Stanford University

SEAN MACKEY, MD, PHD
CHIEF
DIVISION OF PAIN MEDICINE

May 8, 2019

To: Members of The Health Evidence Review Commission, Oregon Health Authority

Re: Value-based Benefits Subcommittee: Chronic Pain Task Force Proposal and Health Evidence Review Commission Staff Suggested Revisions

I am writing, once again, to respectfully urge the Oregon Health Authority Health Evidence Review Commission (hereafter "HERC") to reject its proposal for mandatory opioid tapering of Medicaid patients as detailed in the HERC/VbBS document from March 14, 2019.

I incorporate previous correspondence submitted on March 7, 2019, which was signed by over 100 leaders in pain and addiction medicine, health policy, and patient advocacy, in which we raised grave concerns about the lack of scientific evidence backing Oregon's opioid tapering proposal as well as the lack of any infrastructure for tapering that would ensure patient safety.

In roughly the past month, multiple government agencies have strongly opposed mandatory opioid dose reduction or discontinuation as proposed by HERC.

National agencies and entities opposing mandated opioid tapering include:

- U.S. Centers for Disease Control
- U.S. Federal Drug Administration
- The American Medical Association
- The U.S. Surgeon General

Below I detail these recent calls to cease and desist all mandated opioid tapering - regardless of taper pace - due to patient health risks and harms.

First, the Director of the Centers for Disease Control, Robert Redfield, MD, issued a formal response to a highly-publicized letter drafted by the *Health Professionals for Patients in Pain*, (HP3), which was signed by over 300 clinicians and three former Drug Czars. The HP3 letter raised alarm about patient harms resulting from non-consensual opioid tapering due to misapplication of the CDC's 2016 Opioid Prescribing Guideline.

In his response, CDC Director Redfield stated, "The [CDC] Guideline does not endorse mandatory…dose reduction or discontinuation, as these actions can result in patient harm."
He further explained, "The Guideline includes recommendations for clinicians to work with patients to taper or reduce dosage **only** when patient harm outweighs patient benefits of opioid therapy. (bold in original.) "If a patient would like to taper," he continued, "the Guideline includes recommendations for collaborating with the patient on an individualized plan."

1070 Arastradero Road, Suite 200, MC 5596, Palo Alto, CA 94304-1345 T 650.498.6477 F 650.725.9642 E smackey@stanford.edu

HERC's proposal is in direct opposition to the CDC's guidance and clarifications, as it mandates outright discontinuation of opioids across entire patient populations, affecting both broad classes of current patients as well as those subjected to tapering in previous years under Guideline Note 60.

Next, the FDA Safety Alert on Opioid Tapering similarly underscored the importance of voluntary or consent-based processes in opioid tapering, e.g. "one in which you and your patient have agreed to taper."

Subsequently, in *New England Journal of Medicine,* the original authors of the CDC Opioid Prescribing Guideline gave examples of ways in which the Guideline has been misapplied by policymakers. They reiterated that it should not be used as justification to mandate tapering of current opioid recipients**.**

The *NEJM* article focuses on "inflexible applications" of the CDC's dosage recommendations – which resulted in the dosages of patients on long-term opioid therapy forced down under 90 or 50 MME, or even lower. One primary concern is that policymakers were taking the Guideline out of context and beyond its intentions into an area where evidence is clearly lacking. The authors conclude that policies "should allow clinicians to account for each patient's unique circumstances in making clinical decisions."

Additionally, in an official CDC press release, the CDC announced they oppose policies or practices that result in "hard limits" or "cutting off opioids" as these flawed policies and practices "….put patients at risk."

The American Medical Association (AMA) also took a strong position against opioid tapering policies and practices. In a press release authored by AMA President-elect Patrice A. Harris, M.D., M.A., President-elect of the American Medical Association and Chair of the AMA Opioid Task Force, she stated:

- "The AMA appreciates that the CDC recognizes that patients in pain require individualized care and that the agency's 2016 Guidelines on opioids have been widely misapplied. The Guidelines have been treated as hard and fast rules, leaving physicians unable to offer the best care for their patients."

- "The CDC's clarification underscores that patients with acute or chronic pain can benefit from taking prescription opioid analgesics at doses that may be greater than the guidelines or thresholds put forward by federal agencies, state governments, health insurance companies, pharmacy chains, pharmacy benefit managers and other advisory or regulatory bodies."

No federally-funded health agency or respected authority supports the practices or policies as delineated in the proposed HERC opioid tapering plan. Rather, these statements demonstrate strong opposition to the Oregon plan as unfounded, lacking evidence, and risks exposing patients to unnecessary health risks and harms.

Therefore, Oregon's proposed tapering policy is in direct opposition to the CDC's Guideline, and it is even more extreme, as it imposes an inflexible requirement for complete opioid discontinuation for several broad patient populations. Also, it does not allow for individualized decisions as to the benefits and risks of opioids; it is without careful appreciation of the risks of opioid tapering for each patient; it dismisses the critical decision-making process of the clinician-patient relationship.

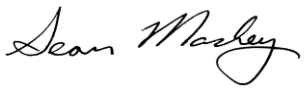
In light of all previous and currently submitted data, I respectfully ask HERC to:

(1) Reject the portion of the proposal that endorses mandatory tapering of opioid medications as detailed in its January 2019 report.

(2) Align all opioid-related policies with federally-issued guidance from the CDC and other public health agencies.

(3) Retroactively rescind Guideline Note 60 that forcefully tapered patients with conditions of the back and spine in 2016.

Sincerely,



Sean Mackey, MD, PhD
Redlich Professor
Chief, Division of Pain Medicine
Director, Stanford Systems Neuroscience and Pain Laboratory
Department of Anesthesiology, Perioperative and Pain Medicine

Citations

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2. Mackey, Sean MD, PhD. "Oregon Chronic Pain Task Force Revised Proposal Regarding Opioids." https://drseanmackey.com/s/Oregon-Letter-Governor-Kate-Brown-120418-final.pdf.

3. Redfield, R, MD. "Response to *Health Professionals for Patients in Pain."* 10 April 2019, https://img1.wsimg.com/blobby/go/3d70257f-a143-4a5b-b9df-f7d265df0d3d/downloads/Alford%20Final%20.pdf?ver=1556148791199m.

4. Kertesz, S., Satel, S., et.al "Health Professionals for Patients in Pain." *www.healthprofessionalsforpatientsinpain.org*, 6 March 2019, https://healthprofessionalsforpatientsinpain.org/the-letter-1.

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7. Food and Drug Administration. "Safety Alert: FDA Identifies Harm Reported From Sudden Discontinuation Of Opioid Pain Medicines And Requires Label Changes To Guide Prescribers On Gradual, Individualized Tapering." ww*w.fda.gov*. 29 April 2019, https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

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9. Kertesz, S., Satel, S., et.al. "Health Professionals for Patients in Pain Press Release." *www.healthprofessionalsforpatientsinpain.org*. 10 April 2019, https://healthprofessionalsforpatientsinpain.org/press-release.

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