Name	Company/Job Title	Comment	References
Sarah Hope		Issues with testing for Fentanyl: 1. Right now its super expensive 2. Its my understanding that it can only be caught within a few hours of use – therefore its irrelevant unless labs figure out a way to make the period of detection longer. 3. When we notify a driver he has to go in for a random DT, while we tell them to go in "immediately", most of the time its not. And the period for detection is over, so a user would know how to avoid detection. 4. I believe testing for fentanyl would slow down the process of getting results back from the labs for the 5 panel DOT, unless they put in new measures in place to allow for that which could take years.	
Cargo Goat		The additional time spent for rulemaking for this specific drug use seems redundant and time consuming. There are already standard tests for Narcotic Opioids in which Fentanyl would be detected. To know that Fentanyl is the specific Opioid drug does not change the outcome of being restricted from performing safety sensitive functions when a positive result for general Opioids is returned.	

Name	Company/Job Title	Comment	References
Lance Beitelspacher		To Whomever, The reason why I am writing you today is the concern about fentanyl. I understand that it's starting to be more reliable and more addictive than regular aspirin or ibuprofen. I have found that incident out when I accidentally took one of my wife's medicine by mistake. My wife was diagnosed with fibromyalgia a couple of years ago and she also has roomatory arthritis. I guess what I am saying is that no matter what the D.O.T. weigh stations, Port of Entries, or even crossing over into Canada, or wherever, how can you regulate all the people that are trying to deliver the product, merchandise, produce and etc. I see what might possibly happen is that changing the rules you will start having more of a perdicament of trying to keep the freight industry moving. We can't tell ourselves that we don't need too have our wisdom teeth removed, we are just a typical human person that has the control of making the correct decision and choices. I have my CLASS A CDL with all endorsement except school bus and Motorcycle. I see what is happening to our Nation. I don't like it cause what has happened is since the Paper Logs got removed and the ELD,(On Board Babysitters) all a person is doing, is running against themselves since we have a shortage of merchandise and etc. Why did we get away from the Paper Logs? Was it for these refugees that couldn't figure out how to tell time. I just think that if you do anymore changes to the trucking industry, well you might as well what the movie, Planes, Trains, and Automobile. I am afraid that as this nation can't accomplish things. I wouldn't change anything regarding of the shortage of truckers that we have already. I probably didn't make any sense to your question. I just would say leave it as it is or whatever works but ask yourself this. We are going to lower the speed of company trucks on the interstate. Why don't you just lower the speed on the interstate instead of idiots driving 85 MPH when a truck trying to pass is only governed at 68 mph. Anyway I appreciate your time and Thank-You.	
Yevette Kelsey		Yes, it is a concern and should be included as extra protection	
Frank Crossin		I support adding Fentanyl to the Analyte testing Table	
Crystal James	Delco Transit / Operations Director	Hello. I'm all for Fentanyl to be added to the drug testing panel!	
Dwight Mattox		Adding any bad substance to a drug screen is the RIGHT thing to do. I am not against any of these substances but for a driver to have an 80,000 lb missile going 70 mph on a public highway is the definition of insanity. Furthermore, I've seen so many drivers ask for my urine, what does that tell you? Just one retired driver's opinion . But I'm right!!!!!!!!!	

Name	Company/Job Title	Comment	References
Lindsey Staton	Cover Tek	Good Afternoon I strongly support having Fentanyl added to DOT drug testing. I work at a company that does both DOT and NON-DOT drug testing and the amount of positive fentanyl tests that we see is much more common then people would think. I have also seen where employee's know that fentanyl is not on their non-dot drug tests and are sent in for non-dot reasonable suspicion testing and are passing their 10 panel urine tests because they do not test for fentanyl. Then when it is decided to add fentanyl to the company non-dot protocol those same people who were passing are all failing for fentanyl. Fentanyl is so common and easily accessible and dangerous. To think that there could be safety sensitive workers using fentanyl and still passing all of their DOT drug tests is terrifying for the safety of the public. I think adding Fentanyl to the DOT testing is a great and needed step.	
Ronald Bibb	Bibb Addiction & Obesity Center / Chief Clinician	I'm board certified in Addiction Medicine and practice such in central Kentucky in private solo practice. I'm also a certified Medical Review Officer for federal regulated entities. To be blunt, I'm not sure why this is even a question up for discussion...the answer is a resounding ABSOLUTELY!	
Natalie Bowe	Safe Trac Solutions / Client Services Administrator	Good Morning, We are a TPA and have had concern from our customers that their drivers are using fentanyl and inquiring if they can screen separately for this. The concern seems to be growing, speaking for myself I feel that adding the fentanyl to the DOT panel would be beneficial for the industry and the safety of our roads.	
Heather Lockhart	LTI Trucking Services / Safety Manager	I am in full support of adding Fentanyl/Norfentanyl to the DOT drug testing panel.	
Kevin Vrablik	LVPG Occupational Medicine / MRO	I support adding fentanyl to the analyte table.	
Bobbie Brewer	Truck Driver	Any drug or medication that can alter your mood severly or your energy ,or your concentration when driving any commercial vehicle let alone a personal vehicle is dangerous I'm a truck driver it's dangerous enough without all the intoxicated or under the influence drivers my vote is yes test for it important to save lives .	

Name	Company/Job Title	Comment	References
Berta Kern	Drug & Alcohol Testing Associates	I believe it is a good idea to add Fentanyl as one of the panels to the current DOT panel. In our area, Fentanyl use is on the rise. I am a TPA.	
Steve Bell	Director of Driver / Safety Compliance / D.E.R. / Drivers Select	Due to the rash outbreak of this controlled manmade substance and its chronic widespread usage and abuse I feel that it SHOULD be added to the list of items tested for on a urine collection. I can personally attest to its use relating to my neighbor abusing it and passing from over usage, (abused), and illegally obtained. So YES it needs to be added 100%	
Ernest Morales		I strongly agree with this movement, please by all means add this testing.	
Linda Richardson	Drug and Alcohol Testing Consulting	To Whom It May Concern, The following are comments requested in Documents Citation 88 FR 71582, Page 71582-71583 (2 pages), Document Number 2023-22797, Published October 17, 2023 regarding the addition of fentanyl/nor-fentanyl to the analyte table for DOT drug testing. The impact fentanyl has had on this county and its citizens is nothing short of reprehensible. The statistics continue to climb as it relates to overdose deaths. We also know that fentanyl is being manipulated into other drugs in order to create greater addiction. Fentanyl use of this magnitude cannot help but spill over into the workforce. Protecting and maintaining safe workplaces, particularly in transportation, needs to be addressed sooner rather than later. One way to do this is through incorporating fentanyl/nor-fentanyl to the analyte table for urine and oral fluid drug testing used for the Department of Transportation regulated testing. For these reasons, I am very much in support of this addition and commend the department's addressing this crucial issue.	
Paula Broughton-Wavra	Key Energy Services / HSE Compliance Specialist - DER	Good morning, I believe with all the number of Fentanyl overdoses we are hearing about and now suppliers using Fentanyl to make more contraband drugs: adding it to the list for DOT testing would be a good idea. We are adding this drug to our Non-DOT panels as well for our company.	
Lynn Beavers		Yes please add Fentanyl/Norfentanyl (along with their proposed testing cutoffs) to its analyte table. We have not currently encountered problems with Fentanyl at our location, but sooner or later it will happen.	

Name	Company/Job Title	Comment	References
Lisa Shields	Vertical Screen / Director of Occupational Health Services and DOT Compliance	The Substance Abuse and Mental Health Services Administration Requests Public Comment on the Possible Addition of Fentanyl to the Urine and Oral Fluid Analyte Table I wish to submit the following Public Comment pursuant to the discussion of adding Fentanyl to the Urine and Oral Fluid Analyte Table; specifically as a DOT standalone substance of abuse. As statistics have proven Fentanyl is the number one substance accounting for overdose fatalities in the US, as such in the interest of public safety this proposed change to current testing parameters will help with both deterrence and detection. In the interest of the safety of the traveling public Fentanyl poses a severe risk to injuries up to and including death. Although Fentanyl has been receiving greater coverage as a serious risk to life in the past few years it still has not garnered the necessary spotlight as a national security threat. The threat of this highly dangerous drug would likely receive greater awareness and help with public awareness. As the opioid epidemic spotlighted many people come to this substance without prior history of substance abuse if we can help save the life of one person it will be worth it. The time to act is now and not delay the technology exists at Forensic labs to proceed with detection so the infrastructure exists and hopefully the willingness to move forward is finally present. I have worked in the workplace drug and alcohol testing industry for 27 years and never have I seen a more glaring safety issue as that posed by Fentanyl for both users and those innocent people that may come in contact with this substance. Thank you for the ability to share feedback.	
Ilene Reilly	UCI Testing / Vice President	We at UCI have added fentanyl testing to several of our client's nonDOT panels at their request. We have seen quite a bit of positivity as a result. We feel as though adding fentanyl testing to the Federal drug screen panel is a good move. I am of course, concerned about cost and turnaround time. At this time, we utilize Quest Diagnostics labs in Lenexa and they only perform the fentanyl screening test – if we need confirmation testing they either forward the test to their Norristown lab which causes delay or, we ship the specimen to Norristown to begin with (which also takes more time as we are situated in Kansas and have a lab-courier).	

Name	Company/Job Title	Comment	References
John Casey	Safety Director	As one of the leading addictive causes of death, Fentanyl should DEFINITELY be included in drug screenings going forward. Since you already cover marijuana and cocaine, it is logical to include Fentanyl. There should be no question to saving lives on public highways with this testing.	
Kevin Breadmore		I agree with the testing thou I don't agree with 2nd chances if a driver test positive then I'd say confiscation of there cdl should be required there should be no room for drivers doing any drug on our roads or highways	
Jeff Sack	Vertex Transportation / Driver	Regarding the Possible Addition of Fentanyl to the Urine and Oral Fluid Analyte Table, as an employer and driver myself, you DEFINITELY should add fentanyl to the test. I am from Seattle, and fentanyl is being used recreationally, not just by daily hard addicts. Some people also take counterfeit pills that have fentanyl in them. Fentanyl is a huge problem, and definitely needs to be tested for.	
Jana Tripodi	Alcohol & Drug Testing Services / CEO - Senior Member	I urge you to add Fentanyl to the list of drugs to be detected. I lost a brother who was a healthcare worker to fentanyl. He had a back injury at work and was prescribed meds. He became addicted and looked to Fentanyl as it was readily available to him as a nurse. He passed away in the hospital bathroom injecting it. He was injecting the medical level but combined with other drugs he died instantly with upper medical levels detected in hs system. I hear similar stories from many. Please consider adding this to the DOT panel to save lives!	
Deanna Bailey	SAP	The need for Fentanyl testing is imperative to the accuracy of determining one"s use of opiates. After working in an outpatient substance abuse program for the past 20 years , the need for fentanyl use has overtaken the use of heroin. Since the Covid p...	
Brenda Franklin	Humboldt CSD / Administrative Services Manager	Be assured the Humboldt Community Services District is in full support of adding Fentanyl/Norfentanyl to the HHS Analyte Table that it subsequently be adopted into the DOT testing program.	
Tim	Tim's Towing	As part of the industry ,it is a must and privilage to " Yes " ... as times are changing and the abuse of drugs are ever widened ,and it is a must to keep our highways the safest we can. We say YES,YES,YES,..... add it to the testing...! (:	
Pam Smith		This is a wonderful idea!	
Phylene Bokor		It is my opinion that adding fentanyl to the drug screen is both vitally necessary and long overdue.	

Name	Company/Job Title	Comment	References
Allen Meyer		I myself am a recovering addict, so I spent a long time in drug use and dealing. In my opinion, adding fentanyl testing cutoffs, is a beneficial thing, not only for safety of people on the roads, but also because, in some cases where people have surgery, or other procedures where fentanyl may be used or prescribed, it allows whatever tolerance to be accepted. Though in my extended using experience, fentanyl is something that regardless of how much was used or when.... If it's in your system, it's absolutely best for you to not be behind the wheel, period... it's a drug that does more in the means of making you under the influence than heroin does, but, at the same time, you don't feel the effects as long as you would heroin or other opiates.... part of why there are so many overdoses is that reason right there... they don't feel like they are affected anymore so they use more.... The reality here is, though they don't consciously feel the effects of Fentanyl, they are still under some sort of influence of it... studies may show this or that, I don't care, I was an active user of Fentanyl myself... I know how it affects me and others who were around me. I DO NOT BELIEVE THERE SHOULD BE ANY ACCEPTABLE AMOUNT IN YOUR SYSTEM IF YOU ARE DRIVING!!!! That's my comments, I'm currently enrolled in Midwest Truck Driving School in Escanaba, Michigan. I have my commercial learners permit in Wisconsin. I am also sober and have been only since the start of May, this year, 2023... that makes 6 months, only 6 months, so it's still fresh how everything was and how it affected me and everyone around us.... It also means, my firsthand experience, more than qualifies me, to say 0 tolerance behind the wheel....	
Kristy Wilson	City of Pensacola / City Nurse	“The City of Pensacola ranks second in fentanyl deaths per capita” according to an article published by the Office of Attorney General Ashley Moody. I am the City Nurse along with the Assistant City Nurses we collect the pre-employment, random, post-accident, reasonable cause PHMSA and FMCSA drug screens. Knowing that there are over 800 employed by the City of Pensacola and the essential job functions of these employees I believe it is crucial for fentanyl/Norfentanyl to be added to the HHS analyte table. Thank you for allowing for the public to submit comments. Even if I were not a city employee knowing the amount of people employed as commercial drivers driving the construction trucks and various large commercial vehicles also that I have natural gas utilized in my home. I would certainly want to know that anyone in the type of jobs mentioned would be free of a drug such as Fentanyl.	

Name	Company/Job Title	Comment	References
Thomas Kirchhofer	DOT E-Z / Certified Medical Examiner	I am happy to see someone in authority addressing this subject. From my recent personal experience, as a cancer patient I was shocked that the pharmacist who designed my Chemotherapy cocktail included Fentanyl in the mix. They had many anti-emetic and pain control chemicals included. They worked wonders and although I don't know the dose, there were no side effects at any time during the six weeks of my once per week treatments. All of my biopsies contained Fentanyl as well. It is a very effective pain killer. As a CME and a drug screen collector, I favor using a 10 panel collection even with those who only require the standard 5 panel DOT collection. If Fentanyl were a cost effective option, I would certainly choose that as an option as well. Without a formal survey, I estimate seeing my average drug screen in the 30 year old and under age group indicating 2 - 3 anxiety medications voluntarily disclosed in 50-60% along with depression symptoms and hyperactivity. There is no doubt in my mind that this age group will be looking to add more for a better result. The popular attitude is to reduce the perceived pain of normal living. Thank you for looking into this issue.	
Sandy Derry		Good morning, With the recent increase in fentanyl use, I believe that the DOT testing process should absolutely include fentanyl and Nor fentanyl. Based on what we are seeing here at the Health center, almost everything, including cannabis is being laced with fentanyl. Also, many employees are aware that the drug testing process does not include fentanyl. With Fentanyl being 50x stronger than heroin and 100x stronger than morphine the impact it has is often fatal. The fentanyl we are seeing here in Montana is the illicit manufactured fentanyl, which is often added to other drugs, which makes it cheaper, more powerful, more addictive, and more dangerous. Many of my client's report , " it's like playing russian roulette."	
Paul Seiferth		In addition to serving as an MRO for various companies, I also treat opiate addiction with Buprenorphine and have seen an increase in presence of fentanyl in new patients and those for whatever reason suffered a relapse. We screen for fentanyl separately due to the presence being seen in those who also use marijuana, not to forget cocaine laced marijuana. Additionally it seems that fentanyl has become more prevalent than heroin in the opiate abusing/using population. It is for the above reasons I advocate for inclusion of Fentanyl in oral and urine drug screening beyond the Elisa testing	
Joseph Glassman		Yes. I support this addition to DOT testing.	

Name	Company/Job Title	Comment	References
James Smith		Hello SAMHSA, I fully and unconditionally support the addition of Fentanyl to the current 5-panel DOT drug screen. Fentanyl use and deaths have skyrocketed in every community, and I believe it will increase the safety of our commercial vehicle operators, and the general public by including it. Furthermore, I believe it would be irresponsible not to add Fentanyl to the drug screen panel, considering it's recent explosion in communities across America, including here in Burlington, VT. It's addition would allow us at the University to more fully educate and advise our employees about the risks and consequences of using this substance. Thank you for your time and efforts	
Julie Lauck	Black & Veatch / Alcohol and Drug Program Manager (DER/DSA), Ergonomic Program Administrator	I think adding Fentanyl to the panel requirements is an excellent decision, I hope is passes.	
Jennifer Ramcke		Good afternoon, Please add Fentanyl to the list of drugs that are Federal workplace tested. It is an Opioid medication that is 50-100 times stronger than morphine. As a semi truck driver myself I am of the opinion that there are NO CIRCUMSTANCES under which someone should drive a semi truck under the influence of this drug. I am shocked that is not already on the list. Thank you for reading my comments. Enjoy our life	
Michele Myers		YES! Fentanyl is a huge national problem. Employees in safety sensitive positions are at much greater risk of harming/killing somebody in the public as well as themselves.	

Name	Company/Job Title	Comment	References
Michael Day		I am fully supportive to the addition of Fentanyl to the drug screening platform. Now that I have a direct link to the panel that takes the screening platform into consideration, I would like to add. Your means of measuring marijuana needs addressed. As we all know you're measuring the by product of the substance, which stays in the system way longer than the effect of the drug itself. Many states have made this legal, with the promise of it becoming federally legal. I'm not trying to advocate that any one on the work force should be allowed to come into work intoxicated. I am simply stating you need to take measures to accurately test for thc if your going to continue to test for such. What one does on their own time in states where it had become recreationally legal, should not be an offense to those that chose to do so. I am certain I'm not the only one addressing this issue. Thanks for you time and consideration.	
Nicolette Martin	TAP Teamsters Assistance Program of Northern California / TAP Counselor	SAMHSA, I am in support of adding Fentanyl to the panel for DOT drivers. We work with DOT drivers and think it is important for this drug to be added to the panel. With the Fentanyl epidemic, it is paramount to test CDL drivers for Fentanyl, especially with the epidemic. My experience is that drug makers are adding Fentanyl to most drugs produced illegally and this includes Cannabis. Adding this drug to the panel is important for safety-sensitive work and the driver could endanger himself or someone else. The driver may not know that Fentanyl has been added to the drug he is using.	
Gail Marshall	Cape Cod Health / Nurse Practitioner	I agree with the adding fentanyl to the urine and oral fluid analyte table (testing).	
Terri Umphlett	GP Transport / Safety Director	As a safety director for a trucking company, I wholeheartedly support the addition of Fentany/Norfentanyl to the drug testing forum. This drug is a killer when abused or misused and certainly has no place in the system of someone behind the wheel of a potential 80,000+ pound vehicle.	
Brandi Ruiz	Any Lab Test Now / Office Manager	Hello, I received an email about this, and it makes me wonder why this hasn't already been done. Our company votes YES on adding FEN to DOT's. Please feel free to contact me with any further questions. Thank you, and have a wonderful day!	
Michael Burk	Accupro Screening / Office Manager	I, Michael Burk of Accupro Screening in Honolulu, HI, vote IN FAVOR of Fentanyl being added to the HHS analyte table	
Christina Shaw		As both an occupational and addiction medicine specialist, I strongly believe fentanyl/norfentanyl should be added to the SAMHSA analyte table and by consequence Federal workplace testing programs (e.g. DOT and NRC). I further believe SAMHSA should approve a CLIA-waived fentanyl POC urine drug test to be used in the outpatient addiction medicine and pain management settings.	

Name	Company/Job Title	Comment	References
Mohamed Turkmani		I am in favor.	
Kim True-Henningsen	Henningsen Enterprises, Inc. / President	Yes! Please add fentanyl to the drug testing.	
John Rodriguez	Canyon AeroConnect / Accountable Manager	To Whom It May Concern, The addition of Fentanyl to the Urine and Oral Fluid Analyte table is needed and would be a great addition to the list of tested drugs. The border is wide open, fentanyl use is on the rise, please consider the addition of Fentanyl.	
Tracey Adams	Idaho National Laboratory / Bus Operations Supervisor	I am documenting that I am in favor of this being added to mandatory testing immediately.	
Loretta Vasso	Alliance Counseling Services / SAP	I am a DOT/SAP in favor of adding Fantanyl to the HHS analyte table. Reason: it is, unfortunately, in wide use at this time	
Stephanie Hanson	Skagit Farmers Supply | AFCO Distribution | Country Store / Human Resources Specialist	In response to the email sent out this morning, “The Substance Abuse and Mental Health Services Administration Requests Public Comment on the Possible Addition of Fentanyl to the Urine and Oral Fluid Analyte Table”. I believe it is pertinent to add Fentanyl to the DOT drug panel. We would like to see this change happen	
Barney Seaton	AAR LLC / CEO / Facility Director	Absolutely, I own 4 licensed OP facilities and the majority of illicit Opioid use is now Fentanyl and without a specific test, it goes undetected.	
Thomas Walker		Most diffently Fentanyl should be part of drug testing!!!	
Linda Laney	SAP	As a SAP /LPC/LADAC/CEAP I see fentanyl broadly abused in our community. I definitely feel it needs to be included in DOT screening panels in the interest of public safety.	
Samer Choksi		I support adding fentanyl to the testing panel.	
Kimberly Henderson		Duhhhhhhh!!!!! You might look into that!!! Ignorant question since so many people are dead from that drug!! What y'all need to do is outlaw fentanyl!!!! It don't take a rocket scientist!!! Thanks for your time	

Name	Company/Job Title	Comment	References
Terri Murray	Fastest Labs / President	I feel based on the influx of fentanyl in our society it should be added to Federal testing. Especially in random and post accident testing. Thank you for your time.	
Julie Blair	Fastest Labs / Owner-Operator	Good Morning! Thank you for the opportunity to give an opinion regarding adding Fentanyl to the DOT testing. My opinion comes as a previous owner of a non-DOT delivery fleet of 60+ vehicles with approximately 115 drivers, and now after retiring from logistics, being an owner of several Fastest Labs testing centers. Fastest Labs is the largest franchise-owned testing facility in the country. As a naive logistics owner, I couldn't comprehend that most people under the age of 30 regularly but not abusively use marijuana. The delivery drivers that I employed did not hold a DOT license and, as a third party contractor, my drivers were not required to have a marijuana test by the company from whom we received the contract. It quickly became apparent that an entire generation has moved from having a glass of wine/beer after work to smoking a marijuana joint. In my experience, most employees did not abuse it but used it to relax, treat anxiety, or to sleep. Any employees who appeared impaired or "high" were not allowed to drive and chronic users were eventually dismissed from their position. The marijuana users were not the employees who had accidents. In my experience, it was users of harsher drugs - methamphetamines or cocaine used to keep up their energy - who were having accidents. Once becoming a Fastest Labs owner who administers post accident tests nearly daily, (I also happen to be the mother of two paramedics and a firefighter who administer narcan regularly), I became aware of how fentanyl is one of the most dangerous drugs and not even being tested in a basic DOT drug test. A 5-panel test has become the standard for employers, and it doesn't include the current most widely used drug of fentanyl. While PCP may have once been a threat, many donors under the age of 30 ask us what that is. These might be the same people who don't realize that their marijuana could easily be laced with fentanyl. In completing thousands of tests across three testing clinics, only ONE person has ever tested positive for PCP. We often wonder how many would test positive for fentanyl. Because the Department of Transportation drug test is considered the ultimate authority, it is my opinion that adding fentanyl to the panel would deter its use. Currently, drivers know that it is not in the panel which could make it a "go to" due to its wide availability. Adding fentanyl shows that the DOT understands the dangers and is staying current with trends in society.	
Fred Hicks		Hi, I Don't usually do this but there are too many things going on and also overlooked these days in the CDL divisions, Yes I think it should be added.	

Name	Company/Job Title	Comment	References
Alma Ramic	MRO	Hello I would support this decision, or at least for reasonable/suspicious cause. This is becoming very problematic and more and more reasonable/suspicious cause tests have fentanyl add on because people are observed impaired at work sites and current panel is returning negative and add on for fentanyl is positive (+). I hope this email will be taken in consideration when decision is made	
Tamara Lipshie	Atlantic Behavioral Health, NMC / Medical Director, Outpatient Behavioral Health	I am writing to express my strongest support for this. As we know, much of the opioid supply is currently exclusively fentanyl. This makes monitoring difficult, and significantly impacts patient safety. I see this impacting most dangerously in the emergency department, where patients clearly at risk for overdose and return to use, who would be excellent candidates for withdrawal management and relapse prevention measures, are routinely missed and discharged with no care. This would be an invaluable and life saving addition And while you didn't ask, xylazine would be good as well	
Nancy Mayo	Kalitta Air LLC / Drug and Alcohol Program Manager	Kalitta Air recognizes the alarming rise in fentanyl abuse and its catastrophic effects on society. As a company committed to safety and well-being, we strongly advocate for the inclusion of fentanyl in the analyte testing table for DOT regulated drug tests. This measure can aid in detecting and deterring fentanyl use, ultimately protecting individuals, families, and communities from its harmful consequences. We stand firm in our belief that any action, big or small, that can contribute to the prevention, reduction, or remediation of fentanyl abuse is crucial in combating this deadly epidemic.	
Traci Valerio	Assurance Screening	Good morning, I support the long overdue addition of Fentanyl and Fentanyl metabolites to the HHS and DOT drug testing programs. The fact that this drug is killing people and even babies and is considered an epidemic is enough to warrant the addition. When considering the safety risks this drug imposes on the public, I believe it is urgent to include this drug to the testing programs. Not only could this addition prevent those that willingly take the drug from continuing to use as the addition is a deterrent of use, but it could also potentially help an unexpected person from overdosing. For instance, someone takes another drug and doesn't know Fentanyl slipped into the drug they chose to take. We hear over and over how drug dealers are adding Fentanyl into everything. If this addition prevents even one overdose it will have a positive impact.	
Traci Valerio	Assurance Screening	Regarding cut-off levels - I feel the lowest possible screening level will help those unknowing users. I suggest 0.75 ng/mL for urine and 5 ng/mL for Oral Fluid.	

Name	Company/Job Title	Comment	References
Traci Valerio	Assurance Screening	I suggest 0.50 ng/mL for urine and 1 ng/mL for Oral Fluids for the confirmation	
Sara Waite		My son's father is addicted to fentanyl. He gets fentanyl patches from drug dealers. He also has 5 kids between myself and another woman- ages 13,5,4, and 6 month old twins. They have visitations with him. He takes drug tests and Fentanyl needs to be on the list of drugs tested to keep our kids safe when they go to see him. If they come in contact with the Fentanyl patches he uses, they could die. Luckily I was able to order some Narcan. I never in my life thought I would have to do that. I got them in case my child or his siblings come in contact with Fentanyl. Fentanyl is a very popular drug in Ellis County Oklahoma and Lipscomb County Texas.	
Melvin Jefferson		Add fentanyl to the list.	
Jeffrey Brody		100% for it - a move in the right direction.	
Rebecca Smart	Demolition Man Inc. / Office Manager	Absolutely this needs to be added to the drug testing panel!!!!!!	
Linda Stennett-Brewer		Yes, I think it would be a good idea.	
Kate Boetto	All About Change / SAP	Considering the existing opioid crisis I am in support of adding Fentanyl to the HHS analyte table. It is an essential step towards improving public safety.	
David Dorry	Arizona Tile / Senior Safety Manager	Good afternoon, At Arizona Tile we would agree that the addition of Fentanyl to the Urine and Oral Fluid Analyte Table would be beneficial and should be included as part of the pre-employment, random and postaccident testing for commercial drivers.	
Katherine Martin	American Leadership Academy / Safety Training Manger	Yes, Fentanyl should be included in the testing.	
Maribel Rivera Sabalier		Yesssss Im agree with the inclusion of that test in the list of Drugs and Alcohol Test. To many people using it without knowing the danger especially driving. Thanks for the opportunity	

Name	Company/Job Title	Comment	References
Alfred Emmel	Duke City Occupational Healthcare / MRO	Ladies and Gentlemen, at SAMHSA: I am in full support of adding Fentanyl/Norfentanyl into the Urine and Oral Fluid panels. As both an Emergency Medicine Physician, Occupational Medicine Physician, and MRO now in practice for over 43 year its addition in my opinion is vital as this drug becomes one of predominant abuse, with tragic human outcomes, and a major threat to workplace safety.	
Vicki Palmer	Yosemite Unified School District / Transportation Services Manager, Certified School Bus Driver Instructor	SAMHSA, I am responding to your request for written comments regarding the addition of Fentanyl to the HHS analyte table. I believe Fentanyl must be added to the HHS. The drug is highly addictive and prevalent in the United States. For the safety of everyone on the highways, drivers who use this substance must be removed from service. Thank you.	
David Paine	American Medical Review Officers / Sr. Medical Review Officer	Thank you for the opportunity to comment on the proposal to add fentanyl and norfentanyl to the drug testing panels.	
David Paine Vergi Geurian	American Medical Review Officers / Sr. Medical Review Officer Pipeline Testing Consortium / President	Dear SAMHSA, We are in support of the Secretary of HHS adding fentanyl and norfentanyl to the HHS drug testing panel for use by federal agencies and the Department of Transportation drug testing program. The reasons mentioned in the Notice of meeting for this subject are enough to add these to the federal drug testing panel. The fentanyl epidemic is wreaking havoc in our country. It is abused as a stand-alone drug but also has been found laced into many other drugs resulting in unintended use and subsequent overdose tragedies. Testing for fentanyl/norfentanyl may be a wakeup call. We are hopeful that detection of fentanyl on a drug test of someone who is supplementing their legitimate opioid prescription with illicitly obtained opioids or other drugs may have their eyes opened if they test positive for fentanyl. This may be a first step in reducing the number of overdose deaths attributed to fentanyl. Fentanyl/norfentanyl have been included in non-federal drug testing panels for years. The technology is available to perform the testing in federal and DOT programs. We hope that adding fentanyl/norfentanyl to the panel can be accomplished expeditiously. Thank you for the opportunity to submit our comments	
Roberta Merriman		I am a testor for Midlands Testing Services. I'm unsure if you want the opinion of everyone, but I feel strongly that Fentanyl should be added to the usual testing table. I know that where I live Fentanyl has become a serious problem. Most of the street drugs now seem to be laced with it.	

Name	Company/Job Title	Comment	References
Mario McGee	Bario Aviation Inc.	Please make the proposed drug testing changes.	
Robert Kelley	Substance Abuse Professional	Dear SAMHSA, I have seen a dramatic increase not only in the purposeful use of Fentanyl but also in its unintentional use. This occurs when a person purchases another illicit substance to which Fentanyl has been either added or for which Fentanyl has been substituted. Regardless, the use of Fentanyl has increased dramatically and probably now constitutes a more serious danger to users and to the general public than prescribed opioids, nonprescribed opioids and heroin. I strongly believe that Fentanyl should be included as one of the drugs included in the DOT testing analyte table.	
Rebecca Polasek		I believe it would be helpful to add Fentanyl to the panel of testing. It would help limit the number of people that think it's ok to abuse this substance.	
Mary Schwieters	SAP	Hello, As a qualified DOT Substance Abuse Professional (SAP), I am in support of SAMHSA adding Fentanyl/Norfentanyl to the analyte table	
Jacqueline Tillson	SAP	As a DOT SAP, I highly encourage testing to include the drug Fentanyl. Enough can't be said about this. Without testing for Fentanyl, we are not getting the complete picture. Adding it to our list of opioids that are included in a drug test are a MUST. I hope to see this in standard & DOT testing as soon as possible.	
Holly Sawyer	Life First Therapy LLC / SAP	Hi, My name is Dr. Holly Sawyer. I am a licensed therapist and SAP. I whole-heartedly support testing for Fentanyl. Fentanyl can be found in just about everything outside of alcohol. Fentanyl is very dangerous and anyone under its influence can cause more harm than most other drugs.	
Peggy Sherman	Wellness Screening LLC	Yes I do believe fentanyl should be added to the test profiles. Thank you Please contact me if you have any questions. Your business is very much appreciated.	
Seth Crisp		I agree add. We need any drugs that impair a driver to be eliminated	
Katherine Hager	SAP	I absolutely agree with adding Fentanyl and its metabolites to the DOT drug testing list. Additionally, once a test becomes available for zylazine, it should also be added.	

Name	Company/Job Title	Comment	References
Jo Moody	Pacific Gas & Electric	Good morning, It would a tragedy if Fentanyl wasn't added to the testing panel. There is a fentanyl epidemic similar to the opioid epidemic. It took far too long for the opioid problem to be addressed, adding to more addiction and severe safety risks. Fentanyl is killing people on a daily basis and is being added to almost every drug on the streets. I would like to see it added to the testing panel. Thank you for your consideration.	
Sabrina Ryan	Crawford Grading & Pipeline	YES to adding fentanyl to the drug screens.	
Robin Zieger	Boeing National Site Services Administrator / HR Operations	I believe this should be added to the drug testing.	
Sarah Orvalle		We would love to see the addition of fentanyl to testing panels as we have seen an increase of fentanyl overdoses in our industry including on job sites.	
Scott Holbrook	Loss Control Manager	I would vote yea to add Fentanyl to the panel	
Debra Bork	Solvay / Occupational Health Nurse Contractor	With the increasing use of these drugs in society, it would be reasonable to add them to the test kits. Not sure what that will mean for the DOT standard, but how else are you supposed to tell if they have these in their system?	
Robyn Larrea	Wienhoff Drug Testing / Specimen Collector	I think that Fentanyl should be added to the DOT testing panel because the mass influx of fentanyl flooding our states is at an all time high and is quickly becoming one of the leading causes of death by overdose. All people are susceptible to addiction and the more we can acknowledge this problem the more we can do to safeguard against our safety workers and businesses being affected by this awful epidemic.	
Jenn Adair	Specimen Collector	I feel that DOT employee's should be tested for this drug.	
Jessica Lesiak		Include the fentenyal information and testing procedures	
Dellena Hoyer	SAP	YES I HAVE BEEN A DRUG COUNSELOR FOR 28 YEARS AND A SAP FOR 15 YEARS. I THINK ALL DRUGS SHOULD BE TESTED FOR FMCSA AND DOT WORKERS.	

Name	Company/Job Title	Comment	References
Jay Jammett	MRO	It is past time to add Fentanyl to the Federal panel. It is also time to require the saliva option to be available for Federal Testing. It is also time to make all Breath alcohol testing UNIFORM across all Federal Agencies, especially 10CFR712 that allows only TWO breath samples. It was my understanding, that there was a mandate in the past to make ALL Federal Drug/ Alcohol programs UNIFORM. Please enter these comments / recommendations into the record. As a Designated Physician, I see the need for all of these recommendations. Jay Hammett MT, MD, MRO (long time MRO since mid 90's and former EBT Trainer) Oak Ridge Tennessee	
Robert Sharpe		If the goal of proposed federal drug testing panels is to reduce fentanyl use, SAMHSA needs to remove cannabis. Urinalysis has been incentivizing hard drug use for decades. Cannabis has the longest urinalysis detection window. Persons on probation and/or in military service use so-called "synthetic" cannabis and harder drugs like opioids to avoid positive test results. Drugs like fentanyl are more common than cannabis in prison settings because they are easier to smuggle and harder to detect. Roughly half of US states have legalized cannabis. Federal government drug testing requirements are damaging the US economy by making certain positions hard to fill. Cannabis is easily less harmful than alcohol, yet there is nothing preventing Americans from going to work hungover, despite the obvious impact on workplace safety. Cannabis prohibition is a cultural inquisition, not a public health campaign. It's time for SAMHSA and the federal government to get on the right side of history and remove cannabis from federal drug testing panels. There is a place for more accurate saliva tests for cannabis in workplace settings. As it stands, a person can test positive for cannabis weeks after using it which is an incentive to use drugs like fentanyl which have a shorter detection window.	
Judy Gatfield	Wienhoff Drug Testing	I have worked in the DOT drug and alcohol testing industry for nearly twelve years and have seen many changes in the drug abuse environment in that time. In my opinion, PCP should be replaced with Fentanyl on the DOT test panel. I have never processed a Positive result for Phencyclidine in all of those years, but am seeing the need for Fentanyl testing. I believe much abuse of this drug is going untested and leaving fellow drivers on the road at risk	

Name	Company/Job Title	Comment	References
Lorraine Martin	National Safety Council / President and CEO	Dear Members of the Board: The National Safety Council (NSC) supports adding fentanyl and its metabolites to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Fentanyl is the leading cause of overdose deaths in the U.S. and a frequent drug of knowing misuse.1 2 As the Substance Abuse and Mental Health Services Administration (SAMHSA) points out, many times, people who use drugs do not know they are using fentanyl as it can be found included in other misused drugs like stimulants and cannabis.3 NSC is America's leading nonprofit safety advocate and has been for 110 years. As a mission-based organization, we work to eliminate the leading causes of preventable death and injury, focusing our efforts on the workplace and roadway. We create a culture of safety to keep people safer in the workplace and beyond so they can live their fullest lives. Our more than 13,000 member companies and federal agencies represent employees at nearly 41,000 U.S. worksites. Workplaces also feel the impact of the overdose crisis. For the past ten years over which data exists, deaths from overdoses on the job have increased 536% and now represent 9% of all workplace deaths nationally.4 5 Fentanyl is the leading cause of these overdose deaths and those off the job too.6 This is the reason NSC has launched the Respond Ready Workplace initiative to educate workplaces about these preventable deaths and advocate for opioid overdose response medications to be at worksites and workers trained to administer these medications.7 Respond Ready is about an action for after an overdose has taken place, and NSC knows prevention is an important part of preventing these overdoses.	References: 1 https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm 2 https://www.samhsa.gov/data/sites/default/files/reports/rpt42730/2022-nsduh-infographic-report.pdf 3 Ibid. 4 https://www.bls.gov/news.release/pdf /cfoi.pdf 5 https://injuryfacts.nsc.org/work/safety-topics/overdose-deaths/ 6 https://www.getsmartaboutdrugs.gov/media/dea-administrator-record-fentanyl-overdosedeaths#:~:text=LAST%20UPDATED%3A,100%20times%20stronger%20than%20morphine. 7 www.nsc.org/respondready

Name	Company/Job Title	Comment	References
Lorraine Martin (cont.)	National Safety Council / President and CEO	Additionally, motor vehicle crashes have increase substantially over the past three years, with 7,000 more people being killed on the roads in 2022 than 2019.(**) Substance impaired crashes are a significant contributor of these, and the number of people killed in these crashes has also increased.8 The National Highway Traffic Safety Administration (NHTSA) worked with seven U.S. trauma centers to collect data on the toxicology from people seriously injured in crashes, and these data show an increase in the number of drivers with opioids, which includes fentanyl, in their system between the 4th quarter of 2019 to the second and third quarters of 2020 from 6.8% to 14.9% and 14.6%, respectively.9 Additionally, they found that drivers with multiple substances that could include opioids, including fentanyl, rose from 16.9% to 22.8% and 24.9% over the same periods of time. As you know, workers are often operating on our roadways and could be some of these impaired drivers too. With proper employer policies in place, adding fentanyl to the panel could help link employees with a substance use disorder to treatment and other employer support programs. NSC has many resources for employers to establish robust treatment benefits and to hire people in recovery.10 NSC knows adding fentanyl to the panel would be an easy addition as many labs are already testing for it. Thank you for your attention to this issue, and I hope you can act swiftly to add fentanyl and its metabolites to the panel. It will save lives.	

Name	Company/Job Title	Comment	References
Michael Vincent	nform / CEO	Attached are my written comments regarding the addition of fentanyl to the SAMHSA workplace oral fluid panel. SAMHSA CSAP Drug Testing Advisory Board: In response to your request for comment pertaining to the addition of fentanyl to the Authorized Drug Testing Panels for Oral Fluid, we have conducted a review of scientific research and publications on this topic. We have leveraged these findings, in conjunction with my 30 years of researching and developing laboratory initial tests across a variety of formats (ELISA, chemistry analyzer reagents) and oral fluid specimen collection systems (including Quantisal®), to respond to the proposed 1 ng/mL initial test cutoff for fentanyl in oral fluid. In determining the initial test and confirmatory cutoffs for drug testing programs, one must balance the concepts of detection and deterrence. Various analytical methods can push detection limits down to low nanogram or even picogram per milliliter levels. However, one must balance the choice of an extremely low cutoff with 1. cost effectiveness of the method chosen to detect a majority of users, 2. whether most laboratories in the program will be able to practically implement the new method and 3. the reliability of existing assay technology to deliver reproducible results, which is a cornerstone of the Substance Abuse and Mental Health Services Administration program for Federal Workplace Drug Testing. Every oral fluid assay in the current Authorized Drug Testing Panel has had robust deliberation regarding the initial and confirmatory test cutoffs prior to inclusion in the mandatory guidelines, and we hope that the current proposals will be subject to the same level of data-based analysis and consideration. Literature Review There are limited peer reviewed publications with respect to the detection of fentanyl in oral fluids. We filtered our literature search to articles that collected either neat oral fluid or utilized a specimen collection device that collected a minimum of 1 mL of oral fluid with a volume adequacy indicator and precise volume of diluent. This ensures consistency with elements of Subpart G of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens. It should be noted that recovery and stability criteria of greater than 80% were not addressed in these	References: 1) Bista SR, Haywood A, Norris R, Good P, Tapuni A, Lobb A, Hardy J. Saliva versus Plasma for Pharmacokinetic and Pharmacodynamic Studies of Fentanyl in Patients with Cancer. Clinical Therapeutics. Volume37, Number 11, 2015 2) Harper CE, Mata DC, Lee D. The impact of fentanyl on DUIDs and traffic fatalities: Blood and oral fluid data. Journal of Forensic Sci 2023;68:1686-1697. 3) Palmquist KB, Swortwood MJ Quantification of fentanyl analogs in oral fluid using LC-QTOFMS. Journal of Forensic Sci 2021;66:1871-1878.

Name	Company/Job Title	Comment	References
Michael Vincent (cont.)	nform / CEO	publications. In patients administered transdermal fentanyl at varying therapeutic doses, the mean saliva fentanyl concentration was 4.84 ng/mL [1]. This was the only study we identified that documented the concentration of fentanyl in oral fluid following the administration of pharmaceutical fentanyl. DUID cases processed by the Alabama Department of Forensic Sciences from 2018 to 2022 demonstrated 83% of oral fluid specimens with fentanyl concentrations exceeding 4 ng/mL, and 59% of oral fluid specimens with fentanyl concentrations greater than 20 ng/mL {2]. A study published by Palmquist and Swortwood showed concentrations of fentanyl in oral fluids from Redwood Toxicology Laboratory, a criminal justice focused laboratory, ranging from 3 ng/mL to greater than 100 ng/mL [3]. Analytical Considerations Currently all laboratories participating in SAMHSA's drug testing program leverage liquid chemistry assays performed on high-throughput chemistry analyzers. These assays serve as the primary analytical 'workhorse' for regulated drug testing programs, accounting for the vast majority of tests performed. The lowest cutoffs within the existing oral fluid Authorized Test Panel are 4 ng/mL for THC and 4 ng/mL for 6-Acetyl Morphine. A 1 ng/mL fentanyl cutoff for oral fluid would prove extremely challenging for chemistry analyzer assays to meet the stringent performance and quality control criteria required by the SAMHSA program. Utilizing neat oral fluid, which is inherently viscous with mucins, would result in assay interference at the proposed cutoff resulting in imprecision. As such, diluent is essential in both extracting and stabilizing the drug while also making the sample less viscous and compatible with chemistry analyzer methods. Specimen collection devices which leverage a buffer solution dilute oral fluid concentrations 3 to 4-fold prior to analysis, thus requiring net immunoassay sensitivity of 0.25ng/mL for fentanyl under the current proposal. These sensitivity levels are well below the capabilities of current chemistry analyzer assays, while meeting the strict SAMHSA performance and quality control requirements.	

Name	Company/Job Title	Comment	References
Michael Vincent (cont.)	nform / CEO	It should be noted that urine chemistry analyzer assays do not face the same matrix challenges as oral fluid. Thus, an initial fentanyl urine test at 1 ng/mL poses less technical challenge to implementation. This is evidenced by multiple urine fentanyl assays with cutoffs at 1 ng/mL or lower currently on-market. ELISA methods, as well as Time of Flight (TOF) / alternative Mass Spectrometry methods, would be able to detect fentanyl at 1 ng/mL in oral fluids. However, these analytical methods do not have the throughput to meet the projected millions of specimens in the federal and DOT workplace programs without considerable capital investment, workflow changes, and scaling of highly skilled labor for the Mass Spectrometry analysis. The economics of these changes would create significant challenges in laboratories practically pursuing certification under the oral fluid program. Conclusion Taking all of these factors into consideration, it is our recommendation that DTAB consider an oral fluid fentanyl screening cutoff of 2-4ng/mL, which would detect the vast majority of fentanyl use while successfully meeting the deterrence intent of the SAMHSA workplace drug testing program.. This will increase the probability of diagnostic reagent manufacturers successfully developing, clearing, and commercializing immunoassay screening reagents which meet the strict SAMHSA performance and quality control requirements. Otherwise, we have serious concerns with the ability of industry to realistically implementing an oral fluid testing program. Thank you in advance for your thoughtful consideration on this matter.	
NDASA comment to be presented at DTAB M. Jo McGuire	NDASA / Executive Director	NDASA conceptually supports the addition of Fentanyl and removal of MDA and MDMA from the Testing Panels for both the Urine Mandatory Guidelines and the Oral Fluid Mandatory Guidelines, as long as the cutoff levels for Fentanyl are supportable, and the laboratories will implement on the same effective date as DOT's amendments to include Fentanyl and remove both MDA and MDMA from its own regulation, 49 CFR Part 40.	
NDASA comment to be presented at DTAB M. Jo McGuire	NDASA / Executive Director	With this concern in mind, we respectfully ask whether there is research to support the 1 ng/mL cutoff proposed for Fentanyl. Is this the most cost efficient and programmatically effective cutoff level? Does this rule out therapeutic use? Are there other considerations supporting the 1 ng/mL cutoff? We are requesting a clear delineation of what choices DWP faced in deciding on the proposed 1 ng/mL cutoff and why this level was chosen for screening and confirmation for Fentanyl and Norfentanyl.	

Name	Company/Job Title	Comment	References
NDASA comment to be presented at DTAB M. Jo McGuire	NDASA / Executive Director	When the DWP adds one or more drugs to the Testing Panels, it is extremely important to NDASA that our members and their laboratories have sufficient time to implement such changes. Since the Food and Drug Administration (FDA) has a complicated double-clearance process, we ask that HHS not implement changes to require testing for Fentanyl or another new drug until the oral fluid reagents are able to be cleared with the FDA.	
Lane Kidd	Alliance for Driver Safety & Security / Managing Director	Hello I would like to publicly introduce (briefly) and submit the attached peer reviewed study at the DTAB meeting tomorrow. Thank you!	Title of Article: COMPARING DRUG TESTING METHODS IN THE TRUCKING INDUSTRY: THE DRUG AND ALCOHOL CLEARINGHOUSE V. HAIR TESTING
Anne Kelly	Substance Abuse Program Administrators Association / Executive Director	Good afternoon Attached, please find SAPAA's response to the request for comment regarding Mandatory Guidelines for Federal Workplace Drug Testing Programs and revisions to the Authorized Drug Testing Panels for Urine and Oral Fluid to add fentanyl and norfentanyl, and to remove MDMA and MDA. If you have any questions, please don't hesitate to reach out.	

Name	Company/Job Title	Comment	References
Brennen Portalski	Substance Abuse Program Administrators Association / President	To whom it may concern: The Substance Abuse Program Administrators Association (SAPAA) serves as a nonprofit trade association with a diverse membership spanning the full spectrum of professionals involved in the workforce alcohol and drug testing industry. Our members encompass third-party administrators (TPAs), in-house program administrators, Medical Review Officers (MROs), HHS-certified laboratories, Substance Abuse Professionals (SAPs), manufacturers of testing devices, and collection sites/collectors. The reach of our association extends across the United States and Canada, ensuring a comprehensive representation of every sector within the industry. SAPAA continues to support HHS in its goal of streamlining and improving the processes for determining revisions to the authorized drug testing panel for Federal workplace testing programs. SAPAA respectfully asks that the following items be considered for the proposed addition of fentanyl and removal of MDMA/MDA testing for federally mandated drug testing: Fentanyl Testing: 1. Prevalence/Positivity a)Based on data presented by Dr. Kuntz of Clinical Reference Laboratory (CRL) at the 2023 SAPAA Annual Conference, the positive prevalence rate of fentanyl in non-regulated testing averaged 1% in both urine and oral fluid testing in 2021 and 2022. b)Based on data presented by Dr. Harwani of Quest Diagnostics at the 2023 NDASA Annual Conference, the positive prevalence rate of fentanyl in non-regulated urine workforce drug testing ranged from 0.16% to 0.13% between 2020 and 2022. c)Both of the foregoing datasets suggest that fentanyl testing in federally mandated programs is warranted.	

Name	Company/Job Title	Comment	References
Brennen Portalski	Substance Abuse Program Administrators Association / President	2. Assay Availability a)There are two commercially available FDA 510(k) cleared immunoassays for testing fentanyl in urine specimens. b)There are no commercially available FDA-cleared or Employment and Insurance (E&I) labeled immunoassays for testing fentanyl in oral fluid specimens. c)While alternate technology is possible for fentanyl testing in urine and oral fluid, most large-scale commercial workplace drug testing utilizes immunoassay for initial (screening) testing. Moreover, those laboratories that utilize immunoassay for the other analytes in the Federal drug testing panel are unlikely to utilize a different technology for a single analyte due to the cost and operational implications. d)Immunoassay manufacturers estimate the timeline to develop and achieve FDA clearance for a new immunoassay to be 3-4 years when no commercial antibody is available and 2-3 years when a commercial antibody is available. The development of an E&I labeled assay is estimated to be 1-1.5 years faster.	
Brennen Portalski	Substance Abuse Program Administrators Association / President	3. Norfentanyl Testing a)There are no commercially available immunoassays for testing norfentanyl in urine (or oral fluid) specimens. b)The commercially available fentanyl immunoassays have a cross-reactivity with norfentanyl of <10% at the proposed (and FDA-cleared) cutoff of 1.0 ng/mL. c)If the requirement for a minimum of 80% cross-reactivity for “grouped” analytes is applied to norfentanyl testing, implementation of fentanyl testing will be significantly delayed – see “Assay Availability” discussion above – due to the time required to develop such an immunoassay.	
Brennen Portalski	Substance Abuse Program Administrators Association / President	4. Cutoff a)The proposed cutoff of 1.0 ng/mL for urine testing is consistent with the current FDA-cleared urine fentanyl immunoassays. (Note the foregoing norfentanyl comments). b)Commercially available and FDA-cleared oral fluid collection systems include a three- or four-fold dilution with buffer, resulting in a concentrations that is one-third (33%) or one-fourth (25%) of the neat oral fluid concentration, respectively. If the oral fluid cutoff (neat) is also 1 ng/mL, then both the screening and confirmatory assays may not be able to routinely satisfy all NLCP requirements (e.g., +/- 25% QC, LOD at 40%) at the cutoff concentration in diluted specimens.	

Name	Company/Job Title	Comment	References
Brennen Portalski	Substance Abuse Program Administrators Association / President	5. FDA Clearance a)Currently, SAMHSA only requires FDA clearance of buffered oral fluid collection systems, but not the immunoassays used for initial testing. However, the FDA requires 510(k) clearance if the immunoassay device is "…intended for use in Federal drug testing programs…" If the E&I process could also be used for immunoassays utilized in federally mandated drug testing, the time to market for new assays could be shortened by 1-1.5 years. This would facilitate the SAMHSA goal of being more agile and better positioned to address changing drug use patterns. b)If adding fentanyl to both the urine and oral fluid testing panels must be authorized at the same time and given the current status of FDA clearance, the minimum timeframe for implementation of federally mandated fentanyl testing in both urine and oral fluid could be as long as four years after SAMHSA formally signals that fentanyl will be added to the analyte table. c)Also impacting a manufacturer's decision to develop a new immunoassay is the degree of confidence that the U.S. Department of Transportation (DOT) will also add the new analyte to their panel. The testing volume related solely to Federal employees (TDPs) is likely insufficient to prompt a manufacturer to incur the costs associated with the development, validation, and FDA clearance of a new immunoassay.	

Name	Company/Job Title	Comment	References
Brennen Portalski	Substance Abuse Program Administrators Association / President	MDMA/MDA Testing 1. Prevalence/Positivity a)Based on data from the 2023 Quest Diagnostics Drug Testing Index (DTI), MDMA/MDA positivity between 2018 and 2022 ranged between 0.002% and 0.003% (3 in 100000 tests or less) in the Federally Mandated Safety-Sensitive Workforce (FMSS) and between 0.010% (in 2020) and 0.004% (in 2022) in the U.S. General Workforce. As a point of reference, in DTI, FMSS data, the positivity rate for 6-AM has declined from 0.013% to 0.003% between 2018 and 2022. Similarly, PCP positivity has ranged from 0.013% (in 2018) to 0.009% (in 2022), in this data set. b)While not directly relevant to Federal employee testing nor all federally mandated drug testing, data from the FMCSA Clearinghouse indicates that MDMA and MDA are the two lease frequently reported positives. Between January 6, 2020, and September 30, 2023, of the 224,476 “tests identified,” there were 251 (0.112%) reports of MDMA and 148 (0.066%) for MDA. MDMA reports are nearly half that of PCP and one-third that of 6-AM during the same time period. 2. Cross-Reactivity a)Should SAMHSA desire to maintain MDMA, but not MDA, testing, the cross-reactivity for several of the urine “amphetamines” (i.e., MAMP/AMP) assays have cross-reactivity of 70% or better to MDMA. Thus, MDMA could be retained as a confirmation analyte. b)The commercially available immunoassay for Methamphetamine in oral fluid also has a cross-reactivity with MDMA of approximately 90%. c)The MDA cross-reactivity with both the urine and oral immunoassays is much lower and would not be a good candidate for “grouping” with other amphetamines. If MDMA/MDA were removed as a standalone “group”, this might result in some nominal cost savings for laboratories and, ultimately, employers. Thank you for the opportunity to provide feedback on the proposed addition of fentanyl and removal of MDMA/MDA testing for federal mandated drug testing.	

Name	Company/Job Title	Comment	References
LabCorp	LabCorp	Good Afternoon. Laboratory Corporation of America Holdings (Labcorp) is one of the largest occupational substance abuse testing providers in the world, with multiple SAMHSA-certified laboratories throughout the United States. As a provider of Federal workplace drug testing services, Labcorp would be directly affected by proposed changes to the analyte table for federally regulated drug testing programs such as the addition of fentanyl and removal of MDMA/MDA. The following comments relate to the proposed changes. The Department has requested public comments on the recommendation of adding fentanyl and norfentanyl to the analyte table in the mandatory guidelines for federal workplace drug testing programs. The Department proposes adding fentanyl and norfentanyl as target analytes in urine with an initial test cutoff of 1 ng/mL and a confirmation cutoff of 0.5 ng/mL. For oral fluid, Fentanyl is proposed as a target analyte with an initial test cutoff of 1 ng/mL and a confirmation cutoff of 0.5 ng/mL. Labcorp has supported development of a process to enable the program to be more flexible and adapt federal drug testing panels to changing drug use trends and prevalence, and also supports the addition of fentanyl to the analyte table. We offer the following comments for consideration:	

Name	Company/Job Title	Comment	References
LabCorp	LabCorp	1. Availability of analytical reagents: The Department indicates that based on a 2023 survey of SAMHSA-certified laboratories, 84% currently analyze non-regulated workplace specimens for fentanyl and/or norfentanyl in urine using commercially available immunoassay kits (p 71583). However, we are not aware of any commercially available FDA-cleared immunoassay kits that currently meet the proposed cutoffs/cross-reactivity requirements for both fentanyl and norfentanyl. If kit reformulation and submission to the FDA is required to meet the proposed cutoffs, the timeline for addition of fentanyl and norfentanyl may present a significant barrier to implementation. There are commercially available FDA-cleared immunoassay kits optimized to fentanyl with limited cross-reactivity to norfentanyl, and at least one kit optimized to norfentanyl at a cutoff of 5 ng/mL. The Department may want to reconsider the proposed analytes/cutoffs in the context of existing products in order to advance this initiative more quickly. There are no FDA-cleared immunoassays for fentanyl in oral fluid at this time; the timeline for adding this analyte to the OFMG will be dependent on availability of a kit that meets the requirements. Unless the regulatory process is streamlined, the timelines associated with assay development and submission/clearance by the FDA will continue to impact the ability of the program to respond quickly to changes in drug use demographics.	

Name	Company/Job Title	Comment	References
LabCorp	LabCorp	2. Cutoffs We are interested in understanding the process used to arrive at the proposed cutoffs of 1.0 ng/mL in the initial test and 0.5 ng/mL for the confirmatory test for both urine and oral fluid. We believe it is important for any changes to analytes/cutoffs to be supported by scientific studies and/or population data that document the prevalence and analyte concentrations across multiple populations so that the final standards are fit for purpose. The relevant concentration ranges in a group of individuals with opioid use disorders may differ from a population of patients monitored for medication compliance purposes. As an example, a sampling of non-regulated workplace fentanyl results in 2022-2023 demonstrated a frequency of fentanyl <1.0 ng/mL at 1.6% while more than 50% had results > 100 ng/mL for fentanyl and > 1000 ng/mL for norfentanyl. The proposed cutoffs should be reviewed in the context of population-based data and revised, if so supported, in accordance. An additional consideration for oral fluid is that specimens collected in buffered devices will be diluted such that the concentration of drug in the device is significantly below 1.0 ng/mL. There will be analytical challenges in developing and maintaining robust assays that support the cutoffs (diluted) and required quality control for this matrix at the proposed cutoffs.	
LabCorp	LabCorp	3. Concordance of analytes and cutoffs across Federal Agencies There are multiple operational and logistical challenges for laboratories if the changes to the analyte table are not adopted across federal agencies and federally regulated industries at the same time. From a laboratory perspective, we urge the various stakeholders to work toward concordance. Thank you for your consideration of our comments on the proposed changes to the analyte table. Labcorp looks forward to working with the Department to revise the panel(s) in the most effective and efficient manner possible, while avoiding unintended consequences.	

Name	Company/Job Title	Comment	References
M. Jo McGuire	National Drug & Alcohol Screening Association / Executive Director	Dear Director Flegel, Ms. Davis, and the Federal Drug Testing Advisory Board, The National Drug and Alcohol Screening Association (NDASA) is a non-profit professional association representing over 5,000 private and public sector employers and service agents who administer and manage workplace drug and alcohol testing programs covered by the Mandatory Guidelines; the Omnibus Transportation Employee Testing Act (OTETA) and the Department of Transportation's (DOT) Procedures for Transportation Drug and Alcohol Testing Programs, as well as the DOT agency regulations; the Nuclear Regulatory Commission's regulations; and non-Federal/non-mandated drug free workplace programs. NDASA's membership includes laboratories, employers' substance abuse program administrators, compliance auditors, consortia/third party administrators (C/TPA), specimen collection facilities, collectors, breath alcohol technicians, screening test technicians, laboratories, medical review officers (MRO) and substance abuse professionals (SAP) who support employers in their Drug-Free Workplace Program initiatives. NDASA is a member owned organization who has led the way for industry education, training, and expertise in the drug free workplace arena through the NDASA University courses, industry specific certifications, annual conferences, educational webinars and NDASA publications that keep our industry apprised of pertinent information. With the recent merger of the former Drug and Alcohol Testing Industry Association into NDASA, we are now the largest trade association representing employers and their drug and alcohol industry service agents in the United States. NDASA thanks the Division of Workplace Programs (DWP) of the Department of Health and Human Services (HHS) for this opportunity to provide public comment on its proposed changes to the Drug Testing Panels. NDASA respectfully submits the remarks contained in this letter in response to the DWP's Federal Register Notice proposing to amend the Urine and Oral Fluid Mandatory Guidelines for Federal Workplace Drug Testing Programs to include Fentanyl in the Analyte Table and remove Methylenedioxyamphetamine (MDA) and Methylenedioxymethamphetamine (MDMA) from the Testing Panels for Urine and Oral Fluid Specimen Testing.	
M. Jo McGuire (Cont.)	National Drug & Alcohol Screening Association / Executive Director	NDASA conceptually supports the addition of Fentanyl and removal of MDA and MDMA from the Testing Panels for both the Urine Mandatory Guidelines and the Oral Fluid Mandatory Guidelines, as long as the cutoff levels for Fentanyl are supportable, and the laboratories will implement on the same effective date as DOT's amendments to include Fentanyl and remove both MDA and MDMA from its own regulation, 49 CFR Part 40. In addition, we applaud the decision of the Division of Workplace Programs to retain phencyclidine (PCP) in the Testing Panels because PCP remains a matter of considerable concern in the DOT-regulated industries.	

Name	Company/Job Title	Comment	References
M. Jo McGuire	National Drug & Alcohol Screening Association / Executive Director	Under the new procedures for amending its urine and oral fluid drug testing panels, respectively, there is inherently a balancing that we strongly recommend DWP conduct. While DWP has a strong interest in developing a "nimble" panel that can respond to substance-related workplace threats, there also needs to be a well-established scientific basis for setting the initial and confirmatory test cutoffs and that basis needs to be clearly articulated by DWP in a Federal Register publication announcing the final decision of HHS on the Testing Panel changes. In the past, DWP has changed cutoff levels for parent drugs and their metabolites in response to public comments. We encourage a continuation of such consideration of substantive public comments from those who are familiar with the effectiveness, efficiencies, and availability of research to support the final cutoffs. We are encouraged to hear from Director Flegel that there will be a longer consideration of public comments. If there is scientific supportability articulated in the DWP's Federal Register notice, then those employers and their service agents who will litigate around the testing (and the testing cutoffs) will have a firm footing to withstand those legal challenges. If there are no statements published by DWP regarding scientific sufficiency, the legal defensibility will be weak. With this concern in mind, we respectfully ask whether there is research to support the 1 ng/mL cutoff proposed for Fentanyl and if so, that it be shared publicly. Is this the most cost efficient and programmatically effective cutoff level? Does this rule out therapeutic use? Are there other considerations supporting the 1 ng/mL cutoff? We are requesting a clear delineation of what choices DWP faced in deciding on the proposed 1 ng/mL cutoff and why this level was chosen for screening and confirmation for Fentanyl and Norfentanyl.	

Name	Company/Job Title	Comment	References
M. Jo McGuire	National Drug & Alcohol Screening Association / Executive Director	When the DWP adds one or more drugs to the Testing Panels, it is extremely important to NDASA that our members and their laboratories have sufficient time to implement such changes. Since the Food and Drug Administration (FDA) has a complicated double-clearance process, we ask that HHS not implement changes to require testing for Fentanyl or another new drug until the oral fluid reagents are able to be cleared with the FDA. If a urine drug test can be conducted by HHS-certified laboratories, but an oral fluid drug test cannot, that will cause significant problems for those who are required to test under the DOT's regulation, 49 CFR Part 40. In circumstances where an employee who is subject to testing begins a urine collection, but then needs to have a direct observation collection, if the individual is transgender or nonbinary, they must have an oral fluid test and not a urine test per 49 CFR § 40.67(g)(3). This situation would become unnecessarily complicated if urine and oral fluid testing could not be available for the same drugs. Also, DOT allows employers to choose whether to use oral fluid or urine drug testing for each drug test type (pre-employment, random, post-accident, etc.). If a DOT-regulated employer has a standing order that requires oral fluid testing in some scenarios and urine testing in others, having a different panel of drugs for urine versus oral fluid could raise Constitutional Equal Protection concerns. Thus, the effective date and the laboratory implementation date for a changed Testing Panel for oral fluid testing must be exactly the same timing as urine testing. Respectfully, we would like to note for the record that the highly valued HHS-certification process for laboratories and the proficiency testing that would need to be done before a drug could be added to the panel will add significant time to the actual effective date that should be determined. This is justifiable and should not be rushed. During the time the National Laboratory Certification Program (NLCP) will use to certify the laboratories and conduct proficiency testing, the DOT and the reagent manufacturers would have more time to prepare. However, we ask DWP to be mindful of the need for synchronous effective dates for HHS and DOT.	
M. Jo McGuire (Cont.)	National Drug & Alcohol Screening Association / Executive Director	If effective dates are set too soon, there are likely to be shortages of reagents because suddenly a market of more than seven million tests annually would open. We don't want to see reagent manufactures monopolizing the market or running into shortages of the available supply reagents that will drive up costs.	

Name	Company/Job Title	Comment	References
M. Jo McGuire	National Drug & Alcohol Screening Association / Executive Director	When removing drugs from the panel, the NDASA membership is very concerned about what will happen if HHS and DOT have different effective dates. If HHS were to remove a drug from the drug testing panel months before DOT is able to undergo a full notice and comment rulemaking and publish a final rule under the Administrative Procedures Act, would the NLCP continue to grant HHS certification to laboratories to test for the removed drugs? If DOT still requires the testing and a transportation employee tests positive for that drug, how could that positive result be sustained if the laboratory was not HHS-certified to test for it? Such a gap between testing and HHS-certification would create legal liability for the DOT-regulated employer and its laboratory. Also, a gap between what HHS requires for its certified laboratories and what DOT requires of its regulated employers would certainly violate OTETA. DOT must follow HHS for the science and must utilize HHS-certified laboratories. It is highly unlikely that HHS would certify a laboratory and conduct proficiency testing for a drug that HHS has removed from its panel. There would be a similar problem if DWP changes the cutoffs for an existing drug in the Testing Panels. In other words, HHS would be certifying and proficiency testing laboratories at cutoffs different from the DOT regulation and thereby leaving the DOT program unsupported. Consequently, we respectfully request extended effective dates for any changes to add or remove a drug from the Testing Panels and that the effective and implementation dates are fully synchronized with the DOT effective dates. We anticipate filing a final version of these remarks as comments later this month.	

Name	Company/Job Title	Comment	References
Caitlyn E. Stewart	The American Waterways Operators / Vice President - Regulatory Affairs	The American Waterways Operators (AWO) is the tugboat, towboat, and barge industry's advocate, resource, and united voice for safe, sustainable, and efficient transportation on America's waterways, oceans, and coasts. Our industry is the largest segment of the nation's 40,000-vessel domestic maritime fleet and moves 665 million tons of cargo each year safely, sustainably, and efficiently. On behalf of AWO's more than 300 member companies, we appreciate the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed changes to the authorized drug testing panels for urine and oral fluid. The tugboat, towboat, and barge industry supports more than 270,000 jobs in related industries nationwide, including 38,000 positions as mariners on board our vessels. While not directly subject to chemical testing requirements established by the U.S. Department of Transportation (DOT), U.S. Coast Guard regulations require mariners to participate in pre-employment, periodic, random, post-incident, and reasonable cause chemical testing that adheres to the federal workplace testing procedures established by DOT in 49 CFR Part 40. AWO members are deeply committed to ensuring the safety of mariners aboard their vessels and upholding public and environmental safety in the waterways on which they work. Maintaining a drug-free workplace is vital to meeting those goals. In the spirit of cooperation toward that shared goal of safety, AWO is pleased to offer these comments. Removal of MDA and MDMA from the Authorized Drug Testing Panels for Urine and Oral Fluid During the December 5 meeting of the Drug Testing Advisory Board, SAMHSA staff provided data indicating that in the past decade the positivity rate for MDMA dropped from an average of 0.004% in 2013-2017 to an average of 0.002% in 2018-2023, with the positivity rate for MDA even lower than that of MDMA, and recommended their removal from the authorized drug testing panels. SAMHSA staff explained that while PCP has a similarly low average positivity rate, regional variations warrant maintaining PCP in the drug testing panels. AWO members have not	

Name	Company/Job Title	Comment	References
Caitlyn E. Stewart (Cont.)	The American Waterways Operators / Vice President - Regulatory Affairs	experienced differing positivity rates or regional variations in MDA and MDMA that would indicate trends in the maritime industry diverge from those SAMHSA has identified. Therefore, AWO agrees with SAMHSA's determination that the low positivity rates for MDA and MDMA justify their removal from the authorized drug testing panels because removal will not adversely affect workplace and public safety. Addition of Fentanyl to the Authorized Drug Testing Panels for Urine and Oral Fluid Like SAMHSA, AWO members recognize the growing use of fentanyl and the dangers it poses to upholding workplace safety. In the interest of safety, AWO supports adding fentanyl and norfentanyl to the drug testing panel provided implementation of these additions does not negatively impact the efficiency and effectiveness of the overall federal workplace drug testing program. Proper implementation must ensure that the addition of fentanyl and norfentanyl: (1) does not create delays in receiving drug test results beyond current timeframes; (2) does not create uncertainty about the validity of oral fluid specimen results as compared to urine specimen testing; and, (3) does not require additional specimens or impose other testing burdens to test for both fentanyl and norfentanyl. If those conditions can only be met by adding norfentanyl at a later date as further scientific means of testing are developed, AWO would support the addition of only fentanyl at this time. Additionally, when SAMHSA considers implementation timelines and effective dates for regulatory changes, AWO urges SAMHSA to coordinate with the U.S. Coast Guard alongside DOT and its regulated agencies. The added step of Coast Guard regulatory implementation of DOT regulations lengthens the process of applying federal workplace drug testing programs to the maritime industry and this should be taken into account to ensure effective implementation and modal parity. Thank you again for the opportunity to submit comments on the proposed changes to the authorized drug testing panels for urine and oral fluid. We would be pleased to answer any questions or provide further information to assist in your decision-making.	
Bobbie Wise	Golden Eagle Charter / General Manager	Please add Fentanyl to your list of drug tests. Thank you	

Name	Company/Job Title	Comment	References
Donald E. Horton Jr.	LabCorp / Senior Vice President Global Government Relations and Public Policy	Please find attached Labcorp's comments to SAMHSA on the proposal to add fentanyl to the analyte table which was discussed at the December 5, 2023 meeting of the Drug Testing Advisory Board. Thank you for your consideration of our comments.	
Donald E. Horton Jr.	LabCorp / Senior Vice President Global Government Relations and Public Policy	Dear Advisor Flanagan: Laboratory Corporation of America Holdings (Labcorp) is one of the largest occupational substance abuse testing providers in the world, with multiple SAMHSA-certified laboratories throughout the United States. As a provider of Federal workplace drug testing services, Labcorp would be directly affected by proposed changes to the analyte table for federally regulated drug testing programs such as the addition of fentanyl to the urine and oral fluid analyte table. The following comments relate to such proposed changes. The Division of Workplace Programs (Division) has requested public comments on the recommendation of adding fentanyl and norfentanyl to the analyte table in the mandatory guidelines for federal workplace drug testing programs. The Division proposes adding fentanyl and norfentanyl as target analytes in urine with an initial test cutoff of 1 ng/mL and a confirmation cutoff of 0.5 ng/mL. For oral fluid, fentanyl is proposed as a target analyte with an initial test cutoff of 1 ng/mL and a confirmation cutoff of 0.5 ng/mL. Labcorp has supported development of a process to enable the program to be more flexible and adapt federal drug testing panels to changing drug use trends and prevalence, and also supports the addition of fentanyl to the analyte table. We offer the following comments for consideration: 1. Availability of analytical reagents: The Division indicates that based on a 2023 survey of SAMHSA-certified laboratories, 84% currently analyze non-regulated workplace specimens for fentanyl and/or norfentanyl using commercially available immunoassay kits (p. 71583). However, we are not aware of any commercially available FDA-cleared immunoassay kits that currently meet the proposed cutoffs/cross-reactivity requirements for both fentanyl and norfentanyl. If reformulation and submission to the FDA is required to meet the proposed cutoffs, the timeline for addition of fentanyl/norfentanyl may present a significant barrier to implementation. There are commercially available FDA-cleared immunoassay kits for fentanyl; utilization of existing products could streamline the changes.	

Name	Company/Job Title	Comment	References
Donald E. Horton Jr.	LabCorp / Senior Vice President Global Government Relations and Public Policy	There are no FDA-cleared immunoassay for fentanyl in oral fluid at this time; the timeline for adding this analyte to the oral fluid mandatory guidelines (OFMG) will be dependent on availability of a kit that meets the requirements. Unless the regulatory process is streamlined, the timelines associated with assay development and submission/clearance by the FDA will continue to impact the ability of the program to respond quickly to changes in drug use demographics. 2. Included Analytes The Division is proposing to add fentanyl and norfentanyl in urine and fentanyl in oral fluid as initial test analytes. Based on information above relative to the availability of reagent kits that meet the proposed requirements for cutoff and cross-reactivity, it may be appropriate to consider whether the goals of the Division might be achieved by utilizing only fentanyl as the initial test analyte, including both fentanyl and norfentanyl in the confirmatory test to maximize detection rate. Unlike initial test analytes such as codeine/morphine, oxycodone/oxymorphone, and amphetamine/methamphetamine, norfentanyl is a metabolite of fentanyl but does not exhibit pharmacological activity. It is listed as a schedule II compound on the CSA as an immediate precursor for synthesis of fentanyl; the DEA has indicated it is not aware of any legitimate uses of norfentanyl other than in the synthesis of fentanyl1. Use of fentanyl alone as the initial test analyte in federal workplace drug testing programs may be sufficient as a deterrent to fentanyl use. In a sampling of more than 16,000 non-regulated urine drug tests positive for fentanyl in 2022-2023, 95.7% contained both fentanyl and norfentanyl, 3.9% contained only fentanyl, and <1% were positive only for norfentanyl. In a sample of more than 15,000 non-regulated oral fluid fentanyl positive samples from the same period, 81.5% contained both analytes and 18.5% were reported positive for fentanyl only. With the exception of five samples with indeterminate fentanyl results, all norfentanyl positive samples contained fentanyl. Observed norfentanyl concentrations were consistently lower than fentanyl concentrations in the oral fluid data set.	

Name	Company/Job Title	Comment	References
Donald E. Horton Jr.	LabCorp / Senior Vice President Global Government Relations and Public Policy	3. Cutoffs We are interested in understanding the process used to arrive at the proposed cutoffs of 1.0 ng/mL in the initial test and 0.5 ng/mL for the confirmatory test for both urine and oral fluid. We believe it is important for any changes to analytes/cutoffs to be supported by scientific studies and/or metadata that document the prevalence and analyte concentrations across multiple populations so that the final product is fit for purpose. The relevant concentration ranges in a population of individuals with opioid use disorders may differ from a population of patients monitored for medication compliance purposes. As an example, the same sample of non-regulated workplace urine samples noted above demonstrated a frequency of fentanyl <1.0 ng/mL at only 1.6%. 87.8% of the fentanyl results were >5.0 ng/mL and more than 50% had results >100 ng/mL for fentanyl and >1000 ng/mL for norfentanyl. Similar results were observed in the oral fluid specimen data set; 1.8% of fentanyl positives were </= 1.0 ng/mL and 85.8% were >5.0 ng/mL. More than 50% exceeded 100 ng/mL. The proposed cutoffs should be reviewed in the context of population-based data and revised, if so supported, in accordance. An additional consideration for oral fluid is that specimens collected in buffered devices will be diluted such that the concentration of drug in the device is significantly below 1.0 ng/mL. There will be analytical challenges in developing and maintaining robust assays that support the cutoffs (diluted) and required quality control for this matrix at the proposed cutoffs.	
Donald E. Horton Jr.	LabCorp / Senior Vice President Global Government Relations and Public Policy	4. Concordance of analytes and cutoffs across Federal Agencies There are multiple operational and logistical challenges if the changes to the analyte table are not adopted across federal agencies at the same time. From a laboratory perspective, we urge the various stakeholders to work toward concordance. Thank you for your consideration of our comments on the proposed changes to the analyte table. Labcorp looks forward to working with the Division to revise the panel(s) in the most effective and efficient manner possible, while avoiding unintended consequences.	

Name	Company/Job Title	Comment	References
Ki Chung	ARK Diagnostics, Inc. / Director, Product Development	To the Drug Testing Advisory Board (DTAB): ARK Diagnostics, Inc. has prepared comments regarding the addition of fentanyl/norfentanyl to the analyte table for federally regulated drug testing. Please kindly see the attached PDF. ARK Diagnostics, Inc. comments to the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board (DTAB) regarding the addition of fentanyl/norfentanyl to the analyte table for federally regulated drug testing. To the Drug Testing Advisory Board (DTAB): ARK Diagnostics, Inc. is a company that develops and commercializes in vitro diagnostics (IVD) immunoassays for therapeutic drug monitoring (TDM), urine drug testing (UDT) and other molecules. Our focus is the production of high quality, convenient, cost-effective products for routine use in research and clinical practice. ARK supports the board’s proposal to add fentanyl/norfentanyl to the HHS analyte table for federally regulated drug testing. As stated in the published Federal Register Notice (88 FR 71582, pp. 71582-71583), fentanyl is one of the main contributors to the opioid epidemic in the United States and is responsible for a large proportion of overdose deaths. In its efforts to support drug testing for fentanyl, ARK has manufactured and commercialized the FDA cleared ARK Fentanyl II Assay for the qualitative detection of fentanyl in human urine at a cutoff concentration of 1.0 ng/mL.	

Name	Company/Job Title	Comment	References
Ki Chung	ARK Diagnostics, Inc. / Director, Product Development	ARK supports establishing the initial test cutoff to 1 ng/mL for fentanyl. However, there are reservations regarding the proposal to also detect 1 ng/mL of norfentanyl in the same assay. Presently, there are no commercially available immunoassays that can detect fentanyl and norfentanyl equally at 1 ng/mL, including ARK's assay, which claims a norfentanyl cutoff equivalence of 15 ng/mL to 1 ng/mL fentanyl or approximately 7% cross-reactivity to norfentanyl. ARK suggests that a 1 ng/mL norfentanyl sensitivity is overly stringent, potentially disqualifying candidate immunoassays indefinitely. In contrast to hydrocodone and hydromorphone, which possess a similar core structure (299.4 and 285.3 g/mol, respectively) and require an 80% cross-reactivity testing standard by SAMHSA testing guidelines3, fentanyl and norfentanyl exhibit structural dissimilarity (336.2 and 232.3 g/mol, respectively). Developing an immunoassay with an antibody capable of detecting both fentanyl and norfentanyl at 1 ng/mL presents a formidable technical hurdle and seems improbable in the foreseeable future. Laboratories have also expressed the desire to limit testing to 1 assay for both fentanyl and norfentanyl.	

Name	Company/Job Title	Comment	References
Ki Chung	ARK Diagnostics, Inc. / Director, Product Development	Fentanyl is rapidly metabolized with more than 90% of the dose eliminated as the major metabolite norfentanyl and hydroxylated metabolites. Less than 7% of the dose is excreted unchanged in urine.2 Fentanyl and norfentanyl are seldom detected separately in urine; instead, they're typically found together, with norfentanyl levels reported as up to 15 times higher than fentanyl.4 Considering the substantially higher concentrations of norfentanyl compared to fentanyl, ARK believes a >5% cross-reactivity to norfentanyl, as demonstrated with the ARK Fentanyl II Assay, represents significant cross-reactivity, allowing the assay detect fentanyl positive samples with fentanyl levels below 1 ng/mL because of the additive effect of norfentanyl in the sample. Table 1 below illustrates the assay's response in mixtures of fentanyl and norfentanyl spiked at varying concentrations in negative human urine. As seen in table, many of the samples with fentanyl concentrations below 1 ng/mL screened positive because of the presence of norfentanyl also in the sample. ARK additionally analyzed ninety-seven (97) confirmed fentanyl-positive unaltered clinical urine specimens that are not individually identifiable. The LC-MS/MS confirmatory method was performed by a licensed reference laboratory (Mayo Clinic, Minneapolis, MN) using a cutoff of 0.2 ng/mL fentanyl and 1 ng/mL norfentanyl. Twenty-two (22) of the samples, shown in Table 2, tested positive with the ARK assay with fentanyl levels below 1 ng/mL because of the presence of norfentanyl in the sample, underscoring the significance of the norfentanyl cross-reactivity. Furthermore, publications have cited the ARK Fentanyl II Assay with an overall agreement of 93% or greater with LC-MS/MS, demonstrating the ARK Fentanyl II Assay as an appropriate screening tool for fentanyl drug testing.5–7.	

Name	Company/Job Title	Comment	References
Ki Chung	ARK Diagnostics, Inc. / Director, Product Development	ARK Diagnostics, Inc. Recommendations Below ARK recommends two possible alternative options for fentanyl and norfentanyl initial test cutoff requirements within the HHS Drug Testing Panel: 1. Initial test cutoff of 1 ng/mL fentanyl with ≥5% cross-reactivity to norfentanyl ARK suggests an immunoassay capable of 1 ng/mL fentanyl cutoff and significant cross-reactivity (≥5%) to norfentanyl serves as an adequate screening tool. 2. Initial test cutoff of 0.5 ng/mL fentanyl with ≥5% cross-reactivity to norfentanyl ARK suggests an assay with a 0.5 ng/mL fentanyl cutoff would result in fewer false negatives. While there are currently no commercially available immunoassays featuring a 0.5 ng/mL fentanyl cutoff and significant cross-reactivity to norfentanyl, ARK is optimistic about the technical feasibility of developing such a device.	
Ki Chung	ARK Diagnostics, Inc. / Director, Product Development	Conclusion ARK Diagnostics, Inc. expresses gratitude to the board for facilitating public comments regarding the proposal to include fentanyl and norfentanyl in the analyte table for federally regulated drug testing. While ARK supports the decision to include these important analytes, there are reservations regarding the initial test cutoff requirements for norfentanyl. ARK remains dedicated to collaborating with the Drug Testing Advisory Board (DTAB) and encourages an open and ongoing dialogue concerning fentanyl testing.	

Name	Company/Job Title	Comment	References
Brian P. Feeley	Current Consulting Group / Vice Presdent	This correspondence is in response to proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs related to the addition of Fentanyl and removal of MDA & MDMA. On behalf of the Current Consulting Group (CCG), we thank SAMHSA and DTAB for the continued effort to improve the Mandatory Guidelines for Federal Workplace Drug Testing Programs related to both urine and oral fluid testing. CCG has been in business for over 25 years serving the drug and alcohol testing industry with a host of compliance and business consulting services, and as such, we interface with both industry providers and end users/employers in the industry and obtain feedback and field questions regarding drug and alcohol testing. Over the past 10 years, there has been a steady rise in the number of inquiries and concerns related to Fentanyl and its deadly impact on society today. Clearly any drug/class of drugs that accounts for greater than 11% of that reported by forensic laboratories is of major concern in both our communities and workplaces and needs to be addressed. As such, CCG is in full support of the addition of Fentanyl and Norfentanyl for urine, at the screening and confirmation levels proposed, as well as the addition of Fentanyl in oral fluid screening and confirmation with the following caveats:	
Brian P. Feeley	Current Consulting Group / Vice Presdent	1) Screening assays at 1ng/mL will push the limits of traditional immunoassay technologies, particularly using controls at +/-25% of the cutoff. We would urge the board to consider feedback from immunoassay developers and laboratories as to the practicality of achieving that performance with reasonable degrees of failure rates as well as regarding the best cutoffs to use. Also, controls set at +/-50% for this assay may be more reasonable.	
Brian P. Feeley	Current Consulting Group / Vice Presdent	2) Ample time for implementation of this change will be needed for assay developers to make these assays, perform clinical studies, obtain FDA clearance, and for laboratories to validate these assays. It is not uncommon for these processes to take 18-24 months to complete. 3) HHS and DOT should be in lock-step regarding these changes to provide DOT ample time to follow their Notice of Proposed Rule Making process, providing time for rule making, public comment and to finalize their rules before the changes are implemented. 4) Implementation of Fentanyl testing should not delay the current oral fluid implementation process that is based on current OFMG's and DOT rules.	

Name	Company/Job Title	Comment	References
Brian P. Feeley	Current Consulting Group / Vice Presdent	Regarding the removal of MDA & MDMA, CCG has concerns related to public safety and the strong possibility for use of these drugs to increase if removed from the program. Therefore, CCG does not support removing these from the federal workplace drug testing program at this time.	
Brian P. Feeley	Current Consulting Group / Vice Presdent	A final area CCG would like to propose SAMHSA and DTAB begin to look more closely at is proctored, directly observed virtual oral fluid collections with laboratory-based testing. Prior to COVID these technologies were beginning to evolve and advance toward methods that can be practically and accurately implemented for diagnostic testing applications including drug testing. As a result of COVID and the need for COVID testing solutions to be available outside of using occupational health/collection sites and doctor offices, virtual doctor visits and testing became paramount to effectively deal with the onslaught of the disease and patient treatment. Due to this, virtual collections and technologies surrounding these further advanced and improved from kitting of tests, rapid deployment, security seals, appointment scheduling, running tests under directly observed conditions by trained professionals, and tightly controlled packaging of samples for shipment to the laboratory. A host of companies are now specializing in these solutions and offer them for non-regulated testing applications. We are certain most, if not all, would be very willing to engage in a process to have this considered for use in the Federal Workplace Drug Testing Program. A few of these providers include eMed Screen, eRAMx, Recovery Trek, and Azova. Use of this technology has several positive outcomes in testing programs, including: 1) Improving compliance of testing programs via 24/7 availability of collections that are not subject to limited appointment slots often experienced at collection sites 2) Solving difficult collection situations, such as remote locations, weekends, holidays and other situations with no scheduling needed 3) Reducing burdens on collection sites so they can prioritize the more important clinical work they perform 4) Reducing contact of healthy individuals needing a drug test with individuals who may be sick at occupational health/collection sites, which is particularly important during peak COVID and Flu outbreaks 5) Improving and accelerating the hiring process in pre-employment testing situations	

Name	Company/Job Title	Comment	References
Brian P. Feeley (cont.)	Current Consulting Group / Vice Presdent	6) Video and audio files generated during the process can be retained for extended periods of time on secure servers, should the need arise to revisit those important recordings 7) Importantly, it also utilizes oral fluid, which provides the many advantages of that sample type described in the HHS and DOT oral fluid guidelines and is the most practical sample type for these virtual type collections We again thank SAMHSA and DTAB for their diligence in maintaining and improving the Federal Workplace Drug Testing Program. Please let us know if we can provide additional information or help in any way in the future. This correspondence is in response to proposed changed to the Mandatory Guidelines for Federal Workplace Drug Testing Programs related to the addition of Fentanyl and removal of MDA & MDMA. Thank you for the opportunity to comment	
Douglas Meiser	Drug Screening / SVP	This correspondence is in response to proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs related to the addition of Fentanyl and removal of MDA & MDMA. On behalf of eMed Screen, we thank SAMHSA and DTAB for the continued effort to improve the Mandatory Guidelines for Federal Workplace Drug Testing Programs related to both urine and oral fluid testing. Over the number of years, there has been a steady rise in the number of inquiries and concerns related to Fentanyl and its deadly impact on society today. Data from NFLIS bears the material evidence to support this statement. As such, eMed Screen is in full support of the addition of Fentanyl and Norfentanyl for urine, at the screening and confirmation levels proposed, as well as the addition of Fentanyl in oral fluid screening and confirmation provided that the rules implemented are commercially reasonable, allow for needed NPRM timeframes and do not delay the current lab-based oral fluid implementation process under DOT.	

Name	Company/Job Title	Comment	References
Douglas Meiser	Drug Screening / SVP	One additional final area eMed Screen would like to propose SAMHSA and DTAB explore more closely is proctored, directly observed virtual oral fluid collections with laboratorybased testing. Prior to COVID these technologies were beginning to evolve and advance toward methods that can be practically and accurately implemented for diagnostic testing applications including drug testing. As a result of COVID and the need for COVID testing solutions to be available outside of using occupational health/collection sites and doctor offices, virtual doctor visits and testing became paramount to effectively deal with the onslaught of the disease and patient treatment. Through this process, virtual collections and innovative technologies improved from packaging of tests, rapid deployment, security seals, appointment scheduling, running tests under directly observed conditions by trained professionals, and tightly controlled packaging of samples for shipment to the laboratory. We have successfully proctored and resulted over 20 Million tests during the pandemic and have pivoted now to other use of our innovative platform in the field of healthcare as well as in forensic drugs of abuse proctoring using an oral fluid point of collection device. Use of this technology has several positive outcomes in workplace testing programs, including: 1) Improving compliance of testing programs via 24/7 availability of collections that are not subject to limited appointment slots often experienced at collection sites 2) Solving difficult collection situations, such as remote locations, weekends, holidays and other situations with no scheduling needed 3) Reducing burdens on labs and collection sites so they can prioritize the more important clinical work they perform 4) Reducing contact of healthy individuals needing a drug test with individuals who may be sick at occupational health/collection sites, which is particularly important during peak COVID and Flu outbreaks 5) Improving and accelerating the hiring process in pre-employment testing situations 6) Video and audio files generated during the process can be retained for extended periods of time on secure servers, should the need arise to revisit those important recordings	
Douglas Meiser (cont.)	Drug Screening / SVP	7) Importantly, it also utilizes oral fluid, which provides the many advantages of that sample type described in the HHS and DOT oral fluid guidelines and is the most practical sample type for these virtual type collections Thank you once again SAMHSA and DTAB for your diligence in maintaining an effective and relevant safety focus in the workplace.	

Name	Company/Job Title	Comment	References
Brenna Lyles	ATA / Director, Safety Policy	Please find attached the American Trucking Associations' written comments regarding the addition of Fentanyl and the removal of MDA and MDMA to the federally regulated analyte table. Please respond to this email with confirmation of your receipt. If you have any questions, feel free to reach out.	
Brenna Lyles	ATA / Director, Safety Policy	Drug Testing Advisory Board Members: The American Trucking Associations (ATA)1 thanks the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services (HHS) for the opportunity to provide public comments regarding changes to the Fluid Analyte Table for federally regulated testing, including the potential addition of Fentanyl, removal of methylenedioxyamphetamine (MDA) and Methylenedioxymethamphetamine (MDMA), and retention of phencyclidine (PCP), as discussed during DTAB's December 5, 2023, meeting. Addition of Fentanyl to Regulated Fluid Analyte Table ATA supports the addition of fentanyl and/or norfentanyl to the Authorized Drug Testing Panels for federally regulated employers, as proposed by HHS. Federal and industry-led data indicate a growing rate of positive fentanyl test results – ranking as the fourth most prevalent drug and accounting for nearly 14% of all drugs reported by nationwide forensic laboratories – alongside increasing instances of standalone use.2 While fentanyl continues to be an additive or filler in illicit drugs detected in a traditional 5-panel test, the drug is increasingly contained in counterfeit prescription medications, like Adderall, Xanax, and oxycodone, commonly taken without other drugs. 3 Within the trucking industry, motor carriers that perform hair follicle testing have seen a substantial increase in positive fentanyl tests in recent years, while the same individuals tested using the mandated U.S. Department of Transportation (DOT) panel receive negative results. According to one drug testing provider, among three motor carriers who performed hair testing that included fentanyl in their non-DOT testing program, 137 fentanyl positives were detected in 2023 – of which, 77 contained fentanyl only (56%) and 60 showed fentanyl alongside other drugs (44%).	

Name	Company/Job Title	Comment	References
Brenna Lyles (cont.)	ATA / Director, Safety Policy	Despite fentanyl's growing prevalence, under current federal requirements, the trucking industry remains limited in its ability to test and screen for the drug in commercial motor vehicle drivers and during the pre-employment testing process. Recognition of fentanyl and norfentanyl as analytes under the Federal Workplace Drug Testing Programs would enable employers to identify and screen safetysensitive employees using the substance, particularly those using fentanyl as a standalone substance as opposed to in conjunction with other drugs currently on the DOT panel. The national rise in fentanyl use not only poses a significant risk of overdose and harm to users but also raises serious traffic safety concerns. A 2020 case study published in the Journal of Analytical Toxicology indicated the most frequently reported incidents amongst fentanyl-impaired drivers included driver unresponsiveness, vehicle lane departure, and vehicle crashes. 5 Expanding the federally regulated testing panel to include these analytes will promote a safer, drug-free workforce and equip commercial motor carrier employers with the tools to identify users of the potent opioid – many of whom currently remain unidentified and undetected to motor carriers. The current federal testing requirements create a situation in which drivers who test positive for fentanyl through employer hair testing may seek and obtain employment by another carrier that does not perform hair follicle or other testing outside the mandated DOT panel. In this scenario, motor carriers are unknowingly and unintentionally hiring drivers with controlled substance abuse issues who may pose potential safety risks to themselves and the traveling public. Thus, the inclusion of fentanyl and norfentanyl in the mandated panel will allow motor carriers to report positive test results to DOT's Drug and Alcohol Clearinghouse, enabling enhanced information sharing of employee violations and providing a clearer picture of the scope of fentanyl use across the industry. While ATA supports the proposed testing addition given promised safety benefits, it urges DTAB to consider the additional costs associated with performing fentanyl testing that will be incurred by employers, especially when considering still relatively low positivity across the industry. Currently, the direct lab cost of a DOT urine drug testing panel ranges from around $12.00 to $20.00 per test.	

Name	Company/Job Title	Comment	References
Brenna Lyles (cont.)	ATA / Director, Safety Policy	The addition of fentanyl will increase that fee by as much as $20.00 – bringing that range from $19.00 to $32.00 per panel, according to one drug testing and employee screening service provider. While total costs of employee drug testing differ across the industry based on workforce size and testing volume, motor carriers will likely experience a substantial increase in testing fees should fentanyl be added to the panel. While drug testing providers report that most employers are yet to add fentanyl to their non-DOT panels and therefore the exact occurrence of fentanyl positivity remains largely unknown, 2017 and 2019 data from HHS laboratories conducting non-regulated workplace drug testing reflected an estimated prevalence of 0.2% of positive tests results.6 By comparison, 2022 Drug and Alcohol Clearinghouse data show marijuana was the most commonly detected substance at just under 60% of positive lab results followed by cocaine, methamphetamines, and amphetamines represented around 15.9%, 8.1%, and 7.8% of positive results, respectively.7 Low fentanyl positivity may be partially attributable to the still significant share of positive results that show fentanyl in conjunction with substances currently tested for in the mandated workplace panel (i.e., attributed to substances “laced” or in part replaced with fentanyl). According to the U.S. Drug Enforcement Administration (DEA), “as the number of fentanyl reports has increased over the years, so have the number and variety of substances reported in the same item as fentanyl.” Between 2013 and 2022, the proportion of drug items submitted to federal, state, and local laboratories containing fentanyl and other co-reported substance(s) doubled – from 15% to 30% of substances. Nevertheless, it is worth noting that the addition of fentanyl to the testing panel may ultimately prove cost-effective for those motor carriers currently performing additional testing for the substance, assuming this could be done through a consolidated urine or oral fluid-based panel.	

Name	Company/Job Title	Comment	References
Brenna Lyles	ATA / Director, Safety Policy	Removal of MDMA & MDA to Regulated Fluid Analyte Table ATA opposes the Department's plans to remove MDMA (Ecstasy) and MDA from the regulated drug testing panel. SAMHSA cites that the proposed removals are warranted given relatively low positivity rates, however, ATA believes MDMA and MDA positivity rates continue to raise safety concerns and testing costs remain low enough to warrant keeping both on the panel. In 2022, FMCSA's Drug and Alcohol Clearinghouse reported 68 and 45 positive results forMDMA and MDA, respectively. These figures have remained relatively steady in the years since the Clearinghouse's establishment (January 2020). As of FMSCA's October Clearinghouse report, 2023 MDMA and MDA positivity rates appear to be tracking to surpass last year's figures. While most truck drivers do not engage in any drug use, anecdotal evidence suggests positive rates for MDMA and MDA amongst safety-sensitive employees, including drivers, may exceed those for fentanyl due to these amphetamine-like stimulants' ability to increase alertness and motor activity. Further, continuing mandated MDMA and MDA screening would be cost-neutral to employers as testing labs typically do not decrease the DOT panel cost in response to removing regulated analytes. Given these factors, ATA believes it is prudent to keep both on the federally regulated testing panel to ensure the highest level of safety for the industry and traveling public. Maintenance of PCP on Regulated Fluid Analyte Table	
Brenna Lyles (cont.)	ATA / Director, Safety Policy	Finally, ATA supports SAMHSA's decision to maintain PCP on the panel. Echoing the comments above, continuing mandatory testing for PCP despite relatively low positivity ensures any level of use is consistently detected and screened out to ensure workforce and nationwide roadway safety. In closing, federal acceptance of fentanyl and retention of MDMA, MDA, and PCP on the mandated testing panel would ensure employers screen for and identify use of potentially dangerous substances amongst safety-sensitive employees, ultimately equipping motor carriers with the greatest number of tools under the federal regulations to keep unsafe drivers off the road. ATA appreciates the opportunity to provide these comments to the DTAB and the Board's consideration of our concerns and input. Please feel free to contact the undersigned at (703) 838-1908	

Name	Company/Job Title	Comment	References
Nadia J. McIlhany	Airline Pilots Association / Senior Paralegal, Legal Department	Please see the attached written comments of the Air Line Pilots Association, International regarding the addition of Fentanyl to the analyte table.	
Jason Ambrosi Suzanne Kalfus Stephanie Spanja	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	Introduction The Air Line Pilots Association, International ("ALPA") is the principal labor union for the nation's airline pilots. It represents more than 77,000 pilots who fly for 43 airlines in the United States and Canada. The pilots ALPA represents are subject to Department of Transportation ("DOT")-mandated drug testing as required by the Omnibus Transportation Employee Testing Act of 1991 ("OTETA"). 49 U.S.C. § 45101 et seq., given their safety-sensitive position. OTETA requires DOT to follow the Scientific Guidelines promulgated by the Department of Health and Human Services ("HHS") in its drug testing procedures governing regulated safety-sensitive employees. 49 U.S.C. § 45104(2). So, HHS's Guidelines apply not only to federal employees but to private sector employees and impact an additional 6.5 million regulated private-sector transportation employees, well beyond the over 400,000 federal employees subject to them through Federal Workplace drug testing. U.S. DOT, Employees, https://www.transportation.gov/odapc/employee (last visited Dec. 18, 2023); 5 U.S.C. § 7301 note & Exec. Order 12,564, 51 Fed. Reg. 32,889 (Sept. 15, 1986). ALPA recognizes that the proliferation of fentanyl is a matter of grave concern to the public health generally and to airline employees, including pilots. ALPA shares that concern and does not necessarily oppose modifying Drug Testing Panels to include fentanyl, but it does oppose how HHS is proceeding to do so because, as explained below, the truncated process proposed, which does not follow notice and comment rulemaking procedures, compromises informed decision-making, especially with respect to the novel and highly technical issues involved.	

Name	Company/Job Title	Comment	References
Jason Ambrosi Suzanne Kalfus Stephanie Spanja	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	The HHS Proposal In text in the middle of a "Notice of Meeting," HHS proposes to add the new drug, fentanyl, and the new drug metabolite, norfentanyl, to the Drug Testing Panels in its mandatory Scientific Guidelines via newly implemented procedures which short-cut notice and comment rulemaking requirements under the Administrative Procedures Act ("APA"). 88 Fed. Reg. 71582 (Oct. 17, 2023). ALPA objects to substituting a truncated process for APA's notice and comment requirements because of the insufficient notice afforded by this process, the lack of detailed explanation and identification of scientific data and studies for its cut-offs and other determinations, and the other limitations that hamper the ability of the public to have sufficient information and a meaningful opportunity to comment on changes to these substantive regulatory standards. This new approach follows prior Notices of Proposed Rulemaking ("NPRMs") in which HHS proposed to make such drug panel changes without APA compliance and which, besides adding new drugs for testing, could also include revising or establishing new drug testing cut-offs, adding new validity tests or "biomarker" testing, and establishing new validity testing protocols, analytes and/or cut-offs. Each such substantive determination should be based upon scientific and technical data timely provided to the public to enable discussion and debate to ensure the most appropriate decisions are made. These seemingly "technical" regulatory details – such as drug or biometric cut-offs – can determine whether employees are deemed rule violators and consequently lose their careers and livelihoods. ALPA objected to the HHS proposal for those procedural reasons. We attach and incorporate by reference our prior comments. See ALPA Comments to Docket Nos. SAMHSA 2022-0001 & SAMHSA 2022-001 (June 6, 2022), attached hereto.	

Name	Company/Job Title	Comment	References
Jason Ambrosi Suzanne Kalfus Stephanie Spanja	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	HHS's Short-cut Process to Change Drug Panels Does Not Accord Fair Process and Violates the APA. We urge HHS to seriously reconsider making changes to the Drug Testing Panel without fully following APA notice and comment rulemaking procedures. Adherence to such procedures provides a better decisional process, see ALPA Comments at 5-6, with numerous examples of improvements resulting from notice and comment rulemaking – including in prior drug panels and the mandatory Guidelines. See description of the vital importance of notice and comments in establishing specimen validity testing standards. ALPA Comments at 10-22; see also SAMHSA reliance on comments in setting oral fluid standards. 84 Fed. Reg. 57554, 57556 (Oct. 25, 2019). HHS cites no caselaw to support its newly claimed exemption from APA rulemaking procedures to the mandatory Guidelines as "a matter relating to agency management or personnel." 88 Fed. Register at 70821; 88 Fed. Reg. at 70772 (Oct. 12, 2023). A plethora of caselaw, however, demonstrates that such exemption is narrowly construed and not applicable to the substantive, comprehensive scientific and technical determinations applicable in the mandatory Guidelines not only to Federal employees, but to millions of DOT-regulated employees. See ALPA comments at 6-9 (citing cases). Moreover, HHS wholly ignores the Regulatory Impact of its changes on the DOT (and NRC) regulated industries, claiming such impact "depends on the extent to which these agencies incorporate the [Guidelines'] revisions into their programs." 88 Fed. Reg. at 70821; 88 Fed. Reg. at 70772 (Oct. 12, 2023). Where the law requires agencies, such as DOT, to incorporate the scientific determinations in the HHS mandatory Guidelines in its laboratory and testing procedures, it is arbitrary and capricious, and contrary to law to exclude that impact from consideration. HHS's revised approach is to provide notice and an opportunity for public comment "as part of the Drug Testing Advisory Board (DTAB) meetings and procedures." 88 Fed. Reg. 70814 and 70768 (Oct. 12, 2023). Thus, in the instant- proposed changes, HHS merely published a general "Notice of Meeting" of the DTAB on December 5, 2023, at which its proposal would be discussed. 88 Fed. Reg. at 71582 (Oct. 17, 2023). The subject line in that notice did not identify the proposed addition	

Name	Company/Job Title	Comment	References
Jason Ambrosi Suzanne Kalfus Stephanie Spanja (cont.)	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	of new drugs to be tested, proposed changes to the Drug Testing Panels nor even changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The one-page notice identified two additional analytes to be added to the urine and oral fluid drug tests and proposed initial and confirmatory cut-offs for each testing medium. The notice provided no explanation for the basis of its proposed cut-offs, no studies or empirical experience on which they are based, and no discussion of the practical or scientific challenges of implementing such cut-offs in each medium. A general "Notice of Meetings" fails to provide reasonable notice to affected individuals of the specific proposed drug testing changes, or even that changes to HHS mandatory Guidelines are being proposed at all. Over the past year, there have been 848 "Notices of Meetings" for federal agencies, and 377 at HHS alone. (Search of federalregister.gov "Notice of Meeting" (Dec. 18, 2023)). A general notice posted will necessarily be missed by many if not most affected individuals who are not scouring all meeting notices in the Federal Register. And without clear and specific notice, there is no meaningful opportunity to comment. Likewise, substituting DTAB meetings for formal notice and comment rulemaking deprives the public and affected individuals of significant and substantive information. The opportunity to obtain information at the December 5, 2023 meeting was limited and inadequate. The meeting Agenda provided 45 minutes for "Discussion of Proposed Analyte Table Changes: The Addition of Fentanyl and the Process for Moving Forward." No written materials were distributed, and no transcript or minutes of information presented was posted as of two weeks after the meeting (December 19, 2023). Accordingly, only individuals physically able to attend the (virtual) meeting on December 5, could access the information provided that day. The absence of a written record also prevented individuals and organizations from carefully considering information presented and subjecting it to evaluation by outside, independent experts.	

Name	Company/Job Title	Comment	References
Jason Ambrosi Suzanne Kalfus Stephanie Spanja (cont.)	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	The oral presentation by SAMHSA's Representative did not identify the process by which the cut-offs were determined, the scientific or empirical data on which they were based, the alternatives evaluated (if any), or the challenges presented by such testing and cut-offs. It was difficult to accurately hear and comprehend scientific details presented orally, without context and by different speakers. Only through a few questions raised by virtual attendees were certain issues identified, such as the lack of an assay that has cross reactivity for both fentanyl and norfentanyl, the lack of a reagent cleared by the FDA for oral fluid testing of fentanyl, the lack of a fentanyl control in oral fluid testing that would pass the requisite validity testing margin of error, and the challenges of testing for fentanyl in oral fluids at the low target levels proposed. Had these individuals not raised those issues, they would not have been identified at all; HHS did not affirmatively report them. Other commenters expressed the same concerns we state here: a need to understand the process by which the cut-offs were determined, the data supporting such cut-offs, the research relied upon for such determinations; the need for review of proficiency test data; and assurance that final decision-making is not rushed. Without HHS providing such data, and the opportunity to comment on it, the so called "opportunity for comment" is without the benefit afforded by the APA. The law requires that when an agency "seeks to promulgate a rule," it must "provide 'notice' of 'either the terms or substance of [the] proposed rule or a description of the subjects and issues involved,' and then 'give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.'" Window Covering Mfrs. Ass'n v. Consumer Prod. Safety Comm'n ("WCMA"), 82 F.4th 1273, 1282 (D.C. Cir. 2023) (quoting 5 U.S.C. § 553(b)(3), (c)).	

Name	Company/Job Title	Comment	References
Jason Ambrosi Suzanne Kalfus Stephanie Spanja (cont.)	Airline Pilots Association / President Senior Attorney, Legal Department Senior Attorney, Legal Department	The D.C. Circuit has long upheld the principle that "It 'is the agency's duty to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules.'" WCMA, 82 F.4th at 1283 (quoting Owner Operator Indep. Drivers v. FMCSA, 494 F.3d 188, 199 (D.C. Cir. 2007)). Indeed, the D.C. Circuit has insisted that "the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation." Air Transp. Ass'n of Am. v. FAA ("ATA"), 169 F.3d 1, 7 (D.C. Cir. 1999) (emphasis in original); see also WMCSA, 82 F.4th at 1283. Without the disclosure of the data relied upon by an agency in formulating its proposed rule, a "'genuine interchange' about the accuracy of the data [will] not occur," thus threatening the integrity of the notice-and-comment rulemaking process. WCMA, 82 F.4th at 1283 (quoting Conn. Light & Power Co. v. NRC, 673 F.2d 525, 530 (D.C. Cir. 1982)). The process accorded in this new HHS approach has failed to provide the essential explanations, data, and research studies on which the proposals are presumably based. Research methodologies differ and experts may disagree. The public and directly affected employees have the right to the information on which substantive drug testing protocols are based, and the opportunity to provide comments in response. We respectfully request this alternative approach to APA notice and comment rulemaking be rejected and the process deficits be corrected.	
Chelse Dyer	Abbott / Senior Manager, Regulatory Affairs	Good afternoon, Please find attached comments from Abbott subsidiaries pertinent to items related to Mandatory Guidelines for Federal Workplace Drug Testing. Thank you for the opportunity to offer feedback on this very important topic	

Name	Company/Job Title	Comment	References
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	Dear Drug Testing Advisory Board: Immunalysis, Corporation, a Subsidiary of Abbott, manufactures oral fluid and urine reagents as well as testing devices. Immunalysis appreciates the opportunity to comment on the proposed rulemaking. We have provided comments to the sections of interest or concern. Our comments are focused on our experience as a manufacturer of reagents. The Secretary should include Fentanyl in the testing panel. Section 8105 of the Fighting Opioid Abuse in Transportation Act, included in the SUPPORT for Patients and Communities Act, required the Secretary to determine whether it is justified, based on the reliability and cost-effectiveness of testing, to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include fentanyl. Section 8105 additionally required the Secretary to consider whether to include any other drugs or other substances listed in Schedule I and II of Controlled Substances Act (CSA). Norfentanyl is a metabolite of fentanyl. Because it is also an immediate precursor used in the illicit manufacture of fentanyl, it is a Schedule II substance under the CSA. 1) Urine data from non-regulated testing presented by two large commercial drug testing laboratories suggest that fentanyl testing would be prudent in the federal workplace drug testing program. •Clinical Reference Laboratory presented at the 2023 SAPAA conference that they found 1%positivity rate for both urine and oral fluid non-regulated samples tested in 2021 and 2022. •Quest Diagnostics presented at the 2023 NDASA conference that they observed 0.13 to 0.16% positivity for fentanyl in non-regulated urine samples tested between 2020-2022.	

Name	Company/Job Title	Comment	References
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	2) Current fentanyl screening assay availability a)There are FDA 510(k)-approved immunoassays commercially available for URINE fentanyl testing with 1 ng/mL screening cutoff. b)There are not any FDA 510(k)-approved immunoassays commercially available for ORAL FLUID testing. c)There are not any Employment and Insurance labeled immunoassays commercially available for URINE or ORAL FLUID. d)Alternate technology is a potential approach for initial testing of fentanyl in URINE and ORAL FLUID; however, it is not an efficient approach for most commercial workplace drug testing laboratories due to cost and throughput limitations. e)It is estimated that the timeline to develop and achieve FDA 510(k)-approval for a new ORAL FLUID fentanyl immunoassay is three-four (3-4) years when no commercial antibody is available and two-three (2-3) years when a commercial antibody is available. The development of an E&I labelled assay is estimated to be 1.0-1.5 years faster. [Note: these time lines are true in general and are not specific for fentanyl.]	
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	3) Norfentanyl inclusion as target analyte/cross-reactant for urine screening a)There are not any commercially available immunoassays for testing norfentanyl in urine (or oral fluid) specimens. b)Currently commercially available, FDA-approved fentanyl URINE immunoassays are calibrated against fentanyl with a 1.0 ng/mL screening cutoff and have <10% cross-reactivity to norfentanyl. c)Inclusion of norfentanyl in the federal URINE drug testing regulations with similar cross-reactivity for both fentanyl AND norfentanyl (i.e. >80% cross-reactivity) would require manufacturers to develop and validate new assays to fulfill those requirements; while also requiring new FDA submissions.	

Name	Company/Job Title	Comment	References
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	4) Fentanyl cutoff concentrations: SAMHSA-DTAB proposed cutoffs Urine Screen: •Fentanyl: 1.0 ng/mL •Norfentanyl: 1.0 ng/mL Urine Confirmation: •Fentanyl: 0.5 ng/mL •Norfentanyl: 0.5 ng/mL Oral Fluid Screen: •Fentanyl: 1.0 ng/mL Oral Fluid Confirmation: •Fentanyl: 0.5 ng/mL •The proposed cutoff of 1.0 ng/mL for urine testing is consistent with the current FDA-approved urine fentanyl immunoassays. However, as previously noted the current assays are targeting fentanyl, but have <10% cross-reactivity to norfentanyl. •Does SAMHSA propose controls be set at +25% and - 25% relative to cutoff for URINE and ORAL FLUID fentanyl testing? Controls set this close to the cutoff, presents analytical challenges when the cutoff concentration is as low as those proposed for fentanyl. •If the requirement for a minimum of eighty percent (80%) cross-reactivity for "grouped" analytes is applied for fentanyl/norfentanyl urine testing, implementation of fentanyl testing will be significantly delayed due to time required to develop, validate and obtain FDA 510(k) approval for such an immunoassay. •We would not support inclusion of norfentanyl in oral fluid guidelines due to its low prevalence in oral fluid (which is consistent with the current SAMHSA proposal). •The commercially available and FDA-approved buffered oral fluid collection system that meets DOT requirements utilizes a four-fold dilution with buffer resulting in a concentration that is twenty-five percent (25%) of the neat oral fluid concentration. If the neat oral fluid cutoffs are also 1 ng/ml (screen) and 0.5 ng/ml (confirm), then, after dilution with the buffer preservative solution, the screening and confirmatory assays may not be able to routinely satisfy all NLCP requirements (e.g., +/-25% QC, LOO at 40%) at the proposed cutoff concentrations.	

Name	Company/Job Title	Comment	References
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	•Oral fluid collected with a buffer-containing device would be further diluted than neat matrix for testing (i.e. 1 ml oral fluid : 3 ml buffer) which would make analytical performance for 1 ng/ml "neat" oral fluid cutoff challenging for immunoassay technology, since true testing cutoff would be 0.25 ng/ml for a sample collected with a buffer-containing device that has 1:4 overall dilution. Would SAMHSA consider a higher fentanyl oral fluid cutoff to enable development of an oral fluid assay that provides more consistent performance for routine lab testing? •Data from high-volume testing lab indicates that of 2648 oral fluid samples that tested positive for fentanyl via LC-MS/MS with 1.0 ng/ml LLOQ between 01- JAN-2023 thru 01-DEC-2023 •3.2% fell between 1.00 - 1.49 ng/ml •6.7% fell between 1.00 - 1.99 ng/mL •9.9% fell between 1.00 - 3.99 ng/mL •Additionally, having 0.5-1.0 ng/ml cutoffs for fentanyl in URINE and ORAL FLUID presents challenges for potential sample-to-sample carryover for routine testing when a negative sample is tested immediately after a high positive sample. Fentanyl concentration distributions have skewed towards higher concentrations during the ongoing fentanyl crisis (compared to 5-10 yrs ago). This is potentially due to tolerance from chronic fentanyl abuse that has arisen during the ongoing crisis. Therefore, a 1.0 ng/ml cutoff for fentanyl in oral fluid might be lower than necessary while increasing risk of confounding results.	
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	5) FDA approval: a.Currently, use of Employment & Insurance ("E&I") labeled assays are not permitted for federal drug testing programs according to FDA guidelines (i.e. FDA 510(k) approval is required). If E&I labeled assays were permitted for federal drug testing, the time-to-market for new assays would be reduced 1.0-1.5 yrs compared to 510(k) path. b.If norfentanyl is a required analyte for urine screening, the minimum timeline to implementation of SAMHSA-regulated testing in urine could be as long as 4 yrs after SAMHSA institutes guidelines for including fentanyl (and norfentanyl) in the mandatory testing panel, since development of new assay with >80% norfentanyl cross-reactivity and FDA 510(k) approval process would be required. Note: this delay for an appropriate urine assay would additionally delay oral fluid implementation, if fentanyl testing must be simultaneously deployed for both urine and oral fluid matrices. c.Additionally, manufacturers are concerned about investing in development, validation and FDA-approval of any new products without assurance that Department of Transportation will additionally act to update their regulations to mirror any changes to SAMHSA's mandatory panel, since the market for DOT-regulated testing is the largest market segment for regulated workplace testing.	

Name	Company/Job Title	Comment	References
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	6) Potential removal of MDMA/MDA from mandatory panel a.Although workplace prevalence data suggests that MDMA/MDA use is low and possibly suggests consideration for removal of MDMA/MDA from the SAMHSA mandatory test panel, other statistics indicate that MDMA/MDA use has plateaued for the past 10 yrs+ (and at similar or even higher prevalence than PCP). Additionally, numerous clinical research studies are in process for potentially using MDMA as part of PTSD or anxiety treatment, which may lead to higher levels of MDMA use/access than previously. Therefore, we would suggest that SAMHSA-DTAB continue including MDMA/MDA in the mandatory panel. •Reviewing the SAMHSA "National Survey on Drug Use and Health" over the past 10 yrs has indicated consistent ecstasy use over that time-frame. Respondents >18 yrs old; reporting any ecstasy use in the past year was 1.0 and 0.8% for 2012 and 2022, respectively. Meanwhile, PCP use statistics were similarly reported as 0.1% for any use during past year for 18+ yr olds for both 2012 and 2022. These data suggest that MDMA use is higher in the overall US population than PCP, suggesting inclusion of MDMA/MDA in the SAMHSA mandatory testing panel is relevant. •The NIH Clinical Trials (www.clinicaltrials.gov) currently lists 8 active MDMA clinical trials mostly evaluating MDMA use as part of treating PTSD or anxiety; with an additional 25 studies that have been recently completed. These clinical studies highlight ongoing interest in potentially using MDMA in clinical settings that may lead to wider MDMA use/access in the future that would make inclusion of MDMA/MDA in the mandatory testing panel valuable.	
Karl B. Scheidweiler	Abbott / Chief Toxicologist, Scientific Affairs	In conclusion, our major points for SAMHSA-DTAB's consideration are as follows: •We support inclusion of adding fentanyl testing to the mandatory testing guidelines for both URINE and ORAL FLUID •1 ng/mL cutoff for fentanyl in urine is consistent with FDA-approved urine screening assays •We'd propose urine screening for fentanyl only, but urine confirmation to include both fentanyl and norfentanyl •Would SAMHSA-DTAB consider an oral fluid fentanyl screening cutoff >1.0 ng/mL? •Would SAMHSA-DTAB support E&I-labeled immunoassays vs. current requirements for FDA 510(k)-approved immunoassays? E&I-labeling route would save 1.0-1.5 yrs for product delivery to labs. •We would recommend including ecstasy (MDMA/MDA) in both the urine and oral fluid mandatory testing panels.	

Name	Company/Job Title	Comment	References
Elizabeth Johnston-Owens	Abbott / DVP, US Workplace Toxicology	Dear Drug Testing Advisory Board: eScreen, Inc., a Subsidiary of Abbott, is a technology-enabled Third Party Administrator (TPA) that provides drugs-of-abuse screening and hiring program solutions for some of the nation's largest employers. eScreen also maintains a nationwide network of collection sites, digitally enabled to collect HHS-regulated samples, and partners with HHS-certified laboratories in processing millions of drug testing transactions each year. As an industry-leading TPA program, eScreen appreciates the opportunity to comment on the proposed changes to the drug panel. The following comments contemplate the potential impact of these changes on a variety of end users across the HHS-regulated market. As fentanyl becomes a more common drug of abuse, both intentionally and unintentionally, we support addition of fentanyl to the HHS panel at a cutoff that has scientific backing and practical applicability for testing. If fentanyl is added to the panel, we recommend that it be implemented concurrently for oral fluid and urine to prevent complexity of different panels for different specimen types. Further, we recommend the additional of fentanyl to the HHS panel only after oral fluid reagents can be created for the established cutoffs and certified in all applicable labs.	
Elizabeth Johnston-Owens	Abbott / DVP, US Workplace Toxicology	It is important to note that addition of fentanyl will add cost to the testing process and ultimately to those purchasing testing. For large organizations administering thousands of customers tests, there is additional cost relative to implementing the change across all systems and communication lines. For this reason, there should be careful consideration given to any compliance timeline associated with the final publication of any panel changes. Finally, we encourage the coordination of HHS and DOT panels to maintain a consistent approach for mandated testing and reduce complexity of program administration. We appreciate the Drug Testing Advisory Board giving careful consideration in the implementation of this change that will impact all those who interact with the Federal Drug Testing Program.	

Name	Company/Job Title	Comment	References
Aimee Halphen	Abbott / Director of Laboratory Operations	Dear Drug Testing Advisory Board: Alere Toxicology Services, Inc. (ATSI), a Subsidiary of Abbott, operates two forensic toxicology testing laboratories both of which are certified by the National Laboratory Certification Program. The laboratories detect drugs of abuse in oral fluid and urine by various screening teclmologies including ELISA, Homogenous Enzyme Immunoassays (HEIA ™), and SEFRIATM immunoassays. Confirmatory testing for both matrices utilizes either GC/MS or LC/MS/MS. ATSI appreciates the opportunity to comment on the proposed rulemaking. We have provided comments to the sections of interest or concern. Our comments are focused on our experience with the analytical processes and the interpretation challenges from a laboratory's perspective. The Secretary should include Fentanyl in the testing panel.	

Name	Company/Job Title	Comment	References
Aimee Halphen	Abbott / Director of Laboratory Operations	Due to the increase in prevalence of fentanyl, the laboratory believes that fentanyl and norfentanyl should be added to the analyte table. However, laboratory results are indicating that low concentrations (<2 ng/mL) of norfentanyl and sometimes fentanyl may be excreted in urine for months following chronic use (SOFT program S20). The referenced presentation at SOFT cited three previously published case studies, as well as five case studies from Redwood Toxicology that speak to the challenges of extended or residual elimination and consequent interpretation challenges. In Case # 1, norfentanyl was detected initially at 2.7 ng/mL and was still present at 0.8 ng/mL over three months later. Fentanyl was not detected in any of the collections. In Case #2, fentanyl and norfentanyl were initially detected at 410 and 1100 ng/mL and the donor was still positive one month later with levels at 3 .6 and 8.2 ng/mL, respectively. At 2 months, drug was still present at 0.90 and 2.4 ng/mL for fentanyl and norfentanyl. We have found the lack of controlled studies to cite in our client interpretation letters to be particularly challenging in our own labs, leading to frustration with our criminal justice clients when low reported levels cannot be definitively determined to be new use after several weeks of collections. While it is understood that passive exposure to fentanyl does not result in clinical toxicity, there are no controlled studies that indicate what low levels may be attributed to passive inhalation or accidental exposure, further complicating interpretation. Thus, reporting low levels for fentanyl and norfentanyl present various legal challenges and provide little information beyond donor use within the past month. Additionally, slightly higher cutoffs do not necessarily detract from the deterrent goal of drug testing. For these reasons, we suggest the Secretary take into consideration higher screening and confirmatory cutoffs than proposed. Additionally, the laboratory would recommend to proceed with only fentanyl in the screening requirement due to the current limitations of the commercially available reagents, as norfentanyl does not have the required cross reactivity. If both analytes are required this would cause a delay in implementation due to the reformulation and additional FDA review of the modified reagents to meet the proposed guidelines.	

Name	Company/Job Title	Comment	References
Aimee Halphen	Abbott / Director of Laboratory Operations	For oral fluid in the Quantisal device (which is I :4 in buffer), a cutoff of 0.5 ng/mL (0.125 ng/mL in solution) may not yield quality chromatography on many instrument platforms. Such low levels also increase the risk of contribution from carryover. For this reason, we again suggest a screening cutoff and confirmation cutoff greater than that currently proposed, taking into account the published case studies and interpretation and analytical challenges seen amongst all the laboratories submitting commentary. We also ask that the Secretary take into consideration the burden on the laboratories when HHS and DOT panel and cutoff changes are implemented in different stages. There is an undue and unnecessary financial and administrative burden associated with updates to infrastructure (i.e. LIMS changes) and processing in the lab. There is also the potential for conflicting and confusing client/TP A/collector/MRO communications from multiple HHS-certified labs. The Secretary should consider alternative cutoffs to those included in the Federal Register publication. A TSI would like to suggest raising the proposed screening and confirmation cutoffs for both matrices based on our experience with analytical challenges across multiple platforms and interpretation challenges among a variety of workplace and criminal justice clients. We believe that raising the proposed cutoffs still allow the addition of testing to decrease drug use by means of a deterrent program while avoiding some of the analytical and interpretive issues that may arise from the lower proposed cutoffs.	
Aimee Halphen	Abbott / Director of Laboratory Operations	The Secretary should not remove methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA) from the testing panel. The rarity of MDMA and MDA positives may be evidence that the testing is working to deter use. If MDMA and MDA are no longer included in the panel, individuals may pivot back to the use of these drugs. The laboratory believes that MDMA and MDA should be retained.	

Name	Company/Job Title	Comment	References
Michelle Alexander	Abbott / MRO	We are responding to the HHS and NRC request for public comment. Abbott Rapid Diagnostics/e-screen Medical Review Officer (MRO) group provided MRO review of approximately 212,236 HHS and 366,601 DOT tests in 2023. Our reported positive rate for these tests are 0.60% and 2.19% respectively. For MDMA under these authorities, the positive rate was very low but still we had positive test verifications. For this year we had 3 positive tests for MDMA under HHS and 9 positive tests under DOT. Federally regulated workplace drug testing programs have always been designed for drug deterrence and we believe this to be the reason for these low positive results. We support the addition of fentanyl to the drug testing panel but encourage that this addition be concordant for both urine and oral fluid when implemented. We recommend this addition for the following reasons: • Fentanyl is a frequent contaminant in many illicit drugs, particularly heroin, cocaine and more recently marijuana. • Fentanyl has become a drug of choice for heroin users because it is less expensive, more potent and can currently avoid most drug panels • Fentanyl is used in pain management and like other opiates can present concerns with safety and performance.	
Michelle Alexander	Abbott / MRO	We do not recommend the removal of MDMA as even with low levels of positivity its impact on safety and as previously mentioned the purpose of regulated drug testing is to deter use. Elimination of this analyte would have just the opposite effect on drug choice and deterrence. We would also encourage the addition of delta-8 THC to the existing panel, given the issues of safety and performance that the use of this drug presents since its legalization in many states and locales. We appreciate the Board's careful consideration of these comments and the impact of panel changes on the industry as a whole.	

Name	Company/Job Title	Comment	References
Dane Farrell	American College of Occupational and Environmental Medicine / Government Affairs Representative	SAMHSA Division of Workplace Programs (DWP), Please find attached comments from the American College of Occupational and Environmental Medicine (ACOEM) regarding adding Fentanyl to the analyte table (per 88 FR 71582). In short, ACOEM strongly recommends that SAMHSA add Fentanyl/Norfentanyl to the Urine and Oral Fluid Analyte Table for HHS Drug Testing Panels. As background, ACOEM represents Occupational and Environmental Medicine (OEM) physicians who promote optimal health and safety of workers, workplaces, and environments, and many of our members are Medical Review Officers (MROs). Please let us know if you have any questions and if we can be of any assistance.	

Name	Company/Job Title	Comment	References
Kenji Saito	American College of Occupational and Environmental Medicine / President	The American College of Occupational and Environmental Medicine (ACOEM) appreciates this opportunity to comment upon the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board's (DTAB) discussion and consideration of the possible addition of Fentanyl to the Urine and Oral Fluid Analyte Table.1 ACOEM strongly recommends that SAMHSA add Fentanyl/Norfentanyl to the Urine and Oral Fluid Analyte Table for HHS Drug Testing Panels. Founded in 1916, ACOEM is the nation's largest medical society dedicated to promoting employee health through preventive medicine, clinical care, research, and education. The College represents Occupational and Environmental Medicine (OEM) physicians and other healthcare professionals devoted to preventing and managing occupational injuries and exposures. The specialty of OEM focuses on diagnosing and treating work-related injuries and illnesses and ensuring that workplace environments are safe for workers. It is the medical field that concentrates on the impact of work on health and the impact of health on the ability to work. The College is in a unique position to reach American workers in various settings, given that our members are employed at hospitals and clinics, colleges and universities, large corporations, factories and industrial sites, law and safety departments, government agencies, the military, etc. Our organization's membership consists of many physicians who are Medical Review Officers (MRO), who are keenly aware of the problem of synthetic opioid abuse and misuse and its subsequent concerns with the safety of workers who are inappropriately using these drugs. The uptick in detection of Fentanyl in non-regulated workplace testing specimens from pain management patients, overdose cases, and driving under the influence of drugs (DUID) cases is alarming, and we support SAMHSA's endeavors to fight against opioid abuse. As you know, opioid abuse and overdoses resulting from that abuse permeate workplace settings, which can potentially lead to catastrophic outcomes for individuals, their co-workers, the public safety and the environment. Appropriate testing is a critical tool involved in managing and ultimately mitigating risks of impairment and opioid abuse in workplace settings, which is a particular concern as it	

Name	Company/Job Title	Comment	References
Kenji Saito (cont.)	American College of Occupational and Environmental Medicine / President	relates to employees engaged in safety-sensitive work. Based on analysis from the National Safety Council, unintentional workplace overdose deaths from nonmedical use of drugs or alcohol have increased 536% since 2011. Overdose deaths totaled 464 in 2021, equivalent to nearly 9% of all occupational injury deaths in 2021. Increases have been experienced among all employee demographics, industries, and occupations.2 Opioids are the leading cause of these deaths. As noted in the Federal Register notice, Fentanyl accounts for a large proportion of overdose deaths in the United States. These trends are a call to action for SAMHSA and all Federal agencies to take actions within their authority to address this growing epidemic infecting workplaces and beyond. We are particularly supportive of this proposed addition, given the potential for revisions to positively impact the U.S. Department of Transportation's (DOT) testing program under 49 CFR Part 40, should DOT decide to promulgate a rulemaking on this matter. Updating HHS scientific guidelines will allow DOT to rely on contemporary evidence to ensure its regulated drug testing laboratory procedures are up-to-date and reflective of current challenges our country and workplaces are facing regarding opioid abuse. ACOEM is prepared and willing to work with SAMHSA to advance this issue and provide additional support for adding Fentanyl/Norfentanyl to the Urine and Oral Fluid Analyte Table for HHS Drug Testing Panels. On behalf of ACOEM, I would like to reiterate our support for SAMHSA and the Drug Testing Advisory Board's attention on this issue. Thank you for considering ACOEM's recommendations. Please do not hesitate to contact Dane Farrell (Dane@cascadeassociates.net), ACOEM's Government Affairs Representative, with any questions.	

Name	Company/Job Title	Comment	References
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	Dear DWP / SAMHSA, We appreciate the opportunity to comment on the potential addition of Fentanyl and the removal of MDA and MDMA to the Authorized Drug testing panel. Attached please find our formal comments and if you have any questions, please do not hesitate to reach out either by email or phone. The following are the comments of Quest Diagnostics Incorporated (“Quest Diagnostics”) on the Proposed Revisions to the Authorized Drug Testing Panels for Urine and Oral Fluid to add fentanyl and (for urine) norfentanyl, and to remove MDMA and MDA. For informational purposes, Quest Diagnostics annually performs more than ten million urine, oral fluid, and hair workforce drug tests. Of these tests, more than two million are Federally mandated to be tested through the Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratories.	

Name	Company/Job Title	Comment	References
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	Part 1 – Proposed Revisions to Authorized Drug Testing Panels for Urine and Oral Fluid to add fentanyl and (for urine) norfentanyl with the following proposed cutoffs Urine Analyte Fentanyl - (initial test cutoff) 1 ng/mL; Conf Cutoff - 0.5 ng/mL Norfentanyl - (initial test cutoff) 1 ng/mL; Conf Cutoff - 0.5 ng/mL Oral fluid analyte Fentanyl - (initial test cutoff) 1 ng/mL; Conf Cutoff - 0.5 ng/mL I. General Comments on Adding Fentanyl urine and oral fluid Authorized Drug Testing Panels Based on Quest Diagnostics' Drug Testing Index (DTI) and recent drug usage trends in the United States, there is a need to add testing for fentanyl in both urine and oral fluid. Data presented in the 2023 Quest Diagnostics' DTI, indicated fentanyl positivity in the general US workforce of 0.13%, 0.14% and 0.17% over the last three years (2022, 2021, and 2020, respectively). This Quest DTI data, along with positivity rates published from other testing populations indicating higher positivity rates (e.g., drug monitoring, medical professional monitoring, etc.), points to the need to test for fentanyl and/or norfentanyl. A more general comment, which would apply to any change and not specific to those being addressed here in, is that unification of changes across testing agencies (i.e., HHS & DOT) allows laboratories to perform testing more easily and efficiently. If these agencies are not aligned and differences occur in the laboratory based on requirements of specific testing agencies, then this creates inefficient processes within the laboratory. These inefficiencies translate directly into increased testing costs for both the laboratory and employer/client.	

Name	Company/Job Title	Comment	References
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	II. Urine Drug Initial Testing/Screening and Confirmation Testing Current cutoffs provided by existing urine fentanyl immunoassay kits and laboratory validated confirmation assays in the industry have not been established based on workforce drug testing data. Furthermore, using such low cutoff levels, there could be a concern of other exposure routes that are currently not well-studied or documented. While the potency of fentanyl, and related analytes require low detection levels, additional supporting data and/or studies are needed to provide better scientific support for the final cutoffs and for potential legal defensibility purposes. For urine-based testing, the market is well-established with FDA-compliant screening reagents and the ability to achieve the cutoffs specified for fentanyl. However, if the requirement is to screen for fentanyl and norfentanyl, there are a number of issues: •Screening for two related analytes as such would create an inefficient workflow that would add to the cost of testing. Such a process would be difficult for laboratories and should not be the requirement for the reporting of the parent drug and a related metabolite. •There are no specific immunoassay kits that screen for fentanyl with adequate cross reactivity with norfentanyl. The cross-reactivity of many, if not all, immunoassay screening kits on the market today do not meet the required 80% cross-reactivity for norfentanyl. •There is a concern over the required controls for the immunoassay kits on the market today. Currently, the kits require ±50% controls and if the requirement, similar to other regulated immunoassay testing, is for controls at ±25%, then it would differ from the FDA-cleared controls that are provided with the kit. In the end, the accuracy and precision of these kits with controls at ±25% of cutoff is unknown and would need to be tested/studied.	

Name	Company/Job Title	Comment	References
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	III. Oral Fluid Drug Initial Testing/Screening (a) Screening by Immunoassay Depending on the final approved oral fluid collection device, an FDA-compliant screening assay would need to be developed since it does not exist on the market today. If an immunoassay is the path forward, then it would seem too early to set a cutoff without having a product(s) on the market that can achieve these limits. (b) Alternative Mass Spectrometry (MS) Screening To achieve this goal without an available immunoassay, it would necessitate laboratories to develop alternative mass spectrometry-based screening technologies. Unfortunately, this would create a burdensome process that could potentially require the procurement of advanced mass spectrometry instrumentation and increased cost for the laboratories. As both productivity and materials costs increase, this could potentially increase the cost for the employer/client and/or decrease the adoption rate of oral fluid drug testing within the industry.	
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	IV. Oral Fluid Confirmation Cutoffs Most oral fluid collection devices utilize a buffer preservative and are therefore diluted. For Quest Diagnostics Workforce Health Solutions (formerly Employer Solutions), the Quantisal collection device utilizes a 1:4 dilution. Consequently, with a 0.5 ng/mL in neat oral fluid (0.125 ng/mL diluted) cutoff and with the requirement of a 40% control, an instrument must be able to detect down to 0.2 ng/mL in neat oral fluid (0.05 ng/mL diluted). Based on good laboratory practice to ensure a robust assay, the instrument limit of quantitation (LOQ) would need to be lower than 0.05 ng/mL diluted oral fluid. While there is published data to potentially support these cutoffs, laboratories may have some challenges in achieving these limits consistently due to the dilutions in the oral fluid collection device(s).	

Name	Company/Job Title	Comment	References
Suhash Harwani	Quest Diagnostics / Sr. Director, Sciences	Part 2 – Removal of MDMA/MDA from HHS Drug Testing Panels The Quest Diagnostics Drug Testing Index (DTI) indicates MDMA/MDA positivity ranging from 0.002% - 0.003% over the last 5 years (2018-2022) in the Federally mandated safety-sensitivity testing population. This positivity data suggests that there are roughly 70-100 positive specimens reported by Quest Diagnostics annually in past years with little to no decline. Data from the Federal Motor Carrier Safety Administration (FMCSA) clearinghouse also indicates similar low positivity. Knowing that workforce drug testing is focused on promoting safety and preventing accidents, the question that needs to be answered before deciding to remove MDMA/MDA is, what level of positivity is acceptable for an illicit substance? While MDMA/MDA does have the lowest positivity percentage compared to other drugs in the current authorized drug testing panel, the removal could allow for increased abuse that would remain unmonitored if removed from the panel. Additionally, laboratories may have to perform supplemental validation studies for confirmation methods related to Amphetamines if the laboratory's current method also includes the acquisition of MDMA and MDA. This would be dependent on the implementation of the confirmation workflow in each laboratory. If this is no longer allowed as part of the testing panel this could create additional work for a laboratory—unless an exception is granted to continue with their existing workflow (if needed).	