

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074

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<http://oversight.house.gov>

December 18, 2015

Thomas Frieden, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Dear Dr. Frieden:

We understand the Centers for Disease Control and Prevention (CDC) is in the process of drafting guidelines to significantly revise many of the rules related to prescribing opioids.¹ We have questions about why a “Core Expert Group” established by CDC to assist with drafting these guidelines is not considered an advisory committee under the Federal Advisory Committee Act (FACA).²

Opioid abuse is a serious problem in America today. By CDC’s estimates, “[a]lmost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013.”³ At the same time, millions of Americans rely on properly prescribed opioids to alleviate chronic pain. The Cancer Action Network of the American Cancer Society asserts that “[w]hile not the only tool, opioid medications are recognized as a mainstay of treatment for moderate to severe cancer pain and can be a beneficial treatment for managing serious, persistent pain.”⁴ Some groups have raised concern that the proposed guidelines may be insufficient to treat those suffering from chronic pain.⁵

We expect CDC’s guideline drafting process to seek an appropriate balance between the risk of addiction and the need to address chronic pain. The CDC has utilized a “Core Expert Group” in the drafting and development of opioid prescribing guidelines, raising questions as to whether CDC is complying with FACA.⁶ FACA provides, in relevant part, that an “‘advisory committee’ means any committee, board, commission, council, conference, panel, task force, or other similar group” that is “‘established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for . . . one or more agencies or officers of the Federal Government.’”⁷

¹ U.S. Centers for Disease Control and Prevention, “Factsheet: New CDC Opioid Prescribing Guidelines, Improving the Way Opioids are Prescribed for Safer Chronic Pain Treatment,” *available at* http://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last visited Dec. 10, 2015) [hereinafter, CDC Factsheet].

² Pub. L. No. 92-463 (1972) (codified at 5 U.S.C., Appendix).

³ CDC Factsheet.

⁴ American Cancer Soc’y Comments.

⁵ *See, e.g.*, Letter from Christopher W. Hansen, President, American Cancer Society Cancer Action Network, to Dr. Tom Frieden, Director, and Dr. Debra Houry, Director, National Center for Injury Prevention and Control, U.S. Centers for Disease Control and Prevention at 1 (Oct. 1, 2015), *available at* http://www.acscan.org/content/wp-content/uploads/2015/10/ACSCAN_Comments_CDC_Opioid_Guidelines_Final.pdf. (“With respect to the CDC’s current effort, we believe the proposed guidelines have the potential to significantly limit cancer patient access to needed pain medicines. We have concerns about the lack of evidence on which the guidelines were based, the methodology used to develop the guidelines, and the transparency of the entire process. Our concerns are so serious that we cannot endorse the proposed guidelines in any way and suggest suspending the process until the methodological flaws are corrected and more evidence is available to support prescribing recommendations.”) [hereinafter, American Cancer Soc’y Comments]

⁶ *See* note 1, *supra*.

⁷ 5 U.S.C., Appendix § 3(2).

CDC has not provided clear information regarding the “Core Expert Group’s” role. In its draft “Guideline for Prescribing Opioids for Chronic Pain, 2016” (CDC Draft Guidelines), CDC notes that it “recruited a Core Expert Group . . . to assist in interpreting the evidence and translating the evidence into recommendations.”⁸ CDC also stated that Core Expert Group “members provided individual consultation and were not part of a designated Federal Advisory Committee.”⁹

However, to date CDC has not identified the group’s 17 members. After describing the members’ professional expertise, the CDC Draft Guidelines state that the group “reviewed summaries of the scientific evidence and CDC’s draft recommendation statements,” that “CDC convened [Core Expert Group] members at an in-person meeting” in Atlanta “to discuss the evidence and recommendations and obtain expert opinions,” that “CDC noted [Core Expert Group] members’ comments and any dissenting opinions on the recommendations,” and that the group’s “members also reviewed the final guideline document and provided written comments for consideration by CDC.”¹⁰

In a recent set of comments on the CDC Draft Guidelines, the Washington Legal Foundation raised questions whether the CDC’s use of a “Core Expert Group” violates FACA.¹¹ That letter refers to the Washington Legal Foundation’s Freedom of Information Act (FOIA) request (WLF FOIA Request)¹² that “CDC release all of its [Core Expert Group]-related documents that should have been released previously pursuant to FACA.”¹³ The WLF FOIA Request seeks documents related to potential FACA issues surrounding the “Core Expert Group.”

So the Committee can better understand the CDC’s compliance with FACA related to the “Core Expert Group,” please provide the following documents and information as soon as possible, but by no later than noon on January 5, 2016:

1. Documents referring or relating to CDC’s selection of members to its “Core Expert Group,” including the identity and affiliation of group members and efforts by CDC to ensure that the composition of the “Core Expert Group” was balanced in terms of the points of view expressed by members of the group.
2. All documents referring or relating to any meeting of the “Core Expert Group,” including the June 23-24, 2015 meeting in Atlanta, in connection with CDC requests that those members provide advice regarding proposed guidelines for prescribing opioids for chronic pain.
3. All documents that were prepared by any member of the “Core Expert Group” and supplied to CDC in connection with that member’s work as part of the “Core Expert Group.”
4. All documents referring or relating to CDC’s compliance with FACA, including any documents referring or relating to how to structure groups to fall outside of the scope of FACA.

⁸ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain, 2016* at 4, available at <http://morningconsult.com/wp-content/uploads/2015/09/CDC-Pre-Decisional-Guidelines.pdf>.

⁹ *Id.*

¹⁰ *Id.* at 5.

¹¹ Letter from Richard A. Samp, Chief Counsel, and Mark S. Chenoweth, Washington Legal Foundation, to Dr. Tom Frieden, Director, and Dr. Debra Houry, Director, National Center for Injury Prevention and Control, U.S. Centers for Disease Control and Prevention (Nov. 17, 2015), <http://www.wlf.org/upload/litigation/misc/CDCComments-Opioids.pdf> (WLF CDC Guideline Comments).

¹² Letter from Richard A. Samp, Chief Counsel, and Mark S. Chenoweth, Washington Legal Foundation, to CDC ATS DR, FOIA Office, U.S. Centers for Disease Control and Prevention (Nov. 17, 2015), <http://www.wlf.org/upload/litigation/misc/CDCFOIARequest-Opioids.pdf>.

¹³ WLF CDC Guideline Comments at 2.

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5. A description of the process the CDC is using to obtain stakeholder input on the draft guidelines.

Please also provide a briefing to Committee staff no later than 5:00 p.m. on January 8, 2016 to address the topics above.

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at "any time" investigate "any matter" as set forth in House Rule X.

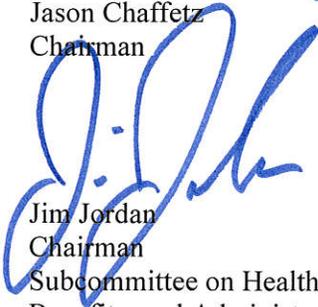
When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information about responding to the Committee's request.

Please contact Cordell Hull with Chairman Chaffetz' staff at (202) 225-5074 or Krista Boyd with Ranking Member Cummings' staff at (202) 225-5051 with any questions about this request. Thank you for your attention to this matter.

Sincerely,



Jason Chaffetz
Chairman



Jim Jordan
Chairman
Subcommittee on Healthcare,
Benefits, and Administrative Rules



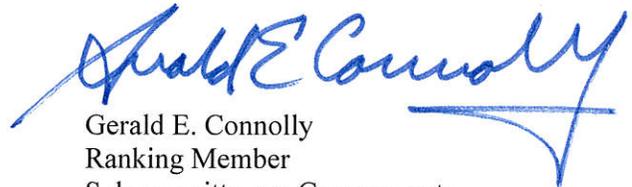
Elijah E. Cummings
Ranking Member



Matt Cartwright
Ranking Member
Subcommittee on Healthcare,
Benefits, and Administrative Rules



Mark Meadows
Chairman
Subcommittee on Government
Operations



Gerald E. Connolly
Ranking Member
Subcommittee on Government
Operations

Enclosure