



Physicians for Responsible Opioid Prescribing
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November 19, 2018

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

Re: HHS Pain Management Task Force

Dear Secretary Azar,

We write on behalf of Physicians for Responsible Opioid Prescribing (PROP) to express our extreme concern about recommendations recently proposed by a subcommittee of the HHS Pain Management Task Force (PMTF). These recommendations directly conflict with the Trump Administration's goal to reduce aggressive opioid prescribing. Indeed, if adopted, the subcommittee's recommendations would worsen the nation's opioid addiction epidemic and undermine federal and state government efforts to bring this public health crisis under control.

The subcommittee's recommendations explicitly contradict 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). For example, the PMTF draft describes the CDC and VA/DoD upper dose of 90 milligram morphine equivalents as "arbitrarily defined"; describes the combination of opioids and benzodiazepines as having "clinical value" despite an FDA black box warning and guidance from CDC and VA/DoD that the combination is dangerous; and it calls for CDC's suggested duration of use for acute pain "to be removed in future revisions of the CDC Guidelines."

These recommendations were produced through a process that was improper and in violation of Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA), Pub. L. No. 114-198, 130 Stat. 695 (July 22, 2016), the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and the PMTF charter. CARA mandates that the PMTF—as a whole—produce recommendations that would be subject to public comment. See *id.* § 101 (e)(2)(b). In violation of this requirement, the recommendations were proposed by a *subcommittee* of the PMTF. We are highly confident that if the full PMTF, including its federal members, had been consulted, the recommendations would have been different.

The PMTF charter has also been violated. According to the PMTF charter, any recommendations by a subcommittee of the PMTF must be presented to the entire PMTF and discussed at an open public meeting:

“The established subcommittees may consider issues in accordance with the mission of the Task Force, and shall, as appropriate, make recommendations and/or reports to the Task Force for consideration. Recommendations and/or reports of the subcommittee that are provided to the Task Force shall be discussed at an open public meeting that is held by the Task Force.”

This procedure was not followed. In fact, at the September 2018 public meeting, federal members of the PMTF voiced concern about their inability to offer input on the recommendations. The PMTF chair instructed them to submit their comments to the docket after the draft is posted. This led federal members to request a disclaimer on the report indicating: *“Information in the draft recommendations do not necessarily reflect the opinions of the Task Force, the U.S. Department of Health and Human Services, or any other component of the federal government.”* Some non-federal PMTF members also expressed their desire for an opportunity to deliberate and vote on specific recommendations in the draft. Their requests were denied by the PMTF chair. They too were instructed to submit comments to the docket.

There have also been multiple violations of FACA. FACA requires advisory committees to be fairly balanced in terms of the points of view represented. We believe the composition of the non-federal PMTF members does not comply with this requirement. Nearly half of the non-federal PMTF members have played leadership roles in pain organizations funded by opioid manufacturers.¹ These organizations have a history of advocating against reductions in opioid prescribing and have been characterized as “front groups” in legal complaints filed by hundreds of cities, counties and states against opioid manufacturers.

In violation of the FACA requirement for fair balance, the PMTF does not include representation from professional organizations that have long advocated for more cautious opioid prescribing, such as Physicians for Responsible Opioid Prescribing, the American Association of State and Territorial Health Officials, and the American College of Medical Toxicology. Nor does it include representation from patient and consumer safety organizations that have supported the CDC’s opioid prescribing guidance, such as Shatterproof, the National Safety Council, and the Steve Rummler Hope Network.

We also believe that HHS violated FACA by failing to disclose PMTF materials. FACA provides that, unless a Freedom of Information Act exemption applies, “the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available

¹ Report by Homeland Security and Governmental Affairs Committee, Ranking Member’s Office. [Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups](#). Accessed on June 30, 2018.

for public inspection and copying.” 5 U.S.C. App. 2 § 10(b). Despite this requirement, materials available to some PMTF members, such as minutes from subcommittee meetings, have not been made available to the public or even to the full PMTF.

Lastly, we have serious concerns about the conduct of the PMTF chair, Dr. Vanila Singh. We do not believe it was appropriate for her to bring her own patients to a PMTF meeting to provide testimonials about the benefits of long-term opioid use. We were also dismayed to see her appear as a speaker at a conference last week² sponsored by the Academy of Integrated Pain Management. This organization received more than \$1 million from Purdue Pharma (the maker of OxyContin) in recent years and has consistently lobbied against efforts to promote cautious opioid prescribing.³

We urge you to immediately address violations of CARA and FACA by taking the following actions:

1. Convene a public meeting of the PMTF that allows discussion and deliberation and, if necessary, a vote by PMTF members on each subcommittee recommendation *before* a draft is posted to a docket for public comment.
2. Obtain a fair balance of views by adding new members to the PMTF from professional and patient organizations that support the CDC’s efforts and the Trump Administration’s goal to reduce aggressive opioid prescribing.
3. Require all PMTF documents, materials, and subcommittee meeting minutes to be posted on the PMTF website for public inspection.

We strongly support the Trump Administration’s goal to reduce the incidence of opioid use disorder and improve pain care by curbing aggressive and irresponsible opioid prescribing. The recommendations by the PMTF subcommittee, however, are a significant step backwards in our nation’s effort to address a public health emergency.

² Global Pain Clinician Summit 2018 Pain Management Conference; November 9-10, 2018. Accessed on November 15, 2018 at <https://www.integrativepainmanagement.org/page/Summit3HeadedMonster>

³ Report by Homeland Security and Governmental Affairs Committee, Ranking Member’s Office. [Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf). Accessed on June 30, 2018. Available at <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>

Respectfully submitted,

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