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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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February 5, 2016

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

Dear Secretary Burwell:

Prescription opioid addiction is a serious condition, and its increased prevalence in recent years is cause for alarm. Since 2000, the rate of deaths from opioid-related overdoses has increased by 200% and in 2014 alone, 61% of all overdose deaths were opioid-related.¹ A recent examination of Medicare Part D prescribers found that total opioid prescriptions are dominated by general practitioners in the primary care setting.² While the study found that opioid prescriptions are concentrated in select specialty services such as pain, and anesthesia, data from Medicare Part D suggests opioid prescribing in the program is a “widespread practice relatively indifferent to individual physicians, specialty or region.”³

Consequently, I was alarmed to read of efforts by the members of the Interagency Pain Research Coordinating Committee (IPRCC) to weaken efforts underway at the Centers for Disease Control and Prevention (CDC) to develop guidance on opioid prescribing practices.⁴ A preliminary review by my staff of the IPRCC has raised a number of concerns including what appear to be personal and institutional conflicts of interest of non-Federal IPRCC members related to opioid manufacturers. The Associated Press also has reported on some of these apparent conflicts.⁵ I am writing today to seek clarification on the procedures and conflict of interest requirements that govern operation of, and membership on, the IPRCC.

As you know, the Secretary of Health and Human Services was required by law to establish the IPRCC.⁶ In addition to members appointed by the Secretary from federal agencies that conduct pain care research and treatment, the Secretary is required to appoint six non-Federal members

¹ CDC, *Increases in Drug and Opioid Overdoses Deaths – United States, 2000-2014*, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm64e1218a1.htm?s_cid=mm64e1218a1_w.

² Jonathan H. Chen, et al., *Distribution of Opioids by Different Types of Medicare Providers*, JAMA Intern Med 2015, available at <http://archinte.jamanetwork.com/article.aspx?articleid=2474400>.

³ *Id.*

⁴ Politico, *HHS split on CDC opioid prescription guidelines*, by Brett Norman, December 3, 2015, <https://www.politicopro.com/staff/brett-norman>

⁵ Associated Press, *Federal pain panel rife with links to pharma companies*, by Matthew Perrone, January 27, 2016, <http://bigstory.ap.org/article/6e22f8ffcded4b2e9ba278bcc00f4f53/federal-pain-panel-rife-links-pharma-companies>

⁶ Sec. 409J, P.L. 111-148,

who are scientists, physicians, or other health professionals.⁷ The Secretary is also required to appoint six members who are representatives of leading research, advocacy and services organizations for individuals with pain-related conditions.⁸ The statute makes no provision that representatives of the pharmaceutical industry are included on the panel. The statute also does not specify terms of service of board members, but it is my understanding that members are appointed to specific terms. At the December 3, 2015 meeting of the IPRCC at which the CDC opioid guidance was discussed, several members whose terms had expired were allowed to continue to serve on the Committee and to participate in the meeting.⁹

Several non-Federal IPRCC members, their organizations, or both, appear to be recipients of funding from major pharmaceutical companies that manufacture opioids or related products at levels that raise concerns regarding the potential for conflicts of interest. These financial and professional relationships raise serious concerns about the objectivity of the panel's members that deserve additional review. In addition, three non-Federal IPRCC public members appear to have strong connections to opioid-related drug manufacturers.

One public member who attended the December 3rd meeting – Ms. Myra Christopher – is financially supported through an endowed chair at the organization that employs her – the Center for Practical Bioethics. According to publicly available records, the \$1.5 million endowment for that chair came from Purdue Pharma, the manufacturer of the opioid Oxycontin, - and was established while she was the chief executive of the organization.¹⁰ Funding for the endowment was provided by Purdue Pharma in three \$500,000 allocations in 2008, 2009, and 2011 respectively.¹¹ She has remained on the staff of that organization.¹²

In addition to the endowment supporting Ms. Christopher's employment, Purdue Pharma provides substantial funding to the organization that employs Ms. Christopher. For instance, in 2013, publicly available records indicate Purdue Pharma contributed \$100,000 to the Center, making the company its second largest contributor that year.¹³ As noted above, Ms. Christopher's term of service had expired, but she continued to participate in the Committee's December 3rd deliberations.

One of the IPRCC's other non-Federal members – Dr. Richard Payne – is also employed by the Center for Practical Bioethics.¹⁴ I am concerned that this single organization with significant ties

⁷ Sec. 409J(b)(2)(B)(i)

⁸ Sec. 409J(b)(2)(B)(ii)

⁹ According to the Committee roster provided by the Department, three of the six public members of the Committee had terms that expired on July 31, 2015 – Myra J. Christopher, Center for Practical Bioethics; Tina M. Tockarshewsky, The Neuropathy Association; and Christin L. Veasley, Chronic Pain Research Alliance. All attended the December 3, 2015 meeting. http://iprcc.nih.gov/meetings/12-3-2015_IPRCC_Meeting.htm

¹⁰ McBride, Lock & Associates, "Report of Examination of the Center for Practical Bioethics, Inc., Kansas City, Missouri for the Year Ended December 31, 2008," April 13, 2008, <http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193>

¹¹ McBride, Lock & Associates, "Report on Examination of the Center for Practical Bioethics, Inc., Kansas City, Missouri As Of And For the Year Ended December 31, 2010," July 21, 2011, <http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193>

¹² Based on tax records and the organization's annual reports, it appears that Ms. Christopher did not step down as President and CEO of the Center until mid-2011. The Greater Kansas City Community Foundation makes publically available the records for the organization at <http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193> (accessed January 28, 2016).

¹³ *Ibid.*

¹⁴ According to Center's website, Dr. Payne is listed as Center staff. <https://www.practicalbioethics.org/about-us/staff>

to a major opioid manufacturer had two paid staff sitting as committee members at the same time.

I also note that Dr. Payne appears to have additional ties to Purdue Pharma. In 2013, Dr. Payne reportedly received \$2,000 in travel and lodging from the company to attend a meeting for which he received an additional \$4,700 for “services other than consulting, including serving as faculty or as a speaker” from a Purdue affiliate – Purdue Transdermal Technologies L.P.¹⁵ Dr. Payne was selected to be one of two coordinators of the IPRCC efforts to critique the proposed CDC guidelines according to the minutes of the December 3, 2015 meeting.¹⁶

Another public member of the IPRCC – Cindy Steinberg – is the National Policy Director of the US Pain Foundation. This organization appears to receive substantial funding from opioid manufacturers. According to publicly available documents posted on the Foundation’s website, a majority of the organization’s funding in 2012 came from major pharmaceutical manufacturers.¹⁷ That year the organization received more than \$180,000 from pharmaceutical manufacturers including Pfizer (\$50,000), Purdue Pharma (\$30,000), Teva (\$43,000), Endo (\$30,000), Johnson & Johnson (\$7,500), and the trade group PHRMA (\$20,000).¹⁸ The organization’s most recent IRS filing for 2014 shows that the organization continues to receive large contributions from the pharmaceutical industry, including \$104,800 from Purdue Pharma.¹⁹

A third public member – Penney Cowan – heads the American Chronic Pain Association. The organization reports receiving corporate support from 11 companies that manufactured opioid based drugs – AbbVie, Collegium Pharmaceutical, Depomed, Egalet, Janssen, Mallinckrodt, Pfizer, Purdue, Shionogi, Teva and Zogenix.²⁰ Its “corporate champion,” which appears to be its highest corporate contributor, is AstraZeneca. The company produces and markets a drug to relieve opioid-induced side-effects – MOVANTIK.²¹ Furthermore, the organization’s advisory board includes J. David Haddox, Purdue Pharma’s Vice President for Health Policy.²² The

The Center’s Form 990 for 2013 and 2014 each list Dr. Payne under Part VII “Officers, Directors, Trustees, Key Employees, and Highly Compensated Staff” with annual compensation exceeding \$111,000.
<http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193>

¹⁵ Centers for Medicare and Medicaid Services Open Payments, <https://openpaymentsdata.cms.gov/physician/1094555>. Open Payments also includes a report for 2014 showing that Dr. Payne received an honoraria of \$1,500 from Teva Pharmaceuticals USA, Inc., another manufacturer of opioid prescription drugs, along with travel and lodging associated with the event.
<http://www.uspainfoundation.org/>.

¹⁶ Interagency Pain Research Coordinating Committee, December 3, 2015 Meeting Minutes, http://iprcc.nih.gov/meetings/12-3-15_Meeting_Minutes.htm (accessed January 28, 2016).

¹⁷ U.S. Pain Foundation, Form 990 for tax year 2012, at <http://uspainfoundation.org/Docs/2012-990-taxes-signed-complete.pdf>, (accessed January 28, 2016).

¹⁸ *Ibid.*

¹⁹ U.S. Pain Foundation, Form 990 for tax year 2014, at <http://www.uspainfoundation.org/wp-content/uploads/2015/12/2014-taxes.pdf>, (accessed January 28, 2016).

²⁰ American Chronic Pain Foundation, Partners and Contributors, at <https://theacpa.org/Partners-Contributors> (accessed January 28, 2016). Zogenix sold its pain franchise in May 2015.

²¹ AstraZeneca, MOVANTIK™ (naloxegol) tablets for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain launched in the US, March 31, 2015,
<http://www.astrazeneca-us.com/media/press-releases/Article/20150330-movantik-launched-in-the-us>

²² The advisory panel also includes three doctors who received \$1,000 or more from opioid-related pharmaceutical companies according to Open Payments data for 2014. One of those doctors, Steven Stanos, received over \$40,000 in consulting fees and other reimbursements from three companies -- Mallinckrodt, Pfizer, Inc., and Zogenix, Inc in 2013 and 2014. Centers for Medicare and Medicaid Services Open Payments, <https://openpaymentsdata.cms.gov/physician/138667>

advisory board also includes Dr. Judith Paice, one of the IPRCC scientific members. Dr. Paice is the second coordinator of the IPRCC critique of the CDC guidelines.

I am requesting that you provide the following information within twenty-one (21) days from the date of this letter:

- 1) The Department's policies on appointments to and terms of service for non-Federal members of the IPRCC.
- 2) The personal and organizational conflict of interest policies and disclosure requirements for non-Federal members of the IPRCC.
- 3) Confirmation that employees and representatives of the Center for Practical Bioethics and the US Pain Foundation who serve on the IPRCC, as well as all other members of the IPRCC, fully disclosed the financial and institutional support they and their organizations receive from Purdue Pharma and other pharmaceutical manufacturers.
- 4) A description of the process by which the IPRCC comments concerning the CDC guidelines were drafted and approved by the Committee.

Thank you for assistance in this matter. If you or your staff have questions concerning this request please contact David Berick, Chief Investigator for the Democratic staff of the Finance Committee at 202-224-4515.

Sincerely,



Ron Wyden
Ranking Member
U.S. Senate Committee on Finance