It is not just one year as we have might have been seeing with cocaine.

For amphetamines, still as a group, amphetamines meaning amphetamines and/or methamphetamines. In our urine testing, it remains the second most commonly detected group. I am almost to the point where I don't have to say it is continuing year over year increases. So we have seen some leveling off in recent years. I don't know if that means that prescribing of Adderall and amphetamine drugs for ADHD is leveling off or what is going on in our data. But it is interesting that there seems to be some leveling off for amphetamines as a group. And in the general US workforce, really have not been seeing change recently.

But let's look specifically at the drugs that make up that amphetamines group, at least in urine testing. So for methamphetamine, in our urine testing, we have seen a decline in the positivity rate. So it dropped 5.9 percent between 2018 and 2017. Still at its highest level since 2006 and up more than 6 percent since 2014. But potentially, some encouraging news with respect to

methamphetamines within this group.

General US workforce testing was flat between 2017 and 2018. It is still at its highest level since really both 2016 and 2006. And up nearly 6 percent since 2014, so over the course of the last five years.

Comparing by specimen type, general workforce urine again, oral fluid positivity. Once again, oral fluid higher positivity than what we see in urine. Oral fluid is, in this case, somewhat contrary to what we reported on urine. Oral fluid went up 9.3 percent between 2017 and 2018. That is why I am again not quite ready to say that any corners have been turned with respect to methamphetamine positivity. It is at its highest level since 2013 and up more than 42 percent since 2014.

Hair, in our testing data, is remaining relatively flat, but not quite historic, but very high levels. It is the highest level since 2006. For amphetamines itself, urine quite flat. Oral fluid did tick up in 2018 as compared with 2017. And amphetamine is the one drug where we see actually lower positivity in oral fluid as compared with urine. But I believe somebody said earlier, it is all about cutoff.

So one of the differences between methamphetamine testing and amphetamine testing is the cutoff that is used

for the screening test. Amphetamines screening is at a higher cutoff. It is a FDA clearance function. So while the confirmation cutoff is the same, the screening cutoff is different. I am guessing, no way to prove it, if we were to screen for amphetamines at the same level that we screened methamphetamines in oral fluid, we may not see quite that pattern.

MS. KELLY: A couple of questions. One on the amphetamine positivity, you don't have a line for hair. Is there any difficulty in testing for that in hair?

DR. SAMPLE: The hair amphetamines test is really a test for methamphetamine. So the immunoassay is targeted towards methamphetamine. So yes, we report amphetamine, but only when methamphetamine is present and results in a positive.

MS. KELLY: Go it. So the previous slide is instructive on that point. Then also, do you have the three matrices for heroin, 6-AM?

DR. SAMPLE: No, I don't have that here. But I could get you that information, if you would like.

Let's talk about all the other drugs that might be included in a non-regulated employer panel. So barbiturates, other than some declines a while back, it is remaining relatively the same with some ups and downs.

Benzothiazines, I thought, are sort of interesting that we have been seeing these with year over year declines over the course of the last five or six years. Methadone has remained relatively flat in recent years.

Now, this is opiates. The definitions of opiates here in general US workforce testing is primarily codeine morphine. We will talk more specifically about prescription opiate testing in just a second. But within this opiates group, probably for the most part, 80 percent of those tests are just codeine and morphine. They did not include other prescription opiates like hydrocodone and hydromorphone. And it wasn't until only recent years that we actually had a specific screening test for those prescription opiates.

And propoxyphene, I don't know if you can actually see that. There is something wrong with that slide, I am sorry. Ignore 2017 and 2018. That has to be a typo in the slide. There really is no propoxyphene. It is so much yesterday's drug.

Just historically, people don't modify, don't change drugs in their panels. If for another reason, it is all tied in with the company policy. It is just easier to continue to test rather than delete it from the panel.

So if we look at some of the prescription

opiates, first of all, looking at hydrocodone, hydromorphone, and oxycodone as a group, and oxycodone in this context would have to mean a specimen is positive for oxycodone and/or oxymorphone. Hydrocodone, we have been seeing dramatic decreases in our hydrocodone positivity. Hydrocodone went down nearly 29 percent at its lowest level since forever. And down nearly 61 percent since 2014.

Hydromorphone dropped 22 percent, at its lowest level since 2003. Declined the last three years and also down about 61 percent since 2014. We have been seeing year over year declines in oxycodone positivity since 2012.

Workforce data, this doesn't always translate into what is happening more broadly in society. It doesn't mean that there isn't an opioid crisis. Opioids continue to be used and abused and are problematic. But at least generally in our workforce testing data, we have been seeing year over year declines in positivity for these prescription opiates, semi-synthetic opiates like hydrocodone, hydromorphone, oxycodone, oxymorphone.

So what is happening in the federal testing? This compares opiates, codeine morphine, opiates, hydrocodone, hydromorphone, and then oxycodone and/or oxymorphone between general US workforce and federally-mandated safety sensitivity. You can see that in blue in

our federally mandated safety sensitive data, the positivity rate for hydrocodone and/or hydromorphone is about four times higher than that for codeine and morphine. Oxycodone is about three times higher than codeine morphine. So clearly, a big impact in the federal program. You can see why we had such a large increase.

One of the main drivers to the large increase in overall positivity in our federally-mandated safety-sensitive data and in our general US workforce. While hydrocodone and hydromorphone, oxycodone, oxymorphone remain higher than our codeine morphine positivity. The delta is not as dramatic, anywhere near as dramatic as what we are seeing in our federal data. Let's see what the 2019 data holds for us.

If we look at positivity by testing reason, we are going to look a little bit at it here. And I will then close with some more opiate data by testing reason. We are seeing two and a half to three times higher positivity rate on post-accident tests for hydrocodone and hydromorphone than we see on pre-employment tests.

Correlation does not equal causation. I will be the first to say this doesn't prove that the use of that prescription opiate is what caused the incident that prompted the post-accident drug test. When we talk to

MROs, they tell us that the MRO verified negative rate really isn't any different on post-accident versus pre-employment versus random.

But it certainly raises the level of suspicion that to put it in DOT, perhaps there should have been a safety concern because the use of these drugs, while maybe being used with a prescription, may not be provably causative, may have played a role or an impact. It is very interesting when you see that type of delta between post-accident and pre-employment positivity. And similar patterns in both general workforce, as well as our federally mandated safety-sensitivity data.

For oxycodone, which would be oxycodone and/or oxymorphone, a similar pattern. This really holds true with the prescription opioids like hydrocodone, hydromorphone, oxycodone, oxymorphone.

Specimen validity testing, so for our specimen validity testing, we saw a big jump in the specimens reported as invalid between 2018 and 2017. So it jumped 80 percent. My apologies for the scale on the left-hand side of the graft. So it was 0.1 percent in 2017 in the federal group versus 0.27 percent in 2018. And for the general US workforce, it went from 0.15 percent to 0.21 percent. A big jump in the invalid rate.

So I have some suspicions of what may be driving that. I believe this group has talked about the increase in invalid specimens related to the use of synthetic urine that sort of got uncovered when 6-acetylmorphine testing was a required analyte, and the technology that is used resulted in an immunoassay interference prompting an invalid testing result when presumably because of the use of certain synthetic urine products.

But I am guessing, I can't prove it, that maybe there was an uptick in the use of synthetic urine because people that heretofore had successfully passed their DOT drug test or even general workforce drug test, they didn't worry about the other opiates because it wasn't tested for. They may now be worried about it. They have decided to use some synthetic urine. Let's just say they chose poorly with respect to the product that they selected.

Post-accident positivity, year over year increases in both general workforce, as well as federally-mandated safety sensitivity. But look at that big jump between 2018 and 2017 in post-accident positivity rate in our federally-mandated safety-sensitive workforce. So for federal, it jumped nearly 52 percent, 3.1 percent positivity in 2017 as compared with 4.7 percent in 2018. It is more than an 80 percent increase between 2014 and

2018. In the general workforce, it went from 7.7 percent to 8.4 percent in 2018, 29 percent increase over the course of the last five years.

MS. KELLY: Dr. Sample, I have a comment. When we are talking about your laboratory data here, you don't have the MRO reviewed results. So when we see a jump up, we all know between 2017 and 2018, 2018 is when we began with the semi-synthetic opioids.

DR. SAMPLE: Wait for it. It is coming. If you don't mind holding your question until almost the end. This compares in our general workforce pre-employment versus post-accident testing rates. You can see the post-accident positivity rate appears to be increasing a little bit faster than our pre-employment positivity rate.

This slide, 2015, 2016, 2017, opioids, codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, one or more of those were represented 15 to 20 percent of all of our post-accident positives. 2018, in our federally-mandated safety-sensitive workforce, 44 percent of all of those post-accident tests involved one or more opiates in that specimen. General workforce didn't change appreciably.

MS. KELLY: But in the federal workforce, we added them that year, and presumably they were already in

the testing panel in earlier years. Correct? So in 2015, you would have been testing for the semi-synthetics, as well as the naturally-occurring opiates?

DR. SAMPLE: Not in federal tests, of course, but in our general workforce.

MS. KELLY: So the big difference in 2018 is not that you suddenly jumped up. It is that we changed the testing panel.

DR. SAMPLE: Absolutely. And this next slide, so we looked at 2017 positivity, all reasons, and then by testing reason, 2018 positivity. And then we backed out the semi-synthetic opiates, opioids, from the positivity rates. So if you are to back out the data that is column C, so the difference between 2018 positivity with column B and 2018 positivity without semi-synthetic opiates, column C, you can see that the difference ranged from 16 percent in reasonable suspicion for cause test, up to as much as 49 percent on post-accident drug test.

So looking at it another way, between 2017 without and 2018 backing up the semi-synthetics, for all testing reasons, post-accident positivity actually went down slightly. Pre-employment was about the same, random, down slightly, post-accident about the same. Really, the only ones that increased and from an all-testing reason

perspective were return to duty in period/medical, backing out the semi-synthetic opiates. Two different ways of looking at it, but clearly, I think what we are seeing here on our federal post-accident positivity rates is the impact of adding the semi-synthetic opiates, opioids to the federal panel in 2018.

I told you I would get to it. So overall positivity rate, 14 year high. Continues to increase overall. Marijuana use continues to increase. Most commonly detected drug. Some encouraging news with cocaine, but one year does not a trend make, as I said before. Still seeing increases in post-accident positivity in both workforces.

But clearly, opiates accounted for 44 percent of the federal post-accident positives in 2018. But the other opiates tend to generally increase in our general US workforce. That big jump in invalid specimens, again presumably because of the increased use of synthetic urine in 2018. If you care to look at positivity in your local area, we have positivity rates by a combined US workforce by three digit-ZIP code. I will answer any other questions you may have.

MS. BURKE: It is interesting looking at the stats for the cannabinoid or the marijuana data from year

to year, and how you compared the different states. Like with Colorado and Washington, that is consistent with the forensic increase. We look at California, and we are different because for forensic science or forensic toxicology, we have county laboratories and we have state lab.

When we look at the county laboratory data, it increases consistent with Colorado and Washington. But when you look at Cal DOJ, our marijuana cases were consistent about 50 percent of our caseload since 2012. And we were dumbfounded at this. Why is it so different from the county labs? We thought, well, our laboratory services 46 out of the 58 counties. And some of those counties would be like Humboldt County or probably selling products under the table when it wasn't legal.

And so also interesting enough, and you probably already pointed this out, when you looked at the increase, you went back to 2011 and 2012. I think that is when Colorado and Washington legalized it around that time, and some of those other states legalized after. But California, our data is weird in comparison to the other states overall. I just wanted to kind of mention that because it looks like the workplace drug testing, if you could look at those stats in comparison to forensics stats,

the trends are very similar.

But with benzos, we actually see an increase in forensics. You are talking about a decrease. I am wondering if the actual drug screen panel, and I know you are doing what enzyme multiplied assay technique versus ELISA, so slightly different. I don't know what drugs, specifically which benzos you are cross reacting when you are looking at your screens. What I am wondering is maybe the low-level benzos, like clonazepam, alprazolam, lorazepam, probably don't cross-react. And our number one drug we are seeing in forensic science or forensic toxicology is alprazolam pretty much throughout the state.

DR. SAMPLE: (Off mic)

MS. BURKE: So if you are seeing a decrease, but we are seeing more of that drug versus diazepam, could that be what is going on with that? There was one more question. Sorry, I am going to be like an attorney and ask you a compound question.

Then the other one is I guess you indicated you saw a decrease in 6-AM. Is it possible that we are now seeing that replaced with fentanyl or some of the other designer opioids. Sorry, I am just throwing a lot at you. I really liked your presentation.

DR. SAMPLE: I am using Ron's mic now, so I am

good. You hit on some of the confounding factors with respect to benzo screening. Our clinical screening, we are able to do some lower cutoffs. We are able to do some other stuff with the screening assay that we are constrained for our workforce drug testing. So it is more difficult to pick up the lorazepam. It is more difficult to pick up the 7 amino clonazepam.

And another factor is just like opioid testing or opiate testing, in our general workforce, there are standard opiates and then there are expanded opiates. We have the same concept with our benzo confirmations. We may have drugs that could cross-react and produce presumptive positive for the urine benzo screen.

But if the employer isn't asking us to do that broader confirmation panel, so we could be missing some of the data clearly in that benzo data. But at least from an apples to apples perspective, we are seeing a delta. But you are right that it could be a change in behavior that we are not able to detect on the basis of what the employers are ordering.

And then you asked about 6-acetylmorphine and fentanyl. We have, at this point, very few of our employer customers requesting fentanyl as a part of their panel. I pulled some data, and we may talk about some of this in

closed. But in the first four or five months of this year, there were only about 2200 tests for fentanyl. So a very, very small number as compared with the millions of drug tests, urine, general US workforce drug tests that we performed in that same period of time.

DR. SCHAFFER: A really quick question regarding the comparisons between the different matrices that you are using with the oral fluid and the urine primarily. I mean, I think a lot of that data is really skewed by the artificial determination of positive or negative based upon the administrative thresholds. Most laboratories offer very limited panels with an LOD, level of detection. Have you ever compared any of that data between different matrices just to see if that artifact would be removed to see if you see any difference.

DR. SAMPLE: Could you expand on that question a little bit?

DR. SCHAFFER: Some of our panels, and I assume most laboratories offer some very limited panels that are tested at a level of detection, so that it would be an oral fluid level of detection versus a urine level of detection. Would you see those drastic differences in prevalence if you used those sorts of panels when you are comparing the results between the matrices? I think it is really an

artifact, at least partially an artifact, of the administrative thresholds that we determined something we presumptively positive as opposed to a real presence of drug.

DR. SAMPLE: Clearly, it is all about cutoff. If we think back even to the federal program and the increases, 20 to 30 percent increase that we saw in positivity rates, in urine tests for amphetamines or cocaine following the lowering of the cutoffs. Now, most of this, really essentially all of this, data I am presenting would be more or less standard, using air quotes, and don't represent LOD testing. But absolutely, depending upon the cutoff, that is going to impact detection rates.

I sort of alluded to that when I was talking about amphetamine itself in oral fluid and calling out the difference in amphetamine versus methamphetamines positivity specifically between urine and oral fluid. And the fact that we have a higher screening cutoff for amphetamines in oral fluid than we do for methamphetamine. That may be driving some of that difference that we see.

MS. MOTIKA: Do you have any information as to the population of employers using the oral fluid kits currently, and whether or not who is using it is skewing

the positivity rate at all? Are they being used as a deterrent because the urine is suspected to be adulterated? I really would like to know that, if you have any information.

DR. SAMPLE: A little bit of information on that. So for non-federally mandated testing, oral fluid is roughly 20, 25 percent of that of the urine non-mandated general workforce testing. Within that group, while it covers all industry types, a large proportion of those oral fluid tests are retail oriented. But then again, a lot of our urine tests are also retail because there is a lot of hiring going on in that industry segment. I am not sure that it necessarily is demographic, but that could be a partial factor.

MR. FLEGEL: I will say on that, if you had a paired specimen, which you will never get if you got a synthetic, if you had a paired specimen, actually look at that comparison of oral fluid to urine, it would be truly interesting. So, good question.

MR. AUMEN: Thank you very much, Barry, for great data. Now we have Dr. Ruth Winecker who will be presenting on fentanyl, the emerging issues. And just as a note real quick, for folks who are speaking, try to speak directly into the microphone. We do have a few folks on the phone

who are having trouble hearing. Thanks.

Agenda Item: Emerging Issues: Fentanyl and Fentanyl Analogues

Ruth Winecker, PhD, RTI International

DR. WINECKER: Thank you for allowing me to make a presentation about fentanyl, fentanyl analogs. I worked for 22 years with the state of North Carolina's medical examiner system. And so I actually saw this develop from the time of oxycontin until the opioid epidemic today. I am going to go back. I am going to cover some of that data. I am going to cover what fentanyl is and et cetera.

So our next slide is just the outline of what we are going to talk about. I am going to talk about what the data I am presenting today has to do with the Support for Patients and Communities Act. I am going to give you some background and definitions.

I am going to talk about fentanyl and fentanyl analogs. I am going to show you the medical death investigation and the crime lab data to kind of give you some context about where that is versus what the data is for the workplace population. I am going to talk about current technologies for analysis, particularly as it has to do with workplace. And then just a summary of the possibilities for adding fentanyl and/or fentanyl analogs

to the Mandatory Guidelines.

You heard this today already, but the SUPPORT for Patients and Communities Act required the Secretary of the Department of Health and Human Services to determine whether it is justified based on reliability and cost-effectiveness of testing to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include fentanyl. That is where I am going to focus on today is the inclusion of fentanyl. And then also to consider whether to include any other drugs or other substances listed in Schedules I and II of the CSA.

So in 2015, fentanyl was considered for inclusion in the Mandatory Guidelines. But based on the information at the time, it was not recommended for inclusion. This is primarily because it was almost always found in combination with heroin in 2015 and those users were already being identified through morphine testing.

So in 2018, the SUPPORT for Patients and Communities Act required that fentanyl be reconsidered. And so the DWP began investigating and data gathering to see whether or not it was advisable to add fentanyl based on reliability and cost.

So some background and definitions here, so fentanyl and fentanyl analogs, all are assumed to be opioid

receptor agonists. And those that have been studied for their receptor activity do have some activity at the receptor and are more or less as potent as fentanyl.

All those with receptor activity can be classified as narcotic analgesics. Some can even be lumped in the catch-all category of new and novel psycho substances. This wave of substances started with the synthetic cannabinoids and stimulants, and then expanded. And laboratories began seeing increased numbers of these substances.

Each new class of drugs showing up were designed to mimic the effects of scheduled compounds ranging from hallucinogenic to anxiolytics to narcotic analgesics. These compounds have specific appeal to drug users because of their perceived legal high status than they were purported to have.

So what is fentanyl? Well, fentanyl is both illicit Schedule II pharmaceutical compound and an illicitly made drug. Fentanyl was first synthetized by Paul Jansen in 1960 and approved for medical use in the United States in 1968 as an adjunct to anesthesia in the form of the intravenous medication, Sublimaze, and then later for chronic pain in the form of the transdermal patch named Duragesic in 2005.

This was followed by a whole host of different formulations, including lollipops, sublingual tablets, film streets and sprays. Illicit diversion of pharmaceutical grade fentanyl has always been a concern and is the basis of hospital-monitoring programs for pharmacists, anesthetists and other health care providers.

Fentanyl is also an illicitly manufactured substance. It can be clandestinely manufactured. It is often sold as a heroin substitute or is considered a heroin substitute, but it is found in many mixtures, as Captain Welsh mentioned earlier. It is found with cocaine, it is found with methamphetamine, it is found with other fentanyl analogs, it is found with heroin and other non-active components, as well. It is actually mixed and diverted with other compounds just like heroin. It is also found in counterfeit tablets. We can talk a little bit more about that in a minute.

So clandestine fentanyl is distributed in the United States in the same manner as heroin. This is from the DEA National Drug Threat Assessment of 2016. It is basically sold as HIPAA with many users not aware of the presence of fentanyl in the substance.

So what is an analog? This is a compound that is structurally related to fentanyl. There are both licit and

illicit versions of fentanyl analog. Not to think that it is simple because it is not.

The illicit ones are all Schedule I. Before February of 2018, the DEA conducted an emergency scheduling of these analogs as they appeared and were identified. They are illicitly manufactured. The appearance of them is driven by the quest of evading penalties associated with use, possession, distribution of controlled substances.

They are found in mixtures with each other, with heroin, with fentanyl and other substances like methamphetamine and cocaine. It is also found in counterfeit tablets. These counterfeit tablets, many are purported to be narcotic analgesics, but others are not. So a user buying a counterfeit tablet expecting Xanax or Alprazolam could end up with car fentanyl. There are also the licit versions. These are all scheduled to analogs with a legitimate medical use. This would include sufentanil, carfentanil, remifentanil and others.

So after February of 2018, though, any analog that appeared and was identified was automatically Schedule I based on the substantial similarity between the chemical makeup and effects of fentanyl, as long as it was not already a Schedule II. So what constitutes substantial similarity? As you can see here, this is a backbone of

fentanyl. This is 4ANPP.

An analog could be defined as any substitution along the main backbone, which is piperidinone compound. You can see here with the addition of the three carbon carbonyl group, you didn't know you were getting chemistry today. This is fentanyl. So all you do is add that, and you have got fentanyl.

You can remove one carbon from that, and you have acetyl fentanyl. Acetyl fentanyl was identified in 2013/2014 in a series of cases, death cases. Nowadays, it is found almost exclusively with fentanyl and is believed to be an artifact of the illicit manufacture of fentanyl.

Addition of a fluorine makes para-flourofentanyl. And you can also add fluorine at the ortho or meta position on that same benzo group.

Substitution of the benzyl group on the end with the thionyl group gives you thionyl fentanyl. And addition of a couple of carbons and an oxygen and a cyclization will give you furanylfentanyl. But really, any addition or substitution along this backbone would result in scheduling as a Schedule I substance. More substitutions and additions along this backbone would form alfentanil, as you see here. That one is closely related to the one that gets all the press, the carfentanil.

I am going to cover some outbreaks of fentanyl and fentanyl analogs deaths in the US over the years to show that it is not just a new phenomenon. It has actually been around a while. Fentanyl has been mixed with heroine on occasion over the years. In 1993, it was mixed with heroin in a version called Tango and Cash. It was produced in Wichita, Kansas. The fentanyl was actually made in a laboratory in Wichita, Kansas, but mixed with heroin. It caused a large number of deaths.

Then in 2005 to 2007, Midwestern states reported heroin mixed with fentanyl, clandestinely produced in Mexico. It costs about 1000 deaths at that time. And then from 2014 to present, the fentanyl that we are seeing now, the illicit fentanyl, is produced in Mexico with precursor compounds commonly bought from China.

From fentanyl itself, from the 1960s to the present, diverted pharmaceutical fentanyl has been known to cause deaths in medical settings through diversion, hospitals, surgery centers, et cetera. From 2004 to present, larger numbers of deaths associated with fentanyl after approval of Duragesic and other prescribed forms of fentanyl show that there was a higher diversion liability because these are outside of a medical setting.

And then from 2016 to present, we are seeing it

increasingly sold without heroin, so by itself. Analog does deaths, the same thing. It is not exactly new, but how much of it is what is new about it.

So back in 1976, alpha-methyl-fentanyl was mixed with heroin and sold as basically high-purity heroin or AKA China white. And then in 1984, 3 methylfentanyl was supplied to heroin users. And then as I mentioned before, acetyl fentanyl came on the scene in 2013/2014 causing deaths in users in Rhode Island and then also in other states along the east coast.

In 2017, though, it has reemerged but largely in combination with fentanyl. It is probably a manufacturing artifact. In 2015, furanylfentanyl was reported. And then things really started to go crazy.

So in 2016, nine new fentanyl analogs were identified and reported. In 2017, 10 new analogs were identified and reported. In 2018, though, the scheduling of all analogs to Schedule I, not really scheduled as Schedule II, showed a sharp drop actually in new analogs being reported.

So just taking a closer look at this medical death investigation of crime lab data, this is no surprise to anybody that the number of drug deaths has outstripped motor vehicle crashes over the years. And like I mentioned

before, I was in the medical legal death investigation system during this entire time. It just goes to show you the number of drug deaths. This corresponds with the release of oxycontin and the treatment of pain more aggressively than it used to be treated.

This graphic here is specific to North Carolina. You can see over the years that the top five drugs poisoning by year changed. And when you look at this, you do have to keep in mind that the numbers of poisonings go up dramatically over this time, as well. But you can see methadone moved from almost exclusive use in methadone maintenance programs to use as a substitute for the very expensive brand name form of sustained release oxycontin.

Up until then, it was actually rarely detected in the medical examiner system. Once that medication was released for patent protection, though, methadone dropped off the map. And oxycontin came back. And also, heroine came back. You can see heroin here in kind of a yellow-orange. You can see it drops off for a number of years and then comes roaring back in, I think, 2012. And then it took the number one spot in 2014. It has remained in the top five ever since.

So fentanyl, the red fentanyl here, this is all from pharmaceutical grade fentanyl. So Duragesic,

lollipops, diverted pharmaceutical grade fentanyl. And now remember, the number of drug deaths is lower there, just to give you an idea. There actually weren't that many deaths for neurogesic. So then, you can see the green fentanyl and then the blue fentanyl.

Okay, so looking at crime lab data on analysis of fentanyl and other substances submitted to the laboratory as exhibits, you can see that there are almost three times as easy of those in 2018 as there was 2016. And you can also see a change; an increase in the number of exhibits submitted, and then also the change in the number that contained fentanyl.

It goes up. It was a low of 66 percent and then a high of 76 percent in 2018. The 2019 data is even more dramatic with an even higher percentage of the number of exhibits containing fentanyl. And the 2018 showed four new analogs, there were zero new analogs in the first quarter of 2019.

And then also about a little less than half of all of these also contain heroin. And it also says that the data says that a little less than half found fentanyl as the only substance identified, but that is a little misleading.

As you can see back in 2016, there is a large

number of samples that have acetyl fentanyl. And that is probably not acetyl fentanyl on its own. And it also has 4ANPP, again probably not on its own. It is a building block, a precursor to the manufacturer of fentanyl.

The next year, you can see those numbers go up again. And then the next year, in 2018, you can see the vast percentage of those are fentanyl, 4ANPP and acetyl fentanyl that are almost always found together.

And so, the other analogs, and then kind of related compounds like the U compounds are not fentanyl analogs, but they are there in the data. I am showing them to you. They are really small. The percentage of these exhibits that have any of the other analogs is very small compared to the ones that have fentanyl.

So moving onto workplace testing, so looking at both federally regulated and private sector, as much as what we know about it, so fentanyl and analog testing by request of federal agency or MROs. That was according to the Mandatory Guideline. So right now, that is the only way in which a federally regulated specimen could be tested for a fentanyl or an analog.

There are currently two HHS certified labs offering fentanyl testing of federal agency specimens upon request. There were three, but one withdrew or

discontinued in October of 2018. The NLCP data for that period, for the period of 2017, there were 34 requests and six laboratory reported positives, all of which were in a hospital setting. And I mentioned before that that is a common thing to look for fentanyl in hospital settings.

So three were reported positives. So six were positive. There were three multiple positives, two with THCA and one with hydrocodone and hydromorphone. So what we don't know is which ones of those other three, and the one with hydrocodone and hydromorphone, whether or not they were certified positive by the MRO.

For 2018, all of 2018, there were 16 requests. Again, all in a hospital setting, and one laboratory reported positive. And again, we don't know if that is certified positive or not. It could be a legitimate medical use of fentanyl. And then for the period of 2019 through the end of May, there was one request with a negative result.

It is not well studied. We heard Dr. Sample saying before that they haven't done that many compared to the high volume of the rest of their workplace testing. So HHS laboratories performing fentanyl testing for non-regulated testing estimate positivity at about .2 percent.

We did some pulse testing studies at the

direction of DWP. In 2017, 2139 regulatory urine specimen aliquots were deidentified and screened for fentanyl. Just keep in mind, these are specimens that were going to get thrown in the trash. The bar code was taken off, and a new bar code was put on. And then they were screened for fentanyl.

And then the confirmation was done for fentanyl and norfentanyl only. And then 2019, 2158 regulated urine specimen aliquots were deidentified and screened for fentanyl. But confirmation testing in this case included fentanyl, norfentanyl and the 11 analogs. So here are our results. In 2017, the specimens were split between two different immunoassays, an EIA and then an ELISA. There were three positives from each. And then two of the EIAs confirmed by CMS and all three of the ELISAs confirmed.

In 2019, all of the specimens were initially tested by EIA, a different one. And eight were positive greater than one nanogram per milliliter with a .37 percent positivity rate by initial tests. But two confirmed. So overall, a .09 percent positivity rate.

In addition to that, specimens between 50 percent of the cutoff and the cutoff for the two EIAs was 1 nanogram per milliliter and the cutoff. So in 2017, that was 31 specimens. And in 2019, that was 29 specimens were

also referred to confirmation testing, but none confirmed.

And the confirmation, the limited detection confirmation, that level was really low at .2 nanograms per milliliter. And no analogs were detected in the 2019 study.

So initial tests positivity rate in the pulse studies ranged from .27 to .37 percent. Overall, low confirmation rate for the two EIAs, 66 percent for EIA number one and 25 percent for EIA number two. This is consistent with a study of another EIA that was published in the literature where there was a 32.6 percent confirmation rate of the initial test positives. Compare that to THCA with a greater than 95 percent confirmation rate.

So just to put this in perspective, the positive test analytes in the two pulse testing days, that was 9,646 specimens. If you look at the positivity rate for fentanyl, it is lower than oxycontin and higher than codeine and much lower than THCA.

So looking at the capabilities of the HHS certified laboratories to test for fentanyl and norfentanyl. 83 percent of these laboratories offer fentanyl and norfentanyl testing. The immunoassays currently in use are targeted toward fentanyl and have

variable cross-reactivity to analogs. Which means that they are unreliable for detection of all of the analogs. They are more or less cross-reactive.

And they are pretty insensitive to norfentanyl, and that is kind of a problem because 30 percent of chronic pain patients treated with fentanyl were only positive for norfentanyl in urine. And the remainder were positive for fentanyl and fentanyl and norfentanyl. And the HHS laboratories use both CMS and GCMS for confirmation.

So GMCS and LCMSMS are certainly appropriate for fentanyl and norfentanyl with appropriate sensitivities and abilities to detect these. But GCMS may not be sensitive enough for some of the analogs. And the CMS can also have a problem.

If you look at fentanyl and alpha-methyl-acetyl fentanyl, they have the exact same molecular weight. You can see that the group has just moved. The problem with that is that on GCMS, they have a very different mass spectrum. But on LCMS, they look exactly the same. Even accurate mass, LCMSMS is not going to help with this one.

So some further considerations here, if you look at fentanyl as an initial test analyte, the current immunoassays are amenable to high volume environment. That is great. The confirmation positivity rate is varied,

though, across the ones that have been tested in the literature and in these pulse testing studies.

Confirmation testing is expensive. If you have a high reaction to the immunoassay with a low confirmation, that causes problems for the laboratories. Norfentanyl, as an initial test analyte, there is no current immunoassay for this particular analyte. And the ones that are available have fairly low cross reactivity with it.

And then analogs themselves, so if you are going to test for analogs, which ones? Is it a moving target? Is it still a moving target? And the prevalence looking at least at the DEA data is actually quite low as compared to fentanyl. And there really isn't a comprehensive high throughput solution for these guys.

And in summary, areas of agreement about fentanyl, fentanyl deaths are increasing. It certainly is a high amount of fentanyl detected in the medical legal death investigation system and in the crime system. It is readily accessible. It is certainly a safety issue. Anybody using fentanyl is going to be a problem in a safety-sensitivity position. Federal agencies could be authorized.

And a good portion of those certified labs already have testing ability for fentanyl concerns, but a

low specificity for the target analytes and the prevalence. The prevalence is not THC's prevalence, and maybe a moving target, if you are going to consider analogs and the cost.

And prior to the DEA actions, fentanyl analogs were considered legal highs and a decreased risk of legal consequences may have played a role in their distribution and use. But the scheduling has appeared to foster a decrease in the incidents of these particular dangerous compounds. That is all I have.

MR. FLEGEL: Are there any questions?

DR. SAMPLE: Did you have the opportunity, or did any of the laboratories that were doing the analysis have the opportunity, to look in detail at their immunoassays? Because one of the things that I believe we have seen is that you can't simply rely on the package insert to assess the ability to detect norfentanyl.

So while the cross-reactivity based on the PI, or whether you actually test it yourself, does appear to be relatively low, at least with some of the products in the commercial market, there seem to be some other fentanyl metabolites that could cross-react, produce a presumptive positive and have little or no fentanyl there. But have norfentanyl above cutoff. So I don't know if you looked into that aspect.

DR. WINECKER: Yes, that is a noticed phenomenon. And it could be, as you say, other metabolites of fentanyl cross-reacting. It could also even be a potentiation right, a little bit of fentanyl with a whole lot of norfentanyl.

DR. FLEGEL: Any other questions?

DR. SCHAFFER: Do you have an opinion about fentanyl testing in the federal program?

DR. WINECKER: That is a question for Mr. Flegel.

MR. FLEGEL: I have no opinion. We have done a notice. We have done a notice. We have looked at a lot of the information. I think it has to be assessed. It is very specific in the Patients and Communities Act, what we are looking at. Other than that, I don't want to make an opinion on what it is. I think the points, as far as the pros and cons, there is a fentanyl crisis out there with the deaths that we see. I think it is a concern.

But looking at the laboratory testing in itself, there isn't a sensitivity, although looking at other matrices, there may be the sensitivity to what we want to see.

PARTICIPANT: If you look at PCP, it is not killing anyone. But we still test for it. Fentanyl kills people.

PARTICIPANT: And again, not opinion pro or con, I think it has to be assessed. And I think there are ramifications to not testing for it, I guess. So we are going to look at that.

One of the discussions I think tomorrow outside of standard variables is within the federal agency partners is we want to have a small discussion in open session just about if fentanyl were to be added to the drug testing panel, how quickly, et cetera, those type of questions as we wanted to look at.

DR. SCHAFFER: Just one comment, back in the low positive predictive value of the EIA test, what we see a lot of times on the NEIA positive, we see some commonly prescribed drugs that are not classified as a fentanyl in the fentanyl class, some of those other compounds.

MR. FLEGEL: So that we stay on time with the agenda because there are people online, why don't we take a five-minute break, and then we will come back and we will start back up at 3:30. We will keep everything open.

Agenda Item: 2019 Update on Cannabidiol and Hemp Products

Charles LoDico, CSAP, SAMHSA

MR. LODICO: Good afternoon, everybody. Thank you for being present. This is the last presentation for the day. Hopefully, it will be worthwhile.

So the title of this presentation is 2019 update on cannabidiol and hemp products. But listening to Faye, I am going to retitle it to June 11, 2019, 3:30 p.m. update on cannabidiol and hemp products. Possibly by the end of the day, it will be updated again. So the point is that it is a moving target. Everybody knows that.

My presentation objective is to give you a quick overview of marijuana, a review of the potency, scheduling and research. The most important part is the policy, and I am referring to federal policy concerning hemp products and the commercialization of marijuana.

In this slide, what you are seeing is the trichome of hemp or cannabis. There are approximately 400 chemical compounds in the plant. 110 known cannabidiols, the most important ones are the ones that are the most productive and most valuable: the delta 9 THC, which is a psychoactive, and the CBD or cannabidiol, which is non-psychoactive.

Another important part of the plant is what is known as terpenes. There are approximately 200. It is an odor. But it is an important element in the plant because of the end user. The end user typically referred to the THC, the flower, with the turns of the terpenes. It adds mellowness and has what they refer to it as an entourage effect. And of course, there is also flavonoids, which is part. Here is a better view. It is a magnified view of a trichome of marijuana. You will see that the oily resin of the trichome is where the majority of the chemical compounds are focused on the plant.

So how is marijuana, hemp, how has it been used in history? We know that there have been different uses throughout the history of mankind. It has been used as industrial fiber, for clothes. It is used as seed oil, as hemp oil. It has also been found to be used as food. You can ground hemp seed into flour.

Of course, one of the most important of the marijuana plant is recreational high. Also, the plant has been used in religious customs, native cultures and rituals. And of course, it has some application in medicine, particularly Marinol, which is a synthetic THC, and Epidiolex. I will talk more about Epidiolex, which is botanical extract from a plant. Its component, a majority

is cannabidiol.

I tried to attempt to create a sort of a better understanding of the term, cannabis, hemp, marijuana. A lot of times, people use it interchangeably. And I try to make it so that it is easier for the lay person to differentiate between a commercial hemp versus medicinal or medical recreational hemp.

If you look at the plant or the tree to the left, commercial hemp is essentially a hemp product that can be loaded with CBD and very little THC. So that leaf, that THC leaf, is representative of a potential .3 percent by dry weight, if you want to just use that as an example.

Well, on the other side, on the reverse side or to the right, you are looking at the tree that contains a lot of THC of plant, a lot of the flowers and very little or a small amount of CBD. So again, the cultivators, the farmers, if they are going to grow medicinal recreation hemp, are going to be focused on the plant to the right. And if you are a commercial hemp producer, you are going to be producing plants that are going to derive more of the CBD, a little of the THC.

Again, so the point I was trying to make here, the structural similarity of CBD and delta 9 THC chemistry, if they were side-by-side, you would see the molecular

structure is almost identical. The only differences are that the molecular mass of delta 9 THC is 314.469. For CBD, molecular mass is 314.464.

In terms of the chemical structure, they both contain 21 carbons, 30 hydrogens and two oxygens. There always has been concern that there is the belief that CBD does, in some form, convert to THC. I will discuss that later on towards the end of this presentation. But I just wanted to give everybody a sort of a flavor as to how similar the molecular structures are. But apparently, you can't see it. For those that don't believe me, this slide does have the chemical structure.

Let's talk about the new normal. When I say the new normal, we are talking about the potency of THC in products. We know that in the '80s, this is not your grandfather's marijuana. Back then at 4 percent was considered a great product. And if you got Mexican marijuana, between 6 and 11 percent, you really had good stuff.

Let's fast forward to 2019. The current 2019 THC on average is between 13 percent and 20 percent. Hash and hash oils can reach between 20 and 40 percent. And the new concentrates can go from 40 to 80 percent THC. The current THC of the flowering plant between 13 and 20 percent is

actually low-balling. Some have reached as high as 35 percent of THC.

Here again is a graph. It illustrates the DEA seizures. If you look at the last date, this was done with University of Mississippi. It was in 2014. They stopped that sort of data collection. But the University of Mississippi will receive the seized marijuana flower plants. And they would conduct a potency test on it and identification.

But what you see here is that the concentrates, which is represented by the blue line, is up to 55 percent. The flowered THC content is in red, and that is about 12 percent. The lower, right at the bottom, is the CBD percentage. And you will see that it is almost near 1 percent or less. So again, the products that were seized by DEA and other law enforcement, the cultivators were primarily trying to create a flowering product that is rich in THC and not really concerned about CBD.

What are some of the marijuana's acute effects? Of course, it has an effect on cognition. It impairs short-term memory. It can create difficulty in doing complex tasks and difficulty in learning. In terms of executive function, it impacts on impaired decision-making. It increases risky behavior. And then as a result of mood,

it can cause anxiety, panic attack, psychosis and paranoia.

Dr. Lev reviewed my presentation, and she said that we need to also include some of the known marijuana risks. I agree with her. I apologize for not including it. But here is a list of some of the known marijuana risks.

There is a belief that marijuana is pure and doesn't harm anybody, when in fact, there are known documented cases of risks. The most important one is new in terms of discussion. If you look down where it says cannabinoid hyperemesis syndrome. Something that is called CHS. And somebody who has no clue of what it was. These are individuals who are chronic users who die, not just are impaired, they die from a vomiting. There are known cases, three cases, that I have from the Journal of Forensic Science that shows that they have died from this condition.

So when somebody says that marijuana is safe and nobody has died from it, I think the evidence is starting to show through these pathological postmortems that, in fact, this drug, this innocuous benign drug is actually much more lethal than we believe it to be.

So how is marijuana consumed? Well, obviously, the most popular way is by smoking. It is absorbed through the capillaries of the lung. It is fast onset of action,

short duration. It can also be eaten and drunk. Chemicals of marijuana absorbed in the small intestines. It is a slow onset of action and long duration.

The concern when you have edibles, as they are referred to, is that individuals do not know the dosage. So you might have a package that says there are 10 squares of chocolate, each containing 10 milligrams. But in reality, the labeling might not necessarily be correct.

And then, if you are a naïve user, and you are not sure that you have never had an edible, so you don't know the latent period of time. It is conceivable that somebody might be taking one dose, not feeling the effects, and then taking another dose because you want to achieve that high. And then all of a sudden, now you sort of overdosed on it. There have been again documented cases.

And in terms of this type of phenomena, it occurs most often in states, particularly in Colorado, where the poison control center and the emergency room visits by individual children in particular who are eating edibles unbeknownst that they contain marijuana. And then lastly, you have mixed drug usage. Marijuana and alcohol is a combination that is probably overlooked. There are cases of the synergistic effect between the alcohol and marijuana. And again, this is considered like an entourage

effect.

The other thing that is prevalent and could be lethal is when you had clandestine sales of marijuana, and the deal is trying to up the potency, and they will sprinkle fentanyl. It has been known in cases where individuals are assuming they are just smoking marijuana, but it is sprinkled with fentanyl and also synthetic cannabis, as well.

Faye this morning presented a slide of the map of the United States. And in the past, when I have shared this map, it is easy to just identify the few states that had legalized marijuana and/or medical marijuana. But it is now easier to identify those states that do not have it. So as Faye has indicated, you had the state of Idaho and South Dakota. And you see the map is as consistent with Faye's this morning.

So ladies and gentlemen, the reality is that almost if you look at the population in the United States, it has access to marijuana in one form of either medicinal or recreational to the degree of greater than 90 percent. And that should be alarming to all of us.

So what is the scheduling concerning marijuana? I am not going to read this whole scheduling statement here because the most relevant part is down at the last bullet.

This is the last scheduling decision that was made. Recently, and this is in August of 2016, the FDA and US Drug Enforcement Administration, DEA, were petitioned to evaluate marijuana for potentially scheduling based on the FDA scientific and medical evaluation, as well as a legal standard in the CSA. It was determined that marijuana would remain as a Schedule I controlled substance. This is to reinforce everybody in this room that marijuana is still a Schedule I controlled substance.

But there is medical research being done. And so, there is a petition among the universities, other forms of academic and plus also NIH to look at some of the potentials for medical research as it relates to cannabidiol. They are looking into research and into anti-inflammatory, anti-convulsant, anti-psychotic, antioxidant, neuroprotective immuno research. And as it relates to THC, they are looking at analgesics, anti-spasmatic, anti-tremor, anti-inflammatory, appetite stimulant and antiemetic

The belief that there is no research is a false narrative. There are petitions by individuals who have legitimate research credentials. They petitioned HHS, HHS in concert with DEA determined the viability of that research proposal. And then with it, they either grant it

or they do not grant that permission.

So let's go to our favorite topic for today, which is the Farm Bill. The Farm Bill is HR5485. And what does the content of that Farm Bill say? Well, it permitted agriculture research pilot programs to grow industrial hemp. The term industrial hemp includes the plant, Cannabis sativa L, and any part of derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes, fiber and seed, with a tetrahydrocannabinol concentration of not more than .3 percent on a dry weight basis. It further states that the term tetrahydrocannabinol includes all isomers, CBD, which is one of them, acid, salts and salts of isomers of tetrahydrocannabinols.

We have this Farm Bill. And earlier this year, I gave a presentation with a co-presenter at the SAMHSA Prevention Day conference. That gentleman is special agent DA Patrick Kelly. He is an agent with the DEA. And I borrow his slide only because I want to illustrate the concerns that the DEA agent has.

Should we be worried about the Farm Bill? And his concerns are that the high potency of marijuana grown is under the guise of hemp. So the point is you have now a farmer who produces a product, and yet, the DEA doesn't

really have a good handle as to whether that is a legal product or it is an illegal product. It is now easier to sell mislabeled edible products made from hemp that contain THC.

This is the most important one. He also is concerned the impact of drug interdiction efforts and the security of our border by making it difficult to distinguish between marijuana and hemp. And lastly, his concern is that it is more difficult to detect and prevent citizens and workers who operate planes, trains, trucks and et cetera from being under the influence of marijuana. So this is his concern in February of 2019. I don't believe that the Farm Bill has alleviated that concern from any one of us in this room.

I am going to talk real quickly about the commercialization of marijuana. As a result of the Farm Bill, there has been an explosion of products out there for the consumer to consume. This is a cartoon that was printed in the Denver Post in 2019. The captions are 'when is it officially time to be concerned?' And the response is when medical marijuana dispensaries squeeze out the Starbucks outlets. Well, ladies and gentlemen, the next slide does in fact give you that sort of scenario.

So here are two states. You have Washington

State and you have Colorado. The bar graph to your left shows Washington State. You have three bars. You have McDonald's, Starbucks and you have the medical dispensaries industries. So that from that graph, the big winner is the medical dispensaries and producers.

Now, you look at some bar graph over to the right under Colorado. You have McDonald's, you have Starbucks and you have the combination. Well, in the case of Colorado, both the McDonald's and the Starbucks are less than the number of marijuana dispensaries and/or industries. So that is squeezing out not only McDonald's, but the Starbucks.

DR. SAMPLE: That was in 2016, if I read the source right? What is it today?

MR. LODICO: That is why I have to say it is updated. Here is from 2017, Barry. I think you will appreciate this. This is from Washington State. And when you are looking at apples to apples, the thing that you need to look at is a price per gram of marijuana.

So this was taken from the Forecast and Research Division of the Washington Office of the Financial Management in 2017. You can get this anywhere, reference it. You will see this slide. What this shows is a reduction in price per gram of marijuana as it relates to

the bar which is the number of dispensaries or availability.

So as you have more dispensaries, this is market forces at its best, you have reduction in cost when you have more availability. Now, the next slide is even more damaging. So here is today's headline. May 31st, 2019. We are talking about a couple of days ago. What happened a couple of days ago. This was from the Oregon newspaper.

So in the Oregon newspaper, it reported that the supply is running twice as high as demand. Surplus from last year's harvest could amount. This is the Oregon Liquor Control Commission. 2.3 million pounds of marijuana, the equivalent of over 1 billion marijuana cigarettes were produced. Oregon population in 2019 is 4.2 million. There are 1,123 active producer grower licenses issued by the OLCC. In comparison, Maryland, this state has only 15.

The price per gram of marijuana in October 2016 was $10. In December of 2018, it is reduced to $5. And as of January 2019, the OLCC study, Oregon has an estimated six and a half year's worth of supply. Do you understand the ramifications? So when Barry Sample produces a slide that shows Oregon hitting the roof, it is not by coincidence. It is funny, but it is sad at the same time.

We know that CBD is used by humans, but what about for pets? It is hilarious, but at the same time, it is disturbing. So now there are products out there for pets.

Here is a dosage chart. Not that anybody can even validate this. As a matter of fact, if you look up the American Kennel Association, they disprove this. They say that there is no accounting for the efficacy of the CBD for animals.

This thing is very interesting. It is a comparison chart. If you look at all the product listed up on top, and you see the dosage. You see it goes 75 milligrams all the way up to 1500 milligrams. And you say what is the 1500 milligram dosage for? Well, that is for your horse. You can use it on your cat, your dog, your rabbits and now your horse.

What they have done is they have broken it down into milligram cost. So roughly, it goes from 8 cents a milligram to 53 cents a milligram. So again, the consumer is putting out money on product that had absolutely no guarantee of its efficacy. And how are you going to tell your dog whether it is healthy or not?

This is a product. It is only important to me because my wife brought it to my home. And she did it

because she got it as a free sample. She went to her gym, and one of her gym buddies said, hey, you should try this stuff. This really works on you. So, of course, my wife knows what I do for a living, chose to come and bring it home and gave it to me and made me look. I took some photographs.

What is important about this is on the product itself, it says CBD clinic revolutionary pain relief. But if you look at the right corner, you see that it is menthol 16 percent, camphor is 11 percent. Ladies and gentlemen, that is Ben Gay repackaged and sold for 10 times what it is worth.

If you go to the next slide, if you look at the active ingredient, it has no mention of CBD, but it contains the active ingredient as menthol 16 percent, camphor 11 percent. I told my wife, I said, this is Ben Gay, dear. Go upstairs, and we have a whole box full of it.

The other important backup, one of the things that was interesting about it, if you look at this bottom part of that product, it says that under the accordance with Section 7606 of the Agricultural Act of 2014. So again, they are using information and product placement of that information to legitimize their products and give it

some sort of credibility.

So we know that in June 27, 2018, FDA did approve Epidiolex, which is a botanical extract from marijuana plant. It is the only one that is approved by FDA. It is a product. It is a Schedule V. It is produced by GW Pharma, a cannabidiol product that is a proprietary oral solution, a pure plant derived cannabidiol or CBD.

It is for the treatment for seizures of Lennox-Gastaut Syndrome or Dravet Syndrome. It is an oral solution, starting dose about 2.5 milligrams per kilogram twice a day, increases to 5. It is for patients 2 years of age and older. It does not produce cannabinoid-like behavioral response like THC.

It is formulated in dehydrated ethanol sesame seed oil, sucrose and flavoring. But this is the most important thing. In the package inserts, it advises patients of the potential for positive cannabis drug screens. And it doesn't say that you are positive for THC, but you could be positive for cannabis drug screen. And the average annual cost is $32,000. This is not something that you pick up at the dispensaries.

We have gone through all of this. The question that everybody has asked is, well, what is the policy? What is the federal policy that is current? I have listed

some of the most current. When I say current, you are going to say it is not really that current.

The first policy that was regarding marijuana is in 2015. This was issued by the Office of Personnel Management. Basically, it reads the same as federal law and marijuana remains unchanged. Marijuana is categorized as a controlled substance under Schedule I of the Controlled Substance Act. Thus knowing or intentional possession of marijuana is illegal.

The next one is from the Department of Defense. So what do they say concerning their position on marijuana? This is from 2018. This memorandum reaffirms the federal prohibitions and the use of marijuana by military personnel at all locations. Military personnel are subject to prosecution, administrative action for marijuana use, possession or distribution under Articles 112A of the UCMJ.

Federal law supersedes the legislative initiatives of the state, district or territories of the United States. And it also adds, the Department of Defense, DoD, civilian employees are subject to restrictions governing the drug use contained in DoD instructions. DoD civilian employee drugfree workplace program and applicable Department of Health and Human Services, Substance Abuse and Mental Health Service

Administration guidelines. So again, it is consistent with OPM.

So now we issued one. In 2017, SAMHSA issued their own. Basically, it says CBD products may contain other cannabinoids such as THC. Therefore, use of CBD oils and marijuana-derived products may result in a positive urine drug test for THCA. As a point of clarification, there have been no changes to the drug testing panel regarding marijuana under the Federal Drug Free Workplace Program. The DFWP, as established under Executive Order 12564, Public Law 100-71, and the Mandatory Guidelines will continue to operate in accordance with federal law which identifies marijuana and marijuana extract examples, CBD, as a Schedule I controlled substance.

And lastly, we have another memo. This is from the major league baseball. What do they say? Well, it says all MLB drug programs ban cannabinoids by category, which includes marijuana, tetrahydrocannabinol, THC and CBD. These are also classified as a Schedule I controlled substance. Regardless of the Farm Bill or any state laws currently in effect, CBD and THC continue to be classified as drugs of abuse. They are banned under all MLB drug programs. As a result, the use or possession of a CBD product can result in a violation of the MLB drug program.

And this was from March 14th, 2019.

You have policy. You have these products out there. Why are we so concerned? We are concerned because two studies have been done, one in 2015 and one in 2017. Both of them were looking at commercial products out there. I refer to this slide as truth in labeling.

The first study was done by Johns Hopkins University. It was in Vandrey et al in 2015. They tested for THC and CBD. They did 75 products. The important thing here is only 17 percent were accurate as labeled.

Now, they followed up in 2017. We are looking at the same. It is Johns Hopkins University study. This is Bonn-Miller et al. They tested for CBD. 84 products were tested. The important thing here is only 26 percent, or one-third, was positive for labeled accurately. And when they say labeled accurately, you are getting a plus minus 20 percent. It is not like FDA accuracy of right on. You have got a plus or minus 20 percent.

And in the 2017 Miller study, which was most important is, in those products, there was THC content that varied from 0 to up to 6.4 milligrams per mill. You could have product that says CBD only, but contains up to 6.4 milligrams per mill, and that will give you a positive result.

We have looked at some of the research questions regarding CBD as it relates to THC. There are two questions that were posed. The first one is can CBD be converted to THC in vitro? And the other one is can CBD be converted to THC in vivo? Let's go through the first one.

So when you ask the question in vitro, that is outside the body, there are three studies that references it. The first one was a conversation of CBD to THC in 1968. That was an acid catalyzed conversion.

The next one was in 2012, where CBD converted to THC by derivatization with TFA, which is trifluroracetic acid. It is very timely because the NLCP sent out an alert just recently that showed if you are a laboratory, and you are using a high acid derivatizing product, you can convert CBD into THC. The way it was identified was that a sample, an A specimen sample, was originally reported out as positive for THC.

The donor requested the B bottle to be sent for B bottle analysis. The B lab, which was used in a different derivatizing agent, reported out as negative for THC. When NLCP asked the A lab to repeat the analysis using their standard procedure, they repeated and produced the same positive THC connotation, when we asked the lab to change the derivatizing agent and report out as a negative.

So the evidence is there.

But all laboratories now cease not to use an acid derivatizing agent as part of their confirmation process. So again, it is not hearsay. It is a valid concern. And then lastly, in 2007, there was a paper that showed that CBD in strong gastric fluid does convert to delta 9 THC and delta 8 THC in a 1.5 to 1 ratio. So that is in vitro. Now, let's look at in vivo.

So we have again reviewed some of the references, and here are four of the references that demonstrate that question. The first one in 2017, rats were treated with oral and subacute CBD and had THC and serum. Then in 2018, mini pigs treated with oral CBD did not have THC in plasma. In 2017 again, conversion of oral cannabidiol to delta 9 THC seems not to occur in humans. That is the study. And then lastly, some literature suggests small amounts of delta 9 THC and delta 8 THC are human urinary metabolites of CBD in 2016 and 1991.

So what these references demonstrate is that there is still some unknown. And what I think is important is that we, as a program, need to address specifically 'can CBD be converted to THC?' And that is where the program and SAMHSA and through their efforts are trying to coordinate those studies with John Hopkins University and

doing some human exposure studies.

I will end with the next two slides. This is the slide that Barry had shown. Again, the important thing about it is that when you are looking at federal and federally-regulated safety-sensitive workforce, and you have states that have legalized marijuana, the belief that availability is going to get you a higher positivity rate. And this is demonstrated by that graph, and it is compared to the national average.

And the last slide that I want to share with you, this is from the 2017, the National Survey of Drug Use Report. And it looks at past month use of marijuana. You can see marijuana use among adults, 25 or greater. And you see that there is an ever-growing increase in that rate. But more importantly, if you look to the right, where you see past year daily or almost daily use, in 2017, we reach 5.3 million.

Ladies and gentlemen, that is a definition for cannabis use disorder. That is the true definition of the DSM IV of that condition. It should alarm us. It should alarm us all because this is in 2017. We don't know what 2018 is, and we don't know what 2019 is. But my prediction is that it is going to be ever more so growing. And the evidences on the amount of availability, the surplus of the

product out there, the unfettered access to these products, and it is impacting everything we do. It is a disrupter, and it is a juggernaut used by anyone who is going to make a fast buck. I will end there.

I will take questions if anybody has any.

MR. FLEGEL: Any questions from board members?

DR. SCHAFF: Just a comment and a caution about terminology that would be important for a lot of people here. When you are dealing with looking at some of the labeling on these CBD products about THC content or THC free, pay attention to terminology. In the workplace testing community, THCA is usually used to refer to the carboxy THC metabolite. When you look at product labeling where marijuana has been legalized, it usually refers to tetrahydrocannabinol acid, which is a phytocannabinoids that is, by most means of administration, efficiently bio converted into delta 9 THC. So it is effectively equivalent to having THC in the product.

The problem is, depending on what state you are in and how the labeling regulations work, for potency and for THC content, some say you just have to list delta 9 THC. Some say you have to list the combination of THC and tetrahydrocannabinol acid. So a cautionary tale about when you are looking at some of this information.

MR. FLEGEL: If there are no further questions, I want to thank Charlie for his presentation. I am going to move on and hand it back over to Matt for public comments, if there are any.

Agenda Item: Public Comment

MR. AUMEN: At this time, anyone from the public who would like to make a comment is invited to address the advisory board at this time. For anyone in the room, please state your name and make sure you speak clearly into the microphone. You can use this one up here, so that your comments are heard and recorded. Please also limit any comments to five minutes or less, please. Do we have any comments from those in the room at this time?

Okay, seeing none, operator on the phone, may we open up the lines for comments at this time?

OPERATOR: If you would like to ask a question, please press star 1, unmute your phone and record your name clearly. One moment, please. We are showing no comments at this time.

MR. AUMEN: Thank you. So at this time, hearing no comments, Ron, is there anything that you want to add before we adjourn?

MR. FLEGEL: I just want to thank all the presenters today, the public DTAB board members and Ex

Officios for being here. Again, I hope it was informative, some of the information we presented.

We do have public open session tomorrow from 9 to 10. We will have one more issue to discuss, and then we will move to closed session. Thank you again.

MR. AUMEN: With no further business at this time, the Center for Substance Abuse Prevention, Drug Testing Advisory Board Meeting is now adjourned. Thank you.

(Whereupon, the meeting adjourned.)