THE DOCTOR PATIENT FORUM
Proud supporter of the Don't Punish Pain Rally Organization

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1. Introduction & Purpose of This Comment

We submit this second formal comment to FDA Docket FDA-2024-N-5331 on behalf of The Doctor Patient Forum, a national nonprofit organization that advocates against harmful prescribing restrictions that led to patient abandonment and forced opioid tapers. DPF provides education, research, advocacy tools, and practical resources to help patients thrive despite their diagnoses. We take no industry funding, accept no grants, and are fully supported by individual donations.

This docket addresses the results of the Postmarketing Requirements (PMRs) originally commissioned in 2013 by the FDA in response to a citizen petition filed by Physicians for Responsible Opioid Prescribing (PROP). These studies were designed to assess the real-world risks of long-acting opioid medications, including potential for misuse, addiction, and overdose. While reviewing these risks is an excellent and necessary start, we must move quickly to the next steps: measuring, acknowledging, and actively mitigating the widespread harm caused by implementation of the 2016 CDC Guideline and related opioid reduction policies.

In 2016, the CDC released national opioid prescribing guidelines that were never intended to become rigid policy. Yet, through a broad implementation plan, including $28 million from Congress to support adoption, those guidelines quickly became entrenched in state laws, CMS and insurer policies, DEA enforcement, PDMP risk scoring algorithms, and electronic health record (EHR) clinical decision support tools. [1] Despite a 2022 revision that removed arbitrary thresholds from these recommendations, the original dosage thresholds and restrictions remain embedded throughout the system and continue to shape care today.

Millions of patients remain affected by these policies, especially those with chronic pain who were forcibly tapered or abandoned by providers. We have heard from tens of thousands of them. Many cannot find a doctor, cannot fill prescriptions, and are marked as “high risk” in PDMPs simply for trying to continue the medications that once gave them quality of life. A 2019 study found that 40% of primary care providers refuse to treat patients on opioids, and since then, the situation has only worsened.[2]

Although multiple federal officials have acknowledged the harms of aggressive tapering and patient abandonment, no formal federal research has been commissioned to measure the real-world outcomes of these policies. Meanwhile, more than 15 studies have documented the risks of rapid or involuntary opioid tapering, including overdose, suicide, illicit drug use, and severe decline in function.[3]

We appreciate the FDA’s role in initiating PMR studies to evaluate opioid risks. But to achieve a complete picture and ensure future policy reflects patient safety, we urge the FDA to now support a

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corresponding research effort to measure the unintended consequences of opioid reduction policies and the healthcare abandonment that followed.

2. Millions Remain at Risk and Time Is Running Out

Although many patients were forcibly tapered or cut off from opioid therapy in the years following the 2016 CDC Guideline, the full impact of these actions may still be unfolding. A 2022 JAMA study found that the risk of overdose and mental health crisis is not just immediate but may increase substantially up to four years after tapering begins.[4] This underscores how urgent it is to act now. The millions of patients who are currently destabilized, including those recently removed from care, remain at elevated risk, and many are still within that danger window.

There currently is no federal program to identify or support medically abandoned pain patients. No infrastructure exists to connect them with new providers. Many cannot even find a primary care doctor. The only program addressing this is called Opioid Rapid Response Program, and they only connect patients to Suboxone providers. When a patient's provider retires, relocates, or is investigated, there is often nowhere to turn. Some are labeled "doctor shoppers" just for trying to find new care. Others are flagged in PDMPs for "traveling too far" to fill a prescription, despite living in rural areas with limited access. Some, even elderly, disabled, or terminally ill, are being pushed into addiction treatment systems designed for people with a completely different medical profile, or worse – to the street in desperation for pain relief.

As one of the only national nonprofits advocating on behalf of these patients, The Doctor Patient Forum has received tens of thousands of messages from individuals and families in crisis, not because of misuse or addiction, but because of forced tapers, stigma, and abandonment. Many reach out to us discussing plans of suicide if they can not find a provider soon.

These patients do not have another decade to wait. Many are already living on the edge of collapse, physically, emotionally, and financially, due to untreated or undertreated pain. Most of these patients were previously stable, as you acknowledged in your briefing for the meeting on May 5. Unless immediate action is taken to support them, more lives will be lost, not because of opioids, but because of policies that went too far.

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3. We Must Measure the Harms of Opioid Reduction

While the Postmarketing Requirements (PMRs) were designed to measure risks associated with long-acting opioids, there has never been a complementary federal effort to quantify the harms caused by

opioid reduction policies, including forced tapers, patient abandonment, and misapplication of the 2016 CDC Guideline. This absence has allowed one-sided narratives to dominate the conversation for far too long.

The FDA's own briefing for this meeting states clearly that:

"The introduction of guidelines, changes in state laws and medical boards, institutional rules, and payor coverage, have resulted in millions of patients losing partial or full access to the opioids on which they were stable, despite numerous studies demonstrating the harms associated with these involuntary dose reductions or discontinuations."[5]

The same briefing cites studies showing that tapering is associated with increased risk of overdose, emergency department visits, suicide, and death especially when abrupt or too rapid. In April 2019 the FDA issued a public safety warning explicitly acknowledging the serious harms of sudden opioid discontinuation, including uncontrolled pain, psychological distress, suicide, and overdose.[6]

Warnings alone are not enough. Since that time, things have only continued to worsen. The CDC's 2022 Guideline update included more flexible, patient-centered language but that hasn't translated into real change. The 2016 CDC Guideline was implemented through a vast, coordinated infrastructure across nearly every level of government and healthcare:

- Congress funded implementation with at least $5 million in 2016[7]
- 38 states enacted laws based on the original guideline[8]
- The DOJ, DEA, CMS, OIG, and private insurers incorporated dosage thresholds into risk algorithms, reimbursement criteria, and enforcement strategies
- Electronic Health Record (EHR) systems still use embedded MME-based alerts
- Prescription Drug Monitoring Programs (PDMPs) continue to flag patients and providers using those same thresholds

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Even now, patients are being cut off from care due to these legacy policies, not because of new evidence or individualized decisions, but because when the CDC Guidelines were updated, there has been no effort on either the state or federal level to de-implement the 2016 guidelines. The FDA's own documents confirm that rapid or large dose reductions are linked to serious harm, including death and illicit drug use, yet we've still never quantified how widespread this damage is, nor provided infrastructure to help those affected.

We are asking the FDA to commission a dedicated set of studies equivalent in scope to the PMRs to measure the full extent of harm caused by opioid reduction policies. Without this, future decision-making will remain biased toward risk avoidance, without regard for the people already suffering.

4. Financial Conflicts and Dangerous Diagnoses

As the FDA continues evaluating the outcomes of opioid prescribing and the PMR studies, it must also scrutinize who is shaping these narratives, and why.

The 2013 petition that triggered these PMRs was filed by Physicians for Responsible Opioid Prescribing (PROP), a group whose members include medical experts who have repeatedly served as paid witnesses in opioid litigation and sit on the advisory boards of addiction industry organizations like Shatterproof. PROP and affiliated individuals have consistently advocated for minimizing access to full-agonist opioids while promoting widespread use of buprenorphine (Suboxone), including among patients without substance use disorders.

This push is now accelerating through a coordinated effort to erase the distinction between chronic pain and addiction.

In a 2024 *New England Journal of Medicine* commentary, PROP's president, Dr. Andrew Kolodny, cited data from the National Survey on Drug Use and Health (NSDUH) suggesting that 62% of people with prescription OUD took their opioids "as prescribed." Rather than interpret this as evidence of misclassification, he argued that there are now five million chronic pain patients who become dependent while taking their medication as prescribed, should still be labeled with opioid use disorder and funneled into treatment with buprenorphine. He advocates for stable patients to be pushed onto Suboxone.[9]

This argument is rooted in flawed diagnostic logic, and it opens the door to widespread misdiagnosis and inappropriate treatment. It also aligns disturbingly well with PROP member Dr. Mark Sullivan's presentation slide, obtained from public records, which calls the "pain-adjusted" DSM diagnosis of OUD

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"outdated" and ripe for removal.[10] That same slide presentation comes from a conference held by ASAM, an addiction organization that has historically taken unrestricted grants from Indivior.

Meanwhile, Indivior, the maker of Suboxone, continues to expand its market reach. Internal marketing documents unearthed in opioid litigation revealed that chronic pain patients were labeled an "untapped market" for buprenorphine, with efforts underway to convert them from full agonists regardless of preference or stability.[11] The company's influence is far-reaching, from funding "unbranded" educational campaigns and nonprofits to shaping the very guidelines and diagnostic definitions now being used to justify this shift.

This would be concerning enough if the medication were without risk, but that is not the case. In 2022, the FDA issued a safety communication warning of serious dental harm associated with buprenorphine formulations dissolved in the mouth, including Suboxone.[12] These harms include tooth decay, infection, and complete tooth loss, sometimes within months of use, particularly in medically vulnerable populations like chronic pain patients.

In April 2025, the FDA hosted a webinar to further explore this issue, confirming that these dental injuries are serious, underreported, and disproportionately affect patients with complex health conditions.[13] While it is true that Suboxone is a life-saving medication for individuals with opioid use disorder (OUD), this risk–benefit profile must not be assumed to apply equally to chronic pain patients who are stable and not addicted. For those being forced off full-agonist opioids and onto Suboxone as the only remaining option, this raises serious questions: Who will pay for the dental treatments when these patients, many of whom are disabled, elderly, or low-income, begin losing their teeth? What protections exist for them?

Meanwhile, the same voices who downplay or dismiss the strong body of evidence supporting full-agonist opioids for chronic pain also fail to provide evidence that buprenorphine is a safe or effective alternative in this population. There is currently no long-term high-quality evidence supporting the use of buprenorphine as a forced replacement for stable patients on full-agonist opioid therapy, yet that is exactly what is happening, all day, every day, across the country. We hear from these patients daily.

In short: we are witnessing the rebranding of stable pain patients as addiction patients, not based on science or clinical need, but on convenience, ideology, and commercial opportunity. The removal of the pain-adjusted DSM diagnosis would strip providers of diagnostic flexibility and allow this dangerous reclassification to proceed unchecked. We urge the FDA not to adopt this proposal and to investigate the financial conflicts of those promoting it.

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The danger of removing the pain-adjusted DSM diagnosis for Opioid Use Disorder cannot be overstated, particularly given the origins of the criteria themselves. The DSM-5 was shaped under significant financial influence, including from pharmaceutical companies with a direct interest in expanding the diagnostic pool for addiction treatment.

The American Psychiatric Association (APA), which publishes the DSM, received over $14 million in pharmaceutical industry funding in the years leading up to and during the development of DSM-5.[14] Among those with significant influence in the Substance Use Disorder workgroup were individuals with financial ties to Indivior (formerly a division of Reckitt Benckiser), the maker of Suboxone.

Considering Reckitt-Benckiser stated in 2014 that pain patients are their untapped market, this is not a scientific shift, it is a commercial one.

We urge the FDA and advisory committee to view current efforts to revise diagnostic standards with extreme caution. The proposed removal of the pain-adjusted DSM diagnosis for opioid use disorder is not a neutral act. It would accelerate efforts to reclassify stable chronic pain patients as having OUD, facilitating their forced transition to a medication that:

- is not FDA-approved for chronic pain,
- carries serious risks including irreversible dental harm,
- and financially benefits the very entities that helped shape the diagnostic framework to begin with.

While government agencies continue to invoke Curtis Wright and the Sacklers as emblematic of industry corruption, It raises concern that a similar pattern may be unfolding again, not in the shadows, but through policies and recommendations currently under federal oversight. Industry-funded narratives, addiction-medicine interest groups, and financially conflicted key opinion leaders are quietly reshaping pain care policy for their own benefit.

We implore the FDA not to let history repeat itself.

5. The Warnings Came Years Ago and Were Ignored

In 2018, the FDA co-hosted a public meeting with the Duke-Margolis Center for Health Policy to discuss the future of opioid policy. It was clear even then that the 2016 CDC Guideline had caused serious harm. Multiple participants, including FDA officials and academic experts, warned of unintended consequences and stressed the urgent need to measure patient outcomes.[15]

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Dr. Judy Staffa, FDA's Associate Director for Public Health Initiatives, gave a deeply sobering summary:

"We heard lots of anecdotal data or information from patients, very compelling stories, about how patients have been forced to taper or decrease their dose or do without completely … after many years of functioning quite well on them. … Tragic stories … of patients who actually committed suicide. … Maybe these are some outcomes we should be looking at."
"Some of the extra steps and burdens … are actually causing [providers] to turn away from prescribing opioids at all."
"How well did these 29 published studies actually look at [patient] outcomes? Not very much. … Not really the focus of many efforts until now."
"Can we be looking at more patient outcomes, things like quality of life and pain? I know these are going to be very hard to measure … but I think the juice is going to be worth the squeeze."

Seven years later, these outcomes still haven't been meaningfully measured.

Myra Christopher, founding director of the Center for Practical Bioethics and co-chair of the National Pain Strategy, warned that:

"Although those of us advocating for comprehensive chronic pain care agreed with the vast majority of [CDC's] recommendations, the guideline caused a firestorm in the pain advocacy community. … Recommendations regarding dosage limits and caps on duration … which were admittedly based on weak evidence … intensified the burden for those who live with this disease and must bear it day after day."

"Patients … without any history of abuse or misuse were told they would have to seek specialty care or were abandoned by their primary care providers."

"Guidelines are surely necessary … but they are not sufficient. And they can be terribly harmful to individuals when they lack an evidence base and lead to a heavy-handed approach."

Dr. Kit Delgado, a practicing emergency physician, described seeing overdose cases firsthand from patients with untreated pain:

"The majority … of overdoses we're seeing now in the ER are a lot of patients … who I think with the new guidelines are getting abandoned by their primary care doctors and sent to pain medicine clinics, which are four-month waits."

"I can remember a patient … who had chronic pain after back surgery … [was] in excruciating pain, couldn't go on, found heroin on the street and overdosed. That was her first use."

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And in a moment that crystallized the entire meeting, moderator Gregory Daniel posed a question to the room:

"How are we doing in sort of getting to the next level of outcomes in terms of, are we actually improving patient outcomes? … Where are we with sort of looking at those kinds of outcomes?"

What followed was an uncomfortable silence, broken only by nervous laughter.

That silence still echoes today. The healthcare system has continued to measure prescribing rates and adherence to guidelines, but not patient outcomes. No federal research consortium has been created to study functional decline, suicides, forced tapers, or deaths resulting from loss of care.

Back in 2018, they knew this was a problem.

In 2025, it is unconscionable that we still haven't acted on it.

We urge the FDA to take these long-ignored warnings seriously and support a full-scale effort to measure the real-world consequences of opioid reduction policies, as passionately outlined by the very experts you convened.

6. We Urge the FDA to Commission a Parallel Study Series on the Harms of Reduction Policies

We respectfully urge the FDA to fund a coordinated research effort comparable in scope to the Postmarketing Requirements to measure the full impact of opioid reduction policies, including the CDC Guideline and its widespread implementation. The PMRs have provided insight into the risks of long-acting opioids, but no such studies have been commissioned to measure the consequences of rapid tapers, discontinuation, or medical abandonment.

Millions of stable patients have lost access to opioid therapy, not because of new clinical evidence, but because of inflexible policies built around non-evidence-based thresholds. The agency's own 2025 PMR briefing acknowledges that these patients exist, and that many were destabilized despite a lack of misuse or addiction. This acknowledgment must now be followed by a commitment to study what happened to them.

There is already a rich dataset available for this research. As Dr. Marty Makary explained in an April 2024 interview on *The Megyn Kelly Show*:

"We now have massive electronic health record data through something called the health information exchange. We can have researchers go into there and look at real-world complication rates."[16]

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This is not a theoretical possibility. The data already exists: EHRs, PDMPs, overdose surveillance, and mortality records. We could study what happens after a clinic is raided or shut down. We could track patients over time: Did they find new doctors? Were they pushed into addiction treatment? Did they end up in emergency rooms, jails, or morgues?

Yet we've never asked those questions. Until we do, we are measuring only one side of the scale: opioid-related risks, not the risks of removing them.

A federally coordinated study series modeled after the PMRs would allow for transparent, real-world analysis of the policies enacted over the last decade. It would also give voice to the millions of patients who, to this day, remain unseen in the data.

7. A Path Forward: What We're Asking the FDA to Do

We understand that the FDA's authority is limited, and that many of the most damaging policies originated from CDC guidelines, state laws, insurance policies, and automated surveillance systems beyond the FDA's direct control. But, the agency still holds enormous influence both in shaping public understanding of opioid risk and in setting the direction for future research and regulatory guidance.

We are not asking for a return to indiscriminate prescribing or to ignore the reality of opioid-related harms. We are asking for balance, honesty, and the courage to look at the full picture, including the people who have been harmed not by opioids, but by the policies created in response to them.

We respectfully urge the FDA to:

- **Commission a comprehensive set of studies** to measure the unintended consequences of opioid prescribing restrictions including overdose, suicide, loss of function, new disability claims, abandonment, and barriers to care.
- **Reject proposals to remove the pain-adjusted OUD diagnosis** from DSM-based outcome tools, which would force stable patients into addiction frameworks and eliminate diagnostic nuance.
- **Initiate regulatory scrutiny** into the financial conflicts of interest that have shaped the push to reclassify pain patients as having OUD especially by parties with commercial ties to the addiction treatment industry.[17]
- **Publicly recognize the absence of patient-centered outcome data** as a critical failure in the policy response to the opioid crisis, and call on HHS, CDC, NIH, and other agencies to prioritize evidence-based measures of function, quality of life, and lived experience.

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- Finally, we ask the FDA to consider the model proposed by Dr. Stefan Kertesz and Dr. Pooja Lagisetty, who advocate for shifting away from a traditional "risk versus benefit" approach and instead adopting a **"**harm versus harm" framework.[18] This model acknowledges that both continuing and discontinuing opioid therapy carry risks, but recognizes that for many stable chronic pain patients, the greater danger often comes from forced dose reductions, medical abandonment, and untreated pain. The traditional model fails patients because it often begins from a false premise: that opioids do not work for chronic pain. If you start there, benefits will never be seen to outweigh risks, and the default becomes discontinuation, regardless of the patient's history or stability. This is how we end up with an entire population of stable pain patients forcibly tapered, cut off, or pushed into treatment systems never designed for them. A harm-based, patient-centered lens is essential if we are to correct course and prevent further suffering. Now that we have accurate statistics of harms of opioids, then measure harms of remaining on opioids vs. harms of forcing stable patients off.

8. Conclusion

The results of the FDA's Postmarketing Requirements studies are valuable, but they are not enough. For over a decade, one narrative has dominated opioid policy, driven by financially conflicted experts, litigation-influenced advocacy, and a near-total absence of outcome data for patients who remained stable on opioid therapy. The harm caused by this one-sided approach is now undeniable. As FDA acknowledged in their briefing, millions of pain patients have been abandoned, stigmatized, and left without care, not because of misuse or diversion, but because policies failed to consider their lives, their stability, and their outcomes.

We are asking the FDA and its advisors to chart a new course, one rooted in evidence, free from financial conflicts, and centered on real patient experiences.

It is not too late to help the patients who remain at risk. But action must be taken now.

Thank you for considering this comment.

Submitted respectfully on behalf of The Doctor Patient Forum.

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