**Kate M. Nicholson, JD**

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I am writing in regard to the proposal to limit coverage of opioid medication to a daily dosage above 90 MME. My primary concern with the proposal is the potential for unintended, negative consequences for people in severe or intractable pain. CDC guidance already addresses both the treatment of patients currently taking higher dosages and dosages in new prescriptions. Rather than taking a one-size-fits-all approach, the CDC guidelines attempt to balance individualized patient care with rule-based guidance. Individualized care is the paradigm of successful treatment for both pain and addiction. I worry that blanket approaches like this proposal are too rigid to address the variability in the pain population and the complexity of issues raised by the treatment of pain.

**My Background (and personal story)**

For 20 years, I served as a Department of Justice attorney and manager overseeing litigation and regulations. I drafted and ushered through the regulatory process the current regulations under the Americans with Disabilities Act and am well versed in Administrative Law. I spearheaded inter-agency coordination on key policy issues, including with the White House Domestic Policy Council. But my primary qualification to address the petition at hand is personal.

After a surgical injury to nerve plexuses in my spine left me unable to sit, stand or walk unassisted and in severe pain, I used opioid analgesics for pain management.

Appropriate pain management with prescription opioids and integrative treatment lifted me from the desperate circumstances of being bedridden and unable to sleep for months at a time to someone who negotiated major settlement agreements, argued important cases in Federal court, and supervised thousands of matters at the Department of Justice in Washington, D.C. and in U.S. Attorney’s Offices nationwide. I still couldn’t sit or stand – I negotiated via video-teleconference, argued from a reclining lawn chair, and supervised from a rigged platform bed – but I functioned as a high level Federal prosecutor for many years.

For a time, my daily dosage was above 90 MME, the dosage ceiling identified in the petition. I never developed tolerance requiring higher dosages for the same pain relieving effect, and when the pain improved, I stopped taking opioids without incident.

I offer my experience only to demonstrate what is gained by appropriate pain management that sometimes includes opioids, even opioids at higher dosages. Given that chronic pain is the chief cause of disability in the US at a cost of half a trillion dollars a year to the economy, rehabilitating people with severe or intractable pain ought to be considered in the balance of competing public health interests.

I recognize that people are different – that the severity of underlying conditions differ, and that individuals and even genetically-related groups may metabolize and respond to opioids differently. This variation argues for a flexible rather than a rigid approach to encouraging the conservative use of opioid treatment.

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**Concerns Regarding Proposal to Limit Coverage to a Daily Dosage of 90 MME**

1. ***The Consequences of Involuntary Tapering***

This proposal is likely to result in the involuntary tapering of individuals already taking dosages

above 90 MME. Although there is not a lot of evidence on forced tapering, initial data by the

Department of Veterans Affairs (VA) is instructive. The VA offered complementary and integrative treatments as part of tapering. Even so, in a recently issued abstract, they found that tapering did nothing to prevent overdose deaths but instead resulted in increased suicide mortality. *See* Manharpa, A., Kertesz S., Olivia E., Sandbrink F., Surprising VA Data About Opioid Discontinuation, Overdose and Suicide: Clinical Implications (Published Abstract). National Rx Drug Abuse and Heroin Summit, 2018. There is other anecdotal evidence of suicide provided by treating physicians who have attempted to taper current patients who are stable and who have shown no history of abuse. *See, e.g.,* Webster, Lynn R., “Pain and Suicide: The Other Side of the Opioid Story,” *Pain Medicine*, v. 15, March 2014, <https://academic.oup.com/painmedicine/article/15/3/345/1844827>

A recent study by Beth Darnall et al., demonstrates the comparative benefits of thoughtful and individualized *voluntary* tapering in a treatment setting. Darnall, Beth. B, Ziadni, Maisa S, Steig, Richard L., et al, ‘Patient-Centered Prescription Opioid Tapering in Community Outpatients with Chronic Pain,” Feb 2018, <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2672574> Supporting efforts like this study will achieve the goal of lowering dosages without sacrificing patient lives.

Importantly, the CDC guidelines already address the situation involving patients taking higher dosages of opioids. The CDC guides physicians to re-evaluate all such patients, and, in so doing, to weigh risks vs. benefits when considering lowering dosages.

1. ***New Prescriptions***

The CDC guidelines also already address dosage concerns in new prescriptions – discouraging physicians from prescribing at higher dosages (50-90 MME).

It is worthy of note that the prescribing of opioids overall has dropped every year since 2012. Non-medical use of prescription opioids has fallen since 2012 to the level of 2002. According to 2017 CDC data, the prescribing of higher-dosage opioids has also fallen considerably. Yet during the period from 2012 to present, drug overdose deaths have skyrocketed. There is growing recognition that the primary culprit of such deaths today is illegal fentanyl and heroin, not new prescriptions.

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1. ***The Risks of Addiction Among Pain Patients***

The data tend to dispute the predominant narrative that prescribing to pain patients often causes addiction and is responsible for the opioid crisis. Studies conducted by the Centers for Disease

Control and Prevention (CDC) and the director of the National Institute on Drug Abuse, Nora D. Volkow, concluded that the risks of addiction among such patients vary from .07 to 8%. When pain patients are screened for a history of substance abuse and provided follow through care, the risk of addiction is reduced significantly.

**Conclusion**

Again, my primary concern with the proposal to limit coverage to doses below 90 MME per day is the potential for unintended consequences in regard to the treatment of pain. We’re already beginning to see negative consequences for pain patients as a rigid application of CDC guidance is being enacted into law in many states. Many states set absolute dosage and supply limits in filling opioid prescriptions. Even where states carve out exceptions for long-term care, insurance companies and pharmacy policies are using the laws as a rationale for denying coverage of fills. Most of the evidence is anecdotal but recent reports suggest that such blanket opioid limits burden the availability of pain medication for all kinds of pain patients, including those they intend to exclude, notably, for cancer and palliative care. *See, e.g.,* “Opioid Epidemic Response May Be Limiting Cancer-Related Pain Management <https://www.oncologynurseadvisor.com/side-effect-management/opioid-epidemic-response-limiting-cancer-related-pain-management/article/710410/> and “Opioid Limits Hit Hospice and Cancer Patients,” [www.bendbulletin.com/localstate/6033839.../opioid-limits-hit-hospice-cancer-patients](http://www.bendbulletin.com/localstate/6033839.../opioid-limits-hit-hospice-cancer-patients). I worry that a blanket limitation of coverage on all opioids over 90 MME will have similar repercussions.

Thank you for your consideration.

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