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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510–6200

March 12, 2019

Dr. Jianguo Cheng
President
American Academy of Pain Medicine
8735 W Higgins Road
Suite 300
Chicago, IL 60631-2738

Dear Dr. Cheng:

I received your letter of December 28, 2018 regarding my previous letter to Health and Human Services ("HHS") Secretary Alex Azar.

In my letter to Secretary Azar, I raised concerns that HHS had inadequately vetted members, including yourself, of the Pain Management Best Practices Inter-Agency Task Force ("Task Force") for conflicts of interest. Rather than resolving my concerns about conflicts of interest, your letter and the accompanying information provided raised additional questions regarding the relationships between the American Academy of Pain Medicine ("AAPM") and opioid manufacturers, medical device manufacturers, and other healthcare interests.

I remain concerned about the appearance of conflicts of interest by individuals associated with AAPM, including yourself, on committees and panels related to pain treatment and opioid prescribing that are convened throughout the federal government. As Ranking Member on the Senate Finance Committee, which has jurisdiction over federal health programs and the tax code, I also am concerned about the potential impact these panels could have on the use of Medicare and Medicaid funds, and the stewardship of tax exempt entities organized under 501(c) of the Internal Revenue Code.

I would appreciate your cooperation in providing the following information and documents no later than April 2, 2019:

1) In your December 28th letter, you wrote that revenue AAPM received from pharmaceutical companies was derived from advertising and educational programming grants. Tax documents your organization provided show that in 2017, AAPM received more than $1.1 million in contributions and grants—nearly a third of the organization's revenue for that year. Of that total, $680,000 came from pharmaceutical manufacturers, including opioid makers; $285,000 came from continuing medical education companies and $40,000 from device

manufacturers. Similarly, in 2011 and 2012, AAPM reported receiving contributions and grants totaling $1 million or more, much of which was also derived from pharmaceutical companies, device manufacturers, continuing medical education companies, and other medical interests, tax documents show. These documents also show that AAPM received significant revenue from conferences and meetings, exhibits, membership dues, and its journal. Please provide Form 990 filings, including Schedule B filings, for AAPM for 2010, 2013, 2014, 2015, 2016, and, when it becomes available, 2018. In addition, please provide an itemized list of payments to AAPM from pharmaceutical companies, device manufacturers and CME companies, including the name of the entity making the payment, the date of the payment, the amount of the payment, and the purpose of the payment, for each year from 2010 through 2018.

2) AAPM reported in its 2017 tax return that it receiving contributions and grants of $98,055 from the AAPM Foundation, an affiliated entity. Funding sources for the AAPM Foundation are not disclosed; however, all of the AAPM Foundation's revenue has been categorized as contributions and grants, according to publically available Form 990 filings. The foundation's Form 990 filings further indicates that it has received contributions and grants in excess of $5,000, which necessitates filing of Schedule B forms. Please provide Form 990 filings, including Schedule B filings, for the AAPM Foundation for 2010-2017, and, when it becomes available, 2018.

3) Rollin Gallagher, one of the Task Force members associated with AAPM, was paid more than $975,000 from 2011 to 2017 to oversee the AAPM's journal, *Pain Medicine*. In your December 28th letter, you wrote that Dr. Gallagher's salary is paid from an "editorial allowance provided to AAPM by the publishers of *Pain Medicine* … AAPM, the Spine Intervention Society ("SIS"), and the Australia New Zealand Faculty of Pain Medicine of the College of Anaesthetists ("FPMCA")."

   a) Have AAPM, SIS and FPMCA been the only funders of the allowance? If not, please identify any other funders of the allowance and the amounts that they have provided to the allowance.

   b) Does either the SIS or FPMCA or any other funder of the allowance receive any type of revenue from opioid manufacturers, medical device manufacturers or other health care interests?

   c) Is Dr. Gallagher's salary the only expenditure from the allowance? If not, please provide a list of the allowance's other expenditures.

4) Open Payments records show that you received a $24,600 payment from Purdue Pharma in 2017. According to information you provided, the payment was for your participation on an "Opioid Sparing Tapering and Discontinuation Committee" ("Committee") that Purdue organized and promoted. According to a request for proposals that the Committee issued in 2016, "preference will be given to proposals that incorporate Purdue's opioid products."

a) You wrote that you "voluntarily divested ... from industry involvement" at the end of 2016. However, Open Payment data show that you were paid $24,600 by Purdue on March 1, 2017. Please explain this discrepancy.

b) On what date did you begin your financial relationship with Purdue (i.e., the engagement that resulted in the payment reported to Open Payment, whether that was a contract, consulting agreement or some other sort of arrangement)? On what date did this relationship with Purdue end? Was the financial relationship with Purdue limited to your work on the Committee? Besides the payment made on March 1, 2017, have you ever received any other payments from Purdue Pharma? If so, please disclose those payments.

c) Please provide any contracts, terms of employment and/or consulting service, related to your financial relationship with Purdue. Please also provide any documents or communications related to terminating your relationship with Purdue.

d) Please describe the responsibilities of the Committee. Please provide a list of the Committee's members, including, but not limited to, any employees of Purdue who participated, facilitated, or were otherwise involved with the operation or decisions of the Committee.

e) Did the Committee meet independently of Purdue employees? What input did the company have on the selection of proposals? Did Purdue employees sit in on deliberations, or were otherwise made aware of the deliberations? Did the company accept as final the committee's recommendations? How many proposals did the Committee receive?

f) Prior to joining the Committee, were you aware that the company planned to advertise that "preference will be given to proposals that incorporate Purdue's opioid products?"

g) What were <u>your</u> responsibilities on the Committee? How many hours did you work in fulfilment of your financial relationship with Purdue? Please provide any documentation that supports these answers.

h) What is your typical hourly rate for consulting work? What was your hourly rate working for Purdue? Did you receive any upfront payments or milestone payments from Purdue? Please detail any such payments.

5) In September 2018, as AAPM's president, you authored an article that promoted Purdue's public relations campaign regarding opioid dependence, writing in part, "as the professional society representing the nation's doctors, nurses, researchers, and other clinicians who are tasked with treating pain, we could not agree more with

Purdue Pharma's statement that we need a new approach to prescribing opioids."[1] The article was contemporaneously promoted by AAPM on its Facebook page.[2]

a) Did you have any communications with Purdue, its employees, contractors, or consultants, regarding the article or its contents prior to its publication? Please provide any such communications.

b) Did any other AAPM employees, board members, officers or contractors, have communication with Purdue regarding the article or its contents in the lead-up to publication? Please provide any such communication.

c) Did you or any other AAPM officer write or otherwise produce any other articles, blog posts, social media content, multimedia products or other product for publication promoting or commenting on Purdue's corporate activities in 2017 or 2018? If so, please identify and provide them.

6) In your letter, you cite that AAPM has been in compliance with the Accreditation Council of Continuing Medical Education ("ACCME"). According to ACCME data, AAPM provides 69 CME courses, for which it received both commercial support and income from advertising and exhibits. Please provide an Excel Workbook that includes the following information for each course or activity:

a) The name of the course or activity.

b) The subject of the course or activity.

c) A description of the learning objective of each course or activity.

d) The name or names of any commercial interest or entity that either (1) provided commercial support, or (2) paid for exhibits or advertising, in connection to the course.

e) For each commercial interest or entity listed, please provide the amount of financial support (or the dollar value of non-financial compensation for items including but not limited providing the facility, paying for use of presentation equipment, etc.) received in connection to the course

f) Whether any conflicts of interests that were disclosed by teachers, authors or other participants in the CME activity, and the identity of the conflicts (i.e. the name of the company or entity that presented a conflict).

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[1] Jianguo Cheng, "Pain care must be patient-centered, integrated, and individualized," KevinMD.com (Sept. 5, 2018), *available* at https://www.kevinmd.com/blog/2018/09/pain-care-must-be-patient-centered-integrated-and-individualized.html.

[2] Facebook, *American Academy of Pain Medicine*, "AAPM President Jianguo Cheng on why we need a new approach to prescribing #opioids via KevinMD.com., 'With a sustained national opioid crisis, it is imperative that clinicians are prepared to address and diagnosis proper pain treatment depending on their patient's needs.'" Sept. 5, 2018, *available* at https://bit.ly/2UU7XHL (shortened link).

7) Your letter cited previous communications authored by a prior AAPM president, written in 2014, regarding the organization's management of conflicts of interest. The 2014 communication discussed steps that AAPM intended to take to reduce the organization's reliance on industry money, and ensure that suitable safeguards were in place to police conflicts of interest.

   a) Please provide the AAPM's conflict of interest policy.

   b) Who are the current members of AAPM's ethics committee? How many times has this committee met since 2014? Please provide a charter for the committee, as well as schedules and minutes from any meetings held since 2014.

   c) You stated that AAPM has adopted the Council of Specialty Medical Societies Code. Is the adoption of this code self-governing? That is, does adoption of the code result in any third-party review or oversight of AAPM's adherence to the code? Please provide the most recent review or audit of AAPM's activities related to the code.

8) According to your letter and the documents that accompanied it, the AAPM criticized the 2016 opioid prescribing guidelines developed by the Centers for Disease Control and Prevention ("CDC guidelines") for a lack of evidentiary support. As an alternative, the AAPM touted a 2009 study it funded with the American Pain Society ("APS"). That 2009 APS/AAPM study was the basis for prescribing guidelines issued by the organizations that defined a "high" dose of opioid therapy as exceeding 200 mg of morphine equivalent[3]—more than twice what the CDC would eventually recommend in its 2016 guidelines. The 2009 APS/AAPM guidelines have been criticized for both their permissive attitude toward prescribing high doses of opioids, and because 14 of its 20 authors reported financial conflicts of interest, many with opioid manufacturers.[4] One author, Dr. Gilbert Fanciullo, has since criticized the guidelines as being "'skewed' by drug companies and 'biased in many important respects,' including its high presumptive maximum dose … and claims of a low risk of addiction."[5] Three years after the 2009 APS/AAPM study was released, its lead author, Roger Chou, said in an interview that "at the time, there wasn't much evidence on incremental risks associated with higher doses, and recent studies suggest that risk starts to go up at really relatively low doses. … there is growing recognition that a substantial proportion of patients with chronic noncancer pain simply don't respond to opioids—and that if these patients have not responded by the time they are

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[3] Roger Chou, et al., "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," *Journal of Pain* (Feb. 2009), v. 10(2), at 113-130, *available* at https://www.jpain.org/article/S1526-5900(08)00831-6/fulltext.
[4] *Supra*, note 3, at Appendix 1.
[5] Complaint, *State of Rhode Island v. Purdue Pharma L.P., et al.*, Providence S. Court (PC-18-4555), June 25, 2018, at 29, *available* at http://www.riag.ri.gov/documents/StateVPurdue.pdf.

at the equivalent of 60 or 80 mg per day of morphine, they probably aren't going to respond at higher doses."[6]

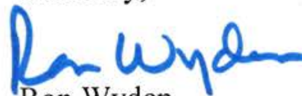
a) Your letter stated that AAPM "supported the development of the CDC opioid prescribing guideline." Has AAPM adopted the CDC guidelines? Does it plan to adopt the CDC guidelines? Does it plan to in any way change the APS/AAPM guidelines to reflect the recommendations made in the CDC guidelines?

b) While the AAPM criticizes CDC's guidelines for a lack of evidentiary rigor, three of the 14 recommendations in the APS/AAPM guidelines rely in part on "anecdotal" experience of panel members.[7] As noted above, the author of the APS/AAPM study on which the guidelines were based said that it lacked evidence regarding risks associated with higher doses of opioids. Furthermore, the 2009 APS/AAPM study are now 10 years old and more than sources cited in the evidence review are 15 or more years old. Does AAPM still fully stand by the APS/AAPM guidelines issued in 2009?

c) Does the AAPM's still stand by the position outlined in the 2009 APS/AAPM guidelines that the "definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent)?"

If you or anyone on the staff of AAPM have any questions, please contact Peter Gartrell at (202) 224-4515.

Sincerely,



Ron Wyden
Ranking Member

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[6] Anesthesiology News, "The APS/AAPM Opioid Treatment Guidelines Revisited," January 2012 (Vol. 38, No. 1), *available* at https://www.anesthesiologynews.com/Pain-Medicine/Article/01-12/The-APS-AAPM-Opioid-Treatment-Guidelines-Revisited/19945.

[7] *Supra*, note 3. For example, Recommendation 6 states "Although evidence to guide optimal management strategies is lacking, anecdotal experience of panel members suggests that patients who are not assessed as being at high risk and engage in a relatively nonserious aberrant behavior, such as one or two episodes of unauthorized opioid escalations, can often be managed with patient education and enhanced monitoring. Patients who are repeatedly nonadherent and patients who engage in more serious aberrant behaviors (such as use of cocaine, use of unprescribed opioids, or obtaining opioids from multiple outside sources) may require consultation or referral (if not already done), major restructuring of therapy, and in many cases discontinuation of [chronic opioid therapy]." See also, Recommendations 7 and 8, which rely on anecdotal evidence.