

WASHINGTON LEGAL FOUNDATION

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November 17, 2015

Tom Frieden, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

Debra Houry, M.D., M.P.H.

Director, National Center for Injury Prevention and Control

United States Centers for Disease Control and Prevention

1600 Clifton Road

Atlanta, GA 30329-4027

Re: Guideline for Prescribing Opioids for Chronic Pain

Dear Drs. Frieden and Houry,

Washington Legal Foundation (WLF) is writing to express its extreme concern with the flawed procedures being employed by CDC in connection with its proposal to issue a Guideline for Prescribing Opioids for Chronic Pain. The overly secretive manner in which CDC has been developing the Guideline serves the interests of neither the healthcare community nor consumers. More importantly, CDC's repeated violations of 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) call into question the viability of the entire enterprise and dictate that any guidelines adopted as a result of the current administrative process could not withstand judicial scrutiny. We call on CDC to withdraw the Draft Guideline and to generate reliable data on ways to ensure adequate treatment of patients while preventing opioid abuse before renewing efforts to write a guideline.

CDC officials have explained their failure to adhere to FACA procedures by asserting that the CEG does not qualify as a FACA "advisory committee." That assertion does not pass the red-face test. We urge you to consult with attorneys with the General Counsel's office in the Department of Health and Human Services (HHS) before repeating that assertion; there is *no* federal-court case law that supports CDC's cramped definition of an "advisory committee."

FACA's definition of "advisory committee" includes any group "established or utilized" by CDC "in the interest of obtaining advice or recommendations" for CDC, provided that at least one member of the group is not a federal employee. FACA § 3(2). The CEG meets that definition. It was "established" by CDC for a very specific purpose: to provide advice to CDC regarding its proposed guidelines on prescribing opioids. Few if any CEG members are federal employees. CEG members met in Atlanta on June 23-24, 2015 to review the then-current draft of the guideline and, at CDC's request, provided their advice regarding that draft within a group

discussion. Indeed, one member of the CEG is listed as a principal author 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. WLF has attached to this letter a request under the Freedom of Information Act (FOIA) that CDC release all of its CEG-related documents that should have been released previously pursuant to FACA.

Although this letter focuses on CDC’s numerous violations of FACA, those violations are not the only aspects of this administrative proceeding with which WLF takes issue. A basic premise of administrative law is that interested members of the public should be informed about proposed actions by federal agencies and provided a meaningful opportunity to comment on such proposals. Yet, throughout these proceedings, CDC has attempted to operate largely in secret and to prevent stakeholders from playing a meaningful role. Such conduct undermines CDC’s stated goal, which is to develop prescribing guidelines that will command greater acceptance than existing guidelines. State governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input and with the assistance of individuals (including several members of the CEG) who have serious conflicts of interest.

I. *Interests of Washington Legal Foundation*

WLF is a non-profit public-interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free-enterprise principles, individual rights, a limited and accountable government, and the rule of law. WLF believes strongly that public support for the work of federal government agencies can be maintained only so long as the public perceives that their proceedings are administered fairly. An essential ingredient of any fair administrative system is the presence of impartial decision-makers.

To that end, WLF has a decades-long record of litigating in support of strict enforcement of FACA, a statute designed to ensure regularity in the proceedings of committees appointed to provide advice to the federal government. *See, e.g., Public Citizen and Washington Legal Found. v. U.S. Dep’t of Justice*, 491 U.S. 440 (1989); *Lorillard, Inc. v. FDA*, No. 14-5226 (D.C. Cir., dec. pending); Citizen Petition No. FDA-2011-P-0497 (FDA, docketed June 30, 2011) (petition seeking to bar use of report of advisory committee on medical devices because committee’s composition violated FACA’s “fair balance” requirement).

WLF is concerned that, with increasing frequency, federal agencies attempt to avoid application of FACA by insisting that groups from which they seek advice not take any formal votes as a group. If the mere absence of formal votes were sufficient to evade FACA, the statute would be rendered a dead letter; agencies could obtain all the advice they could ever need from outside groups without ever seeking formal votes. WLF does not believe that FACA permits federal agencies to so easily evade the statute's transparency requirements.

WLF supports the right of stakeholders outside the Executive Branch to have a meaningful opportunity to participate in the development of government policy by federal administrative agencies. In particular, on a number of occasions it has litigated in support of efforts to require agencies to comply with the notice-and-comment requirements of the Administrative Policy Act (APA) before adopting new rules. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015); *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156 (2012). WLF is troubled by CDC's unwillingness to provide any such meaningful opportunity in connection with its development of opioid prescribing guidelines.

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 Guidelines. 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 a group of individuals who are not government employees.

II. *FACA Requires Transparency with Respect to Groups Established by a Federal Agency for the Purpose of Providing Advice to the Agency*

Congress adopted FACA in 1972, in large part to ensure that the public could remain apprised of the existence, activities, and cost of committees providing advice to the federal government. *Public Citizen*, 491 U.S. at 446. FACA imposes numerous procedural requirements on federal advisory committees, including that they “file a charter; announce their meetings in the Federal Register; hold their meetings in public; and keep detailed minutes of each meeting.” *In re Cheney*, 406 F.3d 723, 727 (D.C. Cir. 2005) (citing FACA §§ 9(c), 10(a)(1) & (2), 10(c), and 11). They must also make public all documents “which were made available to or prepared for or by each advisory committee.” FACA § 10(b). The agency must ensure that the membership of *any* advisory committee is “fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.” FACA § 5(b)(2).

Among Congress's express purposes in adopting FACA were ensuring that "uniform procedures [w]ould govern the establishment, operation, administration, and duration of advisory committees," and that "Congress and the public [w]ould be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees." FACA § 2(b)(4) & (5).

To qualify as a federal "advisory committee" subject to FACA, an entity must meet four principal requirements:

- (1) the entity must be "any committee, board, commission, council, conference, panel, task force, or other similar group";
- (2) it must be either "established" or "utilized" by the President or one or more agencies;
- (3) it must be established or utilized "in the interest of obtaining advice or recommendations"; and
- (4) it must not be composed solely of officers or employees of the federal government.

FACA § 3(2).¹

¹ FACA § 3(2) states:

The term "advisory committee" means any committee, board, commission, council conference, panel, task force, or other similar group, or other subgroup thereof (hereinafter in this paragraph referred to as "committee"), which is—

- (A) established by statute or reorganization plan, or
- (B) established or utilized by the President, or
- (C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) any committee that is composed wholly of full-time, or permanent part-time, officers or employees of the Federal Government, and (ii) any committee that is created by the National Academy of Sciences or the National Academy of Public Administration.

The first requirement ensures that the individuals coming together are doing so in some sort of organized fashion. For example, if an agency simply invites interested members of the public to provide their views on a public issue at an event organized by the agency and does not seek to structure the commenting process, the individuals who come to express their views independently would not be deemed an “advisory committee” under FACA. *Citizens for Responsibility and Ethics in Washington v. Leavitt*, 577 F. Supp. 2d 427 (D.D.C. 2008). Because “a group is a FACA advisory committee when it is asked to render advice or recommendations, as a *group*, and not as a collection of individuals,” “an important factor in determining the presence of an advisory committee [is] the formality and structure of the group.” *Ass’n of Am. Physicians & Surgeons, Inc. v. Clinton*, 997 F.2d 898, 913-14 (D.C. Cir. 1993) (“AAPS”). Criteria relevant in determining whether the group has sufficient formality or structure to qualify as a FACA “advisory committee” include whether the group has: (1) an organized structure; (2) a fixed membership; and (3) a specific purpose. *Id.* at 914.

Courts have universally concluded that the second requirement (the “established or utilized” requirement) is met if the group was *either* “established” *or* “utilized” by the agency. *See, e.g., Public Citizen*, 491 U.S. at 452-53. Accordingly, when (as here) all agree that a group was “established” by a federal agency, whether (and the extent to which) the agency actually “utilized” the advice of the agency is not relevant in determining whether the group qualifies as a FACA “advisory committee.”

The fourth requirement (that at least one member of the group not be a federal officer or employee) reflects FACA’s focus on preventing outside groups or individuals from exercising unwarranted influence over federal policy. FACA requires that if an agency wishes to seek advice in a structured fashion from outside groups or individuals, it must adhere to elaborate procedural rules to ensure that the advice is provided in a transparent manner and that the membership of the group “is fairly balanced in terms of the point of view represented.” FACA § 5(b)(2). FACA assumes that the danger of unwarranted influence by outside groups is substantially lessened if all members of a group providing advice are federal officers or employees.

III. *CDC’s Plan for Developing Opioid Prescribing Guidelines Includes Receipt of Advice in a Structured Manner from the Core Expert Group, a Group Established by CDC Whose Members Are Not Federal Employees*

CDC evidently determined in 2014 or early 2015 that it would issue guidelines for prescribing opioids for chronic pain. Throughout the past year, CDC has conducted the guidelines-development process largely in secret. WLF’s understanding of that process has been hampered by CDC secrecy; the following account of the process is based on the limited information that CDC has disclosed to date.

CDC employees gathered evidence in 2014-15 regarding the prescribing of opioid pain medication in this country, including information about the medical needs of those suffering from chronic pain as well as information about abuse of such medication and deaths attributable to overdoses. CDC established the Core Expert Group (CEG) to assist it with evaluating evidence and to provide advice regarding the guidelines it was drafting. According to CDC:

The Core Expert Group includes CDC scientific staff, professional society representatives, subject matter experts, state agency representatives, and an expert in guideline development methodology. This group reviews the evidence and consults on CDC-drafted recommendations.

CDC, *Draft CDC Guideline for Prescribing Opioids for Chronic Pain* at 4 (available at www.cdc.gov/drugoverdose/prescribing/guideline.html).

CDC did not disclose who were the members of the CEG until it released the Draft Guideline in September 2015. Appendix A to the Draft Guideline lists 17 members of the CEG; none are federal employees.² The Draft Guideline (at 4) states, “CDC recruited a Core Expert Group (CEG) to assist in interpreting the evidence and translating the evidence into recommendations.” It goes on to explain that CDC directed CEG members to provide quantitative advice on a detailed list of very specific opioid prescribing issues:

The CEG reviewed summaries of the scientific evidence and CDC’s draft recommendation statements. CEG members provided individual ratings for each draft recommendation statement based on the balance of benefits and risks, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC convened CEG members at an in-person meeting June 23-24, 2015 in Atlanta, GA to discuss the evidence and recommendations and obtain expert opinions. The CEG provided individual opinions at the meeting within a group discussion; no formal voting consensus processes were used. At the meeting, CDC noted CEG members’ comments and any dissenting opinions on the recommendations. CEG members also reviewed the final guideline document [*i.e.*, the Draft Guideline] and provided written comments for consideration by CDC.

Id. at 5.

² Appendix A also lists a three-member Steering Committee, which apparently is affiliated with the CEG. Two of those members are CDC employees; the third is Dr. Robert Chou of Oregon Health and Sciences University. Dr. Chou is also a member of the CEG. The Steering Committee members are also listed as “contributing authors” of the Draft Guidance.

In addition to CEG-member Dr. Chou's role as one of three "contributing authors" of the Draft Guidance, the CEG members collectively drafted Appendix B of the document, which included several personal disclosures. Appendix B states, in part, "The Core Expert Group (CEG) members wish to disclose they have no financial conflicts of interest or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. . . . CEG members wish to disclose the following activities related to the content of this guideline: Jayne Ballantyne wishes to disclose that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC."³

In September 2015, CDC released the Draft Guidance to 18 individuals who were members of a "Stakeholder Review Group." Those individuals were provided two weeks within which to provide comments on the document. CDC itself has never publicly released the Draft Guidance, albeit it now has been circulated more widely—presumably due to the efforts of one or more of the select individuals to whom the Draft Guidance was disclosed. The only opportunity for comments on the Draft Guidance provided to the general public arose in connection with a September 16, 2015 CDC webinar. CDC provided little advance notice of the webinar, during which CDC officials discussed the Draft Guidance in general terms only (*e.g.*, CDC listed the 12 policy recommendations endorsed by the Draft Guidance but did not disclose the entire document). Participants in the webinar were provided 24 hours to submit comments—a period later extended to 48 hours.

CDC has now submitted the Draft Guidance to three "experts" for their peer review. *Id.* at 5. Once that review is completed, CDC is scheduled to publish a final guidance by January 2016. There is no indication that CDC plans to provide any further opportunity for public comment or to provide formal responses to written comments objecting to the Draft Guidance.

IV. *The CEG Is a FACA "Advisory Committee," and CDC Has Failed to Comply with the Numerous Procedural Rules Imposed by FACA on Such Committees*

Given the composition of the CEG and the manner in which CDC has utilized it, there can be little doubt that the CEG qualifies as an "advisory committee" within the meaning of FACA. The CEG is: (1) a formal group (2) established by CDC (3) for the purpose of providing advice to CDC regarding the contents of any CDC guidelines regarding opioid prescriptions for chronic pain and (4) most if not all of its members are not federal employees. Accordingly, FACA required (and continues to require) CDC to comply with the numerous procedural

³ Cohen Milstein is a law firm that has been soliciting cities across the country to hire it to sue opioid manufacturers for allegedly improper promotional practices that allegedly have led to increased drug abuse and overdoses. It currently represents cities in two such lawsuits, including one lawsuit it filed on behalf of Chicago.

mandates imposed on federal advisory committees by the statute.

There is also little doubt that CDC has not complied with those procedural mandates. Among other things, CDC failed to file a charter for the CEG; to announce CEG meetings in the Federal Register; to hold CEG meetings in public; to keep and make public detailed minutes of each meeting; and to release to the public all documents which were either prepared by CDC for the CEG or prepared by the CEG itself. Nor is there any evidence that CDC sought to ensure that the CEG's membership is fairly balanced in terms of the points of view represented by individual members; to the contrary, the CEG appears to have been stacked heavily with individuals whose prior writings indicated strong support for stringent prescribing guidelines that would cut back significantly on current levels of opioid prescriptions for those suffering from chronic pain. CDC can remedy a portion of its violations by immediately releasing the documents requested by WLF in the accompanying FOIA request. But we seriously doubt that CDC can provide a complete remedy for its violations and simultaneously carry forward with its plan to release a final Guideline in January. The widespread FACA violations have tainted the entire administrative process and strongly suggest that any guidelines adopted as a result of the current process could not withstand judicial scrutiny. *See, e.g., Idaho Wool Growers Ass'n v. Schafer*, 637 F. Supp. 2d 868, 880 (D.Idaho 2009) (enjoining Forest Service from relying on recommendations of an advisory committee established by the Forest Service without complying with FACA). Accordingly, WLF calls on CDC to withdraw the Draft Guideline and to start afresh—in a FACA-compliant manner—with any effort to adopt guidelines for prescribing opioids.

WLF understands that CDC takes the position that it was not required to adhere to FACA procedures because the CEG does not meet FACA's definition of an "advisory committee." That position lacks any legal support. CDC could not and does not contend that the CEG was not "established or utilized" by CDC; the CEG has no existence independent of CDC, which was solely responsible for choosing its membership and scheduling its meetings and agenda. *See Idaho Wool*, 837 F. Supp. 2d at 878 ("An advisory committee is established when it has been formed by a government agency, and utilized if it is 'amenable to . . . strict management by agency officials.'") (quoting *Public Citizen*, 491 U.S. at 457-58). Nor does CDC contest that the CEG was established "in the interest of obtaining advice or recommendations." FACA § 3(2). Indeed, CDC said precisely that in explaining the role to be played by the CEG in the guideline-development process. *See, e.g., CDC, Draft Guideline for Prescribing Opioids for Chronic Pain, supra* at 6. Nor is there evidence that all members of the CEG are federal employees; the Draft Guidance provides affiliation information for all 17 CEG members, and none of that information indicates any employee-employer relationship with the federal government. Draft Guidance, Appendix A, at 38. *Cf. Northwest Forest Resource Council v. Espy*, 846 F. Supp. 1009, 1013 (D.D.C. 1994) (federal agency may not evade FACA requirements by appointing its designated outside advisors as short-term federal employees). The court explained, "FACA would be rather easy to avoid if an agency could simply appoint 10 private citizens as special

government employees for two days, and then have the committee receive the section 3(2) exemption as a body composed of full-time government employees.” *Ibid* (quoting *AAPS*, 997 F.2d at 915).

The sole basis for CDC’s position that the CEG is not a FACA advisory committee is that the CEG is not the sort of “committee, board, commission, council, conference, panel, task force, or other similar group” that Congress had in mind when it set forth its definition of an “advisory committee.” FACA § 3(2). CDC contends that CEG members “provided individual consultation only” and thus “were not part of a designated Federal Advisory Committee.” Draft Guidance at 4. CDC’s own description of the CEG’s establishment and utilization belies that contention.

The courts have recognized that whether outside advice a federal agency receives should be deemed the advice of unrelated individuals (to which FACA is inapplicable) or the advice of an advisory committee (to which FACA *is* applicable) depends largely on whether the individuals are providing their advice in conjunction with a group that has some degree of formality and structure. *AAPS*, 997 F.2d at 913-14. Courts have identified three criteria as relevant in determining whether a group has sufficient formality or structure to qualify as a FACA “advisory committee.” These include whether the group has: (1) an organized structure; (2) a fixed membership; and (3) a specific purpose. *Id.* at 914.

All three criteria point decisively in favor of a finding that the CEG is a FACA advisory committee. The CEG has a fixed membership of 17 individuals, all of whom were selected for membership by CDC. The “specific purpose” of the CEG was to facilitate CDC’s receipt of outside advice regarding its guideline-preparation effort. Committee members were compensated by CDC for their time and travel expenses. Draft Guidance at 27 (stating that “CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support.”). Page 5 of the Draft Guidance provides a detailed account of the highly structured manner in which the CDC sought advice from the CEG. All CEG members were asked:

- To review “summaries of the scientific evidence and CDC’s draft recommendation statements”;
- To provide ratings “for each draft recommendation statement based on the balance of benefits and risks, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation”;
- At the June 23-24, 2015 meeting of the CEG in Atlanta, to engage in a “group discussion” regarding members’ opinion of “the evidence and recommendations” contained in then-current drafts of the opioid guidelines; and

- Following the June meeting, to review “the final guideline document and provide written comments for consideration by CDC.”

Id. at 5. In response to that last request, CEG members sought (and were granted) permission to draft one portion of the Draft Guideline. *Id.* at 39. Indeed, one CEG member, Dr. Chou, is listed as one of three “contributing authors” of the Draft Guideline. At the June meeting, CDC hired Don Teater to serve as “the Core Expert Group facilitator,” for the purpose of facilitating the CEG’s provision of advice and recommendations to CDC. *Id.* at 27. At the meeting, CDC “noted CEG members’ comments and any dissenting opinions on the recommendations.” *Id.* at 5. All of the above information supports a finding that the CEG is a formal, highly structured committee of the sort Congress had in mind when it adopted FACA.

CDC apparently takes the position that the CEG is not a FACA advisory committee because “no formal voting consensus processes were used” in tallying the advice and recommendations provided by the CEG. *Ibid.* But the absence of “formal voting consensus processes” has little bearing on whether a group meets *AAPS*’s three criteria for deciding whether the group’s structure is sufficiently structured to qualify as an “advisory group.” If the mere absence of formal votes were sufficient to evade FACA, the statute would be rendered a dead letter; agencies could obtain all the advice they could ever need from outside groups without ever seeking formal votes.

For example, CDC directed individual CEG members to provide quantifiable “ratings for each draft recommendation statement” based on a detailed list of factors. *Ibid.* It is inconceivable that CDC did not consolidate those individual ratings for the purpose of judging the CEG’s overall sentiment regarding each of the 12 draft recommendation statements. There is no practical difference between the consolidation of individual ratings provided during a group-wide meeting supervised and “facilitated” by CDC and the “formal voting consensus processes” that CDC insists are a prerequisite for a group to be deemed a FACA “advisory committee.”

What CDC overlooks is that “advisory” committees are, by definition, not decision-making bodies. Rather, even when they vote to adopt a collective recommendation, they are doing nothing more than providing advice/recommendations that a federal agency is at liberty to ignore. Accordingly, the role played by the CEG in providing advice/recommendations to CDC is indistinguishable from the role played by a committee that uses “formal voting consensus processes” to convey its advice/recommendations.

WLF is unaware of *any* reported court decision holding that an agency-established group was not a FACA advisory committee, under factual circumstances even remotely resembling those present here. The only circumstances under which courts have concluded that the “group” in question was not a FACA advisory committee have involved groups with no fixed

membership, where an agency simply invited interested members of the public to attend a hearing at which they were free to provide whatever advice they wanted. *See, e.g., Leavitt*, 577 F. Supp. 2d at 431-33 (HHS did not create a FACA “advisory committee” when it scheduled two public meetings at which individuals knowledgeable about the Head Start program were invited to share their views regarding Head Start; there was no official membership roll for the alleged committee, and “[n]o reports or other documents were generated as a result of the meetings other than the participants’ notes.”)

In contrast, when faced with FACA claims involving groups with fixed membership established by an agency and from which the agency solicited advice on specific issues being addressed by the agency, courts have consistently concluded that the complaints stated a claim under FACA. *See, e.g., Espy*, 846 F. Supp. at 1012-13 (group utilized by President to provide technical data regarding forest management issues qualified as a FACA advisory committee, even though it provided only data, not policy-making recommendations); *Idaho Wool*, 637 F. Supp. 2d at 878-79 (similar); *Freedom Watch, Inc. v. Obama*, 807 F. Supp. 2d 28, 35-36 (D.D.C. 2011) (plaintiffs adequately pled claim that “*de facto* committee” established by President Obama to gather information in support of proposed healthcare legislation was a FACA advisory committee); *Heartwood, Inc. v. U.S. Forest Service*, 431 F. Supp. 2d 28, 34-36 (D.D.C. 2006) (group established by Forest Service to provide an ecological assessment of two national forests was a FACA advisory committee, even though the agency directed the group “not to provide any recommendations in their draft reports” to the agency, because the agency contemplated that advice received from members of the group “would play a leading role in developing the forest plan” for the two national forests.). *Heartwood* explicitly rejected the agency’s claim that it was exempt from FACA on the ground it sought advice from the group’s members on “an individual basis”—the court noted that the agency consolidated the responses it received from group members and always “considered the scientists working on [the ecological assessment] to be a team.” *Id.* at 35.

In sum, CDC created a FACA advisory committee when it established a group with fixed membership to play an integral role in CDC’s development of guidelines for opioid prescriptions. CDC closely directed the CEG’s activities and sought the collective wisdom of CEG members. Accordingly, CDC violated federal law by failing to comply with the procedural requirements imposed by FACA. Those violations likely infect the entire regulatory proceedings to the point that they cannot be remedied in a manner that would permit CDC to proceed with a January release of its final Guideline. CDC should begin its remedial process by making public all CEG-related documents specified by WLF in the attached FOIA request.

V. *In Any Future Administrative Proceedings Involving CDC Guidelines for Prescribing Opioids, CDC Ought to Open the Proceedings to Permit Meaningful Participation by All Interested Members of the Public*

Although this letter focuses on CDC's numerous violations of FACA, those violations are not the only aspects of this administrative proceeding with which WLF takes issue. A basic premise of administrative law is that interested members of the public should be informed about proposed actions by federal agencies and provided a meaningful opportunity to comment on such proposal. Yet, throughout these proceedings, CDC has attempted to operate largely in secret and to prevent stakeholders from playing a meaningful role. Such conduct serves to undermine CDC's stated goal, which is to develop a prescribing guideline that will command greater acceptance than existing guidelines. State governments and the medical community are unlikely to accept any guideline tainted by charges that it was prepared in secret without meaningful stakeholder input and with the assistance of individuals (including several members of the CEG) who have serious conflicts of interest. If CDC decides to move forward with these administrative proceedings, WLF urges CDC to open the proceedings to permit meaningful participation by all interested members of the public and to take steps to ensure that the composition of any future advisory committees is fairly balanced in terms of the point of view represented on those committees.

The outcry that has arisen with respect to the current proceedings was entirely predictable in light of the secretive manner in which CDC conducted them. For many months, CDC refused to provide the public with information about the nature of the guidelines it was contemplating, or the names of those from whom it was seeking advice. When it finally scheduled a September 16 webinar to provide information about the guidelines, it continued to refuse to release the Draft Guideline publicly, and it permitted webinar participants only 24 hours (later increased to 48 hours) within which to submit comments. WLF recognizes that because CDC is only issuing a guideline rather than a formal regulation, the APA's formal notice-and-comment provisions are not mandatory for CDC. Many other agencies nonetheless voluntarily provide members of the public with a minimum of 60 days within which to file comments on such documents, running from the date of full disclosure of a proposed guidance document. WLF urges CDC to do the same in this instance, particularly in light of the agency's egregious violations of FACA.

The outcry is also attributable in part to CDC's seeming indifference to the need to maintain a fair ideological balance among members of the CEG. Numerous members of the CEG were on record—well before joining the CEG—as strongly supporting the need to tighten opioid prescribing standards as one means of reducing deaths attributable to opioid overdoses. Conspicuously absent from the CEG, however, were physicians and others with experience in treating patients suffering from chronic pain. Most egregious was the inclusion of Jayne Ballantyne on the CEG. She suffers not only from ideological conflicts of interest—she is

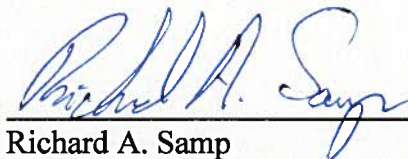
President of PROP, an organization dedicated to limiting use of opioids—but also from financial conflicts. As a paid consultant for Cohen Milstein (a law firm in the business of suing opioid manufacturers) in connection with several lawsuits alleging improper manufacturer promotion of opioids, Ballantyne has a financial interest in advising CDC to adopt guidelines that are critical of current prescribing practices. It is impossible to understand CDC's decision to permit Ballantyne to serve on the CEG at the same time that CDC has adopted a strict rule that bars service by anyone with any sort of financial relationship with a drug manufacturer.

CDC's secrecy, and its apparent indifference to conflicts of interest by those likely to support new restrictions on opioids, have led many to conclude that CDC is uninterested in conducting administrative proceedings that give all interested stakeholders an equal opportunity to attempt to influence the agency's decision-making. If CDC is to overcome its tarnished image, it must begin immediately to eliminate its culture of secrecy and to apply its conflict-of-interest rules in an even-handed manner. The best way to do this is to follow federal law as prescribed in the Federal Advisory Committee Act.

VI. Conclusion

WLF respectfully requests that CDC withdraw the Draft Guideline and, before renewing efforts to write guidelines, generate reliable data on ways to ensure adequate treatment of patients while preventing opioid abuse.

Respectfully submitted,



Richard A. Samp
Chief Counsel



Mark S. Chenoweth
General Counsel