Addressing the Public Health Effects of Opioid Medications

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

Transcript Part 1

Welcome

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

Susan C. Winckler:

[00:00:30] Hello everyone and welcome. Thank you for joining us both here in the room and online for today's public meeting on Addressing the Public Health Effects of Opioid Medications. I'm Susan Winckler, and I serve as chief executive officer for the Reagan-Udall Foundation for the FDA.

For those of you who are new to the foundation's work, we're the nonprofit, non-government organization created by Congress to help the FDA do more to protect and promote the public's health. Today's meeting [00:01:00] is one of several engagement activities that we conduct in collaboration with the FDA in partial fulfillment of Section 112 of the SUPPORT Act for Patients and Communities Reauthorization Act of 2025, Assessment of Opioid Drugs and Actions. Today, we're going to hear from experts across federal sectors about the efforts to improve the management of pain and addiction, and most importantly, hear perspectives from over 45 members of the public on this topic. This is a meeting about shared learning, [00:01:30] which can help inform the agency's work. This is not a meeting about specific regulatory activity, about specific regulatory applications, or any specific regulatory action. The foundation does not engage in regulatory decision-making.

So I have just a few housekeeping notes. We're joined today... we have a small but mighty group here in the room at FDA's headquarters in White Oak, Maryland, and more than 800 participants who are attending virtually. Because of the size of the meeting, [00:02:00] the virtual attendees' cameras and microphones will remain off with the exception of those who requested the opportunity to present public comment, and I will give you extensive directions on how to engage in the public comment when we get to that portion of the meeting. We are recording this event, and we'll post the recording, the transcript, and the slides on the foundation's website next week. The agenda for today and brief slide deck are available on our [00:02:30] event page now. For those of you who are present in person, we ask you to embrace the reality of being here in person and that you don't join the meeting virtually. It simply creates complications to have that dual presence.

Now, before I dive into the agenda for the day, I want to thank each of our speakers for joining us and preparing for the event, and particularly our colleagues in FDA's Center for Drug Evaluation and Research for envisioning the meeting.

[00:03:00] So let's think about our time together. We begin with opening remarks from FDA leadership. Then we're going to have a panel discussion among federal agencies where we'll review the use of

opioid medications and efforts by those agencies to improve the treatment of pain and addiction. And as I noted, the majority of this meeting is invested in hearing from members of the public. We offered public comment slots to over 90 individuals [00:03:30] who indicated their interest in providing comment on one of the three topics, and we are going to hear from 47 of them today, the 47 who confirmed their interest. Those three topics are the scientific evidence regarding conditions of use, safety concerns, or benefit-risk assessment of opioid medications, the second topic is input on FDA's regulation of opioid medications, and the third, additional actions that could be considered to address the public health effects of opioid medications.

[00:04:00] As noted, I will explain more about the public comment process when we reach that portion of the agenda. We will hear from many of you, then we'll take a short, break and then we will resume listening for the remainder of the meeting. I will note that all of our public commenters who will be participating virtually, please check now to make sure that the name that you have on your Zoom meeting for your personal name is the same as the name that you use to register [00:04:30] for the meeting so that we can identify you as a public commenter. Also, the foundation will accept written comments via electronic submission through September 23rd, and there are instructions for that on our website. The meeting will adjourn following the public comment period.

Opening Remarks

Michael Davis, MD, PhD, Director, Center for Drug Evaluation and Research, FDA

And with that, we can get to the substance of the meeting. I am thrilled to be one of the first people to be able to welcome Dr. Michael Davis as [00:05:00] director of the Center for Drug Evaluation and Research. I think that announcement is less than 24 hours old, so we're pleased to do so. But Dr. Davis works to advance FDA's top drug evaluation and research priorities, and we're thrilled to have him join today to open the meeting.

So Dr. Davis, I'll turn the podium to you.

Dr. Michael Davis:

Okay. Testing. Yeah. Hi. Yeah, thank you so much, Susan, and good afternoon everyone. [00:05:30] I want to begin by just thanking the Reagan-Udall Foundation for its partnership in convening today's meeting and to all of you for your taking the time to attend and participate in this important discussion. It's wonderful to see so many of you here in person, and I also want to warmly welcome the participants who are joining us virtually. We recognize that for many individuals, the daily realities of managing chronic pain, navigating recovery, or dealing with substance use disorders can make travel [00:06:00] extremely difficult. Please note that we deeply appreciate your effort to participate in the way that makes the most sense for you. Your presence and your voices are absolutely vital to this process.

For those I haven't met, I'm Mike Davis, and I serve, as of yesterday, as the director for FDA Center for Drug Evaluation and Research. As a physician and as a psychiatrist, actually in my case, I've seen the important role that medications can play in helping patients [00:06:30] manage serious health conditions and maintain their quality of life. For some patients, opioid analgesics remain an important and appropriate treatment option. At the same time, we must confront the reality that these medications also carry profound risks of addiction, abuse, and overdose. This presents us with a difficult but an essential public health responsibility of supporting appropriate access to treatments for patients

who need them while taking meaningful steps [00:07:00] to reduce preventable harms. The overdose crisis remains one of the most pressing public health challenges facing this country, and it remains a top priority for the agency.

To guide our efforts, we recently released our Public Health Pillars to protect and promote the health of all Americans. Our work on pain management, substance use disorders, and overdose prevention falls squarely under our fourth pillar of preventing chronic disease and promoting wellness in America. [00:07:30] Under that pillar, we've made addressing overprescribing and supporting addiction prevention explicit priorities through labeling requirements, guidance documents, and public-facing health information. This work also aligns directly with the January 2026 executive order on addressing addiction through the Great American Recovery Initiative, which is a nationwide effort to help Americans [00:08:00] overcome addiction, find treatment, enter recovery, and stay connected to support in their own communities. And of course, preventing addiction through appropriate evidence-based pain management sits at the center of both of these efforts. This brings us to why we're here today.

The SUPPORT for Patients and Communities Reauthorization Act of 2025 directed FDA to do two important things. First, to publish a plan for assessing approved opioid medications, one that addresses [00:08:30] the public health effects of these drugs, including updates on our risk-benefit assessments and our work supporting the development and approval of non-addictive medical products. Second, to provide a meaningful opportunity for public input because Congress recognized what we FDA already know, the regulatory decision-making is better when it's informed by real-world experience such as those experienced by people who are here today and virtually.

FDA's work does not stop when a drug is approved. [00:09:00] We continuously conduct post-approval monitoring and assessment of opioid analgesics as well as other medications we approve. We look at how these medications perform in the real world, who benefits, who is harmed, and what can we do better. And while the FDA's regulatory reach is extensive, we recognize that regulation alone is not enough to solve this crisis. We must collaborate closely with other federal agencies, clinicians, and community partners to ensure that both balanced pain management [00:09:30] and robust addiction treatment are prioritized together. To do that effectively, we need to understand how our policies and our regulatory decisions actually play out in the real world. We need to hear about how they affect patients, clinicians, families, and communities.

In closing, I want to just ask that, as you participate today, I encourage you to be candid with the agency. Tell us what the evidence shows, tell us what you're experiencing, tell us [00:10:00] where you believe our current approaches are succeeding as well as where you believe that they could be improved. Not just with the FDA, but the people who present, we all may not agree on every issue that's raised today, but hearing different perspectives and grounding our work on both rigorous evidence as well as real-world experience is essential to protecting and promoting public health in the country.

Thank you again to our speakers, our federal partners, and everyone else who's participating in today's public comment [00:10:30] sessions and to those joining us in person and online. Your participation will help inform FDA's continued work to address the public health effects of opioid medications and to refine our approach going forward. I look forward to listening to today's discussion.

With that, Susan, I'll turn it back to you. Thank you.

Federal Partner Panel

Timothy J. Atkinson, PharmD, Acting Director, Opioid Safety, Specialty Care Program Office, U.S. Department of Veterans Affairs
Robert Baillieu, MD, MPH, Physician and Senior Advisor, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration
Wilson M. Compton, MD, MPE, Deputy Director, National Institute on Drug Abuse
Kristine Schmit, MD, MPH, Medical Officer, Health Systems and Research Branch, Division of Overdose Prevention, U.S. Centers for Disease Control and Prevention
Marta Sokolowska, PhD, Deputy Center Director for Substance Use and Behavioral Health, CDER, FDA

Susan C. Winckler:

Thanks so much, Director Davis, for grounding us in that orientation and that we are here to [00:11:00] listen and to learn. I greatly appreciate that.

I'm going to ask our two in-person panelists to come up on stage and join me for our discussion and hope that our virtual panelists are with us both visually and that we can hear them.

Thank you two for making the trip over.

Dr. Wilson Compton:

Glad to be here.

Dr. Robert Baillieu:

Thank you.

Susan C. Winckler:

And look, they've made the virtual trip as well. We have everyone joining us.

This is our panel of [00:11:30] federal agency representatives, each speaking to their role within the federal government's broader initiatives to improve the treatment of both pain and addiction and harness the power of opioid medications.

So I'm going to start with... There is a privilege of being here in the room, and that means that I get to pick on you first. Dr. Compton, I'm going to turn to you first. You are deputy director of the National Institute on Drug Abuse at the National Institutes of Health, and so you're really at the front [00:12:00] end of this three part of endeavor, to see that we make better use of these medications as safely as we can. Would you give us a little bit of the history of NIDA's engagement in this space and role in the treatment of substance use disorder in pain and making the best use of opioid medications?

Dr. Wilson Compton:

Well, certainly. Well, thank you very much, Susan.

Susan C. Winckler:

There you go. Yep.

Dr. Wilson Compton:

Is this working now?

Susan C. Winckler:

Yes.

Dr. Wilson Compton:

Okay. There's no feedback to me, so I trust the audience to tell me.

Thank you very [00:12:30] much, Susan. It's a pleasure to be here today. And really, as I was joining you, I was reflecting on I've been in this room at FDA multiple times because of the extensive collaborations between NIH and NIDA with the FDA to address these issues related to the overdose crisis in our country, in particular, the use of opioid medications. I'm really pleased to reflect with you.

Just a snippet about some of our history here. Remember that the National Institutes of Health and NIDA in particular, our responsibility [00:13:00] is to conduct the basic and applied research that's necessary to help improve treatments, prevention, and public health issues related, in our case, broadly to addiction and substance use disorders. And so, certainly, our work at NIDA has been integral to our broad federal efforts and national efforts related to the opioid crisis writ large.

So I just have a couple of examples for you that I think speaks to some [00:13:30] of the history. Some of it started out in this very room with a meeting between CDC, FDA, NIDA around the development of new formulations of naloxone. Now, this goes back about a decade or a little bit longer, and really our goal was to spearhead the development of naloxone formulations that could be used in real-world settings effectively. And so following that, that inspired industry to come [00:14:00] to NIH for some support and through their own efforts to develop intranasal products that have really revolutionized the availability of naloxone as a lifesaving overdose remedy in our country. That's one of the most proud efforts, and I think one of the furthest-reaching.

Another broad area of impact has been in the buprenorphine area, so both in terms of new formulations of the original research on buprenorphine supported by NIDA now several decades ago, [00:14:30] but also the development of new formulations, whether that's the long-acting formulations and other ways to make sure that these medications have the variety of approaches that our patients need. Our implementation science has been a broad theme as well, and I'll point towards our work that we've developed jointly with many collaborators across agencies, like CDC, SAMHSA, FDA and others, to see that we can get buprenorphine delivered through emergency [00:15:00] personnel, both through emergency departments and more lately through EMS itself with onsite implementation of buprenorphine. Some of these studies are supported by the HEAL program that's a very broad congressional appropriation that has allowed NIH to really accelerate our work in the opioid space, and so we're very proud of that implementation science as well.

Now, a third area that I'll highlight is in the area of pain treatment where the basic science work [00:15:30] at NIH around the sodium channels that are responsible for pain perception, that some of that very basic science led to the eventual. It was a component in the drug approval of suzetrigine just, what, a year and a half ago. So that new non-opioid pain medication is an example of how our basic science program can lead to major new opportunities for discovery, translation, [00:16:00] and eventual treatment for our patients.

I hope that provides some of the examples of our work.

Susan C. Winckler:

Really helpful. It was a great reminder and perhaps for me even an illumination of not just the basic science, but then the application and thinking about how to, as we learn more about these products, continue to improve them and make sure they're used.

Dr. Wilson Compton:

Well, one thing to keep in mind as well, NIH is particularly known for our basic science work. I like to remind people that we study everything from [00:16:30] molecules to managed care. And so, we have robust research programs at all aspects of the translation pipeline from the earliest phases of discovery through development of medications or other interventions as well as their implementation and eventual, some of the issues related to the widespread adoption.

Susan C. Winckler:

Which we'll come back, because we also know, for what has been done, there's also more to be done in this space.

I want to turn now... We know that at least some of the work that's led by NIDA, particularly the basic sciences work, then emerges [00:17:00] at the Food and Drug Administration along with the work of industry sponsors, researchers, and patient advocates. So our FDA voice on this panel is provided by Dr. Marta Sokolowska, who's deputy center director for Substance Use and Behavioral Health in FDA Center for Drug Evaluation and Research. So Dr. Sokolowska, why don't you share some reflections on the agency's activity in improving the treatment of pain and addiction and improving the safe and effective use of opioid medications?

Dr. Marta Sokolowska:

[00:17:30] Well, thank you, Susan, and thank you to everyone who's joining us today. I wish I could be there in person with you, but I'm glad that I can join virtually to discuss this important topic.

And first, I want to emphasize the framing that Dr. Davis provided on the balance we must strike on the pain management and addiction prevention and treatment, and also leverage some of the comments that Dr. Winston just mentioned a few minutes ago.

The overdose crisis has [00:18:00] been an urgent public health priority for FDA for a number of years, and we need to continue to do everything we can to prevent the overdoses and addiction while still

making sure that we are able to provide valuable medication for whom other treatment options are not adequate. So we want to make sure that we can support the patients and the clinicians, so they're able to address the pain as well.

While today's meeting [00:18:30] is in partial fulfillment of the SUPPORT Reauthorization Act of 2025, I think that it's important that we spend a few minutes thinking back to the SUPPORT Act of 2018 and highlight a few of FDA actions that impacted our current environment. They're also addressing, to some degree, some of the comments that Dr. Wilson mentioned. In fulfillment of this requirement, we issued, for instance, two guidances, one on [00:19:00] the development of non-opioid analgesics for acute pain, and that was in 2022, and one on the development of non-opioid analgesics for chronic pain, and that was in 2025. The true impact of such guidances will be seen hopefully in the future, and we are looking forward to having more non-opioid analgesics products being developed and the pipeline really growing so we can approve more of these treatments. But as Dr. Wilson mentioned, [00:19:30] one of the, I believe, good signs is that in January of 2025, FDA approved suzetrigine as first-in-class non-opioid medication to treat moderate to severe acute pain in adults.

In addition, the SUPPORT Act, for instance, required FDA to examine disposal options for opioids. In response to that, in October of 2024, FDA approved to risk evaluation and mitigation strategies [00:20:00] modifications requiring manufacturers of opioid analgesics dispensed in outpatient setting to provide the drug prepaid mail-back envelopes upon request to pharmacies and other dispensers of opioid analgesics as an opioid disposal option for patients and for caregivers. SUPPORT Act also required FDA to develop evidence-based chronic opioid analgesic prescribing guidelines for the indication-specific treatment [00:20:30] of acute pain where such guidance did not exist. Thus, we awarded through cooperative agreements the development and dissemination of such guidelines for management, for instance, of acute dental pain, acute postoperative obstetric pain, acute lower back pain, and acute postoperative laparoscopic abdominal surgeries pain. These guidelines are intended to support patients in obtaining safe and effective relief from acute [00:21:00] pain as well as clinicians in helping reduce the risk of opioid diversion, opioid use disorders, and overdose.

I know that my time is limited, but I want to emphasize a few non-SUPPORT Act-related activities. Over the years, FDA used safety label changes and drug safety communications to ensure that new safety information is reflected in opioid labeling and is communicated [00:21:30] appropriately to patients and clinicians. So for example, in 2019, FDA announced harm reported from sudden discontinuation of opioid medication and required labeling changes to guide prescribers on gradual individualized tapering strategies. And in 2025, for instance, FDA required safety labeling changes and issued drug safety communication emphasizing risk associated with long-term opioid use [00:22:00] and other safety issues. These 2025 updates were based on findings from studies conducted to fulfill post-marketing requirements of PMRs, as well as reflecting the May 2025 advisory committee meeting and discussion, as well as literature review.

We have also done a lot of work on increasing access to naloxone. Again, reflecting back to Dr. Wilson's comments, we really focused on introduction of an over-the- [00:22:30] counter non-prescription intranasal naloxone products as well as on increasing the shelf life of some of these products where data was supported. These demonstrates FDA commitment to the balanced pain management that meets the needs of the patients and empowers clinicians to provide individualized and evidence-based care.

And with that, I'll turn it back to you.

Susan C. Winckler:

Thanks so much, Dr. Sokolowska. And I love what you've introduced to this convention. I'm now going [00:23:00] to call you Dr. Marta and Dr. Wilson. I'm going to move to doctor and first name once I call on you.

It's a great piece. But you remind us, so many people consider the role of the FDA when products reach the market, and you remind us that for every product that reaches the market, then there's an ongoing post-marketing and learning requirement with the agency to keep pace, as you mentioned, not only with things like labeling so that clinicians [00:23:30] know how to use a product, but also disposal so that there's good information about what to do if these products are no longer used.

So let's keep moving through our panel. We're getting a little closer to the patient every time, a little closer to clinical care, and further about the breadth and the depth of the services that the federal government is aspiring to address the challenge in front of us.

So I'm going to turn now [00:24:00] to Dr. Baillieu. Would you tell us a little bit... I'll call you Dr. Rob from now on-

Dr. Robert Baillieu:

That's okay, yeah.

Susan C. Winckler:

You get one last name intro, and then I turn to first names.

But share the role and activity of SAMHSA, which many would know, but the Substance Abuse and Mental Health Services Administration, where you're a physician and senior advisor at CSAT, the Center for Substance Abuse Treatment. So help us continue on our journey.

Dr. Robert Baillieu:

Thank you, and good afternoon, everyone, and thank you all for being here so much and for including [00:24:30] SAMHSA in the conversation today.

My name is Robert Baillieu. I'm a physician and senior advisor in SAMHSA CSAT, and SAMHSA is the agency charged with protecting the behavioral health of the nation. Within SAMHSA is CSAT, the Center for Substance Abuse Treatment, and CSAT is charged with reducing gaps in care, helping people access care, supporting care that is person-centered, respectful, and evidence-based. My role in all that is to work with all of our partners [00:25:00] and across SAMHSA to think about policy from a clinical and implementation perspective. Our shared vision at SAMHSA is to create and support systems of care that truly meet people where they are when it comes to substance use disorders, evidence-based, they're person-centered, and delivered with compassion.

SAMHSA does this using three levers. The first is treatment system oversight, and through CSAT's Division of Pharmacologic [00:25:30] Therapies, they're charged with implementing 42 CFR Part 8, which is the OTP rule, which was updated in 2024. This rule-

Susan C. Winckler:

Opioid Treatment Program?

Dr. Robert Baillieu:

That's right.

Susan C. Winckler:

OTP?

Dr. Robert Baillieu:

OTP, you're right. Apologies, too many acronyms in federal government. But certainly, Opioid Treatment Programs after 2024 were encouraged to become far more patient-centered and to truly meet patients where they are, to the extent that the rule promotes shared decision-making, it promotes the care team [00:26:00] working with the individual to really find out what their treatment goals and needs are and to match them and to readdress these regularly, but to also provide care that is meaningful to the individual and keeps them in recovery. This has been a really important initiative at SAMHSA and one that is ongoing, because implementation starts not just after writing the rule, but many years beyond, making sure people are fully supportive and understanding of the rule, including the patients themselves.

Our second lever, of [00:26:30] course, is financing and systems development, and we do that through our grants programs. Our flagships grants are SOR and TOR. SOR is the State Opioid Response grant and TOR is the Tribal Opioid Response grant, and we have a number of discretionary grants as well. And together, these account for over $1.5 billion in funding for support around the country for systems reform and care. So states through SOR and tribes through TOR are able to work with their communities to create integrated systems of care that [00:27:00] can fully support individuals as they need to access SUD treatment. Our discretionary grants work on very discreet areas, and they can support access to medications, prevention, recovery, peer support programs as well, all of which are very, very important.

And our third lever is implementation support, and this is done through training and technical assistance. SAMHSA offers, we call it TTA, another acronym, a wide variety of TTA [00:27:30] opportunities for not only practitioners, they have direct access to many of our programs, particularly the PCSS, which is the Primary Care Clinical Support Service, yeah, primary care. They allow practitioners to call them directly and ask questions about how to implement MOUD in their practice settings. We have TTA centers that work with clinicians to implement Part 8. We have telehealth support. We have many other [00:28:00] supportive services that are really focusing not just on the provision of person-centered care to populations, but also implementation support to ensure that this is sustained and ongoing.

Certainly, as I mentioned, our shared mission at SAMHSA is to really foster those programs that are person-centered, evidence-based, and truly meet individuals where they are in their recovery journey. In this conversation, our role at SAMHSA is a discreet part. We [00:28:30] deal with substance use disorders, but we take real pride in that and really are very grateful for the feedback that we will potentially receive today because learning from the field is incredibly important in our role.

So thank you.

Susan C. Winckler:

Helpful for that as we're thinking about... It's a very broad topic when we think about the use of opioid medications and better management of pain and addiction and substance use disorders. Thank you for reminding, and I think the patient-centered care is [00:29:00] a component. It's part of what all the federal agencies are supporting in some way-

Dr. Robert Baillieu:

Absolutely, yeah.

Susan C. Winckler:

... and particularly from the SAMHSA side.

So let me turn now to another agency with a prominent role in improving the public health, and that's our colleagues at the Centers for Disease Control and Prevention. Dr. Schmit, thank you for joining us. And would you share some of the activity that you see and lead as a medical officer in the health systems and research branch at CDC's Division of Overdose [00:29:30] Prevention?

Dr. Kristine Schmit:

Susan, I really appreciate the opportunity to be here today and to share in this conversation, and I appreciate the opportunity to share some of the specific examples of what we're doing here at CDC in this space. And I think it follows really nicely from the speakers that have gone before me.

So one of the key CDC efforts in the promotion of safe and effective opioid prescribing and pain management was the development [00:30:00] of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain, which was released in 2022. The 2022 guideline is intended to improve communication between clinicians and patients about the benefits and risks of pain treatment, including opioid therapy, improve the safety and effectiveness of pain treatment, and reduce risks associated with opioid pain therapy.

Before updating the guidelines, CDC funded the Agency for Healthcare Research and Quality to conduct five updated systematic [00:30:30] clinical evidence reviews on treatment of acute and chronic pain with opioid and non-opioid treatments, which provided the evidence base for all of the recommendations in the guideline. CDC also solicited input from a federal advisory committee, peer reviewers, and the public, which included very diverse viewpoints that were critical in informing the recommendations incorporated into the guideline. This voluntary clinical practice guideline provides recommendations

only and is intended to support, [00:31:00] not supplant, clinical judgment and individualized person-centered decision-making.

And CDC's implementation efforts for its guidelines have focused on translation and communication, clinical training, and health systems integration. For example, CDC has developed a suite of electronic clinical decision support tools to promote safer opioid prescribing for pain. Examples of tasks these tools can provide include presenting clinicians with non-medication and [00:31:30] non-opioid therapy options, assessing patient risk, and promoting naloxone prescribing, and alerting clinicians about the risk of co-prescribing certain medications.

CDC is also working to promote linking people to evidence-based effective treatment for substance use disorders. A key strategy to promote this linkage is leveraging our large cooperative agreement, Overdose to Action or OD2A, which is implemented by state and local health departments. [00:32:00] Jurisdictions are encouraged to use OD2A funding to train clinicians to screen, diagnose, and link patients to care for people with substance use disorders and to implement universal substance use disorder screening and linkage to care interventions. Examples of ways local and state recipients have leveraged OD2A funding include, in one county, the implementation of client navigation services to support linkage to care. In this intervention, the navigator is integrated into teams in a local hospital [00:32:30] to provide linkage to care services and has also been able to provide additional overdose prevention resources. In another county, the expansion of access to a high quality telehealth line offers direct text and telephone access to substance use navigators and clinicians who then can immediately connect patients with treatment. And in one state, the implementation of a robust system to support linkage to care from the emergency department via multidisciplinary teams, including peer navigators.

[00:33:00] And OD2A funding has also allowed the state and its partners to broaden the scope of activities to also include strategies, such as making connections during the provision of care for conditions that may represent sequelae of substance use, such as skin or soft tissue infections, and providing enhanced universal screening for substance use disorders among patients presenting for other reasons.

So these are just a few examples of CDC's activities to promote safe and effective pain care and treatment for substance use disorders that I think build [00:33:30] on the groundwork that has been presented by the speakers before me.

Susan C. Winckler:

Thank you so much. I was thinking as you were speaking, two things came to mind. You observed the diverse viewpoints that went into coming up with the work product that you have at CDC and how very important it is to hear from different perspectives and to gather that to then come up with the recommendations, but then also the clinical support available to healthcare professionals addressing [00:34:00] both management of pain and the treatment of substance use disorders.

So now I have to turn to, with all respect to all five of our panelists, but the most important part of our discussion. No pressure, Dr. Atkinson, but we are turning to you for the observation and particularly speaking from the agency where all of the prior work that we've been talking about reaches individual patients and specifically our nation's veterans. Joining [00:34:30] us from the US Department of

Veterans Affairs is Dr. Timothy Atkinson, who is acting director for Opioid Safety in the Specialty Care Program Office.

So Dr. Atkinson, join our conversation. You're going to be Dr. Timothy after this and Dr. Kristine after this too, but tell us more about the whole of government effort that we've been hearing about manifesting in the care of individual patients.

Dr. Timothy Atkinson:

Thank you, Susan. It's a pleasure to be [00:35:00] here. I wish I could be there in person. It's always great to share a panel with so many fantastic federal partners, and I look forward to talking just a little bit about what we're doing at VA.

VA is the largest integrated healthcare system in the United States. And during the opioid crisis over the past 14, 15 years, we focused on a lot of things, and I'll talk a little bit about that first. But probably the most important thing that we've learned through this period is that [00:35:30] you have to focus on person-centered care. This is where evidence-based medicine really intersects with shared decision-making in alignment with the personal values and aspirations of each individual veteran that sits in front of us every day. The Opioid Safety Initiative, which has been a tremendous success over the past 14 years, really reducing the reliance on opioid therapy, the number of opioids prescribed, especially high-dose opioid prescribing and combinations [00:36:00] that can be very risky, including opioids and benzodiazepines.

But the Opioid Safety Initiative has really involved four key strategies for our agency, and that's education, risk mitigation, and then expansion of alternatives to treatment. We can't just talk about the risks of something without the balance of what else can be done in terms of effective treatment, so a major investment in expanding pain management modalities and their access to veterans, [00:36:30] as well as substance use disorder treatment options, including opioid use disorder. And I'd like to talk just a little bit about some of those things and the specifics.

For example, on the pain management side, when opioids are prescribed for pain management, then enters the Opioid Safety Initiative. We also of course have the Psychotropic Drug Safety Initiative. And one of the aims there is to make sure that everyone that has a diagnosis of opioid use disorder has access [00:37:00] to either an opioid treatment program or an office-based opioid treatment program with buprenorphine. One of our most successful programs there has been the SCOUTT program, which really provides training in opioid use disorder management in the clinic setting and allowing us to stand up clinics in primary care and other specialty settings. Not every veteran wants to go into a building that has a sign above it that says "substance use disorder treatment." They would rather go [00:37:30] to someone they already feel comfortable with and receive treatment, and it's important that we take advantage of that moment when they're ready and willing to receive help that we can provide and initiate treatment right then in a place where they feel comfortable so that we can meet them really where they're at.

On the pain management side, one of the most important things that we have done is really focus on the expansion of complimentary and integrative health modalities, making sure that they are available at every VA medical center, [00:38:00] and when not available, that we can ensure that veterans can

access those same services in the community when coverage is often not available for many of those services otherwise.

Also, Whole Health has been incredibly important to teach self-management, nutrition and weight management, whole health and wellness coaches to help them stay motivated and to recognize that they can take charge of their own pain management treatment plan. [00:38:30] We've also been enormously successful in constructing the only national prescription drug monitoring database in the country, and that's at VA healthcare centers. Imagine that providers, with the click of a single button and three seconds later, you have the results from every state and their database. That's something that doesn't exist anywhere outside of VA. There's the overdose education and Naloxone Distribution Program, which has saved thousands and thousands of lives. [00:39:00] And seeing the testimonials and the experiences of family members and even veterans that have used their own naloxone kit to save others' lives is just very inspiring.

But with all the reductions in opioids over the past 14 years, there's also been a lot of lessons learned that I would like to take just a second and share. First, we have to appreciate the balance between appropriately treating pain while reducing the risks of opioids, and [00:39:30] that balance is very difficult. We have learned, for example, that when we highlight risk without balance and we focus just on metrics, that some clinicians really become reluctant to prescribe opioids in situations where they are indicated. They may inappropriately strive to get patients under specific dosage thresholds just to achieve performance metrics. We've learned that the risk of suicide or overdose may increase with non-consensual tapers or abrupt discontinuations of [00:40:00] opioid therapy. Ultimately, education metrics and all of the clinical decision support tools that we've developed to assist providers really must be anchored in a clinical focus that involves shared decision-making, really focusing on the quality of life and engagement and care with our veterans. Behind each metric is a person with a story, and that's what we're focusing on and have been focusing on in VA.

Susan C. Winckler:

What [00:40:30] I'm struck by with each of you, and particularly Dr. Timothy, with what you just described, is the efforts by the agencies to recognize that this is a space where we still need to learn and to evolve and adapt the interventions and the work that you're doing, the acknowledgement about when a metric becomes a rule versus something that could be part of an informed and shared decision-making.

[00:41:00] Is it fair to observe that that's an opportunity for each of your agencies, that you seek that out to continue to learn more in this space and how we might improve?

And you can all jump in now. It's actually compelled. Any thoughts about that and including some of those learning opportunities or current activities that you could highlight and examples where your organizations work together?

Dr. Rob, you gave us some [00:41:30] great ones, as did Dr. Kristine.

Actually, Dr. Kristine, I'm going to come back to you to pick up this idea of how is CDC continuing to learn in some current activities, and where do we see things working together? And then it's going to be a free for all after that while everybody jumps in, but you get to go first.

Dr. Kristine Schmit:

Yeah. Thanks, Susan. A couple things that I'm thinking about. One is we are currently in the process of evaluating the uptake and implementation of that 2022 [00:42:00] CDC guideline that I mentioned before. And so in order to evaluate clinician awareness and adoption of the guideline, we partnered with an external contractor to implement a survey focused on clinician practices in pain care, awareness of the guideline, and then any changes in clinical practice since its release. The survey participants included licensed physicians, nurse practitioners, and physician assistants working in a variety of medical specialties, and we received over 750 responses, [00:42:30] which are currently being analyzed. So we should have those results, and that will, I think, help us learn a lot about how those guidelines may or may not have influenced care, which is really important to how we move forward and how we promote clinician training to more effectively promote safe and effective pain management with and without opioid therapy.

But the other piece that I wanted to mention is an area where we are always learning is when we are [00:43:00] working in conjunction with our external partners, specifically I'm thinking about the local and state health departments that we work with through our large OD2A cooperative agreement, and that's where a lot of the work is happening on the ground, and that's where we can really learn where what we're doing here in our space is affecting what's happening from the ground and how we can be doing things differently or focusing differently depending on where the need is. And so, I think that is a huge learning [00:43:30] opportunity for us. And then we have other external partners that we work with as well where I think learning happens all the time.

Susan C. Winckler:

Yeah, really helps. So I think I can gauge there's some interest here in what you learn in that survey.

Dr. Marta, do you want to share here some thoughts about current activity that you're interested in and collaboration across the agencies and how FDA is continuing to learn?

Dr. Marta Sokolowska:

Just as we redefined the naming convention, [00:44:00] it just indicates how closely we are working together on regular basis. And you can hear throughout that there are a number of initiatives that we are all reflecting on coming from a different perspective based on our agencies and our areas of responsibility and authority, how we are addressing it. But really, I think it reflects a lot of the work that's being done. And the fact that we are here together, it reflects the current FDA initiative that is tied to the SUPPORT Act [00:44:30] Reauthorization that we are tasked of assessing public health effects of opioid medication, and it's part of the reason why we are here today. And the reason why we are having federal discussion is because it is really critical that we pull together all the different agencies and our work across. Because based on that information, we continue assess and conduct our post-approval monitoring and assessment of opioid analgesics, and it informs an [00:45:00] ongoing evaluation of the benefits and risks and how best to communicate it.

The prior comment by Kristine reflects that too. We are really looking forward to getting more of that information, and we are really looking forward to hearing the public comments from today to help us to contextualize our ongoing evaluation. So I'm really eager to hear not only from my federal partners, but

also from the public commenters, both oral and written comments that will be submitted, [00:45:30] to really hear the public input and the opportunities in this space.

But as we are continuing this evaluation, I think it's important to highlight that the SUPPORT Act also tasked us to look at at-home disposal options and to ask us to develop guidance for at-home disposal options as one of the approaches to address the appropriate opioid use and to make sure that [00:46:00] harm is not provided from the opioid medication that are not used for medicinal needs. And for that, in March of '26, FDA issued, for instance, a request for information seeking input on potential new standards for in-home disposal options products. And the SUPPORT Act, this Reauthoritization Act, FDA is also reviewing relevant data regarding scheduling of approved buprenorphine-naloxone products. And [00:46:30] as mentioned by others, there is a lot of interest in the MOUD treatments and buprenorphine particularly. So again, we are working together extensively on variety of these different products.

Susan C. Winckler:

Yeah. I would note that in addition to... We have the lead folks here from different agencies, but we know that there are a number of other employees at these agencies who registered for the meeting, particularly to hear the public comments. So the [00:47:00] listening is extending beyond here.

All right, I'm going to do Dr. Wilson, Dr. Tim, Dr. Rob, thoughts on continuous learning and collaboration and how that infuses the work here to do better, to better serve Americans.

Dr. Wilson Compton:

Well, of course, NIH and NIDA are always looking for the new best idea on how we can improve treatment and implementation of effective treatments. So we want your ideas both to come to us for research proposals [00:47:30] and research support to test your ideas in practice, but we also want them because they can inspire us to work with others and work with our collaborators at FDA, CDC, SAMHSA, the VA and elsewhere.

I want to highlight an area where we've been in very close collaboration, of course, with FDA partners, which is in the area of medication development. NIDA has taken the lead in bringing new compounds into potential consideration for approval as remedies, as treatments for opioid use disorder. [00:48:00] NIH broadly, and to an extent, NIDA have supported work on new pain remedies. And I highlighted one that's been approved fairly recently, but there are multiple others under development, both in terms of opioids that may have less abuse potential in terms of biased agonists and similar agents.

But one issue that I bring to attention that we've worked with the FDA and we continue... and we need help from the outside community as well, have been the area of what should be the endpoints for our studies. We've [00:48:30] certainly seen that abstinence, that not using opioids, is the primary outcome from almost all of our research, but yet many of our patients struggle with that outcome, may make important strides towards abstinence with the help of medications. And how do we quantify that? How do we make sure that those are legitimate, reasonable outcomes that do represent a significant functional and qualitative improvements?

Because that's the goal of our treatments, not just to take something for the sake of taking it, [00:49:00] but in order to produce meaningful changes and improvements. Well, how do we measure that in ways outside of absence? This is something that Dr. Marta and I and many others at NIDA have discussed over the last few years, and we still need help in this. This is an area that we've been supporting at the NIH, and we look forward to your ideas about alternative outcomes that could be meaningful in terms of measuring important progress in patient care.

I'd highlight that. There are many [00:49:30] other areas we could highlight for collaboration, but I think those are particularly germane to the topic today since we're at FDA and talking about medications for the most part.

Susan C. Winckler:

Yeah. And that strikes me that, Dr. Tim, at the VA, you get some of that firsthand reaction about what endpoints are relevant to patients and what matters, and then can bring that type of information back to FDA and NIDA as you're figuring out how do you then have the regulatory standard for that patient [00:50:00] relevant endpoint. Dr. Tim, what would you like to add?

And then I'm going to round back to Dr. Rob to remind us how it all pulls together, because I know he has that.

Dr. Timothy Atkinson:

Well, I think that the comments of my colleagues here are really well taken. That conversation on endpoints is extremely important. For example, with opioid tapering, for example, there's often guidance about the speed of tapers, but there's no guidance about the endpoints, and [00:50:30] we're just looking at outcomes. And oftentimes, there's not recognition by clinicians that someone may have decreased their overall dose by 50%. That's tremendous progress for them. They may not be able to come all of the way off. If we are expanding their available treatments in other areas and they're doing well, that's not a failure. It really has to be evaluated on an individual basis. I think that [00:51:00] that part of it is really key is that we continue to evaluate what is important to each individual patient.

One of the things that I think that has been really reinforced at VA and what we have learned and we're trying to communicate right now is that in so many guidelines and in policy documents, you hear talk about balancing risks and benefits without instructions to providers about how best to balance those risks and benefits. But more importantly, [00:51:30] what do patients want to hear? As clinicians, we think about improvement in function, for example. Patients are actually more focused on pain, and so we need to be able to articulate this more in terms that they understand, more neuroscience education, more reframing, the ability to help them to understand and align expectations with what the evidence can actually deliver, multimodal treatment, and making sure [00:52:00] that we're accessing multiple treatments to be successful.

But at the end of the day, if treatment goals are going to be successful, it has to be measured in things that are meaningful to the patient. What is their mission, aspiration, and purpose? What will motivate them and activate them to be a part of their own treatment plan? We see them, what? If you're lucky, every month in the beginning, then maybe every three months, and in some cases, even less often than that. Who's going to motivate them in between? That has to come [00:52:30] from within, and that's

only going to be successful if it's actually a treatment plan that they created and that they want to engage with and move forward.

Susan C. Winckler:

I think, Dr. Rob, that Dr. Tim might have just given us some of the key phrases that are in some of the SAMHSA patient-centered support materials to help clinicians with these conversations, but help us pull together the collaboration here.

Dr. Robert Baillieu:

No pressure there.

Susan C. Winckler:

No pressure. You can do it.

Dr. Robert Baillieu:

[00:53:00] But certainly what we've heard is collaboration is key, and so working with one another at the federal level, and we all collaborate and talk. I mean, we've all worked together on projects related to high-dose buprenorphine, for example, that resulted in labeling changes. I worked with the VA extensively for years on implementation of contingency management, and then they very generously partnered with SAMHSA to talk through guardrails that should be associated with increased funding for contingency management. [00:53:30] And so those federal collaborations are really important because it talks to implementation and policy, those sort of higher level things. But then all of us are supported by an incredibly robust community of intelligent, interested, really incredible people who want to engage. And certainly at SAMHSA, we have a motto of, "Nothing about us without us," and so we engage with the substance use disorder community, people with behavioral health conditions [00:54:00] to better understand how our policies are impacting them, but what they want to see from us as well.

And that's an incredibly important tool for us because the drug supply is changing. Polysubstance use is the norm. Physical health conditions exist within the context of substance use disorders, and we need to know about this. We need to know how to actually address the issues that are pertinent to individuals who use substances, and so it is incredibly important that we engage with those communities, and they are incredible at engaging [00:54:30] with us. I mean, I've had discussions with people about 42 CFR Part 8, and I have to ask, "Are you from the press? Are you a lawyer?" They're like, "No, man, I use substances, and I'm in an OGP," and it's incredible. Their insight is just remarkable. Learning about how a rule can impact individuals and taking that back to leadership and to the powers allows for really robust discussions around future policy, how to address emerging trends, [00:55:00] and to better understand where we should move as a federal agency. I think to sort of pull the threads here, which you asked me to do, I think collaboration, ongoing discussions, and an openness to change is so important.

Susan C. Winckler:

Right, right. Because this is an area where clearly we're continuing to learn. We're continuing to learn about the impact, continuing to learn about, as you noted, polysubstance use, [00:55:30] how substance

use disorder has changed, as well as learning about interventions that may be more helpful in pain management, certainly just a lot of places to learn.

All right, now I have the lightning round question because we are going to get to the public comment, which is what we are focusing on this afternoon. But I want to give each of you up to a minute, and each of our panelists, you can respond to... You can take one of two paths. [00:56:00] The first path is to share or highlight something that is most exciting or potentially promising, so something that you are excited about on the horizon. The second would be to say what's something that you hope you hear in the public comment, like an area where you hope that we'll hear about in the public comment section.

So while you're noodling on those two options for the answer, we're going to go Dr. Tim, Dr. Rob, Dr. Kris, [00:56:30] Dr. Wilson, Dr. Marta.

Did I give you enough time, Dr. Tim, to think about that?

Dr. Timothy Atkinson:

Yeah, no, I appreciate that. I think I'll take option 2. As far as what I would like to hear from the conversation really, I guess, is... We talk so much about the importance of addressing the risks of opioid therapy. I suspect that from the public, we're going to hear more about the [00:57:00] importance of addressing pain and the consequences of not addressing it, which is probably something that we don't measure and talk about enough.

This past year in VA, we've had a national suicide SPRINT, and that has been an interdisciplinary collaboration, multiple VA programs, really recognizing that pain is the second highest risk factor right behind substance use for suicide among veterans. So it reinforces the [00:57:30] importance of addressing pain proactively, comprehensively. This requires really timely access to care. We don't want desperation and hopelessness to lead to catastrophic outcomes for our veterans and make sure that they have the attention they need when it matters most.

It's also very timely, I think, because September is National Suicide Awareness Month. It's also National Pain Awareness Month. As we in VA are focused on [00:58:00] decreasing suicide risk by making sure that we are addressing these critical needs of our patients, I think it's timely for us all to think about how important that side of the equation is. Thank you.

Susan C. Winckler:

Absolutely. Thanks so much, Dr. Tim.

Dr. Rob, less pressure this time.

Dr. Robert Baillieu:

Thank you. And certainly this month, September 8th, is 988 Day, and that's a very exciting day for us at SAMHSA. I think for us at SAMHSA, the no wrong [00:58:30] door approach is really important. So if an individual is at risk for or develops a substance use disorder, how do they access care? Is that care available to them readily? Can they be screened for an opioid use disorder there? Can they receive

treatment? And this speaks to integrated care. Dr. Atkinson lived this dream in terms of having that integrated system, and we'd like to see that for all Americans. And certainly wherever someone turns up asking for help, they should be able to receive it, and so I'd be really interested to know more [00:59:00] about those integrated systems of care and how they've helped individuals, not just at risk for or developing substance use disorder, but also having or suffering chronic pain. That's an incredibly difficult condition to manage.

Having the ability to say to the emergency doctor, the primary care doctor, the nutritionist or psychiatrist, "I'm in pain, I think I've developed substance use disorder," and then being able to access care through those channels is just essential. It saves lives, it saves people's [00:59:30] quality of life, and it means the world to an individual.

Susan C. Winckler:

In order to address the no wrong door, to make that a reality, we need to know more about the doors and the options.

Dr. Robert Baillieu:

The doors and the barriers, yeah.

Susan C. Winckler:

Yeah.

Dr. Robert Baillieu:

Thank you.

Susan C. Winckler:

Dr. Kristine.

Dr. Kristine Schmit:

Thanks. I think that more and more, a lot of our work is really focused on the intersection of public health and clinical care and really trying to identify innovative ways where those two areas can be mutually more [01:00:00] supported. And so I think that what I'm hoping to hear from the public comment is ways that, as we're going through with that work in that intersection, how we remain really patient-centered, which I think is going to be important no matter what the work is. And so I think there'll be a lot of great comments about how we can stay focused on that key element of our work.

Susan C. Winckler:

And the reminder of the patient-centered [01:00:30] piece.

All right, Dr. Wilson, next to last word.

Dr. Wilson Compton:

Okay, I'm going to do a little bit of both.

Susan C. Winckler:

Okay.

Dr. Wilson Compton:

I already mentioned to you that I'm hoping for alternative outcomes for substance use disorder treatment, but I would put in a plug as well for helping us with outcomes related to pain treatment. Most of us use a scale of 1 to 10, "How bad is your pain?" There are other measures, but we need better measures of pain that can help us objectify and provide valid approaches that can apply across a broad range of patients. [01:01:00] All right, that's a quick version of that.

You also asked what I'm excited about.

Susan C. Winckler:

Yes.

Dr. Wilson Compton:

And there's a lot. I want to start by saying I'm particularly excited by the all of government focus on recovery right now. We have the Great American Recovery Initiative. I'm also very excited about our focus on psychedelics and the potential for psychedelics to treat mostly behavioral health conditions, but that includes substance use disorders, and it may have an impact on some pain conditions as well. And that's an area where the science [01:01:30] is not yet proven, and so we have both basic science as well as translational science approaches that are needed. And certainly working closely with FDA on the regulatory considerations for all of these agents is really going to keep us all challenged for some time now.

I would just put in a plug finally for GLP-1 agonists, as Dr. Rob mentioned the issue of polysubstance use, and this is a set of medications that at least appear [01:02:00] on the surface to have an impact across a range of appetites, both food as well as a variety of substances. Will that hold up in clinical studies? I don't know yet, but that's where we're turning our attention, and I'm certainly quite excited about that.

Susan C. Winckler:

Yeah, so lots of emerging opportunities.

Dr. Marta, you get the last word.

Dr. Marta Sokolowska:

So I'm very much in alignment with all the other panelists, and I'm very excited to hear the comments that we'll be hearing relatively soon.

[01:02:30] But in addition, one thing that I want to highlight as we are focusing on development of new products, I want to highlight our new initiative on drug repurposing, which is essentially focused on identification of potential new uses of FDA-approved drugs where the new uses would be supported by safety and effectiveness data. In May of '26, in our request for information regarding such new products, we received a number of comments about proposed new candidates [01:03:00] for pain treatments as well as for substance use disorder treatments. This is potentially a new pipeline of additional treatments that maybe, if data support it, might be utilized for addressing these disorders. So this is another area that I think is very exciting and provides potential for future.

Susan C. Winckler:

And it's key, if we think about drug repurposing, that's one where it's very much so the patient voice that is being heard at some level, often that we are saying, "Oh, there may be this opportunity for [01:03:30] another use of that product."

Excellent. Please join me in thanking each of our panelists for joining today and sharing insights.

I'm going to let these two gentlemen leave the stage and our virtual colleagues leave the virtual stage, and we will transition to the public comment period.