



Physicians for Responsible Opioid Prescribing
12800 Whitewater Drive, Suite 100
Minnetonka, MN 55343

www.supportprop.org
T 952 943 3937

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The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Docket # HHS-OS-2018-0027- Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.

Dear Secretary Azar,

We write on behalf of Physicians for Responsible Opioid Prescribing (PROP), an organization representing physicians from diverse specialties including, Pain, Addiction, Primary Care, Emergency Medicine, Neurology, Rheumatology and other internal medicine subspecialties. PROP's mission is to reduce morbidity and mortality caused by overprescribing of opioids and to improve outcomes for patients with pain. We appreciate the opportunity to share our serious concerns with you about the draft report "Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations."

In evaluating the proposed draft recommendations, it is vitally important to consider the public health context. Opioid prescribing for common chronic pain conditions in the United States has started to decline, but remains at historically high levels, levels substantially higher than other developed countries that provide high quality care for chronic pain. Opioid overdoses and addiction involving medically prescribed opioids may have plateaued, but they continue to contribute to an unprecedented decline in life expectancy among working age Americans. This decline in life expectancy is also influenced by increased use of heroin and illicit synthetic fentanyl that followed on the heels of an epidemic of opioid addiction caused by overexposure of the population to prescription opioids. The decline in life expectancy, and the increase in opioid-related morbidity, have not occurred in countries with more conservative practice norms for opioid prescribing. The draft recommendations fail to acknowledge the implications of sustained U.S. opioid prescribing practices on declining life expectancy, overdose deaths and addiction; and the fact that rising morbidity and mortality is not observed in other countries with high quality, evidence-based health care for chronic pain.

Additional specific concerns with the draft are listed below:

The draft report rejects the CDC suggested duration of use for acute pain and the suggested upper dose of 90 MME/day. Instead, it states that “dose and duration of opioid therapy should be determined by treating clinicians according to the individual patient’s need and pain condition.”

The recommendation that duration and dosing of opioids should be open-ended came directly from palliative care. When, in the 1990s, this palliative care principle began to be applied to the treatment of extended acute or chronic pain, it became apparent that the prolonged and higher doses were unsafe with unsubstantiated efficacy. Moreover, lack of guidance on duration and dosing led to gross overuse that harmed both patients and communities and is a root cause of today’s opioid addiction epidemic. The CDC’s suggested duration and dosing was welcomed by the medical community, state health officials, and healthcare organizations because it offered limits based on the best available evidence within which most patients could be treated.

The CDC guideline does not state that there are no exceptions to its recommendations. In fact, guidelines must always be understood as guidance to which there will be some exceptions. However, reinstating the broad recommendation that “dose and duration of opioid therapy should be determined by treating clinicians according to the individual patient’s need and pain condition” contradicts what is now known about the risks and lack of benefit of prolonged high dose opioids, and risks a return to the open-ended duration and dosing that have demonstrated little help to patients, and much harm. There is no other instance in the history of American medicine where wide spread adoption of a prescribing practice has contributed to a decline in life expectancy of a large segment of the population-at-large.

The draft report discourages states and health care organizations from implementing policies to promote CDC opioid prescribing guidance.

If states wish to incorporate the CDC evidence-based recommendations in legislation and policies to curb the opioid epidemic, this is preferable to basing legislation on anecdotal evidence. In fact, it was exactly such “model legislation” promulgated by the Federation of State Medical Boards and other surrogates funded by drug companies that led more than 20 states to pass new rules in 1999-2001 that made opioid prescribing more permissive, leading to the current opioid crisis. The draft recommendations place undue reliance on use of risk assessment tools and patient monitoring strategies by individual clinicians. Clinical tools that can predict risk of addiction have not proven effective. And while close monitoring of patients on opioids is prudent, there is no evidence that it reduces the incidence of addiction or that it improves outcomes.

The draft recommendations attribute state and health insurance policies and regulations that constrain reimbursement for long-term opioid prescribing to

misapplication of the CDC guidelines. States and insurance companies are compelled to develop policies and regulations that protect patients from aggressive opioid prescribing because of epidemic levels of prescription opioid overdose, addiction, and declining life expectancy. While review and evaluation of policies and regulations is appropriate, to avoid unintended consequences, the draft recommendations would unnecessarily interfere with the abilities of states and insurance companies to respond to this urgent public health crisis. Moreover, U.S. opioid prescribing markedly exceeds other developed countries that provide high quality care for patients with chronic pain. States and healthcare organizations should be encouraged to implement policies that promote more cautious prescribing.

Despite the CDC recommendation (and an FDA Black Box) warning against concurrent use of opioids and benzodiazepines, the draft report states “this combination may still have clinical value in patients who have chronic pain and comorbid anxiety.”

The CDC and FDA warnings are based on data indicating that prescribing opioids and benzodiazepines in combination is unsafe. There may be rare exceptions, but the recommendation for avoidance of this combination applies to most patients. Rather than lending support to this dangerous combination, it should be pointed out that there are many alternatives to benzodiazepines for treating anxiety, both pharmacological and non-pharmacological, and that combining two addictive drugs increases the challenge of managing dependence and addiction when they arise. Research has found that more than one in ten patients using opioids long-term report having two or more drinks of alcohol within two hours of taking opioids. Concurrent use of sedatives is extremely hazardous for these patients.

Despite evidence that the Fifth Vital Sign campaign contributed to opioid overprescribing, the draft report states that “societal attitudes that equate pain with weakness” should be countered with “an awareness campaign that urges early treatment for pain that persists beyond the expected duration for that condition or injury.”

Attitudes toward pain vary over time, and between cultures, and can be influenced by public messaging. Some level of pain often persists beyond “the expected duration for that condition or injury” but a medical intervention may not be required. The draft report does not provide evidence that the proposed public messaging campaign would help patients. We caution that such messaging, while well intended, has the potential to harm patients and damage the doctor-patient alliance that is essential for managing chronic pain. Research on effects of public messaging should occur before any such recommendations are considered.

Rather than offering guidance on compassionate care for millions of opioid-dependent patients, the draft characterizes them as victims of efforts to prevent opioid misuse and implies that long-term, high dose opioid use is helping them.

The idea that prolonged and continuous use of high dose opioid therapy is helpful is based on two fundamental misunderstandings: 1) that because pain worsens during tapering, pain will be intolerable without opioid treatment, 2) that because opioids were initially helpful, pain will be intolerable without opioid treatment. In fact, as the brain adapts to prolonged and continuous opioid therapy, opioids become needed to treat dependence (to avoid painful withdrawal), and are no longer useful for treating pain. Moreover, after successful tapering or institution of opioid stabilization therapy, general health and function typically improve, leaving pain unaltered. Treating patients who have become dependent on high dose opioids is time consuming and extremely challenging, and guidance on treating these patients is desperately needed. The CDC guideline does not suggest or support that these patients should be cut off their opioids.

The draft recommendations attribute abandonment of patients with chronic pain using opioids long-term to misapplication of the CDC guidelines. Advocates for more conservative and responsible opioid prescribing have consistently recommended care in managing patients dependent on high opioid doses, and consistently stated that such patients should not be discharged from care, whether opioid dependence is due to addiction or to physiological dependence. Clinicians learned through experience that opioids were not as effective for long-term management of chronic pain as advocates claimed, and that risks of addiction and overdose were far greater. They also learned through experience that cautious management of opioids was difficult and time consuming and that opioids impaired the well-being and motivation of many patients with chronic pain. In this context, there is a subset of clinicians who now feel unprepared to assume the responsibilities of long-term opioid management for patients for whom they perceive a low benefit to risk ratio. To attribute this shift to the CDC guidelines ignores the role of two decades of misinformation about opioid effectiveness and risks disseminated by the pharmaceutical industry and by some opinion leaders in the field of pain medicine.

HHS should have excluded individuals and organizations with financial ties to opioid manufacturers from serving on the HHS Pain Management Task Force.

PROP agrees with Senator Wyden's concerns about pharmaceutical industry conflicts of interest of several HHS Pain Management Task Force members. In Senator Wyden's letter,¹ he described financial ties between some task force members and opioid

¹ Wyden Reveals Opioid Industry Ties on HHS Task Force, Probes Advocacy Group's Finances: *Ranking Finance Democrat Calls on Azar to Review Pain Management Panel Members for Potential Conflicts of Interest*. December 19, 2018. Available at <https://www.finance.senate.gov/ranking-members-news/wyden-reveals-opioid-industry-ties-on-hhs-task-force-probes-advocacy-groups-finances>

manufacturers. He noted that 10 out of 15 task force members subject to HHS open payments requirements had direct financial relationships with pharmaceutical companies. We believe pharmaceutical industry bias is reflected in the draft report's recommendations. Instead of supporting efforts to promote more cautious opioid prescribing, the draft explicitly contradicts opioid prescribing guidance issued by the Centers for Disease Control and Prevention (CDC), the U.S. Department of Veterans Affairs (VA) and the Department of Defense (DoD).

Given the many deficiencies of the draft report, we do not believe its recommendations related to opioid use will serve the best interests of patients with chronic pain. Instead, these recommendations will impede current efforts to reverse the Nation's opioid addiction epidemic which is lowering life expectancy of a large segment of the working age population. While the draft may be well intended, it is clear that its key recommendations would not yield benefits for improved management of chronic pain, while they would certainly increase risks of prescription opioid overdose and addiction.

Respectfully submitted,

Jane C. Ballantyne, MD, FRCA

President, PROP;
Professor, Anesthesiology and Pain Medicine
University of Washington

Paul Coelho, MD

Medical Director,
Salem Health Pain Clinic
Salem, Oregon

Gary M. Franklin, MD, MPH

Vice President, State Affairs, PROP;
Research Professor, Dept of Environmental
Health, Neurology, and Health Services,
University of WA;
Medical Director, WA State Dept. Labor and
Industries

Stephen G. Gelfand, MD, FACP

Consultant, Rheumatology
Physicians for Responsible Opioid Prescribing
Myrtle Beach, South Carolina

Chris Johnson, MD

Chair, Minnesota Dept. of Human Services
Opioid Prescribing Work Group;
Board of Trustees,
Minnesota Medical Association

Andrew Kolodny, MD

Executive Director, PROP;
Senior Scientist, Co-Director,
Opioid Policy Research Collaborative
Heller School for Social Policy & Management
Brandeis University

Danesh Mazloomdoost, MD

Medical Director
Wellward Regenerative Medicine
Lexington, Kentucky

Anna Lembke, MD

Medical Director, Addiction Medicine
Program Director, Addiction Medicine Fellowship
Chief, Addiction Medicine Dual Diagnosis Clinic
Associate Professor, Dept of Psychiatry
Stanford University School of Medicine

Jim Shames MD, ABAM

Health Officer, Jackson County Oregon;
Consultant, Oregon Health Authority

Rosemary Orr, MD

Professor Emeritus of Anesthesiology and Pain
Medicine, University of Washington and Seattle
Children's Hospital

Mark D. Sullivan, MD, PhD

Professor, Psychiatry and Behavioral Sciences
Adjunct Professor, Anesthesiology and Pain
Medicine, Bioethics and Humanities
University of Washington

Jon Streltzer, MD

Professor Emeritus of Psychiatry,
University of Hawaii School of Medicine

Betty Tully

Patient Advocate, PROP
Chicago, Illinois

David J. Tauben, MD, FACP

Chief, UW Division of Pain Medicine
Clinical Professor, Depts of Medicine and
Anesthesia & Pain Medicine
University of Washington

Michael Von Korff, ScD

Vice President, Scientific Affairs, PROP;
Senior Investigator,
Kaiser Permanente Washington Health
Research Institute

cc:

Andrew Bremberg, Director, Domestic Policy Council
James Carroll, Acting Director, ONDCP
Robert Charrow, General Counsel, HHS
Kellyanne Conway, Counselor to the President
Uttam Dhillon, Acting Administrator, DEA
Brett Giroir, Assistant Secretary, HHS
Scott Gottlieb, Commissioner, FDA
Joseph Grogan, Associate Director, OMB
Eric Hargan, Deputy Secretary, HHS
Daniel Levinson, Inspector General, HHS
Elinore McCance-Katz, Assistant Secretary, HHS
Robert Redfield, Director, CDC
Seema Verma, Administrator, CMS