CDC Bows To Demands For Transparency And Public Input On Draft Opioid-Prescribing Guidelines

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Over the past year, the Centers for Disease Control and Prevention (CDC) has been drafting a Guideline for Prescribing Opioids for Chronic Pain in relative secrecy, relying upon the input of a hand-picked group of advisers and a limited number of stakeholders. Such a stealth approach drew criticism from numerous interested parties, including Washington Legal Foundation, which explained in a November 17, 2015 letter to CDC that the agency's drafting process ran afoul of the Federal Advisory Committee Act (FACA).

This week, CDC took several unexpected steps towards greater transparency for its prescribing guideline project, implicitly conceding its prior FACA violations. The director of CDC's National Center for Injury Prevention and Control informed WLF on December 14 of its about-face in a letter responding to our November 17 missive. That same day, CDC published a notice in the Federal Register that seeks comments on the draft guideline and also directs the public to numerous previously-unreleased documents. In addition, CDC announced that it will ask a federal advisory committee, its Board of Scientific Counselors, to review the draft guideline and public comments and make recommendations to the agency.

In our November 17 letter, WLF argued the "Core Expert Group" that CDC's National Center for Injury Prevention and Control selected to draft and review the guideline qualified as a federal advisory committee under FACA. In convening the Core Expert Group, CDC had failed to follow numerous FACA requirements, including formally filing a charter; announcing meetings in the Federal Register; holding meetings in public; and keeping and making public detailed minutes of those meetings. We also questioned whether the Core Expert Group complied with FACA's requirement that advisory committees be fairly balanced in terms of the points of view represented.

Instead of holding meetings in public, for instance, the Core Expert Group met secretly in Atlanta in June to provide recommendations to CDC regarding the guideline. The first time that the public had access to even a general outline of the draft guideline occurred in September, when CDC convened a hastily-called webinar to discuss its plan. CDC agreed to receive comments by email for 25 hours after the webinar, which it later extended to 49 hours. Technical difficulties with the September 16 webinar limited stakeholders' access, forcing CDC to re-run it the following day.

WLF's November 17 letter also addressed the CDC's seeming indifference to FACA's fair-balance requirement. Numerous members of the Core Expert Group were on record as strongly supporting the need to tighten opioid-prescribing standards. The panel did not include physicians and others experienced with treating chronic pain, and featured only one pain-management expert, Dr. Jane Ballentyne. The group for which Dr. Ballentyne serves as President, Physicians for Responsible Opioid Prescribing (PROP), has, among other activities, petitioned FDA to curb opioid use and lobbied Congress for legislative limits (PROP's Vice President is also a member of CDC's Core Expert Group). In addition to her pre-existing ideological bias, Dr. Ballentyne suffers from a financial conflict of interest, having acted as a paid consultant to a law firm representing the State of California and the City of Chicago in novel lawsuits against opioid manufacturers - clients who stand to gain from a strict federal guideline.

We explained to CDC that if the final opioid-prescribing guideline relied on the Core Expert Group's recommendations, the agency ran the risk of a legal challenge by stakeholders under the Administrative Procedure Act.

It is unclear whether these latest developments, and the involvement of a chartered federal advisory committee, will result in a fresh look at the draft prescribing guideline, or the release of a document that relies in any way on the advice of the tainted Core Expert Group. Stakeholders and other interested parties, such as WLF, will certainly continue to scrutinize the process to find out. We will also keep an eye on the makeup of the working group that the Board of Scientific Counselors will be appointing in January to review the draft guideline to see whether it is fairly balanced and free of conflicts of interest.

Congress adopted FACA in 1972 because it believed process matters, and because that process should be open to the public that regulators serve. The final Guideline for Prescribing Opioids for Chronic Pain may not constitute a formal regulation, but CDC intends it to be the federal government's definitive statement on the topic. It will not only influence the work of thousands of public-health officials and private physicians, but directly impact millions of patients who suffer from chronic pain. Only a process that is transparent and informed by robust debate and discussion will provide the type of reasoned outcome that such patients deserve.

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