DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

April 8, 2016

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
Washington, D.C. 20510

Dear Ranking Member Wyden:

Secretary Burwell has asked me to respond to your February 5, 2016, letter regarding conflict of interest policies and procedures for non-federal members of the Interagency Pain Research Coordinating Committee (IPRCC). Your interest relates to the discussion during the December 5, 2015, IPRCC meeting where the Centers for Disease Control and Prevention presented information on their opioid prescribing practices guidance.

We share your concerns about the overprescribing of opioids. The Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) support efforts to guide prescribing practices that will contribute to reducing the harm of opioids and provide better care for people with pain. The HHS is part of a multi-pronged strategy across the government to combat the growing opioid epidemic. In addition to these targeted efforts, HHS has many activities focused on coordinating and advancing research to understand and better manage chronic pain, which will provide an integral part of reducing the need for opioids in chronic pain management. These efforts need to be balanced and coordinated for either to succeed.

One important component of that pain research effort is the IPRCC, mandated by the Affordable Care Act (ACA), Public Law 111-148. The IPRCC is advisory to HHS and its activities are managed by the NIH. This Committee has led several important efforts on pain care and pain care research. On behalf of the HHS Secretary, the IPRCC developed a National Pain Strategy, based on the Institute of Medicine's recommendations to improve the way pain is perceived, prevented, and treated. The implementation of this strategy will support the objectives of the federal opioid initiatives. The Committee also oversees a trans-agency effort to develop a federal pain research strategy to coordinate and advance the science nation-wide.

1. HHS Policies on Appointments to IPRCC

The policies on appointments to and terms of service for non-federal members of the IPRCC are mandated by the ACA and align with agency policy for members of federal advisory committees. As required by the Federal Advisory Committee Act, the IPRCC membership is balanced in terms of the points of view and the functions performed, which ensures that major and sometimes opposing viewpoints are represented. Members are not representatives of their

employers or institutions and provide advice based on their own points of view. As mandated by the ACA, the Committee must include six non-federal members consisting of scientists, physicians, and other health professionals, and six from the general public who are from leading research, advocacy, and service organizations for individuals with pain-related conditions. The Committee reports to the Secretary, and its primary role is to coordinate within HHS and other federal agencies all activities that relate to pain research.

Nominees to serve on the IPRCC are solicited for a 30-day period in a Federal Register Notice (FRN). The public and scientific community is notified of the FRN posting through a broad dissemination process. All candidates are reviewed for eligibility through criteria for leadership, expertise, and contributions to pain care and pain care research by NIH staff and Institute and Center Directors with pain care research expertise. The nomination slate is drafted at the National Institute of Neurological Disorders and Stroke (NINDS), forwarded to the NIH Director for concurrence, and then approved by the Secretary. Final appointments are not made until after submission and review of conflicts of interest and financial disclosures.

Committee members are invited to serve for overlapping three-year terms and may serve for an unlimited number of terms if reappointed. Under some circumstances, their terms may be extended administratively for a specified period. Because incoming members were not yet officially appointed prior to the meeting, the terms of three existing members were extended administratively through the end of 2015. The meeting roster for the December 3, 2015, meeting is posted on the IPRRC website and notes term expiration dates for all non-federal members as active on the meeting date (http://iprcc.nih.gov/meetings/2015/12-3-2015_IPRCC_Meeting_Roster.htm).

2. Conflict of Interest Policies and Disclosure Requirements

The conflict of interest policies and disclosure requirements for non-federal members of the IPRCC follow agency policies for members of federal advisory committees. 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.

Non-federal members of the IPRCC are also 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. These members agree to recusal, consistent with applicable law, from discussions that might specifically involve a particular company or product. The financial disclosure forms are reviewed by the Designated Federal Official for the Committee and vetted by the appointed NIH ethics official prior to appointment. This process is repeated bi-annually during their terms of service. All documentation is collected, recorded, and maintained by the designated Advisory Committee Management Officer.

3. Disclosures by Members of IRPCC

All members fully disclosed, as required, the research support or earned income they receive from pharmaceutical manufacturers and other biomedical entities. All conflict of interest forms are on record and current. As mentioned above, IPRCC Committee members are not representatives of their employers or institutions and provide advice based on their own points of view. While certain members of the IPRCC have connections to the Center for Practical Bioethics, they do not serve on the IPRCC as representatives of the Center.

4. Process for Drafting and Approving IPRCC Comments

The agenda for the December 3, 2015, IPRCC meeting included a presentation of the CDC Guideline for Prescribing Opioids for Chronic Pain. Sara Patterson, Associate Director for Policy, National Center for Injury Prevention and Control, CDC, participated in the meeting by phone and provided the overview of the CDC guidelines and the process for their development. There was a great deal of discussion following Ms. Patterson's presentation. As an Advisory Committee to the Secretary, the IPRCC current voting members unanimously agreed that the IPRCC should prepare a scholarly critique of the CDC Guideline to provide to the Secretary for consideration and any further action. A letter reflecting the IPRCC members' discussion at the December 3, 2015 meeting was drafted, reviewed, revised, and approved by a majority of the membership. The letter was sent to the Secretary for her consideration.

We appreciate your interest in and support of research to enhance pain research efforts and to reduce the misuse and overprescribing of opioids, two major public health efforts.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director