
Docket No. CDC-2015-0112

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

**CENTERS FOR DISEASE CONTROL AND PREVENTION
DEPARTMENT OF HEALTH & HUMAN SERVICES**

Concerning

**PROPOSED 2016 GUIDELINE FOR
PRESCRIBING OPIOIDS FOR CHRONIC PAIN**

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 80 *FED. REG.* 77351 (DECEMBER 14, 2015)

Richard A. Samp
Mark S. Chenoweth
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

January 13, 2016

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, DC 20036
202-588-0302

January 13, 2016

Submitted Electronically (www.regulations.gov)

Nat'l Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway N.E.
Atlanta, GA 30341

Re: Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain
80 Fed. Reg. 77531 (December 14, 2015)
Docket No. CDC-2015-0112

Dear Sir/Madam:

Washington Legal Foundation (WLF) appreciates this opportunity to submit comments in response to CDC's Proposed Guideline for Prescribing Opioids for Chronic Pain. We have previously written to CDC's Director, as well as the Director of the National Center for Injury Prevention and Control (letter attached), to express our concern regarding the overly secretive manner in which CDC has gone about developing its Proposed Guideline. WLF views CDC's decision to open up the process to public comment as a step in the right direction. More needs to be done, however, to eliminate the taint created by the improper administrative procedures previously employed by CDC; WLF urges CDC to do so by undertaking the additional steps outlined below.

WLF takes no position on whether CDC should issue a guidance document on prescribing opioids. Government standards for the prescription of opioids to treat chronic pain are highly controversial, as evidenced by the considerable number of protests that have been raised in connection with CDC's Draft Guideline. Some individuals believe that CDC should

establish guidelines that impose significant controls on opioid prescriptions as one means of reducing deaths and injuries resulting from drug abuse. Others oppose such efforts, believing that new controls on prescriptions will prevent many patients from receiving the medications they need to treat their chronic pain. WLF lacks the necessary scientific expertise to take a strong position in that debate. Our interest is in ensuring that that debate takes place in public, not behind closed doors at CDC—particularly given that CDC has chosen to seek advice on the issue from groups of individuals who are not government employees.

As explained in the attached letter (which we hereby request be included as part of WLF's comments on the Draft Guideline), CDC repeatedly violated the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, § 1 *et seq.*, in connection with its establishment and utilization of the Core Expert Group (CEG) in its development of the Draft Guideline. Because the CEG was/is a FACA “advisory committee,” CDC was required to comply with each of the numerous obligations that FACA imposes on such committees—including opening all meetings to the public, publicly releasing all documents that CDC made available to the CEG, and preparing (and publicly releasing) minutes of CEG meetings. CDC complied with *none* of those requirements. Accordingly, federal law bars CDC from relying on any advice provided to it by the CEG. The integrity of the administrative process requires that, going forward, CDC undertake measures designed to ensure that any guidance document ultimately issued by CDC has not been influenced by the extensive advice it received from the CEG.

WLF understands that the National Center for Injury Prevention and Control's Board of Scientific Counselors will be holding a public meeting on January 28, 2016 to consider the

Proposed Guideline. WLF applauds that decision. The Board of Scientific Counselors is an officially sanctioned federal advisory committee that conducts its proceedings in compliance with FACA requirements. WLF notes that the Board of Scientific Counselors has appointed a ten-person “Workgroup” to provide it with advice regarding the Proposed Guideline. WLF cautions that the Workgroup, because its members are not federal government employees, are also subject to the requirements of FACA to the extent that it has been organized to provide advice to the Board. WLF thus expects that the Workgroup will conduct its work in compliance with FACA requirements; otherwise, its work product will suffer from a taint identical to that of the CEG’s work product. We have been disturbed to hear reports that the Workgroup has been meeting in private; if those reports are accurate, we urge CDC to reverse that policy immediately and bring the Workgroup into compliance with FACA. WLF also calls to CDC’s attention FACA’s requirement that all federal advisory committees be “fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.” FACA § 5(b)(2). WLF is not familiar with the backgrounds of the ten individuals named to the Workgroup. We nonetheless fervently hope that the Board expressly took into account the “fair balance” requirements when selecting Workgroup members. If not, any CDC reliance on the recommendations of the Workgroup would likewise be subject to challenge.

While opening up of the review process to public comments and the scheduled additional review by the Board of Scientific Counselors are both positive developments, the CDC must do more to ensure that any guidance document it ultimately issues is purged of the taint of its past FACA violations. WLF is concerned, for example, that the Proposed Guideline on which the

public is being asked to comment is virtually unchanged from the proposed guidance that CDC promulgated last September based on considerable input from the CEG. A reviewing court might easily conclude, therefore, that if CDC were to issue the Proposed Guideline in its current form, it had acted in reliance on advice provided by an improperly constituted advisory committee.

The only way to ensure that any guidance document ultimately released was not influenced by the CEG would be to ask some properly constituted group (whether a FACA-compliant Workgroup or a group of full-time CDC employees) to make a truly independent set of recommendations. That new set of recommendations might (or might not) end up being similar to the current recommendations; but so long as the new recommendations are not derived from advice provided by the CEG, CDC would be free to rely on them in its final determination; and CDC staff would be free to draft a new version of the Proposed Guideline in reliance on those recommendations.

WLF notes that Dr. Robert Chou of Oregon Health and Sciences University, who is a member of the CEG, is listed as one of three “contributing authors” of the Draft Guideline. Because of his involvement with the improperly constituted CEG, WLF deems it inappropriate for Dr. Chou to continue to serve as a “contributing author” with respect to current and yet-to-be-revised drafts of the guideline. Any guidance document which was drafted in substantial part by a CEG member and is ultimately issued by CDC could only be viewed as having been influenced by the recommendations of the CEG.

Finally, WLF urges CDC to release all documents related to the operations and

deliberations of the CEG, as requested by the Freedom of Information Act request that WLF submitted to CDC on November 17, 2015, and as six Members of Congress requested in a December 18, 2015 letter to CDC. Unless CDC releases those documents, it will be unable to demonstrate to the general public—and to any reviewing court—that it has fully purged the CEG recommendations from its administrative proceedings.

CONCLUSION

WLF applauds CDC's decision to open up the administrative process to public comment. It urges CDC to: (1) ensure that all advisory work undertaken by the Workgroup be conducted in full compliance with FACA; and (2) take the steps outlined above to ensure that any guidance document ultimately issued by CDC has not been influenced by advice provided by the CEG.

Sincerely,

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel

/s/ Mark S. Chenoweth
Mark S. Chenoweth
General Counsel