Center for Substance Abuse Prevention (CSAP)
Substance Abuse and Mental Health
Services Administration (SAMHSA)

Drug Testing Advisory Board (DTAB) Meeting

OPEN SESSION

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Virtual

Proceedings by

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Agenda Item: Call to Order, Approval of December 2022 Minutes

MS. DAVIS: Good morning, everyone. Thank you for bearing with us through all the technical difficulty. My name is Lisa Davis, and I am the designated federal officer for the Drug Testing Advisory Board, otherwise known as DTAB. I would like to welcome everyone to the March 2023 quarterly DTAB meeting. We are conducting this meeting remotely, so please bear with us through any technical issues that occur and continue to occur.

I officially call this meeting to order and want to welcome staff of the Division of Workplace Programs, federal partners, contractors, invited guests, members of the public, and finally our board members. Thank you, board members, for your service.

Today's open session is scheduled from 10 a.m. to 2 p.m. Eastern time. Just a reminder, before our board members speak, please state your name for the benefit of the transcriptionist and all other attendees.

With that, I will start the roll call.

Jason Schaff?

DR. SCHAFF: Present.

MS. DAVIS: Barry Sample?

DR. SAMPLE: Here.

MS. DAVIS: Kristen Burke?

MS. BURKE: Here.

MS. DAVIS: Deborah Motika?

DR. MOTIKA: Present.

MS. DAVIS: Stephen Taylor?

Alison Stockdale?

MS. STOCKDALE: Here.

MS. DAVIS: David Engelhart?

Elizabeth Stuyt?

DR. STUYT: Here.

MS. DAVIS: David Roberts?

Lindsey Everson?

MR. EVERSON: Present.

MS. DAVIS: And our DTAB chair, Ron Flegel.

MR. FLEGEL: Present.

MS. DAVIS: I'll now call the ex officios and federal partners. Bohdan Baczara?

MR. BACZARA: Here.

MS. DAVIS: Joseph Kotarek?

DR. KOTAREK: Present.

MS. DAVIS: Brian Zaleski?

MR. ZALESKI: I'm here.

MS. DAVIS: Capt Erin Wilfong?

CAPT WILFONG: I'm here.

MS. DAVIS: Lynn Wagner?

DR. WAGNER: Present.

MS. DAVIS: That's it for roll call, and we do have a quorum.

In today's open DTAB session, we will discuss the Mandatory Guidelines for Federal Workplace drug testing programs. The Department of Transportation, the Nuclear Regulatory Commission, the Department of Defense, and the Food and Drug Administration will provide updates.

Dr. Svante Vikingsson will give a presentation on the summary of pulse testing studies for fentanyl and opioids, initial test positive, and delta-8 THC and THCA initial positive specimens.

Dr. Eugene Hayes will present an update on the electronic chain of custody form.

Please mute your phones when not speaking to prevent any background noise. We have a public comment period scheduled at 1:40, following the last presentation prior to adjourning at 2 p.m. If anyone would like to provide a comment, they will be able to do so at that time. All the information in today's open session meeting, including a meeting summary and meeting presentations, will be posted on the DTAB website. Any questions or public comments will also be posted.

Once again, thank you for attending, and now I'll turn it over to Ron Flegel, the chairman of the Drug Testing Advisory Board and the director of Division of Workplace Programs, for his opening remarks.

Ron.

Agenda Item: Welcome and Introductory Remarks

MR. FLEGEL: Thank you, Lisa. Also, thank you for all that you do. I know sometimes it's very difficult technology-wise as well as putting everybody into the meeting. So with that, I wanted to also thank you.

Just as a reminder, you may want to turn down your speaker on your laptop when you're speaking because that causes an echo. It did on mine so I turned it off.

So, again, I would like to welcome all the board members, ex officios, federal partners, industry leaders and representatives and also members of the public to this Drug Testing Advisory Board meeting, and also thank you for choosing to take time out of your schedule to attend. I would like to acknowledge we will have two new members of the Drug Testing Advisory Board at our next meeting, which means we have two board members leaving us after this one.

I would like to acknowledge and thank Barry Sample and Jason Schaff for all of their contributions to the Drug Testing Advisory Board over the last several years. Their expertise in all areas of the science and insights into the research have been so beneficial for this board, especially during this time, that I cannot thank them enough. Thank you, Barry, for your willingness to always contribute to moving the science forward, and thank you, Jason, for always contributing to discussions of the regulatory complexities involved in proposed board decisions.

I have a certificate of appreciation for each of you that I will show you later. But thank you again for everything that you guys have done.

SAMHSA continually strives, again, to improve the quality of the services under both the NLCP program and the Federal Drug Free Workplace Program. We also look to our federal partners to continually assess forensic workplace drug testing for federally regulated testing and private sector testing by reviewing the science and technology used in drug analysis, which again improves the quality of related laboratory services and processes for forensic drug testing.

Our standards for laboratory certification for Federal Workplace drug testing programs extend to many of the regulated and nonregulated drug testing sectors. Additionally, we recently completed a Comprehensive Review of the Drug-free Workplace Program, existing practices, policies, and emerging issues, by performing what we're saying is a SCOT analysis, which stands for Strengths, Challenges, Opportunities, and Threats. I will update the public on our progress of the Comprehensive Review of the Federal Drug Free Workplace Program later in this meeting.

Regarding the DWP status update, which I know everyone is interested in, the notice of proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using hair was published in the Federal Registry on September 10, 2020 for public comment.

The public comment period closed on November 9, 2020, and DWP has since then revised the proposed Mandatory Guidelines and they are currently under review at the Office of the Secretary of HHS. Once this review and departmental clearance is complete, the Mandatory Guidelines will be sent to OMB for review and clearance, followed by a Federal Register Notice to the public.

I did want to answer one question. Why has it taken so long? HHS published the proposed HMG with a 60-

day period on September 10, 2020, in the Federal Register, which is 85 Federal Register 56-101, which everyone can see. HHS completed the review of approximately 700 comments received, as well as scientific articles and other documents submitted with the comments, for reference by commenters, and revised the proposed HMG based on this review.

On June 8, 2021, HHS provided a preliminary draft of the final guidelines to SAMHSA's Drug Testing Advisory Board, and we received an additional 188 comments for review. These new revisions to the proposed hair Mandatory Guidelines were reviewed by SAMHSA's Drug Testing Advisory Board on September 20, 2022 and moved into the clearance process under HHS in October 2022.

Again, we anticipated the proposed guidelines will be published in the Federal Register in the second quarter of 2023 with a 60-day comment period.

DR. SAMPLE: Ron, do you have slides that are supposed to be advancing?

MR. FLEGEL: No, I'm going to give a program update with slides later in the program. I should have explained that, but I really just wanted to do a brief introduction as to what we'll discuss. It will be later in my presentation, later on in the day.

Again, the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing using urine and oral fluids were published in separate Federal Register Notices on April 7, 2022, and the public comment period closed on June 6, 2022. Again, 22 commenters submitted 57 comments for the urine Mandatory Guidelines, with 53 commenters submitting 204 comments for the oral fluid Mandatory Guidelines. Many included attachments. All comments and attachments have been reviewed, and the Mandatory Guidelines are currently, again, under review at the Office of the Secretary of HHS.

I will again, as indicated, discuss some of the major changes in the revisions to urine and oral fluid later in my presentation.

I do believe that to have an effective drug testing program, you need a comprehensive approach, which I think includes urine, oral fluid, and hair. DWP continues to focus on other special projects underway with the National Laboratory Certification Program in conjunction with RTI International and Johns Hopkins University, and I want to thank them.

Again, I would like to thank everyone for attending the Drug Testing Advisory Board meeting today. I hope you find the presentations informative on all accounts of what we'll be presenting, and also of the federal partners.

With that, I will turn it back over to Lisa to continue with the program.

I should say, is there any comment at least from board members currently on the introduction? Again, I will have a presentation later with slides and will be going over some of the things that I indicated in the briefing.

MS. DAVIS: All right. If there are no questions, we're going to move onto the next presentation.

Bohdan Baczara? Thank you.

Agenda Item: Department of Transportation (DOT) Update

MR. BACZARA: Thank you and good morning, everybody. Ron, thank you for having us on the agenda so we can give a very brief update.

Basic things that we're going to cover is the guidance we have out there today related to COVID-19; provide you with some statistics on the Driver Clearinghouse Database within FMCSA; talk about our rulemaking that we have out there; and again, briefly describe the MIS aggregate data that's available on our website.

So still in effect, we have two guidance documents, one by Federal Rail Administration, the other by the Federal Aviation Administration, related to COVID with respect to drug and alcohol testing. Those guidance documents are available on our guidance page, and in summary they basically talk about that if you cannot perform a test, fully document the event, so that when the employer is audited, they have all the facts when they're reviewing the situation.

We also have a guidance document out there that went into effect January 1, 2023, and basically what it did is it allowed authorized Substance Abuse Professionals to conduct remotely assessments and evaluations that are required under Part 40. There is no termination date for this document. The document will be in effect until we issue a final rule as a result of the notice of proposed rulemaking that we published in February of this year.

Onto the FMCSA Driver Clearinghouse. Again, became effective January 6, 2020, and it requires that employers, MROs, Substance Abuse Professionals enter drug and alcohol violations into the database, and as of January 2023, there were 17,634,326 queries conducted. This is employers checking on the driver's status. There were 182,000 drug violations reported, 182,745, 4,203 alcohol violations reported into the database. With respect to drug violations, the top three drugs reported were marijuana, cocaine, and methamphetamine, in that order, and the reason with the most drug violations is pre-employment. Currently, those drivers that are in a prohibited status, meaning that they tested positive or had a refusal and they have not completed the return-to-duty process, is 120,325.

The link provided at the bottom of that slide is where you can get the full report.

ODAPC rulemaking. As you all know, we published in the Federal Register in February 2022 our Notice of Proposed Rulemaking to authorize oral fluid in the DOT drug testing program. The comment period ended April 29, 2022. We received 417 comments to the docket, and we are currently working on the final rule.

With respect to electronic signatures and forms and records storage in the Part 40 program, we published a rule on August 5, 2022. The comment period closed October 4, 2022, I believe it received close to 77 commentors, the comments to the docket, and we're currently working on the NPRM.

For these rulemaking and for any other rulemaking as you all know, when we do publish a final rule, we will be putting it in the Federal Register, publishing it via the Federal Register. At the same time, we will be putting it on our website, and we will be sending out a list serve letting the public know that the rules have been finalized.

For those of you who are not on our list serve, I will highly recommend subscribing to it so that when these rules do become final you're in the know.

As we said before, we have a webpage out there that provides the MIS aggregate data, and basically what that is that every year certain employers are required to submit their aggregate drug and alcohol testing data for each of their employees. There is no personal information there. There is no somebody tested positive for this drug and for that drug. It's just overall industry data that talks about how many tests were conducted in the aviation industry, the rail industry, transit, pipeline, motor carrier, how many were positive, how many were negative, and for what test reasons.

It's there for public consumption. If you have an interest in it, please let us know. If there's anything we can do differently with this particular data.

That's all I have, I believe. Thank you.

Next slide is just our resources, and again, it's completely public information. It's on our website right now. Like I said, there's the link for the list serve, and also “Am I Covered” is a very highly visited webpage, which basically helps employers determine whether or not they are covered by the DOT regulations.

That's all I have. Thank you.

MS. DAVIS: The next presentation will be from Brian Zaleski.

Agenda Item: Nuclear Regulatory Agency (NRC)

MR. ZALESKI: Good morning. I'm Brian Zaleski. I am a Fitness for Duty Access Authorization Specialist with the U.S. Nuclear Regulatory Commission. Today, I am going to provide a few highlights from the Part 26 program that we oversee.

There's three topics I'd like to discuss today. One is rulemaking update. We issued a final Part 26 rule in November 2022. Second update will be one fitness for duty program performance trend. This is on subversion attempts that have been identified. And the third bullet will be to highlight laboratory performance issues that we have been notified by our licensees. They are required to report events from laboratories where unsatisfactory performance is identified.

The next two slides will be about the final rulemaking that was published on November 22, 2022. The changes to the rule became effective one month after publication on December 22, 2022, and compliance is required by our licensees by November 22, 2023. So one year from the date of publication, compliance is required.

When we talk about licensees, we issue licenses to power plants that generate nuclear power. That's primarily who we are talking about. We're talking about any of the data under part 26. We have two fuel fabrication facilities that manufacture fuel that's used by the Department of Defense. But primarily we're talking about operating nuclear power plants. There is one site under construction, the Vogtle site, but primarily operating nuclear power plants around the United States.

So what does this rulemaking do? We align the drug testing panel and the cutoff levels with revisions that have been made to the HHS Mandatory Guidelines for Federal Workplace drug testing programs that had been issued two subsequent revisions, one in 2008 and one in 2017. We also have implemented a number of lessons learned from our last rulemaking under Part 26. That was back in 2008, so 14 years later, we have updated the rule based on lessons learned. The most significant change is to improve methods to identify subversion attempts.

The other change in the rule that's notable is now we're providing licensees and other entities the ability to collect an oral fluid specimen from an individual and test this under direct observation collection conditions. This is a new opportunity for licensees to collect a specimen other than urine. This is the first time the NRC has supported this activity and it's solely because of the Mandatory Guidelines that were issued by HHS back in 2019 for oral fluid. We understand that there's yet to be a certified laboratory, but as soon as those laboratories are certified, our licensees will have the opportunity. They can still use urine for direct observation collection conditions, but they have the opportunity to also use oral fluid.

And I should highlight the green box there. If anybody is interested in seeing a track changes version of all the changes that we have made in the rule, you can go to the link below. This is a relatively new invention from the ECFR, where you can actually do a compare from the current rule and a changed rule in a time period. It's a very nice website. So if you just hit that link, it's comparing what the rule was prior to the November 22 final date, and you'll be able to see everything in track changes.

This presentation is primarily highlighting changes that are going to impact HHS-certified laboratories.

Changes impacting HHS-certified laboratories is one section in 10 CFR 26.163. That includes initial and confirmatory cutoff levels as well as substances. So what are the changes that are we aligning with in the guidelines?

We are adding the testing for hydrocodone, hydromorphone, oxycodone, oxymorphone, MDMA, and MDA. And we're implementing the cutoff levels that have are established in the guidelines. We are adding initial drug testing for 6-acetylmorphine, and we're updating the confirmatory drug testing method. This is an improvement, because right now the method that we have in place is used for testing for 6-acetylmorphine after a confirmed positive morphine. So this will help speed up the reporting on test results for this heroin metabolite.

Lowering initial and confirmatory cutoff levels for amphetamine, cocaine metabolite, and methamphetamine, and as I said in the previous slide, this is a lessons learned change. We're updating and expanding the special analyses testing provisions. This is a bit unique in the federal space.

So right now, licensees have the option to use lower cutoff levels if the specimen is diluted if the validity test results indicating that the individual likely consumed excessive amounts of fluid to potentially reduce the quantity of drug. People may also have a dilute specimen simply because they drank a lot of water. But this is one method individuals may employ to try to avoid a positive result.

So under the previous rule, licensees have the opportunity to implement this testing for dilute specimens. Almost all of industry has been using this since 2009 when the rule was effective.

We have now mandated special analyses testing for these dilute specimens. We have also expanded using these lower cutoff levels with specimens collected under direct observation. So if there is a reason to believe an individual is likely cheating, that's primarily why we're collecting the specimen under direct observation -- actually it's the only reason to collect specimens under direct observations -- we are lowering the concentration of those tests.

When is this conducted? So initial drug test any drug is within 40 percent of the cutoff, before it was 50 percent of the cutoff. So if the cutoff is 100, and drug concentration is 50, we would go to confirmation and it would be the LOQ. The final rule changes that to 40 percent of the cutoff, so a little bit lower, and the confirmatory cutoff level would be the LOQ instead of the LOD.

I'd like to thank HHS for working with the NRC to distribute an NLCP notice to HHS Certified laboratories.

As I said on the previous slides, there's a one-year implementation timeframe. I believe some licensees will attempt to comply with the full rule maybe midyear, so six months in, and others may wait until the end. There will certainly be some of our licensees that will come in at the end of the year, but we anticipate that licensees will start implementing the rulemaking throughout the year.

This is a slide that we've seen; I have presented this many times at the Drug Testing Advisory Board. It's one of the reasons why oral fluid testing will be beneficial once we implement it. We see a lot of subversion attempts.

What is a subversion attempt? A subversion attempt is any willful act or attempted act to cheat on a required test. So that's refusing to provide a specimen, simply do not provide a specimen, but the majority of incidents that we have or where individuals willfully attempted to thwart the drug testing process, by using something other than their own urine. Synthetic urine, putting something in the urine that's to interfere with the testing process.

This is a trend that we've seen for many, many years. We started monitoring the data associated with subversion attempts back in 2009 when we changed the data collection system that we used. We have an annual reporting requirement just like the DOT was talking about, their MIS requirement, that we call the FFD program performance requirement, and that reporting requirement, we get one unique form completed for each testing positive or testing refusal. We can provide a lot of information about subversion attempts. Each year, we have seen roughly a third of all drug testing violations are subversion attempts, and the top line in this is specific about the actual magnitude. There were roughly 305 in 2017, 264 in 2022. The percentage is roughly the same, about a third. Most of the cheating is identified at pre-access testing, and that is a critical testing event. Between 67 and 76 percent of subversion attempts are identified, that testing, that's before an individual is granted unescorted access to the power plant. That's the criteria that we have in place. If you're granted unescorted access, you can walk around by yourself. You're subject to the rule and you have to have a negative test result, both alcohol and drugs.

Most of the individuals that cheat in NRC space are contractor/vendors. These are typically short duration employees. Primarily but not exclusively brought in to do short duration activities, the most significant which is refueling outages. Every nuclear power plant in the United States is in an outage every few months to change out the fuel.

And finally, subversion attempts have been identified throughout the industry. It's not just one site. It's throughout the industry. It's between 64 and 75 percent of the sites each year reporting at least one subversion attempt. These are somewhat cyclical based on how often we're processing people. Pre-access testing, you're processing a lot of people. In outage conditions, you could be bringing in 1,000 people to perform an outage over a 30-day period of time, versus normal operations at a single use site where you might have 600 or 700 people. So it's quite a large number of people. Like I said, pre-access testing is where we see most of this.

There's a requirement under NRC for a licensee to report to the NRC within 30 days of completing an investigation of unsatisfactory performance. What that simply means is that the intended test result that laboratory was to report to the licensee was not provided. We primarily see these events associated with the blind testing program. Our licensees are required to submit a minimum number of specimens each quarter for all the substances they test, including challenging the validity testing requirements.

Two of the reports that we are talking about, number 1 and number 2 on this slide, relate to a blind performance test sample where it is a known concentration of drug metabolites in that specimen, and the quantitative result, the confirmed positive test result from the laboratory was outside the expected range. In one instance, this was related to a calibrator material that had deteriorated. In another instance, it was a minor variability and it wasn't related to any other type of investigation.

Generally when these events occur, laboratories are retesting these substances at the same laboratory. They may be testing at others, some licensees will take the blind specimen, split it and send it to two independent HHS-certified laboratories to evaluate the result. So there is a lot of challenge in the laboratories to ensure that the results we're getting are accurate.

Number 3, and this has happened a few times, the laboratory did not report test results within five business days of receipt. NRC has a requirement in place that laboratories return that result within five business days. Typically negative results come back quite fast, and we understand that performing confirmatory testing on a specimen can take longer. So you have a number of days to complete that report.

Why is that really critical for us? If somebody has unescorted access and they're performing activities inside the nuclear power plant, whether an armed security officer, a reactor operator, supervisor, or they're maintaining safety and security-related systems, we want to make sure that we remove that individual performing their job functions as soon as we can with an identified positive test result. That's why we have that reporting requirement. It's not an issue if an individual hasn't been granted access yet, but it is an issue for individuals that have access and they're actively working.

Number 4 on the list is the false negative for a blind specimen. This occurred for a site that had already implemented an expanded panel opioid testing protocol for a subset of testing events. In this case, the laboratory used the wrong testing code. So they used the wrong testing panel. They implemented the standard testing panel that that licensee always uses, but in this case they were challenging the standard panel. So the wrong code was implemented, negative result was reported, and the licensee identified it and they reached out to the laboratory.

Last two related to situation -- and I have should have noted that the timeframe was listed on these reports, and all of these reports are publicly available in the NRC agency docket system. I didn't put the ML number. That's the accession number. That's how you find it on our docket. But all these records are publicly available and any event that's related to the laboratory performance within our rule, we provide these records to NLCP, HHS, and they many times are going to look into it if it's an appropriate thing for them to look at. Sometimes it's not related to laboratory performance, might be blind performance issue, formulation or preparation issue, on the licensee end.

The last two are related to specimens that were sent to the wrong HHS-certified laboratories. Our licensees are required to audit their HHS-certified laboratory every 12 months, and that includes testing at that specific laboratory. So if a specimen is sent to a laboratory that has not been approved by the licensee, that's noncompliant with our requirements.

So in two cases, these are both laboratory chains that have multiple locations. They sent donor specimens to another one of their laboratories. Number 5 listed, the reason the specimens were sent, 15 specimens were sent to wrong laboratories, the shipping label was incorrect.

Number 6, two donor specimens were sent to another laboratory. The licensee only became aware of it when they received the donor retest request, and in both of these situations, the retest requests were not processed within one business day, and that's a requirement we have for donor protection to ensure that we have processed shipping of these specimens to another laboratory, and in one of these two cases, the specimen was sent to the wrong secondary laboratory. This was related to staffing issues and it was related to one individual who was training.

That's the summary of all the events that we had in 2022. HHS was engaged with the majority of these early on. Most of these events occurred early in last year, and the next slide is just contact information for myself, Brian Zaleski, and my colleague Paul Harris. Thank you for the opportunity to present to the DTAB. I appreciate any questions. Thank you.

MS. DAVIS: Thank you, Brian. Does anybody have any questions for Brian or for Bohdan about his talk? Any board members have any questions? Board members only, please.

DR. SAMPLE: Lisa, this is Barry. I did have a question for Bo. When he was providing the summary data on the clearinghouse, I didn't see anything about refusals. We had the positives and the predominant analytes, but do you have information readily available on the number of refusals that are in the clearinghouse?

MR. BACZARA: I could look it up. It's definitely in the report that's in the link that I provided, but I'm not sure why I overlooked it in the presentation.

DR. SAMPLE: Thanks, Bo. I'll follow the link and try to find it and let you know if I have questions.

MS. DAVIS: One bit of business. I just wanted to make sure David Roberts, you were able to call in, correct? Are you there? David Roberts, were you able to connect?

Okay, we'll check back with him in a minute. He is on. He emailed me. I just wanted to get him on the record.

But we're scheduled right now for a break. We're a few minutes ahead of time, but our break is scheduled from 11 to 11:15. So we'll go ahead and take a break until 11:15, and if board members will come back a little early, and I'll just do a doublecheck roll call real quick to make sure everybody is still able to see and hear, I'd appreciate it. Thank you.

(Brief recess.)

MS. DAVIS: All right, thank you. I want to take a really quick roll call once again and make sure everybody is back and connecting correctly.

Jason Schaff?

DR. SCHAFF: Present.

MS. DAVIS: Barry Sample?

DR. SAMPLE: Here.

MS. DAVIS: Kristen Burke?

MS. BURKE: Here.

DR. DAVIS: Deb Motika?

DR. MOTIKA: Present.

MS. DAVIS: Alison Stockdale?

MS. STOCKDALE: Present.

MS. DAVIS: Libby Stuyt?

David Roberts?

Lindsey Everson?

MR. EVERSON: I'm here.

MS. DAVIS: Ron Flegel?

MR. FLEGEL: Present.

MS. DAVIS: And our speakers after the break. Capt Erin Wilfong?

CAPT WILFONG: Present.

MS. DAVIS: And Joey Kotarek?

DR. KOTAREK: Present.

MS. DAVIS: And one more time, Libby Stuyt, are you present?

And David Roberts?

Okay, thank you, everyone. Our next speaker is Capt Erin Wilfong from the Department of Defense.

Agenda Item: Department of Defense (DoD)

CAPT WILFONG: Good morning, everyone. I'm Erin Wilfong. I'm from the Office of Drug Demand Reduction for the Department of Defense. Thank you for continuing to include our organization in these meetings. We appreciate having the opportunity to present our work.

Since most folks are probably pretty familiar with us and I've only got 15 minutes, I thought I'd jump ahead to slide four and specifically talk about some of the drugs that we test on our military drug testing panel that are not on the current SAMHSA panel. I figured folks might be more interested in some of those statistics in terms of prevalence.

I'll start with THC. So we brought delta-8-THC onto our testing panels for the military in 2021. It was the last quarter of the fiscal year. So 2022 was the first year where we had that drug on the panel for the entire year.

We were able to actually pretty quickly pivot and bring that online, because the year prior we had banned all hemp products for active duty military. I thought what folks might be interested in was what we see in terms of the breakout in confirmation coming from the screened positive samples.

So basically, what screens positive, about 57 percent of that will actually confirm positive for delta-9-THC, which is traditional THC to most folks. Again, that's above the 15 nanogram per milliliter cutoff. About 20 percent of the samples confirm for delta-8 only. Again, for both of those scenarios, you could have the other compound present, just below the cutoff, or the other compound may not be present.

Then about 16 percent of what screens positive confirms for both compounds, meaning we're picking up both delta-8 and delta-9 above the cutoff. And then we sit at about a 5 percent failure to confirm percentage right now, meaning that it screens positive by our microgenics kit, but it's not confirming positive for either drug. That amount actually doubled starting in March 2022. So there is more than likely another hemp-derived product out there in the population that we're just not confirming for at the moment.

If you follow the business trends for delta-8, I don't think it's going anywhere anytime soon. I believe there was an article just recently released where it reported that last year, there were more than $2 billion in sales of the hemp-derived marijuana products, and delta-8 alone made up $1 billion or half of those sales. So I don't think this compound is going anywhere. If you're curious, the other $1 billion in sales of synthetic compound was hemp-derived delta-9, HHC, delta-10, and THC-O. I will tell you that similar to the SAMHSA trend, delta-9 is our number one drug. Delta-8 is number two in terms of what we see in prevalence.

LSD is another one that is on our panel currently. We brought it back in 2020. We are currently only pulse testing for this drug. In October, we made sure that all five of our testing labs were at a minimum doing a 10 percent pulse testing rate for LSD or the LSD metabolite. I will tell you, in terms of prevalence, if we take the positive numbers that we see pulse testing at 10 percent and we extrapolate it out to 100 percent, this drug would definitely be in our top five in terms of prevalence. Again, that kind of fits with some of the reports that are starting to come out. There was a 2020 report basically stating that LSD use had increased nationally by over 56 percent in a 3-year period.

I believe Oregon is the most forward-leaning in terms of decriminalizing some of the psychedelics, but there are some cities that I think are also going down the same path. I don't think any cities per se have decriminalized LSD, but there are a number of states and cities trending in this general direction.

The other one that I think a lot of folks are probably interested in is fentanyl. So we added fentanyl and the metabolite norfentanyl to our panel back in fiscal year 2019. We use a 1 nanogram per milliliter cutoff. We have been maintaining a 100 percent testing rate since fiscal year 2021.

I will tell you that when you look across all of the opiates and opioids that we test for, so the hydroxys, oxys, codeine, morphine, and including that with heroin, this is probably the top one by prevalence. It sits right above oxymorphone in terms of prevalence in our population, again, when you're holistically looking at opioids.

Unfortunately, this probably shouldn't be shocking when you look at all of the reports CDC has been putting out in terms of the amount of fentanyl that is now in the illicit drug supply and then the role that fentanyl is playing with overdose deaths. Unfortunately, despite our best efforts to deter folks from using this drug, the DoD is not exempt, especially from the overdose issues.

There were some articles that started coming out in Rolling Stone in September that you may have seen. More recently, there's been some additional press on the number of overdoses in the Department of Defense. I will tell you that I think we are a unique population because we have to drug test everyone once a year at a minimum. We tell the services the ideal testing number is twice a year, but they are required to maintain frequent random drug collections.

So we've got a lot of data. This data is probably more useful than what we're currently using it for, meaning that I think we need to pivot and look at using our drug testing data to help identify potentially individuals or installations or geographical regions that might be at a higher risk for drug overdoses. So we're trying to do some forward leaning in that arena with our drug testing data, specifically the fentanyl data and specifically looking at polydrug users, so those that are positive for more than one drug class.

The next one I'll jump to are synthetic cannabinoids. Again, these, if you're wondering is she talking about the original spice and K2? Yes, yes, I am. This still is the same class of drugs. We brought on a panel of seven drugs in 2013. We really hadn't seen -- our positives dramatically dropped off over the years on that panel. So last year, in October 2022, we brought on a brand new panel of eight new synthetic cannabinoids.

Again, what I have here are the abbreviations that we use in our LIMS system. If you need the full names of the drugs we're testing for, just reach out. We're happy to provide that. But the ones that we selected are based on our surveillance testing. They're based on what the DEA was reporting is trending and also what the Armed Forces Medical Examiner System was seeing in their cases.

Again, we're testing it at 10 percent pulse rate for these, but I will tell you, since October since this new panel went online, we are definitely seeing positives. It's kind of a large number of positives, considering we're only pulse testing. So without a doubt, these compounds are still in our population. I think we realize that these compounds change year over year and that we're probably going to have to update this panel perhaps on an annual basis to keep pace.

So that wraps up the drugs that we test for that aren't on the SAMHSA panel. Since I'm limited on time, if you don't mind jumping ahead to slide 11, I thought I'd talk about what we have seen with regard to poppy seeds and pass that information along. You may have seen some news stories with regard to poppy seeds in the Department of Defense. This was because in February, we'd actually put out a memo to service members warning them to avoid poppy seed-containing food products because there was a risk that they could be positive on a drug test.

That's what kicked off the immediate interest in the topic. Prior to that memo going out, there had also been a Brady notice that went out as well. So I thought I would talk about what we were seeing in the three studies that prompted us to take the action of putting out a Brady notice, putting out the memo, and where our testing is currently with regard to the issue.

So in 2022, our office started to hear rumblings of an uptick in the poppy seed defense. If you've been in drug testing for years, especially if you've gone to court, this probably isn't a new thing, but typically when we talk about claims of poppy seed causing a positive drug test, it's associated with morphine, and there are 20-plus years of papers and publications that support that morphine is typically the primary contaminant on poppy seeds. If these seeds are not washed or treated properly before they enter the food supply could be problematic for drug testing.

What was unique with what we were seeing is that it didn't have anything to do with morphine. These were codeine positives. So these folks were above the codeine cutoff of 2,000 and in some cases there was zero morphine or very little morphine, below 1,000. I say we were receiving reports of clusters, because we were hearing reports of multiple service members that were stationed at the same command, happened to be drug tested on the same day, all happened to come up codeine positive, and all happened to have a similar breakfast, meaning somebody brought in or wherever they ate, they all ate poppy seed muffins or they had poppy seed bagels. So that was interesting, and those numbers kept growing and growing.

So what we did is one of our labs contracted to have a study of three brands of poppy seed. They contracted with an independent lab. They had three brands of poppy seeds testing. They were looking at the contamination profile in these seeds of codeine and morphine.

So they had Costco brand tested, Great Value brand tested, and McCormick tested. I will tell you that the Costco and Great Value showed what we consider to be a unique contamination profile. It was very high codeine with little morphine. So for example, the codeine for the Costco was 291 milligrams of codeine per kilogram of poppy seed.

To put this in perspective of what does this mean, well, the European union has limits on poppy seeds. They put these in place in 2021, so basically any poppy seeds entering the marketplace for food consumption has to be at or below 20 milligrams of total alkaloid per kilogram of poppy seed. So when we use the EU formula and plug in the numbers from the Costco or the Great Value seeds that we found, those seeds are basically three times higher than what the EU is permitting.

That was two brands of seeds. The third brand of seed, which was McCormick, didn't show this contamination profile. It looked more consistent with what I would call a traditional poppy seed contamination profile and a wash profile, meaning it had some trace morphine and no codeine. So the morphine came in at about 2 milligrams of morphine per kilogram of poppy seed and there was no codeine detected.

So again, we didn't test every possible brand out there. We didn't test every possible poppy seed-containing product out there, but I think what this study did show is that there are seeds on the market that have a different contamination profile than what's been previously reported. So if you dig into the patent literature, this is kind of supported by a patent that's out there, too, for a high codeine variant for the opium poppy.

There were two studies, we went back in the literature to see if there were any other studies that showed what we were seeing, potentially either a variant of poppy seed that was high in codeine or was there any actual urine numbers that supported this, and there were two that we found, one from 2021 and one from 2022.

Actually, for the sake of time, I'm going to jump to slide 13. The 2021 study was the one that I think really caught our eye. They had 17 participants. They gave each participant one Costco wholesale poppy seed muffin. Then they measured the codeine and morphine in their urine 4 to 6 hours after ingesting the muffin and then at 21 to 25 hours after ingestion.

This was just one muffin. The maximum codeine concentration they saw at the 4 to 6 hour period was just over 2,600. When you looked at the data, there were three individuals that would have been over our 2,000 cutoff. Basically, their urinary codeine concentration exceeded 2,000 nanograms per milliliter. So again, this was concerning us. This was also fitting the narrative that we were hearing from some of the service members that were claiming that poppy seed ingestion was the cause of their drug positive.

In terms of where we stand now with this issue, we are currently still testing for codeine. We are just not reporting at the moment. We're on hold for reporting. We are kind of working through the data and looking at potentially raising our cutoff.

As you can see, though, the amount of studies are very limited. When you look at the number of participants in all of these studies, it's very limited. So it's really unclear at this point if there is going to be a cutoff that really is going to resolve the issue of innocent ingestion codeine.

So not only are we looking at raising the cutoff, but we are also looking at some supportive testing, meaning also monitoring thebaine and papaverine in some of these samples to see if we can pick up maybe a second chemical indicator of poppy seed exposure that would help us further delineate innocent ingestion from illicit codeine use.

So as of now, we have not made any final determinations. We are working to wrap this up in the next month, month and a half, and develop a way forward. But I believe I am out of time and slightly over, so I am going to go ahead and stop there and pause for any questions.

MS. DAVIS: Thank you very much, Erin. Are there any questions from the board?

DR. SAMPLE: This is Barry Sample. Very interesting data, a lot to think about here. Will you be sending the full deck out or are there other pertinent slides you had to skip over in the interest of time that the board may want to look at?

CAPT WILFONG: The full deck can go out. You can either send me an email and I'm happy to share the three studies, especially the one that we had done. I believe the Brady notice, which also included all three studies, is also on some legal blogs. So I believe if you Google it, you will find it that way, too.

DR. SAMPLE: I've seen the DoD notice, yes. Thank you. Then a second question unrelated to this interesting poppy seed data is you talked about the rate that drugs are being tested. Is the Department making the prevalence rate publicly available? I didn't see any positivity rates, just the testing rates.

CAPT WILFONG: Well, here's the thing. What I would have been able to show you was pretty outdated. It would have been 2021. We're just now working through our 2022 data just because our fiscal year ends at the end of September, and we have to give a three-month period to let anything work its way out of the system that might have a script.

So probably by the next meeting I will be able to show you 2022 data, how it compares to 2021 data, and that would probably have much more utility especially for some of the stuff like fentanyl and some of the other drugs that folks might be more interested in.

DR. SAMPLE: The cannabinoids and the fentanyl and even the LSD I would be very interested in learning what those prevalence numbers are.

CAPT WILFONG: Yeah, I just figured I'd wait until the next one when I can show you 2022 and 2021.

MR. ZALESKI: This is Brian Zaleski at NRC. I just had a quick question. These are all active duty soldiers? This isn't before they join the services, is that correct for all of the results you're sharing? Or is that also you're screening before you bring these folks on board?

CAPT WILFONG: What I shared with you in terms of what we see in terms of prevalence our top drugs, those are folks on active duty. Our drug testing panel and our cutoffs are all identical, though, for those coming into service, as well.

MS. DAVIS: Thank you, Erin. All right, our next speaker is Joey Kotarek.

Agenda Item: Food and Drug Administration (FDA)

DR. KOTAREK: Thank you, Erin, that was really interesting. I have a relatively brief update from FDA regarding fentanyl testing, and I want to talk a bit about the in vitro diagnostics that we've cleared for fentanyl testing and detecting fentanyl in human specimens and just talk a little bit about testing availability and access and the goals we have for that, where we are, the gap between where we are in those goals, and again, just an update to try to show that there is progress being made to bring those two things closer together.

So again, just to provide some backdrop for the discussion, in vitro diagnostic drugs of abuse tests are intended to detect the presence of drugs in human specimens, what we call class II devices with moderate risk, and the sponsors will provide what we call a 510k, a submission documenting their performance, before they are marketed as in vitro diagnostics.

Now, these drugs of abuse tests that we review vary in complexity. On the left you see what we call a central lab test and that's where you might imagine a large instrument where you are bringing the sample to the instrument. This isn't next to a patient; you have to get the sample to the instrument. It might take, there's transport time, there's measurement time, there's backlog, it might be what you envision in the core labs.

Conversely, we have visually-read test strips. That's going to be the opposite paradigm where you can bring the test to the patient. These include over-the-counter tests, things that you're able to buy at Walgreens or CVS, but they also include tests that might be used in CLIA-waived environments. They're simple, they're fast, and again, you're bringing the test to the patient.

In the middle, we have what we call point of care tests which is near-patient testing. This is kind of a middle ground. By definition, it's near patient testing. It's not necessarily as simple or as quick or rapid as you might envision for a visually read test strip, there's often an instrument involved, but you are still bringing the instrument to the environment near the patient.

So in general, for drugs of abuse tests, we've cleared everything from the large lab-based tests to visually-read test strips to point of care tests in all sorts of configurations and in panels. Sometimes they be individual, they can be large drug panels. But when we get specifically to fentanyl testing, we are more limited in what we have cleared. There is no FDA-cleared visually-read test strip. There is no FDA-cleared strip that we have cleared that is intended for in vitro diagnostic use in a CLIA-waived environment. That is a point where it has been to our attention that that creates some issues.

Again, this is just providing a little more documentation of the landscape for what we have cleared for fentanyl in vitro diagnostics. We have cleared devices for detection of fentanyl in urine and hair. This is just a snapshot of FDA's website; you can go to our website and look up any of these and find more information on the tests themselves. But all of them are instrument-based tests and the vast majority of them are what we consider you have to bring the sample to the instrument. They are going to be run on a large immunoassay or maybe LCMS, but you're never going to bring this instrument to the patient, with one exception and I'll get to that in just a moment.

So late last year, we had an update that I wanted to share. We have cleared the first fentanyl test for in vitro diagnostics for point of care use. This is a urine-based fentanyl assay. It's a small instrument, this is not CLIA-waived, it is categorized as moderately complex, but it is a point of care instrument. It's relatively small. You could certainly call it more portable. A person could in theory pick this up and move it. It's not like a large instrument that's going to live in a core lab where that would be the only place it would ever live.

I do want to acknowledge that this is still not, in terms of testing availability and access, it is not a visually-read test strip. There is no device that FDA has cleared for measuring fentanyl in any human sample that could just be quickly read by eye. This does represent unmet public health need. There is obviously the quote here from Governor Baker. We also hosted a listening session in 2020 with the Reagan-Udall Foundation in the fall where they talked about how clinicians don't have FDA-cleared test strips that they can bring into a CLIA-waived environment and get quick screening testing done for their patients.

I just want to say we recognize this is something that we need, and we look forward to working with in vitro diagnostic developers to meet this need. That's the update. That's the announcement.

This is just a snapshot, again, this is all available on the website, but there is progress being made. This is a link to the point of care instrument-based test for fentanyl testing that we cleared last December. We look forward to working with additional manufacturers who are bringing these devices to market, point of care devices, as well as we look forward to eventually having an FDA-cleared visually read rapid test strip that would be appropriate for use, especially in CLIA-waived environments.

That's all I have. So with that, I'll close. Thank you very much for your time. Thank you for listening.

MS. DAVIS: Thank you, Joey. Do any board members have any questions for Joey?

DR. SAMPLE: This is Barry Sample. I have a question. Are you aware whether or not there are any employment and insurance-exempt or ENI-labeled visually read point of collection type test devices that have been registered with the FDA for fentanyl specifically?

DR. KOTAREK: For fentanyl specifically, the short answer is no. If there are such devices being marketed, it'd be good for us to know that.

DR. SAMPLE: That's not something one could easily query. You could go manufacturer by manufacturer on the FDA site to see what they have listed that they're manufacturing, but there is no query that I am aware of that we can do to look to see what ENI products are in the marketplace.

DR. KOTAREK: Yeah, the registration listing database is admittedly not the most user-friendly of databases.

MS. DAVIS: Any additional questions? Next up is Ron Flegel with his regulatory program update and Mandatory Guidelines update, proposed urine, oral fluid, and hair guidelines.

Agenda Item: Regulatory Program Updates and Mandatory Guidelines

MR. FLEGEL: Thank you, Lisa. I'm Ron Flegel, director of the Division of Workplace Programs. This is a regulatory program update and Mandatory Guidelines for the Drug Testing Advisory Board. If there are any questions as we go through this, please feel free to ask them.

So again I want to thank all of the staff. It's really been a busy last six months, at least, if not all of the things that we've been doing, we've had a Comprehensive Review of the Drug Free Workplace Program. We've done a lot of studies. We've revised the guidelines, all three. So it really has been a busy time for us and I'm happy to report out, I wish I could report out more for the board members where we currently are with Mandatory Guidelines and all of the other things that we've been working on.

Just a shout out to all of the staff, and I also want to, with condolences, we had a member pass away in December, Dr. Deborah Galvin passed away. So that has also been another thing for our division that's been hard.

Again, just the Drug Testing Advisory Board members, and again I want to thank the members and also thank Jason and Barry for all of their work in the last four years that they've done on this board and helped with all of the complex issues that we've had and tried to deal with in getting the guidelines out and revised.

Our objectives and goals, the overall goal is we continually assess the science and technology used in drug detection to, one, advance national drug policy, and that is based on the latest scientific findings. Not only the science behind it but also the emerging threats, as Erin talked about, that we see with fentanyl and this nuance to the opioids, around poppy seeds, that we're looking at ourselves very closely. So a lot of things that we look at we have to look at as far as the emerging issues that come into the drug testing program.

Our goals are HHS certification of the first oral fluid testing lab. We hope that that will be soon. Again, within the program, that gives us another authorized sample or specimen to use other than urine, and eventually hopefully we will move forward to hair.

And again, the notice of publication of the final Mandatory Guidelines using hair is one of the goals. During the present, we have program implementation of the oral fluid as an alternate assessment to enhance the Federal Workplace Drug Testing Program, and as I mentioned earlier in my opening remarks, under the Drug Free Workforce Program, we've conducted a high-level review of the Drug Free Workplace Program, and we've identified key policy issues, technical issues, as well as existing challenges of the SWOT analysis, and I'll talk about that, or the SCOT analysis is what we're calling it.

But there are a lot of challenges, and we had three different working groups which have really, really helped us focus on certain things that they see as the importance of what was in the Drug Free Workplace Program we should be looking at currently as well as in the long term.

In the future, again, the referral of the revisions to the Mandatory Guidelines, and I use this broadly as all three as final Federal Register Notices.

Again, just the programs impact the Federal Executive Branch agencies, Department of Transportation, Nuclear Regulatory Commission, and we also had Department of Defense, which I don't have listed here, but it is a very important part because we do have a lot of civilian employees or federal workers working under contracts for civilians within DoD. So important that we go across all spectrums, all entities, of the regulated entities, and I think with aligning what we talked, Brian had talked about with NRC is with the new Part 26 is aligning these are even more important as we move forward.

I think all of us know employee and employer differences when it comes to drug testing policy. The CBD/hemp products or CBD and hemp products along with all the other, the delta-8 and the delta-10 and the different isomers of THC have all created different nuances that folks, the testing issues, again state laws when it comes to decriminalization of marijuana, legal issues, and of course the federal law that oversees for us the Mandatory Guidelines.

So it's really complex, and it's sort of difficult sometimes to figure this all out, and I think as Erin talked about with DoD, they can move a little bit quicker with their drugs as far as the analytes they test. It's a little bit more difficult in our program because of the rules and regulations we follow as far as putting it out for public comment, et cetera, when we change analytes, et cetera.

Again, two parts which are only two -- two major parts, but are only two parts of what we do along all the things. One is the science under forensic drug testing. The next is in the policy. Both for workplace programs.

So in the science, as far as program outcomes, there's the national drug testing standards that we have. There's multiple specimen types which we are currently working on in the revisions around urine, oral fluid, and hair. Of course the HHS-certified labs, eventually will have HHS-certified labs for urine and oral fluid, hair to come.

And then the DTAB recommendations for the Assistant Secretary as well as national MRO certification standards that we're currently working on. Also, around updating these based on the revisions that we proposed in the urine and oral fluid.

Under the Drug Free Workplace Program, as I mentioned earlier, we have had a Comprehensive Review, and that is also looking at policies as far as evaluating the impact of policies and legislation on the Drug Free Workplace Program, such as the Farm Bill, state marijuana decriminalization, among many other things.

We have certified Drug Free Workplace plans for all federal agencies, or most; we're still working on several. We also had Drug Free Workplace policies and procedures for all federal agencies. We have ongoing discussions with ONDCP, not only around policies, also recovery-ready workplaces, et cetera, that may fit into the Drug Free Workplace Program at some point.

Also, we have policy and legislation impact that we see and what that impact will be on the Drug Free Workplace Program.

This is one of the routing processes I always show. I put an arrow into where we currently are with the Mandatory Guidelines, depending on if it's urine, oral fluid, or hair, and really we are in hopefully the final routing process around the guidelines, and that will go to under HHS review, once it's currently reviewed and cleared, it will go to OMB, go out for public comment or finals, depending on if it's urine or oral fluid or hair, and at that point, we will set both an effective date as well as implementation date. But I just wanted to put the arrow there. So we're really, I would say, hopefully close to the end of the process for all three, and that's important because we've really had to align all three Mandatory Guidelines, because virtually in a legal sense, et cetera, testing sense, they're all the same. So that was really important to the process of what we tried to do, especially over the last six to eight, ten months, is to align these properly.

Again, just a reiteration of the urine and oral fluid Mandatory Guidelines when it comes to the analytes tested. I've put additional analytes. That decision will go forward as to what additional analytes, et cetera, if it's approved or not, will go forward, but I think the codeine morphine, which I'll talk a little bit about later, I think Erin touched on all of those and our concerns also about what we put in the proposed revisions for urine specifically, but again, we're monitoring that closely.

So this is just a standup or an update as the standing of where we are with urine, oral fluid, and hair. You can see the proposed urine was in 2022 or April 2022, the oral fluid was again April 2022. We have published those all at the same time. Again, the revisions are currently under HHS review for hopefully what will be final clearance.

The hair was proposed in September 2020. It has taken some significant time to look at all the comments, the reference papers, et cetera, that was put in and there were several, as I mentioned earlier, additional comments from board members in 22 that we had to incorporate into those guidelines. So that again comment period for the public ended November 9, 2020. But that's ongoing under the review of HHS.

Current urine Mandatory Guidelines and oral fluid Mandatory Guidelines status, again as I just mentioned in April 2022 we proposed urine, and the comment period ended in June 2022. We had 22 commenters with 57 comments. Not significant amount.

In April 2022, the proposed oral fluid, and again that ended in June 2022. We had 53 commenters and 204 comments, which was more in the oral fluid, but again, this is a brand-new or newly implemented oral fluid mandatory guideline, so I would expect there to be more comments with that.

Again, both the public comments for both urine and oral fluid have been addressed, and the final urine and oral fluid have been drafted.

Some of the revisions that I have actually said before in the last meeting, and unfortunately due to the fact they're under current review, I can't really talk about what the final outcomes of those are. But what I did want to do is look at some of the revisions just to make the public aware again.

We revised the timeline and process for publishing the authorized drug testing panel, or at least we proposed that, and that would look at drugs, analytes, and cutoffs. We also proposed to revise the report of specimens as substituted based on biomarker testing. These concentrations were inconsistent with the established for human specimens. I think that's important. Especially as we move forward, we see a lot of adulterated, invalids, et cetera specimens, and there is definitely concern, high immunoassay response rates, et cetera. So there is some concern there's products out there along with synthetic urine that we have to look at.

We've also established a timeline and process for publishing an authorized biomarker testing panel, and this would be the biomarker analytes and cutoffs. As mentioned earlier, we did raise the morphine confirmatory test cutoff from 2,000 to 4,000 in urine. I didn't mention codeine here, because that is something that we did not change the cutoff concentration. We left that at 2,000. But we are taking a look at that, as Erin pointed out, with the high concentration of codeine in the poppy seeds, and we've received numerous emails on this issue.

But being that the Mandatory Guidelines currently in effect still have the rule of where we are for 2,000 both codeine and morphine, again, that's going to be looked at from an MRO perspective around poppy seed ingestion.

We have also revised the Medical Review Officer verification process for positive codeines and morphine. That is ongoing within the MRO guidance manual, and we've also required MROs to submit semiannual reports to HHS or designated representatives specifically on federal agency specimens that were reported as positive for drug or drug metabolite by the laboratory but verified as negative by the MRO. So we want to link that back and figure out what was verified as what was reported positive but also verified as negative by the MRO.

Under the hair Mandatory Guidelines, the status report is, again, SAMHSA's public comment review. We had public comments by subject. We had over 700 individual comments from 213 commenters. We reviewed all comments, submitted information, scientific studies referred by commenters, and we prepared the draft hair Mandatory Guidelines. Under DTAB review, under March 2021, we summarized public comments and presented that for DTAB in closed session. Under June 2021, the members reviewed this as a draft HMG and also provided input as I mentioned earlier, with the comments that DTAB solicited to us.

The hair testing laboratories, I did mention this last time, we also had listening sessions for seven hair testing laboratories. It was, one, to look at topics such as proficiency testing requirements, quantitative agreement between labs, reporting criteria and future technical working groups in order to resolve some of these issues.

So it really was a good conversation between labs as to what these issues or the topics that we discussed, where they felt these needed to go when it comes to regulation.

We also revised the draft HMG submitted, and this is again, as I mentioned earlier, throughout is this is currently under HHS review.

This is just a current update of our applied studies under the National Laboratory Certification Program. We have a lot of ongoing studies. We have a lot that have been completed, as you can see from the top. Hair lab results, urine adulterants, delta-8-THC cross-reactivity, again analysis of acidic foods containing CBD concerning that it would metabolize to THC or delta-9. Opioids and glucuronides in hair, we have topical application studies, web monitoring, THC, CBD, pulse studies, et cetera.

There is a lot of ongoing studies, and we'll add these to the next one as we add more studies in the future. But we have looked at hair extract analyte formation. We have also looked at the hair PT development program, Q-TOF screening methods around this, the study for chronic dosing of CBD, which is ongoing, the delta-8 dosing study that we are now beginning to look at, we're beginning to implement that and look at studies. Cannabinoids in hair and then hydroxy cocaines and hair data sharing in which I believe that Svante is going to talk a little bit about that today.

Again, under the Drug Free Workplace and evolving environment, we have emerging issues which was legislation or past legislations. We have the 2015 FAST Act. We have the 2018 Farm Bill, and it defined hemp and set legal limits for THC. But it is making it difficult to discern between legal and illegal sources of THC ongoing. And we have the 2018 Opioids Crisis Response Act.

Changes in the science and technology around drug testing and specimen collection technology are continually improving, and again, these Mandatory Guidelines for Federal Workplace Drug Testing Programs using oral fluid was effective January 2020. So we're really looking forward to having the first HHS-certified oral fluid testing laboratory.

I think some of that is also under the NPRM, the final rules for DOT. I think that's a really important step forward once that's complete and moves forward it will help for HHS-certified labs to get the applications to come in.

Under the evolving environment, we have new and novel drug use and it continues to emerge, and again, these are around the synthetic designer drugs. We have increased public acceptability and availability of marijuana and CBD products, significant, and not to say that it's not a workplace safety or security issue, especially around the delta-8 or the other THC isomers and state initiatives to decriminalize marijuana. So it's all something that we're looking at closely.

And then increased demands on the Drug Free Workplace Program. Again, as in the federal agencies, the COVID-19 and return to the office, the challenges around teleworking, when you're in a safety and security sensitive position. So all of those are challenges we're trying to address and have addressed for federal agencies.

Just real quick, I changed this SWOT analysis, because that's usually what it's known as. We call it the SCOT analysis, the strength, challenges, et cetera, under that. But of the Drug Free Workplace Program, and I had mentioned this earlier, we assessed the critical issues affecting the program, not only now but in the future. We reviewed the state of the art and the science, upcoming, which I think needs to keep pace with everything else when it comes to emerging issues.

We identified key policy and technical challenges, and we've also looked at highlight best practices for the future of the Drug Free Workplace Program.

Again, the same slide basically, but under the Comprehensive Review for working groups, which again, I have to say for the federal program in itself as well as the federally regulated entities, I think all of these challenges we're hoping to not only assess and summarize all of this ongoing work that we've done around these working groups, but possibly come out with a white paper that we can also share with federal partners, because some of these same issues are around all regulated drug testing, not just federal agency drug testing.

So in working group 1, we looked at the current legal, political, and social issues. Of course that is around legislation as well as bills, Farm Bill, FAST Act, et cetera. Working group 2, we looked at the science, especially laboratory issues such as emerging drugs, evolving technology, and alternative matrices. And then working group 3, we wanted to look at the managing the program in 2022 and beyond, now 2023 and beyond, around telework, information flow from EAPs, supervisors, employees, training, et cetera.

So there's a lot of significant changes we see in the future, and also significant changes within the program around the science side as well as the testing, or alternate testing side.

The Comprehensive Review again, the process continued. We've had a plenary 1, that was on May 17 and 18, 2022. We have looked at the working groups. We met over the summer to assess the strengths, weaknesses, opportunities, and threats. We changed weaknesses to actually challenges. I think we have a great program, but I think there still are some challenges that we have with that.

And then we've tried to identify these challenges in the science and policy, and like I said, we're starting to summarize those and set them down as to what is the priority, different things within that, which we gain from each of the working groups around the strengths, weaknesses, opportunities, or threats in the program.

Our desired outcome would be a plenary 2 session that would be October 19 and 20, 2023. So that would be after the summer. Again, as I just mentioned, we're preparing a summary report of the issues and describe future tasks to address these challenges.

Again, the Drug Free Workplace Program resources, if there's anything there as we have updated a lot of these, especially in the last six months we have updated a number of these. So these are the new information on the website that you can go to if you need any information on the Drug Free Workplace Program.

And I believe the next slide, which is the last slide, again, I want to thank you, thank all the board members, the public, for attending this. Hopefully that was informative. I wish I could say a little bit more about where we are with the review, but currently the guidelines are under review, and for that reason, we will wait for that to be pushed out to the public.

Thank you very much. Lisa?

MS. DAVIS: Thank you, Ron. Any questions for Ron? Hearing none, we have reached our scheduled lunch break time, and we will resume promptly at 1 o'clock. Board members, if you could please come back a little early just so we can make sure we have everybody connected in speaker and presenter mode. We'll see everybody back here at 1. Thank you.

(Recess for lunch.)

AFTERNOON SESSION (1:00 p.m.)

Agenda Item: Call to Order, Lisa Davis, Designated Federal Officer

MS. DAVIS: Welcome back, everyone. Let's take a quick roll call and make sure everyone is here. Jason Schaff?

DR. SCHAFF: Present.

MS. DAVIS: Barry Sample?

DR. SAMPLE: Here.

MS. DAVIS: Kristen Burke?

MS. BURKE: Here.

MS. DAVIS: Deborah Motika?

DR. MOTIKA: Present.

MS. DAVIS: Alison Stockdale?

MS. STOCKDALE: Here.

MS. DAVIS: Libby Stuyt?

David Roberts?

Lindsey Everson?

MR. EVERSON: Present.

MS. DAVIS: Ron Flegel?

MR. FLEGEL: I am here.

MS. DAVIS: Svante Vikingsson?

DR. VIKINGSSON: I am here.

MS. DAVIS: Eugene Hayes?

Okay, still waiting on Elizabeth Stuyt.

MR. FLEGEL: I think she is having trouble with her phone.

MS. DAVIS: David Roberts?

Eugene Hayes? I don't see that Eugene is back yet. Well, he has a few minutes to get back.

So I'm going to go ahead and get started with Svante Vikingsson who is giving a presentation on his summary of pulse testing for fentanyl in opioids and initial test positive samples and delta-8-THC and THCA initial test positive samples.

Agenda Item: Presentation: Summary of Pulse Testing Studies of Fentanyl in Opioid Initial Test Positive and Delta-8-THC and THCA Initial Test Positive Specimens

DR. VIKINGSSON: While my title is a mouthful, I'm here to wake you up a little after lunch, to talk about our pulse testing studies, and the pulse testings themselves are designed to measure the prevalence and/or concentrations of analytes not currently in the NLCP scope. And they are part of the NLCP surveillance efforts, and the purpose is really to inform the DWP decision-making.

The first study I'm going to talk about is our opioids survey, where we especially wanted to look at the potential effects of the proposed changes to the morphine decision rules and also to investigate if fentanyl at this point is a better marker for illicit heroin other than 6-acetylmorphine.

This is going to sound a little strange to you, because the recently proposed increase of the morphine cutoff from 2,000 to 4,000 nanograms per milliliter, as proposed in the Federal Register, and what I'm going to talk about is how that is going to increase the positivity for morphine that we see. The reason for this little paradox, as we touched about briefly earlier today, is that between 2,000 and 15,000 nanograms of morphine, the MRO will only report a positive if there is clinical evidence of drug abuse or if 6-acetylmorphine is positive.

And the reason this thing was put in place, and it is in place also for codeine, was to avoid positives caused by poppy seeds. Our research shows that adjusting the cutoff to 4,000 will still eliminate the risk of poppy seed positives. So it is our impression that the clinical evidence is rarely used by MROs to report morphine concentrations below 15,000 as positive, even though it is difficult to know the exact number here. But for the rest of this presentation I'm going to assume that none of these cases are reported as positive with the clinical evidence.

We know that that's not completely true, but we think it's fairly close to, as an estimate.

The other topic that we wanted to move into here and cover today is fentanyl, and fentanyl requires little introduction. It's a potent opioid, and there is ample evidence that it's substituting for heroin in the drug supply in the United States. We have once before evaluated adding fentanyl to the scope of testing, but it was deemed that the 6-acetylmorphine was the better marker at that point in time, and one of the aims here was to study if that was still true.

Thankfully, the prevalence of drug positives in the federally regulated drug testing is very low, and this also includes opioids. However, that also means that to get a sufficiently large number of positive specimens, we have to test thousands of specimens in a pulse testing study if you just picked them randomly.

So in the two studies that we're talking about today we did things a little bit differently, and we only tested specimens with a positive initial test. In this case it was a positive initial test for morphine, and this gives us an enriched dataset with more positive findings, but it also means that we miss a few things, and the important thing here is that specimens only positive for fentanyl or norfentanyl but not positive for morphine would not have been included in this dataset.

In brief, the specimens were deidentified after their inclusion, and then we retested them for morphine, fentanyl and 6-acetylmorphine by immunoassay. And in addition, we did an LCMS confirmation for morphine, and for any initial test positives for the fentanyl and 6-acetylmorphine.

Now we've talked about the why and the how of this study, and we can start to discuss our findings, and this colorful graph actually shows the distribution of morphine confirmation results. The red bars there are specimens that were below 2,000 nanograms per milliliter, and regardless of which decision rule, the current one or the proposed one, we apply here, they would all be reported as negative. Similarly, with the green ones, they're all above 15,000, and they would be reported as positive with either rule.

The orange ones are between 2,000 and 4,000, and they would definitely have been reported as negative with the proposed rule, but with the current rule, if there was clinical evidence or a 6-acetylmorphine positive, they would be reported as positive.

And similarly, the yellow ones between 4,000 and 15,000, they would be reported as positive with the proposed rule, but under the current rule most of them would probably be reported as negative. So the simplest way to really look at this change would be that a majority of the yellow specimens here would be reported as positive rather than negative under the proposed rule. As you can see, they are about the same number as the green ones.

When we analyze the fentanyl part of this data, we notice that the concentration of the major metabolite norfentanyl was higher than those of fentanyl itself. So in the bar chart there in the top right, you can see the percentage of fentanyl as the sum of fentanyl and norfentanyl. And the median case here has 15 percent fentanyl and 85 percent norfentanyl. And there were really only four cases where fentanyl was at a higher concentration than norfentanyl, and it's really only in one case, the little blip there on the far right of the graph, where we had a significantly higher fentanyl concentration than norfentanyl. In that specimen we have 60 nanograms of fentanyl and 5 nanograms of norfentanyl.

Taken together, this indicates that if norfentanyl was used as the confirmation analyte for fentanyl, we could probably use a higher urinary cutoff than if we used fentanyl.

Now we're going to focus on the red bars and the orange bars here, which are the ones that under the proposed rule would be reported as negative. In total, we have 214 specimens, but for 54 of them or about a quarter, we have identified either 6-acetyl fentanyl or norfentanyl, and looking at this closer we can see that only seven specimens, or 3 percent, had the 6-acetylmorphine but no norfentanyl. And for comparison, 33 specimens or 15 percent of the specimens were positive for norfentanyl but not 6-acetylmorphine. And the conclusion here is that things might have changed since the last time we looked at this, and we might be able to identify more of these specimens using norfentanyl than using 6-acetylmorphine as a marker of illegal heroin use, if we used air quotation marks.

If we move to the next slide, if we sum this up a little bit we can look at the impact on positivity for morphine here, and adding norfentanyl as an analyte would increase the positivity by 27 percent, and this is just looking at morphine, 6-acetylmorphine, and norfentanyl. It doesn't include oxymorphone, hydrocodone, or any of those drugs.

If we change the decision rules to the proposed ones, that would increase positivity by 65 percent, and if we made both of those changes, positivity would increase 81 percent compared to where we are now. But before we move on, I would like to take this opportunity to also call out the elephant in this graph, and that is that the way this study was designed we have no ability to identify the specimens which were just fentanyl-positive and not morphine-positive. And we don't know how large that number is, but personally I would think it's a significant number of the specimens that we would also find in that category, which would impact the effect that the addition of fentanyl would have.

Now I'm going to need some help. This is another visualization of the complete dataset. The different bars here are different ranges of morphine concentrations, and the coloration of the top is the fraction that were positive for norfentanyl, 6-acetylmorphine, or both. So if you click again on this one, we're going to highlight the parts that under the current rule would be most likely to be reported as positive, and if we click again we can see that making the changes we have discussed would increase that sort of field of positivity that we can find.

We also hear a lot about the fentanyl analogues and the confirmation method we used here had a scope of 11 analytes that were tested for. And we didn't find much. We did find two specimens with para-fluorofentanyl concentrations higher than the fentanyl concentration. Which would be consistent with using the fentanyl analogue. Para-fluorofentanyl is also seen as a minor byproduct of fentanyl, but in two specimens we do think that it looks more like the analogue use.

While these results seem to indicate a low prevalence of fentanyl analogues among employees, there are other potential explanations. There could be limited cross-reactivity with the fentanyl immunoassay. We know that for some analytes. And there might also be novel analogues out there that we have not yet included in our scope of testing. Neither were the nitazene drugs, which aren't really fentanyl analogues but still novel opioids. They were not in the scope of this study.

With that, I think we're concluding the opioids, and if we move onto the next slide, I'm also going to talk about our cannabinoids study. Here the main questions were how common is the delta-8-THCA and how does that and THC isomers or analogues contribute to cannabinoid testing.

And we also wanted to see if CBD and/or its' metabolites could produce positive initial tests for cannabinoids.

Delta-8 is a cannabinoid that produces similar effects as delta-9-THC, which is the main psychoactive component of cannabis. The potency is reported to be somewhat lower, but most likely this can be compensated for by increasing the doses used. And in my mind this is more than enough to make delta-8 a concern for both workplace safety and driving, which is why we're looking at this.

The legality of delta-8 is a very interesting topic for another day and most likely another speaker. However, to understand this, the most important thing to remember is that delta-8 is perceived as legal by the shops selling it and the customers buying it, and we do see that these are advertised both online and in brick-and-mortar shops, and there is reports of rising prevalence, which prompted this study. And of special implication for the NLCP is the risk delta-8 is used as a cannabis alternative to avoid detection in our regulated testing.

This is the study design. It's a similar design, but a slightly larger study, where we included 1,500 specimens with initial test for cannabinoids. And while this test targets delta-9 THC, delta-8 is highly cross-reactive and will also be detected. And the confirmation testing here included 15 different cannabinoids, including the carboxylic acids metabolites of delta-8, delta-9, and delta-10 THC, and it also included CBD and its metabolites.

This slide is really looking into the immunoassay performance of specimens that had a positive initial test, but a negative confirmation. Not going to dig too deeply into this, but basically it's six specimens out of 1,500 that are a little bit difficult to explain in the table on the bottom. First, I would like to highlight the top specimen here that has 370 nanograms of 7-hydroxy-CBD detected. But not much else. And this is really the only instance in this rather large study where CBD or CBD metabolites might be associated with a positive initial test. So we think that the risk of CBD metabolites causing positive initial test is very low, and also a CBD positive specimen would not create a positive drug test on its own, because the confirmation assays can distinguish between the CBD and CBD metabolites and the delta-9-THCA.

In another two specimens, we did find more than 100 nanograms of delta-9-THC but not THCA. This explains the positive initial test, but it's still a highly unusual finding and I have no really good explanation to why there was no THCA in these urine specimens. And finally, in the last three specimens on this table, we only have low concentration of the cannabinoid metabolite, and it's unclear why they tested positive. As we talked about earlier, it could be that they have used a THC isomer that is not yet included in our scope.

If we move to the next slide, and I promise this is not the same table as I just showed you. Here, we are instead looking at that repeated initial test that we did. Remember, that we deidentified all the samples and then tested again, and in this case we're looking at the specimens that were negative in that second test. And there's a couple of reasons for that, but again, on the bottom are the five interesting specimens where we have more than 50 nanograms of delta-9-THCA, which should generate a positive initial test, but all of these have a fairly low or very low initial test result in the leftmost column where the cutoff was 50. And of special interest is the specimen with 1,000 nanograms of delta-9-THCA that still has one of the very lowest results in the initial test.

These results could be consistent with an adulterant that's specifically added to interfere with the initial test. And we have previously in previous studies we have identified a couple of such adulterants. Their use could all be identified due to the SVT testing and other abnormal results. But we have not collected that data in this study.

If we move to the next slide and leave the initial tests and focus on our findings here. I find that this pie chart is the most important part of this study, and what we see here is the number of specimens that were positive for delta-9-THCA and delta-8-THCA, or both of them. And we can see that 9.7 percent of the specimens were positive for delta-8-THCA only, and that's a typo on that slide. The 11 percent is actually the increase in positivity that we would see if -- that we estimate -- if we would add delta-8-THC to the scope of testing.

Using our 2022 data on positive cannabinoid positive specimens, we estimate that that could translate into another 7,500 specimens or so that would be nonnegative if delta-8 was added.

Delta-8 is not only a THC isomer of abuse on its own, it's also a minor constituent of cannabis. And in this bar chart where we have looked at the percentage of delta-8-THCA of the sum of delta-8-THCA and delta-9, we can clearly see that. Sixty-one percent of the specimens had less than 10 percent delta-8, which in my mind is consistent with using cannabis, and similarly 14 percent of the specimens had more than 90 percent delta-8, which would be consistent with what we expect using delta-8 products. And the last quarter of the specimens are sort of evenly distributed between 10 and 90 percent delta-8. This could be consistent with donors using both cannabis and delta-8 products.

I also said we included delta-10-THCA, and we did not find a single specimen that contained delta-10-THCA, but I think it's a little bit optimistic to chalk that up to employees not using delta-10 products. My best guess at this point is the delta-10-THCA is not a major metabolite of delta-10, and there is a couple of other data points out there that speaks to that, too. And the metabolism in general is poorly understood still, and I think this is an area where we need to keep working and keep looking to find, make sure we have good urinary markers for these analytes.

I am almost done, I promise. It's time to sum these up, and the things I wanted to keep bringing with you home is that for the opioid study, we noticed that the proposed decision rule changes for morphine is estimated to increase morphine positivity by 65 percent in the program. And we have also discovered that norfentanyl is more common than 6-acetylmorphine in heroin-positive specimens, and it says fentanyl on the slide there, and fentanyl is also more common. Most specimens actually contain both fentanyl and norfentanyl, even though the fentanyl concentrations were lower. And we also found that the norfentanyl might be a more promising urinary marker than fentanyl.

And in the cannabinoid study, we discovered that including delta-8-THCA in the scope of testing could increase cannabinoid positivity by around 11 percent, compared to delta-9-THCA alone, and that positive initial test due to CBD metabolites and THC analogs were rare in this study.

So thank you so much for listening. I do not know if we have time for questions from the board, but I have included my email address here for everyone, so if you have any questions about this presentation, feel free to send me an email.

MS. DAVIS: Thank you very much. Do any of the board members have any questions for Svante?

DR. SAMPLE: I have a couple of questions. For your opioid specimens, were those DOT specimens? I assume they were federally regulated, right?

DR. VIKINGSSON: Yes, they were federally regulated, but we don't know under which regulation.

DR. SAMPLE: You knew where my next question was going to go. Presumably then you also don't know the testing reason as well as testing authority?

DR. VIKINGSSON: No

DR. SAMPLE: Just so I am clear, the slide where you showed the 65 percent increase for just the morphine cutoff, that value is because the MRO wouldn't be able to verify those as negative because it's an automatic positive, absent a prescription. Is that --

DR. VIKINGSSON: That's correct.

DR. SAMPLE: Normally a higher cutoff means fewer positives.

DR. VIKINGSSON: Yes. And it does include the specimens that would be reported as positive due to having 6-acetylmorphine in there, but it wouldn't include any that were reported as based on clinical evidence. We're still looking at obtaining the data -- figuring out exactly how much of a difference there would be, because that happens at the MRO level.

DR. SAMPLE: Yeah, and you still wouldn't know whether or not perhaps those people had a valid prescription that wouldn't have been looked at.

DR. VIKINGSSON: Right. That wouldn't be included here either.

DR. SAMPLE: I guess in my mind that 65 percent increase might be a little skewed, sort of like worst case, or best case, depending on one's point of view.

DR. VIKINGSSON: I will agree with you on that.

MR. BACZARA: Real quick question, I missed it in the slides. What was the number of specimens for the delta-8-THC study?

DR. VIKINGSSON: The delta-8-THC study used 1,500 specimens, 1,504 I think.

DR. SAMPLE: I'm ready for my follow-up two questions. One was on that very unusual 1,000-nanogram per ml urine. While an adulterant is, an unidentified adulterant may be a possibility, but did you investigate possible hook effect?

DR. VIKINGSSON: We didn't look at the hook effect, but I have looked at the data, and we do have positives that are much higher than 1,000. And I'm not going to say -- I did look at that a couple of days ago, and now I've forgotten whether it was -- I think we have specimens up in the range of 5,000 to 10,000 that are still reported as very positive by the assay.

DR. SAMPLE: Okay, so if you were to semi-quant or try and assess a response that the ones with 5,000 or 10,000 were quite high from an absorbent value perspective.

DR. VIKINGSSON: Yes. And the interesting thing is that while this shows up as profoundly negative, to be included in this study it needs to have had a positive initial test for cannabinoids at some point in time. Now, due to the deidentification process, I don't know if that was 51 or if it was 100. That data we don't have. That's why we reanalyzed them.

DR. SAMPLE: Got it. And then my last question is about the delta-10-THCA. As I recall there were something like three or four possible isomers. Has the exact metabolite been figured out at this point in time, or is it sort of like best guesses?

DR. VIKINGSSON: The reference material that the NLCP has developed is a -- there's four enantiomers, which forms two diastereomers. So if you have a chiral separation, you should get four peaks, and if you have a normal separation, you should get two peaks. And our reference materials should get -- it should contain both of those peaks, because the reference material is not completely enantiomeric pure. Which makes it very hard for us to use it in immunoassays, but it's good for using in the LCMS, because we do get a signal for both peaks.

There is also some other studies that's been conducted and presented, for example by VCU in Virginia, that are looking at generating these metabolites in vitro, and they as far as I've understood they have still failed to generate the carboxylic acid metabolite. They don't know what metabolites they have generated, or at least not discussed it. But they have not reported that one. That makes me also wonder if there is a possibility that this particular drug it hydroxylated somewhere else, for example on the side chains.

DR. SAMPLE: Which makes ultimately analysis difficult for laboratories and the program. Thanks. Very interesting presentation.

MS. DAVIS: Are there other board member questions?

Our final presentation in this open session is from Eugene Hayes with an update on the electronic chain of custody form.

Agenda Item: Update on Electronic Chain of Custody Form (ECCF)

DR. HAYES: I am going to do my best to get us back on track and on time. My name is Dr. Eugene Hayes. I am going to give an update on the CCF. We're going to discuss the Federal Custody and Control renewal submission and give an update on the electronic custody and control form implementation.

Just to give a little background, the Mandatory Guidelines establish the custody and control form and procedures, and then OMB kind of takes it from there and establishes the rules and guidelines for using that particular document and making sure that all that are using that form use it in the same manner, and that the data collected on that form is used in the appropriate manner.

We submitted a request for comment or a Federal Register notice on the new submission in January. That request for comment closes on March 13. We have received very little comment so far, but those comments will be taken into consideration into the final approval of the CCF as we move forward. And we will look to have the final approval on the CCF completed and the final out to the public hopefully by mid-July, so that it can be in place in August.

The approval process was to request the renewal of the document kind of as is. We did not make any changes to the document in this particular iteration, as we did not need to. We did not convene a working group this time. So we didn't actually have any changes. We don't expect very many comments to come through, so I'm hoping that the turnaround time to get the final out to the public and to get things in place won't be that long.

This slide just pretty much goes over the date it was published, January 10, the date it closes, and the date that the new one will go active and live.

I'll talk a little bit about ECCF usage. ECCF usage by approved labs. Quest Atlanta withdrew from the program in March of 2021. They were approved. LabCorp South Haven increased their ECCF usage from 2020 to 2021. Fort Meade was approved to use in August 2022. LabCorp South Haven was approved to use in July of 2022, but there was no digital ECCF usage in 2022 and LabCorp Houston and LabCorp Raritan and LabCorp RTP was approved in 2023. So we do have some movement towards ECCF.

Regulated specimen testing by HHS-certified labs approved to use ECCF, 89 percent versus the actual utilization for ECCF is about 53 percent. So there is a little bit -- well, not a little bit -- there's about 30 percent of variance right there.

Year-to-year we've had at least a 300,000-sample increase in total ECCF utilization, with the smallest increase being in 2022, and we still have a strong push to move the ECCF usage. However, we have run into some hiccups lately.

Due to some complications with laboratories being able to access the required services in the current market, SAMHSA will be extending the deadline for Federal Workplace Drug Testing Programs to switch from paper to electronic custody and control forms from August 30, 2023, to August 30, 2026. This extension applies to both urine and oral fluid testing, as the current market for laboratory services has made it difficult for many laboratories to meet the technical requirements for electronic forms.

This extension will provide laboratories with the additional time to make necessary upgrades to their systems and processes to ensure that they are able to provide the electronic custody and control forms for Federal Workplace Drug Testing Programs. This extension will also give federal agencies and their contractors more time to prepare for the transition to the ECCF and to ensure that they have the necessary systems and processes in place to support the ECCF.

And within the division and the NLCP, we will continue to explore our own options to provide laboratories within our system with support in this area when laboratories are unable to access current market-available items, because this small roadblock can't inhibit our entire system from moving forward. And I did want to let everyone know that an NLCP notice will follow this meeting to announce this particular change.

This next slide was supposed to be a thank you with my information on it, but I deleted it somehow. So I do apologize. But thank you. If there are any questions, I'm willing to take them. But I do believe I got us back on track.

MS. DAVIS: You did, Gene. Thank you. Questions from the board? We did have a comment earlier in the meeting, I believe Barry, Bohdan, a follow-up question before we move on to public comment. Bohdan, did you have an opportunity to find the answer to that question?

MR. BACZARA: I did. Thanks for raising that. So the question, as I understood it, did the report contain any specifics related to drug test refusals, and the answer is yes. It's on page 4 of the document, and I believe since the inception of the program there have been 25,552 drug test refusals entered into the clearinghouse.

And that number would include not only employer-decided refusals, such as at collection sites, but also MRO reported adulterated and substituted specimens. But there's no breakout to my knowledge in the report in those three categories.

MS. DAVIS: Thank you very much, Bohdan. I appreciate that.

Now we're going to move to the public comment period. I will begin with those registering online to do so.

The operator will provide instructions as to how to become a speaker.

(Instructions for comments.)

Agenda Item: Public Comment

DAN HORVATH: Good afternoon, everybody, and I appreciate the opportunity to provide brief comments. We submitted, the ATA -- I'm Dan Horvath with the American Trucking Association -- we submitted written comments prior to this. So hopefully you have those. If not, we'll be happy to provide.

I'll just hit the highlights in lieu of reading every detail and giving others opportunity to weigh in here. Obviously, the gist of our comments focuses on the hair testing guidelines, which for those of you that are part of this board, you're no stranger to ATA's position on hair testing and advocating for the use of hair testing as an approved alternative to urinalysis. We on a regular basis are receiving data from our motor carriers that utilize hair testing, showing us the comparison between the positive hair tests versus the DOT regulated urinalysis, and it's baffling to know the number of drivers that, while these carriers are able to not hire them or not move forward with employment, those drivers are going down the road and getting jobs elsewhere simply because that data, those positive results, cannot be reported to the drug and alcohol clearinghouse.

So this is certainly a safety issue. The faster HHS can move on this to get to a final guideline that's acceptable to the industry, the better, and it's going to improve highway safety. While we certainly appreciate the efforts HHS has done to date, the 2020 guidelines are, in our opinion, flawed, simply because of the recommended follow-up or secondary confirmation test in the event of a positive hair test, and really doesn't change anything in the process of how things work today.

So we're encouraged that we're looking that we're looking at a quarter two timeframe for the next round of revisions. We hope that HHS has addressed the concerns raised by industry prior to this, particularly with that secondary test. So again, we want to be a partner and we want to do everything we can to help identify drug-using/controlled substance-using drivers and get them off the road and get them the treatment they so need.

So we submitted comments. We highlighted an NTSB crash that looked at hair testing specifically, and if there are any follow-up questions, feel free to reach out to the team at ATA. But thank you for what you do, and we do look forward to the next round of revisions, hopefully in the very near future.

That's all I have. Thank you.

MS. DAVIS: Thank you very much for your public comment. Anybody else who wishes to make a public comment?

JERRY LIGHTFOOT: Thank you. Good afternoon, everyone. Going back to the delta-8, I actually put this in the chat. I just wanted to know that even though delta-8 is being tested for on these drug tests, isn't it still considered legal from the 2018 Farm Bill, and if so, then what does those positives really mean for these federal drug tests consequence-wise?

MS. DAVIS: Thank you very much for your public comment. We are not allowed or permitted to answer questions at this time. But I thank you for your comment for the record.

Is there anybody else that wishes to make a public comment?

DR. ALEXANDER: Thank you very much for the presentations. They were excellent. I just wanted to ask two things. I understand that there -- my name is Dr. Michelle Alexander. I am the director of medical affairs for Abbott Rapid Diagnostics eScreen and certified medical review officer, and I have been so for close to 30 years now.

So my question is on the virtual evaluations by Substance Abuse Professionals and the fact that it seems to be ongoing, and I wanted to find out if there was any studies to really evaluate the effectiveness of such virtual evaluations, because I do feel from the number of positive results I've seen on return to duties, as soon as a couple of days to weeks after the evaluation, I'm very concerned about safety in terms of these donors returning to duty quickly.

I know that virtual evaluations cannot determine alcohol use and continued abuse of alcohol. So I'm just wondering about how the Advisory Board is going to look at that specifically.

And then my next question is just in general I'm seeing really large amounts of opioid use among drivers in particular. We have to verify them negative, because they're taking prescription medication under the authorization of their physician, but we're seeing literally people taking 15 tablets of -- 15 milligrams of oxycodone or hydrocodone six and seven times a day and getting 120 tablets and I'm just -- this is a really concern for us. We document what we see. We express to the employers that there is a safety concern. But a lot of these drivers are on the road.

So those are my two comments.

MS. DAVIS: Thank you very much for your comments. As I stated earlier, unfortunately we're not permitted to respond to comments at this time. But to you and anyone else who may have a comment, the Division of Workplace Programs has a Workplace Helpline, and that might be an appropriate place to turn to ask a question and perhaps get a response back or follow-up that way. So I hope that information is helpful.

Is there anybody else with a public comment at this time?

This now ends the public comment session. Before I adjourn, I have one bit of housekeeping. All those joining the closed session this afternoon at 2:15 will need to join via a separate link in a separate email. Please be sure to log in early so everyone can get into the meeting room before the meeting starts. I attached a document for the meeting link as well. So please verify that you received that document again, view it prior to joining the meeting.

I will now turn it over to Ron, the Chair, for closing remarks.

MR. FLEGEL: Thank you, Lisa, and again, thank you for all your work you do on these meetings. There's a lot of logistics that go into this.

Again, great presentations. I want to say thank you to all the federal partners who presented the information. I think it keeps the public up to date where we are on the regulatory rules and what we're doing. So I do appreciate that.

I want to thank the board members, the questions that came from some of the presentations. I think there was some good information. Obviously we can see there are emerging issues out there, and we need to deal with those, which we're looking at very closely.

I want to thank the public and public comment. We do take these under consideration and discuss those. So again, the board members are aware so it's great to receive public comments on these issues that we may not be aware of actually. So great to have those.

With that, again, I'll turn it back over to Lisa, but I'll see everyone in a few minutes in closed session.

MS. DAVIS: With that, I adjourn this open session of the Drug Testing Advisory Board. Thank you all for attending.

(Whereupon, the meeting was adjourned at 2:05 p.m.)