United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 23, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Burwell:

On April 8, 2016, I received a response from Dr. Francis Collins to my February 5, 2016 letter regarding apparent conflicts of interest associated with the Interagency Pain Research Coordinating Committee (IPRCC).

After reviewing Dr. Collin's response, I am even more concerned that the Department of Health and Human Services does not adequately consider financial and organizational conflicts of interest when creating and managing advisory committees. For example, an opioid manufacturer directly funded an endowment for one of the Committee's participants, and despite this relationship, that individual participated on the panel – including deliberations regarding the CDC's opioid prescription guidelines. In my view, this is indicative of a flawed conflicts of interest policy.

Dr. Collins also asserts that these conflicts of interest are absent given that Committee members are not representatives of their organizations when they serve on the Committee. This assertion conflicts with the requirements of the authorizing statute which establishes that six of the twelve non-federal members "…shall be members of the general public, who are representatives of leading research, advocacy, and service organizations…" (emphasis added).[1]

Dr. Collins' assertion that Committee members are not representatives of the organizations is further undercut by the Committee's website,[2] minutes,[3] and members' statements at meetings. For example, Dr. Richard Payne, one of the two panel members who lead the panel's discussion of the proposed CDC opioid prescribing guidelines, identified himself as being "from Duke and the Center for Practical Bioethics in Kansas City" during that discussion.[4] I would note that

[1] 42 USC 284q
[2] National Institutes of Health, *12-3-15 IPRCC Meeting Roster*, December 3, 2015, https://iprcc.nih.gov/meetings/2015/12-3-2015_IPRCC_Meeting_Roster.htm, accessed on June 16, 2016.
[3] National Institutes of Health, *Meeting Minutes Interagency Pain Research Coordinating Committee,* December 3, 2015, https://iprcc.nih.gov/meetings/12-3-15_Meeting_Minutes.htm, accessed on June 16, 2016.
[4] National Institutes of Health, *Interagency Pain Research Coordinating Committee -- December 2015*,6:05:58 (comments at 4:58:15), December 3, 2015, https://videocast.nih.gov/summary.asp?Live=17523&bhcp=1, accessed on June 16, 2016.

although the meeting roster and minutes identify Dr. Payne as being affiliated with Duke, they do not identify his affiliation with the Center.[5]

In regards to the concerns I raised about two employees of a single organization filling two of the twelve statutorily designated, non-federal positions failing to provide balance—like Payne, Ms. Myra Christopher also is employed by the Center for Practical Bioethics, Dr. Collins reiterated his argument that members do not represent their own organizations. Dr. Collins also insisted that HHS has taken great care to ensure that Committee "...membership is balanced in terms of the points of view and the functions performed..." when this appears not to have been the case.

Dr. Collins's acceptance of these conflicts is of serious concern, particularly considering that Dr. Payne, in his capacity as a panel member moderating the discussion on the CDC prescribing guidelines, appeared intent on holding CDC to a much higher conflict of interest standard than NIH has appeared to have done with its own IPRCC panel members.

During the December meeting, Dr. Payne questioned both the methodology the CDC took in developing its opioid prescribing recommendations, and the objectivity of CDC's reviewers:

> So I guess just one more question and follow-up from me. So if there is strong recommendations (sic) with weak evidence, that suggests that you are heavily dependent on kind of the expertise of the reviewers, which then leads to the question of who are the reviewers, and what were the processes by which the reviewers were selected – who they were, how transparent was the process by which they were working, etc. ... Were there any conflict of interest (sic) – beyond just financial conflict of interest – but conflicts of interests in terms of, possible – you know – perceptions, biases, intellectual kinds of conflicts of interest or confluence, conflicts of interest that need to be disclosed as part of the guideline dissemination process? ... It just seems to me that if there is weak evidence, then you are – having been involved with guideline processes myself in the old [Agency Healthcare Research & Quality] days – it does really suggest you are very dependent on the expert reviewers and then the question is, you know, do you have a really kind of –, for want of a better term – balanced perspective in terms of who is reviewing what.[6]

Given these continuing concerns, please provide responses to the questions and information requests below:

1. According to the letter of April 8, 2016, candidates for the public and scientific panels "are reviewed for eligibility through criteria for leadership, expertise, and contributions to pain cure and relevant research by NIH staff and Institute and Center Directors with pain care research expertise."

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[5] *Supra*, notes 2 and 3.

[6] National Institutes of Health, *Interagency Pain Research Coordinating Committee – December 2015*,6:05:58 (comments at 5:01:16), December 3, 2015, https://videocast.nih.gov/summary.asp?Live=17523&bhcp=1, accessed on June 16, 2016.

a. Please provide the standards for each of the above-listed criteria, and any such guidance that is used by staff to evaluate candidates in the selection process.
b. Please provide an analysis of each individual Committee member, and how each scientific and public member of the IPRCC met these criteria as of December, 2015.
c. Please provide any documents, including but not limited to: emails, memos, notes, or any additional written or electronic materials that discuss the appointment of past or present members to the IPRCC and their qualifications met the required standards.

2. The statute establishing the Committee requires that six non-federal members "shall be appointed from among scientists, physicians, and other health professionals", and that the remaining six shall be appointed from members of the public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions."

    a. Please provide the standards and any relevant guidance utilized to evaluate and select the scientific appointees, in addition to the members of the public serving on the Committee.
    b. Please provide a member-by-member analysis of how each scientific and public member of the IPRCC met this criteria, as of December 3, 2015.
    c. Please provide any documents, including, but not limited to: emails, memos, or any additional written or electronic materials that discuss the appointment of former or current members on the IPRCC, and the ways in which their qualifications met the required standards.

3. According to the letter received on April 8, 2016, "the nomination slate is drafted at the National Institute of Neurological Disorders and Stroke (NINDS), forwarded to the NIH Director for concurrence, then approved by the Secretary." Please provide all nomination slates that were drafted by the NINDS, and occurrences or alterations made by the NIH Director and the Secretary since the creation of the Panel.

4. According to the April 8, 2016 letter, "under some circumstances, [committee member's] terms may be extended administratively for a specific period."

    a. Please detail all policies and guiding materials that were utilized in setting standards and terms for extension.
    b. Please provide a list of all IPRCC members, past or present, whose terms have been extended.
    c. For each such person, provide the documentation and material proof that these guiding policies were used in the approval of each member's term extension.

5. According to the April 8, 2016 letter, "the conflict of interest policies and disclosure requirements for non-federal members of the IPRCC follow agency policies for members of federal advisory committees."

a. Please provide all such policies and disclosure requirements.
b. Do agency policies differ from the Department's policy? If so, please explain how they differ.
c. Please provide a list of all advisory committees within NIH to which these "agency policies" apply regarding conflicts of interest.

6. According to the April 8, 2016 letter, "before serving as a member of the IPRCC, each non-federal member is appointed as a Special Government Employee, and is required to file a detailed financial disclosure form (OGE 450), which is updated bi-annually during their term of service". The letter also notes that each member disclosed "the research support or earned income they receive from pharmaceutical manufacturers and other biomedical entities."

    a. Please provide completed copies of these forms for each non-federal member since the inception of the IPRCC.
    b. Please provide a detailed, written itemization of the research support or earned income received by each IPRCC member from pharmaceutical manufacturers and other biomedical entities, and associated documentation disclosing this support or income.

7. According to the April 8, 2016 letter, IPRCC members are "advised, in writing, of applicable standards of conduct, including conflict of interest statutes, and must affirm with signature that they received and read the information."

    a. Please provide copies of the above-referenced materials that were provided to members.
    b. Please provide the signed forms for each non-federal member of the IPRCC since its inception.

8. According to the April 8, 2016 letter, IPRCC members "agree to recuse, consistent with applicable law, from discussions that might specifically involve a particular company or product."

    a. Please provide a list of all instances in which IPRCC members recused themselves from Committee discussions, the dates, and the topics of the discussion.
    b. Please provide a list of all instances when the IPRCC discussed prescription opioids, including but not limited to those manufactured by or being developed by Purdue Pharma, Pfizer, Inc., Teva Pharmaceuticals, Teva, Endo, Johnson & Johnson, AbbVie, Collegium Pharmaceutical, Depomed, Eglat, Janssen, Mallinckrodt, Shionogi, or Zogenix.
    c. Please provide a list of all instances when the IPRCC received written or oral communications or presentations related to its work from representatives of any of the companies listed in question (b), other manufacturers of prescription opioids, or any group or organization that represents or is funded by manufacturers of prescription opioids.

The public expects governmental advisory committees to be impartial authorities when it comes to research and guidance on policy. When conflicts of interest are not sufficiently transparent or accounted for, that impartiality can too easily be called into question. Given the public health epidemic rooted in prescription opioid addiction, current policy governing these powerful drugs merits particularly close scrutiny, and at this time appears to be inadequate.

Please provide your responses to this request by June 30, 2016. If you or your staff have questions concerning this matter, please contact David Berick or Peter Gartrell of the Democratic staff at (202) 224-4515.

Sincerely,

Ron Wyden

Ron Wyden
Ranking Member