Addressing the Public Health Effects of Opioid Medications

Hybrid Meeting
September 09, 2026 | 12:30 – 4:30pm (e*astern*)

Transcript Part 2

Public Comment:

Moderated by Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler:

We'll transition to the public comment period. This requires a fair amount of stage management. So bear with me as we move into and discuss the way that we will approach public comment today. And in particular, I'm going to remind the folks who are virtual that this will actually be true for our virtual public commenters [00:00:30] and our folks who are in person. I'm going to give you a rolling cue of who it is that we will hear from.

We are organizing public comment by topic area, and we're going to begin by those who requested the opportunity to speak to the first topic. As a reminder, the first topic is scientific evidence regarding conditions of use, safety concerns, or benefit risk assessment, including consideration of the public health effects of opioid medications. So [00:01:00] let me give the heads-up to the first three who will be providing public comment in this, and then I will explain why I'm calling your name.

So our first three will be Amy Applebaum, Ashley Berryessa, and Kaylin Bower. So I will call those three names in that order. As I introduce each commenter and then I list the next three, here's what you need to listen to.

When I first say your name and you're joining us virtually, look for the Zoom prompt to [00:01:30] become a panelist. The second time you hear your name, prepare to deliver your remarks. So be prepared to unmute and turn on your camera. When the speaker before you completes their remarks, turn on your camera, unmute your microphone and wait for my introduction. Our producers will bring you on screen as you are introduced, and you will have up to two and a half minutes to comment. If you do not begin speaking within 10 seconds of my turning the virtual stage over to you, we will move to the [00:02:00] next commenter.

If time allows, we'll circle back and pick you up at the end of the section's virtual commenters. You have a countdown clock displaying on screen showing the time you have remaining. And so monitor that. When we get to the two and a half minute mark, we'll end your audiovisual support and move to the next public commenter.

The approach is quite similar for our in the room commenters. We'll ask you to use the podiums on the stage. [00:02:30] Staff will help direct you to which podium you should approach. When you hear your name the first time, make your way to the front of the room by the wall. And then we will put you to the

podium when I call your name the third time. As a reminder, no one from the foundation or the FDA will be responding to any of the comments. We are here focused on listening.

Public Comment:

Topic 1: Scientific evidence regarding conditions of use, safety concerns, or benefit-risk assessment (including consideration of the public health effects) of opioid medications

Susan C. Winckler:

So let's turn to topic number one. As a reminder, our first three commenters are Amy Applebaum, [00:03:00] Ashley Berryessa and Kaylin Bower. I'm going to turn now to Amy Applebaum and note that Ashley Berryessa, Kaylin Bower and Carolyn Concia are in the queue. Commenter Applebaum, if you are present, please turn on your camera. I see you at least. And please proceed.

Amy Applebaum:

Good morning members of the FDA and the Reagan-Udall Foundation. My name is Amy Applebaum. I'm speaking today as a long-term chronic [00:03:30] pain patient who is opioid stable. I am here to address a parallel public health crisis that is often ignored, the severe collateral damage inflicted on compliant suffering Americans in the wake of the nation's opioid scandals.

While I understand the critical need to curb illicit drug use and corporate misconduct, the pendulum has swung too far. The regulatory fallout from these scandals has perpetrated a second [00:04:00] tragedy, this time against legitimate pain patients. I live with several very serious diagnosed medical conditions. My need for opioid therapy has been consistently proved and documented by my doctors.

I am stable. I follow the rules and this medication is what allows me to maintain a basic quality of life. Yet every single month, I am met with terrible headwinds just trying to fill a valid prescription. It has become almost impossible to [00:04:30] access my medication without experiencing immense difficulty, delays, and suspicion.

We are facing severe pharmacy shortages, terrified doctors, and bureaucratic red tape that treat patients like criminals rather than people in pain. We are suffering deeply because of these artificial barriers. My medication is not a luxury. It is a medical necessity.

When the FDA adjusts demand forecasting, supply quotas [00:05:00] or prescribing guidelines, you must remember that blunt cuts do not just stop misuse. They cut off stable, responsible patients who rely on these therapies to survive. I urge the FDA and the Reagan-Udall Foundation to establish clear protected pathways for long-term stable pain patients.

Do not let regulatory overcorrection punish the very people the medical [00:05:30] system is supposed to protect. Please ensure that our access is safeguarded and that we can receive our treatment without this agonizing difficulty. Thank you for your time.

Susan C. Winckler:

Thank you. Our next comment will be from Ashley Berryessa. In the queue, we have Kaylin Bower, Carolyn Concia and Todd Davies. Commenter Berryessa, I see you. Please proceed.

Ashley Berryessa:

Excuse me. Hello and thank you for your time today. My name is Ashley. I have [00:06:00] Dercum's disease, which is a super rare disease that causes painful tumors to grow in the adipose tissue causing severe chronic pain. I was one of many patients who were taken off of stable pain medications due to fear and stigma.

I was once able to live a full life due to treatment and now I'm unable to work and contribute to my family, excuse me, and I'm suffering. I do want to preface that I do agree that there needs to be oversight with medications, [00:06:30] and I also believe in proper addiction treatment. However, the harm from medically appropriate opiate treatment being tapered, taken away and stigmatized is immense.

People that live in chronic pain are being treated with suspicion instead of compassion. I cannot tell you how many people I see in online forums that are giving up, are frustrated, are being treated as a drug seeker, are being dropped from care suddenly and are considering ending their lives. Treating people with rare disease, spinal injuries, nerve conditions [00:07:00] as if they deserve to be in pain is horrific.

This is leading to a huge lack of trust in our doctors and is leading to doctors directly harming their patients. The fear of potential addiction should not compromise effective treatment of pain. We should be working to enhance the doctor-patient relationship, provide more education for proper pain management and to help people in pain, not punish them for having it.

So imagine the worst pain you've ever had. [00:07:30] Now imagine that pain never stops. You're depressed, isolated, bedbound, and considering suicide. Now imagine you go to your doctor and you beg for help, and you are told that the risk of you possibly becoming addicted outweighs the benefit of treating your pain.

You are left to suffer. That is what is happening to people. We need to remember that the opioid is a medicine. It is not a drug. Prescribed opioid medication is not [00:08:00] the cause of the crisis we currently have on our hands and we all know that.

Untreated pain is causing millions of patients to commit suicide. There is a serious crisis right now in the chronic pain community. Currently, the focus is finding the addiction, but we're not thinking about the patients without addiction who are currently suffering greatly.

The overdose rates have gone up. We need to separate pain patients from addiction patients. They require completely different approaches. Thank you.

Susan C. Winckler:

Thank you. Our next commenter is [00:08:30] Kaylin Bower. Then in the queue we have Carolyn Concia, Todd Davies, and Raoul Estrada. Commenter Bower, please proceed.

Kaylin Bower:

Hi, I'm Kaylin Bower. Thank you for allowing me to speak today. I am a patient living with stage four endometriosis and the chronic pain that this condition entails. For me, pain isn't an abstract statistic. My disease can cause episodes of severe and extremely debilitating pain requiring many emergency room [00:09:00] visits.

I have tried other medications that are routinely prescribed as alternatives to opioids. They did not work for me. They did not adequately control my pain, and I ended up still having immense suffering and excessive numbers of ER visits for pain management.

My appropriately prescribed opioid medication does control the pain of these episodes for the most part and has significantly decreased the number of emergency room visits that I have had and currently have. However, [00:09:30] it was very, very difficult to access, almost impossible.

There is an important difference between saying that opioids carry risks and saying that every patient has an equivalent alternative because I do not. The evidence I am submitting today also challenges some of the assumptions underlying our approach to opioid prescribing. A review of the available literature cited in my materials estimated the risk of abuse or addiction in chronic pain patients using opioids at only 3.3%, [00:10:00] but among patients without a current or previous history of abuse or addiction, the estimate was only 0.19%. Aberrant drug-related behavior fell from 11.5% to 0.6% when patients with a history of abuse or addiction were excluded. Another review found that carefully diagnosed addiction rates averaged less than 8% in published studies.

These numbers don't mean that opioids are risk-free, rather they mean risk must be assessed [00:10:30] in the individual patient rather than assuming every pain patient presents the same risk or will go on to become an alleged addict or substance use patient. The main driver of the opioid overdose epidemic crisis has been synthetic opioids, primarily fentanyl, now mixed with even more deadlier substances such as medetomidine and nitazene.

It is not prescription opioids used responsibly and carefully by pain patients [00:11:00] that need access to this medically necessary treatment that are driving the opioid overdose epidemic. This narrative is harmful to pain patients such as myself and must stop. Thank you.

Susan C. Winckler:

Thank you. Our next commenter is Carolyn Concia. In the queue, we have Todd Davies, Raoul Estrada, and Chad Kollas. Commenter Concia, please proceed.

Carolyn Concia:

Hi, thank you for the opportunity to speak. My name is Carolyn Concia. I'm a geriatric and [00:11:30] palliative care nurse practitioner and a PhD student at the Catholic University of America in Washington, DC.

I just completed my research study. It focused on opioid tapering in older adults with chronic pain. I'm happy to share my results with you if time allows. I was asked to speak on the scientific evidence

regarding conditions of use, the safety concerns or benefits, sorry, benefit risk assessment of opioid medicines. [00:12:00] Scientific evidence shows that the conditions of use for opioid medications strongly determine outcomes, stable dosing, appropriate monitoring, access to supportive care can improve function and reduce harm. And I think Dr. Compton was saying we need something better than a one to 10 scale. Participants in my study all agree and maybe we can develop a scale that has to do with quality of function because the participants in my study when their opioids [00:12:30] were tapered, their quality of function absolutely took a nosedive.

Safety concerns arise from abrupt dose disruptions, co-prescribing without monitoring, system level barriers, especially with insurance companies perhaps reducing reimbursement for alternative interventions. What are patients to do if there aren't any prescribers to prescribe [00:13:00] opioids and there is less reimbursement for interventions? I worry that there won't be any place for them to get pain relief.

So patients with severe chronic pain, many patients with chronic pain don't achieve meaningful relief from non-opioid therapies or even interventions. I believe that there's a subset of the population out there who respond well to long-term opioid [00:13:30] therapy. Yet policies that are designed to eliminate illicit opioids have unintentionally suppressed prescribing of all opioids, and it blurs the line between medically supervised therapy. And I know my time's up. Thank you so much for allowing me to speak.

Susan C. Winckler:

Thank you. Our next comment will be from Todd Davies. In the queue we have Raoul Estrada, Chad Kollas, and Sara Lewis. Commenter Davies, please proceed.

Todd Davies:

[00:14:00] Good afternoon and thank you for the opportunity to comment. I'm an addiction researcher and would like to reinforce the importance of comments from Dr. Compton and Dr. Atkinson on the need to develop more appropriate outcome measures. I believe it is important to understand that the public health effects of opiates depend not only on the medication itself, but also on formulation, route of administration, treatment settings, and the outcomes we choose to measure.

Now two and a half minutes is not enough for me to discuss specific measures, but I want to give an example [00:14:30] from addiction, although the need for improved measures are equally important for pain patients. Long-acting injectable buprenorphine formulations, for example, were developed to address limitations associated with daily dosing and may improve medication adherence, yet some real world evidence suggests lower treatment retention among patients receiving injectable formulations compared to sublingual treatment. The critical question is how do we interpret that finding?

Treatment retention has become one of the most commonly used indicators of success in addiction treatment, but is ultimately [00:15:00] a surrogate endpoint. It tells us whether someone remained in treatment, but it does not necessarily tell us whether their health improved or if they achieved greater independence or if they have experienced meaningful recovery. It's possible that lower retention reflects different recovery trajectory rather than a poor outcome, but our current measures are not well-suited to answer that question.

Opioid research and policy discussions frequently emphasize short-term outcomes and severe adverse events. These outcomes are critically important and must remain central to safety evaluations. [00:15:30] However, they do not fully describe the long-term experience of much of the larger population exposed to opioid therapies, and these ineffective measures can often lead to much of the stigmatization conveyed by many of the patients here. The HEAL Initiative was appropriately emphasized, the importance of standardized outcomes, the impact initiative recommended moving beyond pain intensity alone, incorporating broader measures of patient outcomes.

But despite these efforts, we still lack widely accepted clinically actionable [00:16:00] measures capable of distinguishing meaningful long-term benefit from meaningful long-term harm across diverse opioid treatment settings. Such measures should be developed in conjunction with treatment program evaluations, new uses of approved medications or any regulatory changes. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Raoul Estrada. In the queue, we have Chad Kollas, Sara Lewis, and Denise Zecca-George. Commenter [00:16:30] Estrada, please proceed. You appear to still be muted. If you unmute, we will be able to hear you.

Raoul Estrada:

There we go. Sorry about that. I'm Dr. Raoul Estrada from Merced, California, and good morning and good afternoon to those around our country.

This pandemic does cause a lot, not just on those that are in need, but those around [00:17:00] the world. Some look for just a quick fix, many are in need. Just in 2020 to 2023 peak, approximately 105,000 total deaths on drug overdose and 80,000 of those were caused by opioids, just 76%. From Alabama all the way down to Wyoming and in our DC, many of them I have written [00:17:30] multiple times throughout the past six years trying to figure out how I as an individual could help. Many have never written me back or tried to contact me. A lot of them tell me it's not their jurisdiction, but yet they like to ask for handouts and a donation. They are those who represent us, but they don't want to do the work to help us.

I don't consume any type of drugs or alcohol because I let my body fight it off. But those [00:18:00] in need, many do abuse it, many actually use it to what the doctors prescribe, but I've never really seen a research to where many ask for a lower dose or a minimal amount of medication. It's always about a higher dose and more prescription.

The time that it takes to make a medication and sell it is, what, [00:18:30] cents on the dollar that they could tax the taxpayer anytime they feel like. And I don't think that's right. I mean, there are a lot of people in need that don't know where to turn to, but there are organizations that they put out there, but many refuse that because they think it's not going to help. But they don't take that time because it's the mindset, the mentality of wanting to get better.

But again, thank you for this time, and I just hope that our government [00:19:00] does wise up about this pandemic and many others that are happening around our country. Because again, we're a big

team. If one fails, we all fail. One succeeds, we all succeed. United, we stand, and I hope our three branches of government understand this, and thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Chad Kollas. Then our last two virtual commenters in this section will be Sara Lewis and then Denise Zecca-George. We'll then move to in-person public comment hearing first [00:19:30] from Adriane Fugh-Berman. So Commenter Kollas, please proceed.

Chad Kollas:

Thank you. Good afternoon. I'm Dr. Chad Kollas, and I'm a palliative care physician in Orlando, Florida. I'm testifying as an individual to correctly contextualize the benefits and risks of long-term opioid therapy. My disclosures and a few key references are pictured.

Americans are suffering from dual epidemics of undertreated pain and non-medical opioid [00:20:00] use, but federal opioid policies broadly reduce prescribing of opioid medications, harming patients and causing problems in the sphere of opioid policy. Unfortunately, opioid policy experts involved in creating some of this federal policy had disqualifying conflicts of interest, and a lot of the policy that arose served litigation against opioid manufacturers and distributors rather than serving the public. There are two false narratives [00:20:30] at work right now in the country, and one is that overprescribing is the cause of the opioid crisis, and the other one is that there's insufficient evidence for long-term opioid therapy to treat chronic pain.

Both of these false narratives were useful in supporting opioid lawsuits, but neither reflect clinical reality. One of the earlier speakers mentioned the AHRQ review upon which the CDC's federal opioid guidance was based. That review didn't account for populations most likely to benefit from opioid therapy, [00:21:00] and it was written by an author with hidden and disqualifying conflicts of interest who later admitted those publicly.

There are methodological problems with looking at long-term opioid therapy and that long-term randomized controlled trials deprive controlled participants of a potential therapeutic benefit, and that's unethical. Current benchmarking for opiate effectiveness is ableist and depends upon a cure recovery-based model of illness that ignores the realities of serious illness. There is evidence for long-term opioid therapies. [00:21:30] Large EERW trials have shown about a third of patients with chronic non-cancer pain benefit from long-term opioid therapy, and perhaps that's why opioid reductionists have asked the FDA to eliminate that methodology in different hearings that the FDA is held in April 2023 and May of 2025.

Our research at Orlando Health has shown that palliative care patients who receive long-term opioid therapy can achieve 50% reductions in pain intensity that are durable over four years, have improvement in their performance status, and [00:22:00] overall reduction in their overdose risk scores. FDA must re-examine long-term opioid therapy, and its medically legitimate role through the lens of serious illness. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Sara Lewis. In the queue, we have Denise Zecca-George, and in the queue in person, we have Adriane Fugh-Berman and Douglas Smith. Commenter Lewis, please proceed.

Sara Lewis:

Hello, my name is Sara Lewis. I'm here today on behalf of Arachnoiditis United, [00:22:30] here as a disabled patient, as well as an inactive nurse and here for a number of patients that were unable to partake today. I originally came here to tell FDA and everyone about my sad story about how I was injured with a spinal cord injury at age 26, having my son thinking that it would pull on the heartstrings, make it seem like I'm an actual human being to all of y'all.

But then I learned that [00:23:00] the FDA had already had hearings just like this for the last decade, hearing over 2,500 comments alone in 2018. Thousands responded asking for help in change. That was nearly a decade ago. So we're talking about 2018, '19, '20, '21, '22, '23, '24, '25, '26. Do y'all follow what I'm saying? So thousands of comments over the years.

Where did all [00:23:30] of that information go? What did you guys measure from it? What changed? And how is this meeting going to be any different?

We all know opioids have risks because all medications have risks. Providers weigh the risk against the benefit of the medication for each patient. That is called individualized pain care. So where is the other half of the equation? Have you measured what happens to people [00:24:00] when effective treatment is taken away? Where are you tracking the patients who lose function, end up hospitalized, become desperate enough to turn to unsafe measures, die, commit suicide from a lack of ongoing, compassionate, palliative pain care?

You say no one should be forced, tapered or abandoned. However, we have been coming to you for a decade nearly [00:24:30] and nothing has changed. So I'm here today asking what are you guys going to do to make actual changes?

We can't come back here in another decade to have the same conversation. Humanity deserves humane care, and it should be standard of care to have humane care. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Denise Zecca-George, then we'll turn to in-person comment from Adriane Fugh-Berman [00:25:00] and Douglas Smith, and then we will turn to topic two. Commenter Zecca-George, please proceed. Commenter Zecca-George, Denise Zecca-George, if you turn on your camera and unmute your microphone, please proceed.

Denise Zecca-George:

Yeah. Okay. Thank you. Good afternoon. As both a caregiver and a patient, I appreciate the opportunity [00:25:30] to share this important data with the panel today.

I am one of the over 18 million Americans who live with high impact chronic pain. There seems to be a dangerous misconception amongst our doctors, regulatory bodies, and the general public that prescription opioids inherently carry a high risk of addiction for every patient who takes them. In fact, opioid risk varies with dose and comorbidities.

An international [00:26:00] study has concluded that out of the 91.8 million patients whose pain is properly mitigated with opioids, only 2.1% will ever develop opioid use disorder or OUD. A 2024 study of over 4.3 million patients concluded that roughly 90% of chronic pain patients do not develop clinical OUD or any dependency. To put this into [00:26:30] perspective, the annual mortality associated with high dose opioid therapy is one quarter of 1%. That statistic is comparable to the risk associated with chronic blood thinner use in stroke prevention.

Another dangerous misconception is that broad restriction of opioid pain medicine is a noble and effective public policy done for the greater good. The reality is that the numbers simply don't bear that out. [00:27:00] One in four chronic pain patients consider suicide when opioid pain treatments are withheld or withdrawn. Access to well-managed opioid pain medication is essential in providing humane medical care.

In closing, remember that sound public health policy should target misuse and high-risk prescribing. Sound public health policy should never make appropriate opioid access collateral damage [00:27:30] for the overwhelming majority of pain patients who will never develop opioid use disorder. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Adriane Fugh-Berman. Then in the queue, we have Douglas Smith for this topic and we'll return to virtual commenters in topic two with Tony Collins and Anne Fuqua. Commenter Fugh-Berman, please proceed.

Adriane Fugh-Berman:

Good afternoon. I'm Adriane Fugh-Berman. I direct a rational prescribing project called Pharmed Out at Georgetown University Medical Centers. [00:28:00] A few points to consider. Overprescription of opioids, especially among oral surgeons who are the highest prescribers of adolescents who are very likely to get addicted, is still a major public health practice that contributes to the epidemic of opioid use disorder.

Prescribers and patients and many people in this room continue to believe that opioids are our best pain meds, but many studies show that NSAIDs are as effective or even more effective than opioids, even for severe acute pain. Clinicians often prescribe [00:28:30] opioids when we should have given NSAIDs and reducing new opioid prescriptions reduces the risk for OUD. Federal agencies should take care not to inadvertently foster inappropriate prescribing by underplaying harms.

For example, the study cited in FDA's July 2025 drug safety communication cites separate risks for addiction, abuse, and misuse. The slicing and dicing plays into the opioid industry's hands because it minimizes perceived harms rather than subcategorizing [00:29:00] these risks. The FDA and other agencies should cite the incidence of opioid use disorder, a broader category.

Regarding the FDA's draft guidance on opioid analgesic drugs, please rethink risk evaluation and mitigation strategies. Industry-funded education always contains marketing messages, and my own research team has specifically documented numerous covert marketing messages in the Opioid Analgesic REMS program that promote rather than [00:29:30] discourage opioid use. Any education on opioids must be completely independent from industry, including using only CME companies and faculty that receive no industry funding.

Although the draft guidance contains appropriate warnings about long-term opioid use, it should also specify that opioids are generally ineffective for chronic pain. Opioids are also overused for acute pain. The answer isn't always new drugs. Sometimes stop ignoring classic drugs, NSAIDs, IV [00:30:00] acetaminophen and combinations of analgesics are often equivalent to opioids, even for kidney stone pain.

There's numerous studies on this and they have far fewer adverse effects, both acute and chronic. A multimodal approach to acute pain often avoids opioids. In conclusion, opioid prescribing is still too high. Opioid manufacturers are invested in reducing perceptions of harm and government agencies should take care not to contribute to watered down warnings on opioids.

Susan C. Winckler:

Thank you. Our final comment [00:30:30] in this section will be from Douglas Smith. Then we will turn to topic number two. In the queue, we have Tony Collins, Anne Fuqua and Nazia Fiazi. Commenter Smith, please proceed.

Doug Smith:

Thank you. Thank you FDA for this opportunity to speak. My name is Dr. Doug Smith. My background is emergency medicine. Four years ago, we presented overwhelming scientific evidence to this FDA that the opioids were causing genetic damage, a type of genetic damage known as methylation.

Associated with this methylation was a poisoning from [00:31:00] the adrenal glands, adrenal toxicity. The American Heart Association data right here is showing that from 2011 to 2023, four million people have died from this adrenaline toxicity and yet the FDA still has not recognized the methylation as a result of the opioids. This methylation can be inherited.

It is believed to be causing developmental delays in autism in the children. The deaths from the adrenaline toxicity is why your overdose deaths have gone down and the passing the gene down [00:31:30] to the children is why your autism rates have gone up. Dr. Rigoberto Roca here at the FDA has buried our data for four years and prevented us from doing further research.

So we did the only thing that made sense. We went out and developed our own DNA test. We developed a DNA test for the damage from the opioids. This DNA test will tell you whether or not you are an opioid addict or whether you were genetically damaged by the opioids. The beauty of this DNA test is that it resets the clock on the statutes of limitations, which means [00:32:00] you do the DNA test, you show you have genetic damage, you can go back and file a mass tort lawsuit against the opioid manufacturers and distributors.

And to the tort lawyers who see this, okay, the type of DNA test that we did, this is what's called biomarker of exposure. Now what that means is it means the day that you file the mass tort lawsuit, you have won because there is no known legal defense [00:32:30] for a biomarker of exposure. Thank you.

Public Comment:

Topic 2: Input on FDA's regulation of opioid medications

Susan C. Winckler:

Thank you. That concludes our comment for Topic 1. We'll now proceed to Topic 2, which is input on FDA's regulation of opioid medications. The commenters in queue are Toni Collins, Anne Fuqua, and Nazia Fyazi. I do want to explain, we offered each public commenter the opportunity to submit a slide that would be displayed alongside their remarks, and some chose to do [00:33:00] so, and some did not. So that's the disparate in some having slides and some not having slides. Let's turn to Topic 2, input on FDA's regulation of opioid medications.

Commenter Collins, if you are ready, please proceed.

Toni Collins:

Hi, everybody. Thank you for having me again this year. I had a whole speech ready to go, and I listened to some of the previous commenters, and I decided to shake [00:33:30] things up a bit.

So one of the things that patients are constantly feeling is being shoved aside. We are facing guidance that is being used as hard limits, MME in particular. Everywhere we go, MME limits are used as hard law, hard rule, and every clinic is constantly undertreating patients. Many patients don't need opioids. Many patients do. One of the main [00:34:00] factors that goes into this is we've got to get back to individualized healthcare again. Policy is overshadowing healthcare. It's overshadowing patients feeling like they are someone who matters, that their conditions matter. It's frustrating.

I've been dealing with chronic pain for over 30 years now because of a sports injury. I have tried and failed everything out there. I currently [00:34:30] have a pain pump, and I'm actually getting back to my life again, slowly but surely. I do feel that cognitive behavioral therapy is just as important as physical therapy. I feel like we have to open our options to what our conditions can be treated with, but our doctors are afraid.

How do we fix that? How do we fix patients feeling like criminals when they have to sign pain contracts, [00:35:00] go in for pill counts, urine drug screenings? It makes a patient who is seeking relief from a medical condition feel like they don't matter. Yes, we do need to address the substance use disorder, opioid use disorder, but pain patients have been shouting for years that we have not been hurt. Nothing is changing for us. We are still suffering. We are still [00:35:30] losing people in our community because of suicide. They're undertreated, they're not seen, they're not heard, and we're tired of losing people in our community. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Anne Fuqua. In the queue, we have Nazia Fyazi, Joseph Hermosillo, and Tina Kanak. Commenter Fuqua, please proceed.

Anne Fuqua:

Yes, ma'am. [00:36:00] I want to thank you for the opportunity to speak today and impress upon you ...

Susan C. Winckler:

We lost your audio. Could you check your mute?

Anne Fuqua:

I want to thank you ... I'm sorry.

Susan C. Winckler:

Go ahead.

Anne Fuqua:

I'm sorry. I apologize.

Susan C. Winckler:

Go ahead.

Anne Fuqua:

Can you hear me now?

Susan C. Winckler:

Yes.

Anne Fuqua:

I want to thank you for the opportunity to speak today and impress upon you the dire need for protections to ensure continuity of care. I'm a long-term patient who has been on a stable but high dose without need [00:36:30] for increase for 18 years. I've experienced dramatic functional improvement after only limited benefit from alternatives. Pain does far more than just hurt. When the endocrine system's fight-or-flight response remains triggered on an ongoing basis due to severe pain, there is a cascade of harmful biological processes.

When my care with my previous physician was disrupted by a DEA action in 2022, there was no assistance for patients. Even [00:37:00] with treatment from a methadone clinic, my blood pressure and pulse remained dangerously high. I was fortunate to resume treatment after two months with a

physician I met through my advocacy efforts. However, those two months of pain and suffering have had lasting effects on my overall physical health. I developed diastolic heart failure from this experience that my cardiologist has told me I would not be dealing with now were it not for this.

This has been manageable [00:37:30] on the medication, but it still had a significant impact on my daily life and mobility. We desperately need protections that will prioritize continuity of care and protect other patients from experiencing the same harm. The registry of harms occurring in patients with pain I started in 2014 contains 114 fatal cardiac events along with close to 200 instances of nonfatal cardiac events. These plus the 1,297 suicides [00:38:00] I've found capture only a fraction of the harm occurring. These deaths aren't occurring because science has not yet identified a treatment for a catastrophic illness. These are preventable iatrogenic harms that occurring due to regulatory efforts to reduce opioid prescribing. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Nazia Fyazi. In the queue, we have Joseph Hermosillo, Tina Kanak and Kristin McGarrity.

Commenter Fyazi, please proceed. [00:38:30] Commenter Fyazi, if you would turn on your camera and your microphone, we're ready to hear from you. Commenter Fyazi, we will return to you if your audiovisual becomes available.

Next comment will be from Joseph Hermosillo. Then we have Tina Kanak and Kristin McGarrity [00:39:00] in the queue. Commenter Hermosillo, please proceed.

Joseph Hermasillo:

Hello, my name is Joseph Hermosillo. I'm a patient, and I am not a statistic. I'm going to walk you through a case the way you should have walked through before you changed our lives. Whose pain was ignored, who ignored it, the warning signs, the promises made, what could have been done? The pain that was ignored was mine. I have lived with chronic pain since I [00:39:30] was 13. I was stable. I was functional. I told you I was in pain. I told Kaiser Permanente I was in pain. I told the system after 2019 crackdowns that cutting me wouldn't make me safer. I was dismissed anyways. Who ignored it? Decision makers who never had to sit in the body they were regulating. Insurers, clinics, a culture that treated a forced taper as a public health win.

Kaiser denied the CBT [00:40:00] therapy that they pointed me to. Then the alternatives as reasons to take the medicine that was already working. A vacation and a refill gap became a cutoff. That is not care. That's abandonment with the protocol number on it. The warning signs were not subtle, function dropping, sleeped-on, independence going, a nervous system and withdrawal, and a mind in collapse. I said this out loud. Patients like me [00:40:30] said it out loud. You did not need a new study to hear it. You needed to believe the person in front of you. The promise was that this would reduce harm. After they cut me, I overdosed, I had a breakdown, I lost work. This is a public health effect you are assessing. Not a theory, a body.

What could have been done? Leave a stable functioning patient on the regimen that kept him alive until there [00:41:00] is an objective safety reason to change it. Do not taper by policy. Do not taper by fear.

Do not call a denied therapy an alternative. Give a patient time, measure pain, independence and quality of life and outcome, not as noise. I am one named case. There are many others that didn't make it. [00:41:30] I'm sorry, this is kind of hard for me.

Jacqueline Spicer back-

Susan C. Winckler:

Thank you so much.

Commenter Fyazi, I understand you are now ready. If you turn on your camera and unmute your microphone. Yes, we see you. Please proceed.

Nazia Fyazi:

Hi, thank you so much. Good afternoon. My name is Nazia Fyazi. I trained in addiction neuroscience at the Narc Lab at [00:42:00] Mount Sinai a long time ago, and today I'm an MPH student in data analytics and public policy. More importantly, I've lived as a chronic pain patient, worked with pain patients in personal injury cases and the legal cannabis market, which taught me something by contrast.

Since the 2016 guideline, the dominant risk for many stable patients is no longer addiction. It's abandonment. Physicians facing DEA scrutiny and malpractice exposure are declining to prescribe or tapering stable patients, [00:42:30] and pharmacists sometimes compound this by refusing to fill valid prescriptions. The result is unmanaged pain, functional collapse, and in documented cases, suicide or the illicit market. The exact outcome this policy was meant to prevent. This partly comes from conflating two phenomena I studied in addiction research, dependence and addiction. Dependence, tolerance, withdrawal or cessation happens with long-term opioid use in nearly everyone. Addiction is separate, [00:43:00] compulsive use despite harm, and it doesn't track with dose.

An MME cutoff, converting opioids to a single morphine equivalent number treats every patient's biology as identical. It isn't. Genetics, metabolism, and pain ideology all shape real risk. I saw the opposite mistake with cannabis. Instead of one rigid federal rule, we got no federal framework, 50 consistent state systems often within thin [00:43:30] evidence behind dosing. But cannabis was still there as a real option, and for some, simply the treatment they prefer, not a fallback. Patients deserve access to whichever treatment works for their body, not a one-size-fits-all on either substance.

I have seen people with real needs beg for treatment. So I'd ask FDA to direct REM's requirements towards individualized [00:44:00] risk stratification, not fixed dose thresholds. Issue guidance force tapering of stable patients is not recommended practice, and invest in provider education, distinguishing dependence from addiction. Thank you so much to the foundation and to the FDA for your time.

Susan C. Winckler:

Thank you. Our next comment will be from Tina Kanak. In the queue, we have Kristin McGarrity, Carmen Orlowski, and Erica Roy.

[00:44:30] Commenter Kanak, please proceed. Commenter Tina Kanak, I apologize if I'm mispronouncing your name, if you unmute and turn on your camera, we're ready for your comment.

Tina Kanak:

Good afternoon. Thank you so much for having us. I am a long-term pain patient. I actually started with horrible pain at [00:45:00] 18 years old. And today, no one would offer me anything of the type of medication that I needed. And I wanted to explain to most people, I'm not even sure if they've even had to take pain medicine like this, because no one would choose to have to take this. It causes extreme itching and sleepiness. It's not a drug that other people out there take for weird whatever they take them for. All [00:45:30] of our pain patients, this has been miserable. It has destroyed our lives. They want me to come every month. Everybody's required every month. Nobody has this amount of time to say, "Hey, I'm going to just take off and go to the doctor." It's ruining our ability to work.

I got to the level of a CEO, and this whole initial management of even trying to figure out what was wrong, get this under control, and become productive again at the highest levels [00:46:00] is absolutely impossible at the state. Our doctors are miserable. Pharmacists are rejecting people. Walmart and HEB will not even fill medicines such as this. I have been kicked out. Just calling a pharmacist when one pharmacy's out, and they're often out. And you're only given 30 days, you're not given any amount to say, "Hey, if you have an accident or you can't get to the doctor." You're always left without [00:46:30] medicines. And if you have to take it every day, you can't do what you're required to do."

We are really literally in impossible situations. This is the wrong war. They have taken the war from what's going on in the streets and applied it to law-abiding citizens who just want to live. We want to love our families. We want to go to work. We want to be productive. It's destroyed ... Our doctors don't want to be like this. I [00:47:00] right now have my doctor telling me they've already reduced my medicine. They said, "Well, we're getting ready to have to drop it in half from what we've already reduced it." Over the 13 years of my worst situation, of even taking myself off at periods of time, this is not addictive like they define addictive. We need to look at the-

Susan C. Winckler:

Thank you. Our next comment will be from Kristin McGarrity. In the queue, we have Carmen [00:47:30] Orlowski, Erica Roy, and Bev Schechtman.

Commenter McGarrity, please proceed.

Kristen McGarrity:

Thank you. My name is Kristin McGarrity, and I chair the Chronic Pain Opioids Work Group for NCIL, the National Council on Independent Living, the nation's longest-running organization run by and for people with disabilities. When we talk about the public health effects of opioid pain medication, we need to acknowledge a meaningful subset of the disability community who live with painful medical conditions and regained participation [00:48:00] in life, working, parenting, volunteering, with long-term opioid therapy after other options failed.

Now, our message is much the same as it was when we presented at the FDA in 2019. To prevent harmful changes to care, it is critical for the FDA to avoid hard limits on dosage or duration of opioid therapy, and whenever possible, keep existing medications available. 10 years ago, studies correlating higher dose and higher risk spawned the idea that dosage reduction would lower risk. [00:48:30] Since then, over a dozen newer studies have shown involuntary dosage reduction increases risk for life-changing and life-threatening harm.

Opioid taper is a high risk medical intervention. It was imposed on millions of Americans over the last 10 years, many without their consent. The CDC's acknowledged misapplication of a 10-year-old guideline is still woven into insurance systems, federal and state agencies, corporate policies, and law enforcement. All this happened while our organization [00:49:00] and other volunteers, never paid by anyone, repeatedly warned every federal agency. We warned that the decline in prescribing 60% per capita in 10 years requires attention to track and mitigate adverse effects.

In 2019, the FDA did issue a much-needed warning against rapid tapering. We saw very little effort to find out how many people this had happened to, what happened to them? Are they still working? Are they alive? This is where the FDA can lead the way. The public health effects of opioid [00:49:30] medication include the public health effects of losing access or never having access in the first place. To bring people with disabilities into decision-making and advisory work groups and committees going forward, please feel free to reach out to NCIL anytime, and we thank you for your time today.

Susan C. Winckler:

Thank you. Our next comment will be from Carmen Orlowski. Then in the queue, we have Erica Roy, Bev Schechtman, and Christine Wallace.

Commenter Orlowski, [00:50:00] please proceed.

Carmen Orlowski:

Hello, my name's Carmen Orlowski. I've struggled with chronic pain for 25 years. It started at age 22. I had severe migraines, fibromyalgia, and chronic pain every day. I went through numerous treatments and renowned specialists with no relief. And eventually, I found a compassionate doctor who prescribed me a stable low dose of hydrocodone, and it was the only thing to give me quality of life. And I remained on that same low dose for 20 years, followed all the rules, [00:50:30] the drug tests, mandatory appointments. I never increased my dose. I never misused the medication. I did not get high from it. It just took the edge off the pain enough so that I could live and have quality of life. And it allowed me to do many things that most people take for granted, like sleep, go to family functions, just have company, participate in the world instead of spending all my time homebound, trying to survive the pain.

And two years [00:51:00] ago, my good doctor left, and the new one who came in just force-tapered me with no alternatives and no options for no reason. And I've now spent the last year and a half basically homebound with drastically reduced quality of life. And my pain didn't disappear just because my pain medication disappeared, it's just the only difference is now I can't function like I used to, and I don't have quality of life.

And I ask that you please remember that chronic pain patients [00:51:30] are individuals and not statistics and patients who have demonstrated decades of stability, compliance and benefit from opioid treatment should not automatically lose access just because some people abuse it. Kind of like if someone is speeding on the road, they don't ticket everyone who's following the rules. So just the same, we deserve individualized care and access to opioid medication treatment.

So please, please consider the real human cost of policies [00:52:00] that leave legitimate chronic pain patients suffering without effective treatment and no quality of life, because we all only have one life, and chronic pain patients deserve the opportunity to actually live it just like everyone else. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Erica Roy. In the queue, we have Bev Schechtman and Christine Wallace. Then we'll transition to in-person comment hearing, first from Gail Groves Scott.

Commenter Roy, please proceed.

Erica Roy:

[00:52:30] Yes, my name's Erica Roy. I am a nurse and a chronic pain patient, and I just want to say to you, imagine waking up every morning that the pain you went to sleep with, if you got any sleep at all, is the same pain that you are going to wake up in the morning. And for millions of chronic pain patients, including myself. This is every day, this is our reality. The FDA does have an important role to protect, but also has an important [00:53:00] role to look at regulations, and allow chronic pain patients to be treated as individuals and not as a group.

Yes, we know that regulations surrounding opioid medications are intended to reduce misuse addiction, overdose, and death, but the policies designed to address the opioid crisis have been interpreted too strictly. We could see this in 2016 and 2022. We said it's not law, however, these strict imposing 50 [00:53:30] MMEs have been written into law, right? And one of the biggest concerns is that doctors, pharmacies, insurance companies, and healthcare systems have become so concerned about regulatory scrutiny that providers don't want to treat us anymore. Pharmacies don't want to fill anymore. Nobody wants to help us anymore, so what do we do?

This result has been devastating, including increased suicides. Patients have been cut off [00:54:00] their medication or abruptly reduced. This is not going to work. People are losing ability to work, sleep, function in family. We just want to function in daily life. For many, that's not happening. So the issue is not about ignoring safety, it's about finding a better balance. Patients need protection from medication-related harm, but also need protection from harm that could be caused by undertreated or untreated pain. This is why the [00:54:30] change is important. The goal should not simply to be reduce prescriptions. It should be to improve patients' lives safely, and the regulations are preventing this from happening.

Safe pain care and compassionate care should not be opposites. Patients deserve both. We should start looking at patients with individual necessity and need. I see this as a nurse. I see patients get denied pain medication. I say something, and I'm saying something now. This needs to change. Thank [00:55:00] you for letting me speak today.

Susan C. Winckler:

Thank you. Our next comment will be from Bev Schechtman. Then in the queue, we have Christine Wallace, and in person, Gail Groves Scott and James Hackworth. Commenter Schechtman, please proceed.

Bev Shechtman:

Good afternoon. I'm Bev Schechtman, vice president of the Doctor-Patient Forum. For over a decade, reducing prescription opioids has been the main public health goal. We track prescribing rates, and we celebrate when they fall, but we do not systematically track what happened to the patients who lost [00:55:30] treatment. Where are the patient outcomes? Every day, patients tell us medication that let them function and thrive was reduced, stopped, or made inaccessible. They lose independence, hope, and sometimes their lives. Their medication did not fail them. The medical system did.

In 2018, FDA's Judy Staffa described patients harmed by forced tapering or loss of opioid treatment, including worsening disability and suicide. She said, "We have no data to quantify that. Maybe these are some outcomes we should be looking at and paying attention [00:56:00] to." That was eight years ago. Where are the data? When does maybe become a requirement?

FDA required major post-marketing studies to measure addiction, misuse, abuse, and overdose. Yet in 2025, FDA acknowledged neither was designed to assess harms from dose reduction or discontinuation, despite its earlier warning about uncontrolled pain, psychological distress, and suicide. We built systems to monitor prescriptions, but not the patients who lost them. A reduction in a prescription is not a patient outcome.

When FDA wanted [00:56:30] reliable addiction data, it required PMR 3033-1, its validated pain-adjusted primary analysis found 12-month moderate to severe OUD, which is the outcome FDA treated as addiction of 1.4% and 1.6%. Those are FDA's own primary findings, yet doctors still hear dramatically overstated estimates, including 25% presented as fact. What was the point of requiring rigorous studies if the FDA does not make sure clinicians are taught the results? Clearly [00:57:00] communicate these findings and labeling REMS education and distinguish mild OUD from addiction, and use that same authority to require a parallel long-term study of patients whose opioid treatment is rapidly reduced, stopped without their buy-in, or made inaccessible, track overdose suicide, pain, function, disability, illicit opioid use, harms from opioid alternatives, and death, and follow patients long enough to capture delayed harm.

After over a decade of opioid reduction, we should know what happened to the patients. Fewer prescriptions are not proof [00:57:30] of better public health. Patients do not disappear when their prescriptions do. Measure the harm, stop the bleeding. Act. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Christine Wallace, then we'll turn to in-person comment. The queue is Gail Groves Scott, James Hackworth, and Corey Wetzel.

Commenter Wallace, please proceed.

Christine Wallace:

My son is not dying from an opioid overdose. He is being harmed by a healthcare system so afraid of opioids that doctors are terrified [00:58:00] to treat his pain. My name is Christine Wallace, and I am the full-time caregiver for my son, Luke Taylor.

In 2018, Luke broke his neck, becoming a complete quadriplegic. He has undergone eight invasive spinal surgeries, and lives with adhesive arachnoiditis, tethered cord, and devastating centralized neuropathic pain. For years, he has been confined to his bed because sitting up triggers unbearable full-body agony. I [00:58:30] have watched my son scream and cry from pain, begging us to end his suffering. But I have also seen what happens when doctors listen. The late Dr. Forrest Tennet recognized Luke's disease, and gave us hope, and courageous physicians like Dr. Mark Ipsen described abandoned individuals like Luke as pain refugees. Yet Dr. Ipsen faces intense scrutiny over his treatment of pain.

The message to other physicians is terrifying. [00:59:00] Treating complex pain puts your license and livelihood at risk. When doctors become afraid, patients pay the ultimate price. These are not abstract policy problems. These are people. They are patients who lost access to doctors who treated them safely, left abandoned and desperate. People are dying because they can't get their medication. I understand why the FDA must address addiction, but public health cannot [00:59:30] mean protecting patients from one danger while abandoning them to another.

Untreated severe pain is a public health crisis. Where is the harm counted when a patient becomes trapped in bed, losing independence and quality of life? Where is the harm counted when families must become full-time caregivers because adequate treatment is withheld? I am asking the FDA to measure these consequences. Include the harms [01:00:00] of undertreated severe pain in your opioid benefit risk assessments. Please do not make legitimate pain patients collateral damage. My son does not need to be protected from appropriate pain treatment. He needs access to it.

Susan C. Winckler:

Thank you. Our next comment will be from Gail Groves Scott. Then in the queue, we have James Hackworth and Corey Whetzel. Commenter Groves Scott, please proceed.

Gail Groves Scott:

[01:00:30] The causes of the drug overdose epidemic are multifactorial, but the crisis was sparked by the overpromotion of opioids for pain. I was part of the problem during my 16-year career as a pharmaceutical sales rep, a drug rep. We believe that we were educators, not salespeople. I was a trusted advisor to hundreds of clinicians, and influenced how they prescribed. But my extensive training came from the companies I worked for. I was not aware [01:01:00] of the bias in my training and my sales materials. I believe that the FDA strictly regulated the marketing pieces we used. I later learned that the agency reviews only a small fraction of these sales pieces and that submitting marketing pieces for advanced review is mostly voluntary.

The years I spent selling opioids for pain and for addiction treatment, including my experience as a whistleblower to the Department of Justice, led me to want to better understand [01:01:30] how drug marketing impacts public health. I went to graduate school. I studied the regulation. I'm doing research

now in this area. I learned there are ways to keep sales messages and commercial bias out of clinical education. We should not allow industry salespeople to fill public health and clinical education gaps. I eventually left industry to become a researcher and policy advocate. I'm now a doctoral candidate in health policy. I received no outside funding for my work.

Pharmaceutical [01:02:00] marketing is evolving. There are now half as many drug reps and more restrictions on their access, on branded drug samples, and on free meals. Voluntary industry guidelines have been tightened, yet industry still influences non-rational prescribing, and engages in shadow marketing. Voluntary industry regulation will not eliminate this. Civil and criminal litigation, although a powerful tool is too reactive. The FDA needs to do more. Licensed clinicians have a duty to warn when they learn [01:02:30] that a colleague might be a danger to the community. Yet when drug companies learn of illegal or dangerous opiate prescribing and dispensing, they repeatedly kept this information to themselves.

There are too many gray areas around surveillance. We must do more to address the conflicts of interest that arise in public safety surveillance. HHS prioritizes radical transparency. I suggest they need to prioritize ways to make hidden industry marketing much more visible.

Susan C. Winckler:

[01:03:00] Thank you. Our next commenter is James Hackworth, followed by Corey Whetzel. Commenter Hackworth, please proceed.

James Hackworth:

Thank you. I'm James Hackworth from Adneuris Therapeutics. First, I'd like to thank the FDA for holding this public forum and for the administration for fostering innovation and being open to addressing and changing regulations when needed. We're here to talk about opioids for two reasons. [01:03:30] They're highly addictive and have fueled up a massive public health crisis, but also because they're necessary to treat more severe pain. And if it weren't for both of those facts, the solution would be pretty easy. But unfortunately, that has been and remains the central conundrum in pain care even in 2026.

Going forward, thinking about new medications, we'd like to encourage the FDA to reorient away from just thinking opioid [01:04:00] versus non-opioid though and focusing more on addictive versus non-addictive. And the reason is something that Dr. Compton alluded to earlier and that is because there's multiple avenues of research underway, including ours that's late stage, that leverage the opioid system but that doesn't have the same addictive properties. At Adneuris, we think we actually have the solution to get us out of this box. This is not a time to talk about science and so I won't but just a couple of quick [01:04:30] points.

We have cebranopadol which is a first in class dual NOP/MOP receptor agonist, it's very late stage. And we have, in collaboration with the Division of Analgesic and Anesthetic Products and CSS, have designed a series of clinical trials and ... Designed and executed a series of clinical trials where we've proven that the drug can treat pain at least as well as oxycodone but that is superior in terms of abuse potential, [01:05:00] physical dependence and risk of overdose and substantially superior. And the second point I would make is that when we came across and met NIDA a few years ago and, once they became aware

of our research in the pain space, they actually invited us to apply for a grant which eventually led to a $17 million award to study cebranopadol also for the treatment of opioid addiction.

As I said, the drug is late stage, we are submitting an [01:05:30] NDA for the treatment of moderate to severe acute pain in the United States in 2026 and we think it can be a solution to the opioid crisis without sacrificing the treatment of pain. It's imperative though-

Susan C. Winckler:

Thank you. Our next comment will be from Corey Whetzel and then that will conclude the comments on topic number two. Please proceed.

Corey Whetzel:

Good afternoon. My name is Corey Whetzel, I'm a pharmacist speaking on behalf of the American [01:06:00] Pharmacist Association which represents the nation's pharmacist, student pharmacist and pharmacy technicians in all practice settings. I want to thank the FDA and the Reagan-Udall Foundation for convening this meeting. As experts in medication management and among the most accessible healthcare providers, pharmacists play a critical role in ensuring the safe and appropriate use of opioid medications. As such, APHA encourages FDA to maintain a regulatory framework that balances the important goals of protecting public health and preserving [01:06:30] access to opioid medications for patients with legitimate medical needs.

First, APHA encourages FDA to more fully recognize and leverage pharmacists as essential partners in opioid stewardship. As the last healthcare professional to interact with patients before opioid therapy begins, pharmacists are uniquely positioned to educate patients on appropriate use, storage and disposal and to identify potential safety concerns.

Second, APHA supports FDA's efforts to continue to modernize the Opioid [01:07:00] Analgesic REMS program. Because this program influences how healthcare providers are educated on pain management, opioid safety and opioid use disorder, FDA should ensure that pharmacists are fully integrated into REMS related education, patient counselling, monitoring and follow-up activities, expanding pharmacist engagement would advance these REMS objectives.

Third, states are increasingly authorizing pharmacists to prescribe or furnish medications for opioid use disorder such as buprenorphine and APHA urges FDA to [01:07:30] continue supporting policy approaches that expand access to evidence-based treatment.

Lastly, as FDA expands prescription to non-prescription pathways including under the ACT NEW framework, APHA strongly urges FDA to recognize the value of pharmacists provided patient education. Take naloxone for example, while over the counter naloxone can increase access, access alone is not enough if patients cannot afford it and do not know how to use it, pharmacist counselling often serves as the critical link [01:08:00] between access and effective use. Accordingly, for products being considered for an OTC switch or available under the ACT NEW pathway that raise patient user safety concern, pharmacist-led education is vital to promote safe and effective use while also increasing medication access. APHA has shared recommendations with FDA and welcomes continued dialogue and engagement. Thank you.

Public Comment:

Topic 3: Additional actions that could be considered to address the public health effects of opioid medications

Susan C. Winckler:

Thank you. We're now turning to topic number three, which is additional actions that could be considered to address the public health effects [01:08:30] of opioid medications. If we could advance the slide, please, thank you. In our queue for public comment, we will hear first from one commenter in person, that is Kevin Roy, then we will proceed to our virtual commenters. The queue is Sara Batchelder, Lisa Bright and Jessamyn Butler. Let's turn first to an in-person comment. Commenter Roy, please proceed.

Kevin Roy:

Thank you. Good afternoon, I'm Kevin Roy, policy director for the Center on Addiction Science Policy and Research, [01:09:00] CASPR, I will begin with three core problem statements to help frame the opportunity. Addiction drives enormous social and medical harm, the problem of addiction cannot be solved in free society without new and more effective therapeutics and the ecosystem for addiction drug development and adoption is a need of new and robust addiction treatment options. Here's why.

Only 15.7% of the 4 million Americans with OUD receive medication for it, 84% don't. And I think many [01:09:30] of us assume that they were unaware or just needed some encouragement of some kind, however, I think it's reasonable to conclude that, a significant percentage of that population, those medicines don't work or are unappealing for one reason or another. Current guidance gives sponsors no clear way to test a new treatment for that population, solving addiction at a population level can be catalyzed by action from the FDA.

To start, the FDA should convene a public workshop with NIDA patients, clinicians, trialist statisticians [01:10:00] and developers and issue updated OUD drug development guidance that, one, defines new entrants, partial responders on MOUD and clinically stable patients as separate development populations and states that trials should generally include people with concurrent stimulant use unless a product specific safety concern or inability to complete essential procedures justifies exclusion.

Two, provides a clear default for placebo, active control and other modified designs [01:10:30] with safety rescue and early escape protections. Three, requires pre-specified estimands and continued follow-up for MOUD initiation, rescue treatment switching, transfer and missing assessments. Four, directs FDA and NIDA to analyze existing participant level OUD trial data validate candidate reduce use thresholds and qualify one or more clinically meaningful endpoints. And, five, defines whether reduced use endpoint could support accelerated approval under [01:11:00] section 506C for novel non-opioid treatment and new entrants and states applicable context for use and confirmatory evidence requirements.

Finally, as a pharma independent organization, CASPR can convene sponsors, investigators and others without the conflicts that prevent any individual developer from leading this work and we welcome the chance to do so. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Sara Batchelder. In the queue we have Lisa Bright, Jessamyn Butler [01:11:30] and Terecita Elizabeth Carrion Zavaleta. Commenter Batchelder, please proceed.

Sara Batchelder:

Hello, my name is Sara Batchelder, I've lived with daily pain for over 20 years and I've tried almost 100 different treatments. My pain is severe today so bear with me. Prescription opioid dispensing has fallen by more than half since it peaked in 2012 and total opioid, excuse me, overdose deaths nearly quadrupled anyway. We were told in 2016 that cutting our prescriptions would lead to less people [01:12:00] dying, excuse me, the results of these policies were and still are quite the opposite.

The CDC's own numbers tell us that only 1.9% of all overdose deaths in 2024 involved a prescription opioid alone, that means 98.1% either didn't involve one at all or involved prescription opioids plus other drugs. And even that 1.9%, roughly 1,000 people is an upper bound, we still don't know how many were taking their own prescription as directed versus pills bought or stolen from someone else. There [01:12:30] is an overdose crisis but it is clearly not a crisis of prescription opioids being used by legitimate people in pain.

Meanwhile, access to legitimate therapy keeps getting harder because guidelines, state laws, DEA production quotas and litigation fallout push prescribers towards defensive undertreatment. My own father was denied opioid medications the day he died in 2023 under hospice care, I've been told more times than I can count you're a good candidate for opioid therapy but the government won't let us prescribe. It's now been 10 years since the 2016 CDC [01:13:00] opioid guidelines, CDC's own 2022 revision admitted they were misapplied.

My asks are, one, separate the overdose crisis from legitimate physician supervised care and finally get people in pain the care they've been begging for and a seat at the table. Two, redirect federal action towards illicit supply not towards doctors and patients who are stable, monitored and doing everything asked of them and more. Three, fund the work to finally confirm how many overdose victims were taking only their own legitimate prescription [01:13:30] and fund work to determine how many patients like my father and me have been harmed by opioid public policy. And, four, show us the outcome of the last decade of testimony at meetings like this one because people in pain keep showing up and our outcomes keep getting worse.

Here's hoping the next decade shows actual improvement for both people in pain and people with addiction. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Lisa Bright. In the queue we have Jessamyn Butler, Terecita Elizabeth [01:14:00] Carrion Zavaleta and Nancy Connolly. Commenter Bright, please proceed.

Lisa Bright:

Thank you. Good afternoon. Before I tell you why I'm here, I want to tell you more about my son. Will was 25 years old when he passed away from a heroin overdose, his addiction started with opioids, the way it starts for so many, and what began as pain management became something none of us could stop. We lost Will on November 27th, 2012. My husband Bill and I made the decision [01:14:30] in the worst season of our life that his name would stand for something that is why we started the Will Bright Foundation and why I do this work every day.

In addition to my role at the Will Bright Foundation, I'm honored to serve as a founding board member of another non-profit organization called Voices for Non-Opioid Choices. Voices was founded in 2019 with an eye towards preventing opioid addiction by increasing access to non-addictive pain management approaches. [01:15:00] The premise is simple, many people never intend to encounter an opioid, they encounter one in a hospital, a dental chair, an emergency room. If we can offer a different option at that moment, we can prevent addiction before it ever begins.

What we are asking for is straightforward, patients should have a choice in how their pain is managed and that choice should be covered by insurance. No addictive option is a real option if it's not on the table or if the patient cannot afford it. [01:15:30] Now in our seventh year, Voices has more than 350 members across the nation with representatives in all 50 states. Our members include individuals affected by opioid crisis, healthcare professionals on the front line, public health organizations and leading clinical societies.

Our executive director Chris Fox, whom you'll hear from in just a bit, will tell you more about our work with Voices and about the opportunity to avoid unnecessary [01:16:00] exposure to prescription opioids by enhancing access to non-addictive pain treatments. I will close with this. Every policy conversation we have is about someone's son or daughter, mine was named Will. I thank you for making sure fewer families have to tell a story like ours.

Susan C. Winckler:

Thank you. Our next comment will be from Jessamyn Butler. In the queue, we have Terecita Elizabeth Carrion Zavaleta, [01:16:30] Nancy Connolly and Paul Giacinto. Commenter Butler, please proceed. I'm sorry-

Jessamyn Butler:

Hello, good afternoon.

Susan C. Winckler:

Yes, go ahead. Commenter Butler, please proceed.

Jessamyn Butler:

Okay, good afternoon. In light of all the so-called collaborating agencies here today, I'm curious where's [01:17:00] the AMA and where are any organizations representing the interests of pain patients because I didn't see any. But speaking as a long-term chronic pain patient and patient advocate, I think the most appropriate actions that we could take now would be requiring the agencies as a group to announce

publicly their admission [01:17:30] of what they've known for more than five years that legally prescribed opioid medications are not and never were the cause of the opioid hysteria that's going on, now renamed to the overdose epidemic. These were proven to be illicit drugs from the get-go.

The other thing would be to return the legally prescribed opioid medications [01:18:00] to the treatment options available to healthcare professionals for well-screened and well-monitored chronic pain patients. Chronic pain has been positively correlated with a number of preventable biological complications such as cardiovascular issues, hormonal, increased blood sugar and cholesterol, insomnia [01:18:30] and malnutrition. Not to mention the very benefits of the alleviation of human suffering and returning physical mental function to these who are disabled by chronic pain and allowing us to have, as Dr. Timothy from the VA said, a quality of life.

The risk-benefit ratios get a lot of air [01:19:00] time but how many times does anyone give voice to the actual benefits of opioid medications? Patients should not be told, oh, wait around, they're coming out with new medications when there are medications that can help us now. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Terecita Elizabeth Carrion Zavaleta and then in the queue we have Nancy Connolly, Paul Giacinto and Mark [01:19:30] Ibsen. Commenter Carrion Zavaleta, we are ready for you. Yes, please proceed.

Terecita Elizabeth Carrion Zavaleta:

Yes. Good day, everybody, thank you for letting me participate. Well, I would like to briefly discuss the public health impact of opioid medicine and some strategies. Opioid provide essential medicine for the treatment of moderate to severe pain, however, the inappropriate [01:20:00] or prolonged use may increase the risk of dependence. After the review, science, research and international public health strategies, for example, in Canada has [inaudible 01:20:18] harm reduction strategies including education on overdose prevention and broader access to naloxone.

Another example for Australia. In [01:20:30] Australia, promoted opioid stewardship, this approach encourage appropriate opioid selection, patient education, shared decision making, treatment review and planning for dose reduction when opioids are no longer necessary. The object is to reduce harm [01:21:00] without compromising effective pain management. In another country, for example, is European Union and this is emphasized in pharmacology and risk minimization [inaudible 01:21:15]. This [inaudible 01:21:17] include safety information for patient and healthcare professional, education materials, monitoring and evaluation of whether [01:21:30] risk control strategies are actually effective.

In conclusion, the future of opioid safe should combine rational use, education, active pharmacology and share responsibility. The goal is not simply to prescribe fewer opioid but to prescribe them better, monitor them better and education patient better. Thanks.

Susan C. Winckler:

[01:22:00] Thank you. Our next comment will be from Nancy Connolly then in the queue we have Paul Giacinto, Mark Ibsen, and San Irving. Commenter Connolly, please proceed.

Nancy Connolly:

Hi, I'm Dr. Nancy Connolly, thank you for the opportunity to speak today. I'm a doctor boarded in internal medicine and addiction, for decades, I have taken care of patients both helped and harmed by opiates. As a Robert Wood Johnson Health Policy Fellow, I studied how we regulate these powerful drugs, I understand [01:22:30] how laws and regulation influence the practice of medicine, the experience of our patients and the public's health. First, I applaud FDA's opioid labeling change of July '25, a necessary and long overdue step. I am optimistic that this FDA can act decisively seeing all the health effects of opioid medications, prescribed and illicit. But focusing too narrowly on tightening regulations can make us miss the bigger picture, the harms created by the policy itself like untreated pain and abrupt tapering and movement toward an increasingly dangerous, unpredictable [01:23:00] and nimble illicit supply.

I'm asking you to expand this conversation to ask more than how we should regulate opioids but whether our whole approach to regulating psychoactive substances is adequate for today's world. That's why I urge FDA to use this opportunity to envision our regulatory system more broadly. Remember the unique and politicized conditions surrounding passage of the Controlled Substances Act in the turbulent decline of the Nixon administration codifying our current drug scheduling system. Today, our science is much more advanced and we are even [01:23:30] now taking action to streamline and reform outdated systems. In this unique time, I'm calling for a re-evaluation of the entire scheduling system so we can move forward to regulate all controlled substances in a way that is more rational and supports the needs of patients and the health and safety of the public at large.

Our current system puts profoundly different substances into a handful of categories that can't possibly capture these differences, this isn't aligned with our current scientific understanding nor does it take into consideration what we've learned from 50 years of misguided policy. Of course, [01:24:00] FDA doesn't dictate scheduling but FDA and HHS are respected advisors to the DEA advising on the scientific merits of regulation affecting the public's health and safety. We deserve a system that asks more thoughtful questions, how can we ensure product safety, reduce addiction and overdose, encourage research while reducing the terrible harms created by criminal markets.

Now is our opportunity to rethink the mistakes of the past to build a modern regulatory system guided by science, responsive to evidence and experience, compassionate toward people and honest about the complexities of these [01:24:30] substances. My hope is that you will have the courage to build that system, thank you.

Susan C. Winckler:

Next comment will be from Paul Giacinto then the queue is Mark Ibsen, San Irving and Neil Jackson. Commenter Giacinto, please proceed.

Paul Giacinto:

Hello, everyone, thank you for allowing me to speak. I had a speech prepared but I'm throwing it out the window because, everything I've heard, I'm angry. [01:25:00] I was cut off, my last opioid was April 30th, 2025. I was warned that it was going to happen and I went to a pain specialist to see what my options were and I heard steroid injections to the spine, spinal cord stimulators, that standard buprenorphine,

methadone even and [01:25:30] I worked in addiction through college and I seen how methadone failed and I've already seen how buprenorphine is no different, it's just the socially acceptable drug at this time that you all agreed to and will pay for, that's how I feel. I know many people who are on buprenorphine for addiction and they haven't come off of it in over five years. They've relapsed, they've overdosed, all [01:26:00] that yet we're saying it's a successful drug to treat pain when it can't even treat what it was intended for.

But anyhow, I'm going to go to just my medical history, okay? I will open up my records gladly for you all, I will submit myself to any testing you like but, when I was cut off, I was told that I wouldn't survive, I'd wind up going to a drug dealer and illicit [01:26:30] drugs if I refused everything that they were offering that I wasn't willing to subject myself to because all those options, for me, were not medically safe, I knew that. Well, we're over a year now, I have a drug dealer within less than a block from me, my life has drastically changed, I'm going on over 30 hours of no sleep and this is my norm and then I'm [01:27:00] lucky if I get two hours.

My life, I was independent on my medication. I saw five different doctors regularly plus a mental health professional, not one of them ever sent an alarm that they had any concerns about my high dose of opioids.

Susan C. Winckler:

Thank you. Our next comment will be from Mark Ibsen. In the queue we have San Irving, Neil Jackson and Richard [01:27:30] Lawhern. Commenter Ipsen, please proceed.

Mark Ibsen:

Greetings, this is Dr. Mark Ibsen talking. I'm throwing out my speech too, I appreciate the comments of the patients and other physicians that have been here. There are a lot of specialists talking today and the number one specialists who are talking today are the patients. The patient knows what they need and they're asking for help, let's help them. You talked about opiate [01:28:00] use disorder being frequent but does that mean diabetes should be called insulin use disorder? There should be no diagnosis of opiate use disorder. There's a sacred physician-patient relationship that needs to be acknowledged. It's too busy in the exam room now, we have regulators, CDC people, policymakers and law enforcement in the exam room with us declaring how we're going to practice medicine, let's restore [01:28:30] the sacred physician-patient relationship.

And since I mentioned the elephant in the room, let's talk about it, that would be the DEA and other regulatory agencies that have created a hostile regulatory environment for patients to get their pain needs taken care of. These are legacy patients that should have been excluded and were excluded in the CDC guidelines but they're not excluded in the practicality of what they're getting and not getting.

So, I don't have anything else to say factually, I have some questions for [01:29:00] you though. Who benefits from all this? I'm a doctor, I'm not benefiting from these rules that handcuff me from prescribing medications from people who need it. I didn't start these patients on their medications, they were started years ago when we thought that treating pain was a good idea and it turns out it was a good idea. Why are we taking out pain patients now? Because of some belief that, if Johnny is the high school quarterback and he breaks his collarbone and he gets some Percocet and he dies seven years

later of [01:29:30] a heroin overdose, that it must have been the Percocet, that is a national narrative that, with all due respect to the lady whose son died and I feel terrible about the loss of your son from heroin, but heroin's not in my prescribing mix, I don't prescribe heroin.

So, when patients suffer from addiction, we got to look at other values and other variables so let's get the DEA out of the doctor's practice room, let's reformat our entire regulatory system [01:30:00] and thank you for letting me share. Oh, by the way, I may not be a smart doctor but I know a pain refugee when I see one.

Susan C. Winckler:

Thank you. Our next comment will be from San Irving. In the queue we have Neil Jackson, Richard Lawhern and Vanessa Moreno. Commenter Irving, please proceed.

San Irving:

Good afternoon, my name is San Irving and I am a chronic pain patient and a patient advocate but I'm speaking on behalf of myself today. I've lived with severe back pain [01:30:30] for more than 15 years, when opioids became a part of my treatment, I am able to work full-time, help support my family, stay independent and live my life but getting this care has become harder and harder. At one pain clinic, I was treated like I had done something wrong because of a legitimate prescription from my dentist, they required me to come back every two weeks for drug testing and I later received a $3,800 bill for those two drug tests. I also was pressured into procedures that were not helping me, those injections caused me more pain [01:31:00] and spasm but I was asked to say that they helped so they could continue to bill my insurance and so the insurance would keep paying. When I refused more procedures, I was told they would no longer prescribe my medication.

So, I called around 40 offices trying to find another doctor, now I drive 2.5 hours each way and I lose a whole day of work every month just to keep getting care. My copay has gone from $30 quarterly to 260 monthly. For years, [01:31:30] almost everything we hear about opioids is the harm that they can cause but what about people like me who benefit from them and what about the harm that happens when treatment is taken away, when patients are forced off medications, pushed into treatments or simply cannot find anyone willing to care for them? Those stories matter too. Our experiences should be part of public health records too.

So, if you're asking what else should be done, I have one request. Create a formal way to collect and study experiences and outcomes [01:32:00] of patients harmed by opioid reduction, discontinuation, loss of access and substituted treatment. Collect patient stories, follow the patients, find out what happened to us. Did we lose our jobs, our doctors, our ability to function? Were we harmed by treatments we were pushed into? Did our health get better or worse? Patients harmed by opioid reduction policies have been left out of the conversation for far too long. If you want to understand public health effects of opioids, you have to look at both sides, [01:32:30] not just the harm from taking them, but the health benefits some patients get from them and the harm that can come from taking them away. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Neil Jackson then in the queue we have Richard Lawhern, Vanessa Moreno and Ty McCord Amesis. Commenter Jackson, please proceed.

Neil Jackson:

I come to this discussion as a fentanyl and opioid chronic pain patient [01:33:00] and addict, now an advocate who experienced what happens when medically necessary, fentanyl overdoses leads to severe addiction, I was just overprescribed all the time. We devote enormous amount of resources in this country to addiction and overdose, however, it's usually after the crisis occurs. I believe we must make more about prevention equally urgent, giving doctors some tools to intervene while the patients are still in their care [01:33:30] before dependency becomes harder to reverse or addiction develops and overdose increases relative to the acceptable levels of pain.

My name's Neil Jackson, after cancer surgery, I spent seven years severely addicted to prescribed fentanyl. My doctor lacked a graduated way to control my dose and to taper me off, I came dangerously close to street drugs, I came close to suicide. [01:34:00] But fentanyl is an important and proven pain medication, I've heard that today, it works and it's safe. The problem for some patients isn't getting on it, it's safely getting off at the right time if you can. So, I call these patients the forgotten patient like myself.

The CDC gives guidance recognizing that long-term patients may need gradual tapering of 10% or less per month, the commercial fentanyl patches don't provide that provision. I know that problem personally as well, [01:34:30] larger reductions from patch to patch failed me so I studied the tapering challenge instead of going to the street and I invented a thing called FenBlock, it's a patented drug barrier device that's designed to give doctors greater precision in prescribing, in reducing and in determining when to pause, when to continue or to reduce and end its use totally.

I now use Motrin. The Great American Recovery Initiative also gives us an opportunity to make prevention part of America's [01:35:00] strategy. Well, FenBlock begins with prescribed fentanyl, it's a platform designed to improve dose precision and I think that's the cause to support gradual reduction in other dependency forming medications. In summary, my message is simple. We need greater attention on prevention with the same urgency we put on rescue and recovery, thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Richard Lawhern followed by Vanessa Moreno and Ty McCord Amesis. Commenter [01:35:30] Lawhern, please proceed.

Richard Lawhern:

Thank you. Good afternoon, I am Richard A. Lawhern, PhD, I'm a co-founder of the National Campaign to Protect People in Pain. We have over 1,800 members including 140 practicing clinicians. I speak today on actions needed to address public health effects of opioid medications, our recommendations are based on these facts. One, FDA estimates of incidents [01:36:00] of moderate to severe substance use disorder in pain patients is about 2.7%. Other sources are much lower, indeed as low as 1 in 1,000 patients who are treated. The DSM-5-TR made major changes to the DSM-5. Two DSM criteria of the 11 were dropped for pain patients. Drug dependence and tolerance are now known as expected effects of

treatment [01:36:30] unrelated to addiction. After these changes, the estimated incidence of SUD dropped by 60% in pain patients. Multiple sources tell us that despite CDC and VA assertions to the contrary, overprescribing by doctors did not create and is not now sustaining the so-called U.S. opioid crisis. Indeed, the CDC SUDORS database informs us that there is [01:37:00] no correlation between state prescribing rates versus mortalities involving prescription opioids. Recent consensus guidelines of the American Society for Interventional Pain Physicians confirm this reading of the CDC data. We also know that addiction is driven by user demand, not by drug supply.

No drug enforcement strategy can possibly work to reduce addiction. Three actions are required. U.S. CDC and Veterans Administration [01:37:30] must repudiate and withdraw their 2023 guidelines without replacement. Two, the FDA must schedule and announce listening sessions for patient advocate organizations to follow up on the present meeting. Three, as required by inter-agency Memorandum of Agreement, FDA, CDC, NIDA, and DOJ must coordinate to remove political influence from their guidelines on opioids and to correct their profound misinformation in public media. [01:38:00] This concludes my briefing, I'm available for follow-up at FDA discretion.

Susan C. Winckler:

Thank you. Our next comment will be from Vanessa Mareno. I will remind commenters Taye McCord-Amasis and Finesse Muya, if you wish to comment please accept the panelist promotion. Our queue then includes Susan Ousterman and Regina Sen. Commenter Mareno, please proceed.

Vanessa Mareno:

Good afternoon, my name is Dr. Vanessa Mareno. I am [01:38:30] a hospital-based dental public health specialist and clinician, and my research and clinical focus is on integrating oral health into medical and behavioral healthcare for populations experiencing significant barriers, including individuals with substance use disorders. People with substance use disorders are 42% less likely to receive early stage dental care than those without a substance use disorder. And in 2022, the U.S. Food and Drug Administration issued a drug safety communication warning that oral transmucosal [01:39:00] buprenorphine has been associated with 305 reported cases of adverse dental events, with most involving dental caries. And I want to emphasize that this is a particularly important public health issue because it represents a medication specific oral health risk associated with a first line lifesaving treatment for opioid use disorder. The appropriate response is not to discourage or withhold buprenorphine, but the FDA's recognition of this effect creates an opportunity to ensure that patients and [01:39:30] prescribers have the information and infrastructure that they need to prevent, identify, and manage dental disease while maintaining access to this essential treatment.

The FDA has an important opportunity to work across federal agencies and healthcare systems to translate recognition of this adverse effect into meaningful prevention. So for example, Medicaid Section 1115 demonstrations could be used to support comprehensive dental benefits for individuals with OUD who are at elevated risk for dental disease. And [01:40:00] in fact, Utah's experience demonstrates the potential values of this approach. Providing comprehensive dental care to individuals with SUDs was associated with improvements in substance use treatment outcomes, including clinical and quality of life measures. So, getting at meeting those critical patient-centered endpoints that were discussed before. And similarly, SAMHSA's Certified Community Behavioral Health Clinics or CCBHC model provides an important infrastructure for integrating these kind of services. [01:40:30] Oral health should be considered within that integrated approach, particularly for individuals on buprenorphine.

Ultimately, we cannot simply treat our way out of the opioid crisis, we also need comprehensive strategies that use a public health approach to prevent disease and address conditions that ultimately undermine the quality of life of people living with OUD.

Putting the mouth back into the body requires us to recognize oral health as overall health, and by extension of that, to treat it that way. Thank you for the opportunity to comment.

Susan C. Winckler:

[01:41:00] Thank you. Our next comment will be from Taye McCord-Amasis. Our queue includes Susan Ousterman, Regina Sen, and David Smith. Commenter McCord-Amasis, please proceed. We see that you're unmuted but we cannot hear you. Please begin speaking.

Taye McCord-Amasis:

[01:41:30] Can you hear me?

Susan C. Winckler:

Yes, please proceed.

Taye McCord-Amasis:

So sorry. My name is Taye McCord-Amasis, I am a USC senior studying pharmacology, and I wanted to get on here and talk a little bit about my research I've been doing with the USC regulatory science research team, as well as ask a question to you all. Through my work with the regulatory science research team, I've spent the past several months researching pharmacogenomics, specifically how variants in the CYP2D6 and CYP3A4 affect opioid [01:42:00] metabolism. What we found is that a person's metabolizer phenotype has a direct impact on both safety and efficacy, where poor metabolizers of drugs like codeine and tramadol often get inadequate pain relief, while ultra rapid metabolizers can experience dangerous, even fatal toxicity, including respiratory depression. This isn't speculative, It's already acknowledged in FDA box warnings for these drugs, but right now that knowledge isn't built into how these medications are actually prescribed or dispensed.

So on that gap, I outlined a potential pharmacogenomic [01:42:30] enabled REMS framework. The structure works in three stages. First, genotype guided prescribing at the point of care. Second, rapid EHR integrated pharmacogenomic testing that returns results fast enough to inform that prescribing decision in real time. And third, genotype verified dispensing, meaning the pharmacy confirms metabolizer status before releasing a high risk opioid structurally similar to how iPLEDGE verifies status before dispensing. This isn't purely theoretical, CMS MolDX [01:43:00] already reimburses these tests when deemed medically necessary, and testing turnaround times have improved enough to support this kind of real-time integration. What I'm ultimately looking to do is get this kind of framework pursued and piloted at the regulatory level.

I am not trying to reinvent the wheel, I'm simply just trying to mirror other FDA approved REM systems such as iPLEDGE. So my question for the panel is, given that the reimbursement pathway and testing infrastructure already largely exists, is there an appetite [01:43:30] to formally pilot a genotype verified

dispensing requirement for high risk opioids like codeine and tramadol within an existing REM structure rather than continuing to leave pharmacogenomic guiding prescribing as optional, non-mandated, and one dose fits all? Thank you very much.

Susan C. Winckler:

Thank you. Our next comment will be from Susan Ousterman. In the queue, we have Regina Sen, David Smith, and Tamera Stewart. Commenter Ousterman, please proceed.

Susan Ousterman:

Good afternoon, my name is Susan Ousterman. [01:44:00] I'm the executive director of the Vilomah Foundation where we support and advocate for bereaved families. I came to this work after I lost my son Tyler to an opioid overdose in 2020. I needed to understand why my son was no longer here, and why my mother, after becoming dependent on opioids prescribed for pain, was abruptly cut off and turned to the illicit drug supply. My family has lived on both sides of these policies that we are discussing today, and for the last six years I've studied every aspect of this crisis, from drug policy and regulation to harm reduction, criminal [01:44:30] justice and emerging therapeutics. And importantly, I've listened to countless bereaved families and people who use opioids for various reasons, and one glaring problem remains. Public trust. This crisis grew from the normalization and aggressive marketing of opioids compounded by regulatory failures, and then we swung too far in the opposite direction, allowing regulation and enforcement to intrude in medical care.

Both caused tremendous harm. Our response to one policy failure created another. We [01:45:00] need structural reform. First, restore regulatory independence. Congress must fully fund FDA to remove its financial dependence on industry user fees. Second, protect the physician-patient relationship. Clinical judgment should be governed by medical standards, not commercial interests or fear of law enforcement pressures. Third, remove commercial influence from medicine. End direct pharmaceutical solicitation of prescribers and direct to consumer prescription drug advertising. [01:45:30] Fourth, redefine success. Abstinence cannot be our default endpoint. Reduced use and overdose risk are very important and so is restored agency, increased connection and quality of life. I'm excited about ibogaine. This is a treatment my son saw and I have researched extensively since his death, but those outcomes should design the models of care. I lost my son to this epidemic and I have every reason to want strong safeguards around dangerous drugs.

I'm not asking for less regulation, I am asking for regulation rooted [01:46:00] in science, because for me and many others, FDA approval is not a standard that I trust and that should concern all of you. Public trust can be earned back, but it requires regulators to acknowledge their role in this crisis and intentionally rebuild that trust through transparency, independence, accountability, and integrity. Thank you.

Susan C. Winckler:

Thank you. Our next comment will be from Regina Sen. In the queue, we have David Smith, Tamera Stewart, and Sarah Tompkins. Commenter Sen, please proceed. [01:46:30] You're still muted. There you go.

Regina Sen:

Hopefully my time's still available.

Susan C. Winckler:

It is, please proceed.

Regina Sen:

Good afternoon. I'm Regina Sen, a caregiver and founder of Emily's Place The One, restoring dignity and voice to women sidelined by catastrophic illness [01:47:00] or injuries since 2020. Like many here I carry a painful story, but I'm not here only to tell it. I propose capturing these experiences, connecting them and acting before more families reach crisis. This slide is an invitation to people bedbound, housebound, and living with severe pain as life shrinks to survival. Today, this QR code opens to a proposal for an academic research partnership, turning this QR code into a real-time collection of lived experiences where patients and caregivers [01:47:30] document loss of care, function, continuity, pharmacy insurance barriers, caregiver burden, financial and public cost. Their experiences can be connected instead of scattered and uncounted. This groundbreaking step catalyzes isolated testimony to evidence infrastructure, and invisible crises and a pattern recognition, preventability review and action.

I ask this foundation FDA to help convene this trauma-informed design to detect, measure, review, and prevent harm from disrupted pain care [01:48:00] and undertreated pain. For two and a half years I watched my loved one endure life-altering pain after treatment was reduced, legislated out of functioning, bedbound in agony. I searched for help believing I failed her. She's lost nearly all her 30s. In a pivotal grocery store conversation, I learned a pain physician had stopped practicing under pressure. That led me to finding a pain advocacy community I didn't even know existed. When my loved one faced a life-threatening gap of care in unmanaged withdrawal, an advocate from [01:48:30] that community helped us find one of the few humanitarian doctors left. In a formidable painscape of care, I was not failing her. We hit an iron wall that families face alone. No family's survival should depend on a chance grocery store conversation.

Massachusetts, where I live, reviews maternal harm across patient, family, clinician, facility, system, and community factors. Please help adapt that learning model for pain care. See QR code for proposal [01:49:00] here on this slide. Please count the harm, review preventable causes, include patients, caregivers, and decision makers. Protect patients and clinicians during vulnerable transitions, publish the findings and responses, fund the remedies. We've lost too many stars from our skies for heartbreaking years. Please help us bring them back.

Susan C. Winckler:

Thank you. Our next commenter will be David Smith. Then I would ask potential commenters Tamera Stewart and [01:49:30] Sarah Tompkins to accept the panelist prompt if you would like to provide comment. We will then turn to Tyler Varisco. Commenter Smith, please proceed.

David Smith:

Thank you. We have been bombarded with messaging about the potential risks to the public health associated with opioid pain medications after an increase in overdose deaths reportedly caused by doctors over-prescribing opioid pain medications. We now know that the increase in deaths [01:50:00] were not the result of over-prescribing by doctors as portrayed by the multi-district litigation narrative against Purdue, against the distributors and pharmacy chains, and by the National Opioid Settlement, but were rather a diversion issue caused by pill mills operating with the intention to release prescription medications onto the illicit market. The resulting increase in deaths came from misuse and abuse, and were not in any way caused [01:50:30] by the treatment of pain patients. We now know that overdose deaths caused by prescription opioid medications taken by pain patients while being followed by a doctor are so rare as to be almost immeasurable. We even have several authors of the CDC guidelines admitting that the opioid crisis was erroneously blamed on prescription opioid medications.

At this point, any assertion that prescription opioid medications cause the parabolic [01:51:00] rise in deaths from illicit fentanyl analog compound poisonings that began in about 2010 is completely fraudulent. What has been completely omitted from this conversation are the benefits to patients of opioid pain medications, and the massive amounts of harm and deaths caused to patients by the de-prescribing agenda. No agency has tracked patient outcome of the de-prescribing agenda. This public health initiative intended to reduce [01:51:30] overdose deaths by reducing the use of opioid pain medications has caused a different public health emergency that remains unacknowledged. We must begin to assess and tabulate the numbers of harms and deaths caused to patients by this public health initiative to determine the patient outcomes resulting from the de-prescribing initiative, and we must then make a course correction to stop the needless literal torture and deaths that continue. Opioids [01:52:00] save lives. It is time to make pain medication great again, and I yield back.

Susan C. Winckler:

Thank you. Our next comment will be from Tamera Stewart, then we'll turn to Tyler Varisco, and then our in-person comment beginning with Chris Fox. Commenter Stewart, please proceed.

Tamera Stewart:

Thank you for this opportunity today. I'm Tamera Stewart, the policy director for the P3 Alliance and a patient who benefits from pain medication. Section 112 [01:52:30] of the Support Act directs the FDA to address the broader public health effects of opioid analgesics as part of its benefit risk assessment. Our request today rests on one premise, that outputs are not outcomes. To honor the fact that Congress explicitly used the word benefit four times, we suggest that four additional actions come from the FDA. First, we measure benefits. Second, measure risks and harms from undertreatment and lost care. Third, assess [01:53:00] consequences before any more changes. Fourth, create an accountability loop, publish, review, then respond. Is it simple? No, but it's not impossible either. Luckily, and the FDA already acknowledges the difficulty of the situation, but they have already built the framework. This omission has continued despite repeated warnings in response to props 2012 petition to the FDA, again throughout the CDC guideline process, and even [01:53:30] again at the 2025 advisory committee meeting in May of last year.

The FDA REMS framework separates implementation from outcomes, while federal law requires both assessment and then provides for modifications as needed. Applying that rigor here is the bare minimum. The FDA should first mine prior docket comments to count the benefits and harms that have already been reported, then use the patient's own language [01:54:00] to define required measures

going forward. Alongside the extensively covered treatment risks, we submit that meaningfully fulfilling section 112 requires the FDA to first measure benefits, pain, function, relief, quality of life, independence. Second, measure the risks and harms resulting from current guidance and labeling, including your undertreatment, involuntary tapering, [01:54:30] discontinued treatments.

Third, before any more changes, changes to labeling, availability or guidance, the FDA must assess likely consequences for the patients like us who benefit. Although this begins as measuring patient level outcomes, public health level benefits can be captured and extrapolated. Fourth, we've got to create an-

Susan C. Winckler:

Thank you. Our next comment will be from Tyler Varisco. Then we will turn [01:55:00] to comment in the room. Our queue is Chris Fox, Peter Lee, and Charles Stillings. Commentor Varisco, please proceed.

Tyler Varisco:

Good afternoon. My name is Tyler Varisco, I'm a pharmacist, pharmacoepidemiologist and director of the Pharmacy Addictions Research and Medicine program at the University of Texas at Austin College of Pharmacy. Buprenorphine is arguably the most accessible treatment for opioid use disorder, and has been shown to reduce the risk of opioid overdose by approximately 60%. It is also very safe. In one analysis [01:55:30] of 74,474 opioid overdose deaths, only 2.6% involve buprenorphine and 92.3% of these involved another substance. Despite this evidence, only 39% of community pharmacies in the United States routinely dispense buprenorphine. Pharmacists often express reluctance to dispense buprenorphine because of concerns about diversion and non-medical use. Prevailing evidence, however, demonstrates that nearly 80% of people who report using diverted buprenorphine do so to prevent [01:56:00] withdrawal or to maintain abstinence from non-prescribed opioids. In other words, this is not misuse, but a symptom of insufficient access to care, a finding that also calls into question buprenorphine's DEA schedule 3 classification.

FDA is well positioned to improve access by ensuring its policies and educational materials reflect the current standard of care. In December of 2024, for example, FDA recommended labeling changes acknowledging that doses of buprenorphine above 24 milligrams [01:56:30] may be appropriate for some patients, and evidence-based and timely change that has positively improved access to care. But more can be done. I encourage FDA to consider the following changes to three relevant REMS programs. First, FDA should update the buprenorphine containing transmucosal products for opioid dependence REMS materials. The current dear prescriber and dear pharmacist letters remain focused on diversion prevention, potentially reinforcing reluctance to prescribe or dispense buprenorphine. The prescriber letter recommends induction under appropriate [01:57:00] supervision despite evidence and current guidance from ASAM and SAMHSA supporting the appropriateness of home-based initiation. Secondly, FDA should revise the opioid analgesic REMS education blueprint to encourage additional education on opioid use disorder treatment beyond the limited addiction related content currently included.

Third, FDA should study how REMS requirements for long-acting injectable buprenorphine affect access across settings of care. Stakeholder engagement and mixed methods research should be used to determine if current REMS requirements create unnecessary barriers [01:57:30] without meaningfully improving safety. To conclude, FDA should examine how opioid agonists and buprenorphine REMS

programs can be used to promote access to evidence-based treatment rather than inadvertently discouraging physicians ...

Susan C. Winckler:

Thank you. We will now turn to in-person comment. Our first comment will be from Chris Fox, then we'll turn to Peter Lee and Charles Stillings. Commenter Fox, please proceed.

Chris Fox:

Thank you. Good afternoon, my name is Chris Fox and I'm the executive director of a Washington D.C.-based coalition [01:58:00] called Voices for Non-Opioid Choices. I'm grateful for the opportunity to speak today. Voices for Non-Opioid Choices believes that we can prevent many of the effects of opioids by reducing what we'd call unnecessary exposure to them. That is why we launched Voices in 2019. At the time, the opioid addiction crisis was claiming tens of thousands of Americans every day. While opioid-related overdose deaths have come down significantly from their peak a few years ago, opioid-related overdoses are still today historically high. In fact, [01:58:30] opioid-related overdose deaths are basically the same today as you were in 2017 when the U.S. government declared the opioid crisis a public health emergency. The FDA has a critical role to play to mitigate this crisis, and we at Voices want to encourage them to do even more by increasing access to opioid alternatives.

I do want to be clear on one point. While our organization advocates strongly for the increased patient access to non-opioid pain treatments, we are not against prescription opioids. Rather, we believe that these are important medications [01:59:00] that may make good medical sense for certain patients, but we believe that it is the FDA's responsibility to consider the public health impacts of prescription opioids and thoughtfully pursue other options. As for our members, the public health impacts are personal. The path to addiction can and does start with medical exposure to an opioid. Research shows that this occurs in approximately 10% of surgical patients. The simple reality is that for many Americans, they have no choice in how their acute pain is managed, so we must continue to double down on efforts to bring more options [01:59:30] to patients to fit their unique needs. This dynamic is changing slowly, but more work remains.

As a nation, we have invested billions trying to spur innovation in the development of non-addictive pain medications. The FDA has announced plans already to fast track approvals for such approaches, and we're just now starting to see the fruits of these investments, and more and more non-opioids are moving along in the development process, including cutting edge approaches incorporating gene therapy to treating acute pain. We hope that the [02:00:00] FDA continues to appreciate pain for the complex medical condition it is, and focus the appropriate resources to encouraging the development in this space. Without this kind of commitment, we will be taking on risk that no individual or community should have to bear. That's what Voices is attempting to do, to align availability with accessibility, to ensure that all patients in all settings can just as easily access a non-opioid as they could a prescription opioid, because [inaudible 02:00:27] matter.

Susan C. Winckler:

Thank you. Our [02:00:30] next comment will be from Peter Lee, and then our final comment will be from Charles Stillings. Commenter Lee, please proceed.

Peter Lee:

Good afternoon, everybody. I'm a co-founder of the SpaceRx. We're a team of neuroscientists developing a non-opioid mechanisms to treat opioid and polysubstance overdose. Naloxone has saved many lives, but survival alone is not the only goal. Patients also requires a quick recovery from effective breathing, [02:01:00] protection against hypoxic brain injuries, and maximize the chance of full recovery. Today's overdose environment is becoming more complex with a potent and long-lasting synthetic opioids and polysubstance use, and accidental overdose involving alcohol. We're asking the FDA to support the development of the rescue therapy with non-opioid mechanism that complement Naloxone. We are also asking the agency to include the time of [02:01:30] restoring effect breathing, durability respiratory recovery risk, precipitated withdrawal protection against hypoxic brain injury as a clinical meaningful outcome. Naloxone remains essential, however, additional rescue mechanism could improve patient outcome in this incredibly complex overdose landscape. Thank you.

Susan C. Winckler:

Thank you. We will conclude public comment with Charles Stillings. Commenter [02:02:00] Stillings, please proceed.

Charles Stillings:

Thank you for the opportunity to speak today. My name is Charles Stillings, I'm representing NeutraNarc, a leading manufacturer of drug disposal systems, including in-home systems for opioid disposal. The NeutraNarc system is already in many healthcare systems across the nation, facilities, and in partnerships with communities and law enforcement stakeholders to help reduce diversion risks and improve safe disposal of unused controlled substances and other dangerous drugs. [02:02:30] We are here today to help deliver on Secretary Kennedy's commitment to preventing addiction while supporting recovery and making communities safer. Opioid medication provides important clinical benefits in pain management and addiction treatments when prescribed, monitored, and used appropriately. Those benefits come with risk, and such dependencies, misuse, overdose, accidental and intentional exposure to adults and children and diversion. Research shows that unused opioids commonly remain in the home after treatment, even available disposal options [02:03:00] such as mail-back envelopes and take-back programs as these programs can result in inconsistent and delayed patient fall through.

Too many unused opioids remain in homes across America for far too long. We believe strongly that existing technologies to address this public health concerns, in-home disposal systems can offer an immediate low friction option at the moment a patient determines the medication is no longer needed and can play an important role in ensuring that unused prescription opioid medications are safely, promptly, [02:03:30] and effectively rendered unavailable, thus preventing diversion, misuse, and abuse and accidental exposure. In-home disposal systems that will be most affected are those that are simple, easy to use with minimal potential for errors, supported by testing, demonstrating that active ingredient is rendered unavailable across a range of opioid ingredients and dosage forms with high unavailable thresholds achieved in a relatively short period of time, products such as with child-resistant caps and also suitable for solid waste disposal in the household. [02:04:00] But these solutions cannot be achieved their promise unless they are given to patients who receive opioid medication.

We encourage the FDA and other stakeholders to adopt regulations and framework that promote availability of in-home disposal systems to patients. Every opioid treatment plan should include a clear instructions for secure storage, prompt disposal each medication, and is no longer needed or medically needed. Take back locations and mail-back programs remain important, but not every patient can readily use those options. This is [02:04:30] why we need properly evaluated multi-use in-home disposal kits to increase disposal compliance. Thank you and the foundation and the FDA for allowing me to speak.

Susan C. Winckler:

Thank you. That concludes our public comment portion of the meeting, it also concludes our meeting. I must say on behalf of the foundation and FDA, thank you to everyone who participated in today's discussion, particularly the individuals who invested in preparing and delivering public comment. Your contributions are greatly appreciated. The [02:05:00] recording, transcript and slide deck from today's public meeting will be posted at reaganudall.org sometime next week. We appreciate you spending the afternoon with us today and hope that you have an excellent rest of the day. Take care.