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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

JEFFREY WRASE, STAFF DIRECTOR AND CHIEF ECONOMIST
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December 18, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I write with continued concern that the Department of Health & Human Services (“HHS”) is inadequately vetting advisory board members for conflicts of interest related to medically prescribed opioids.¹

Earlier this year, HHS appointed multiple individuals to a pain management task force who appear to have significant conflicts of interest.² The Pain Management Best Practices Inter-Agency Task Force (“Task Force”) was originally authorized to review best practices for chronic and acute pain management and prescribing pain medication.³ The Task Force’s purview was recently expanded, and it will now be involved in making recommendations that could dictate Medicare and Medicaid payment and coverage policies for treatment of opioid use disorder, including the use of medical devices.⁴ The expansion of the Task Force’s responsibilities increases the need for HHS to ensure that panel members do not have conflicts of interest.

Fifteen of the Task Force’s members are subject to the HHS Open Payments reporting requirements. From 2013 through 2017, the most recent year for which data are available, 10 of these individuals reported receiving payments totaling nearly \$180,000 from pharmaceutical companies, including opioid makers, and medical device manufacturers. While some of the payments are small and consist of food and beverage fees, others are reported as consulting fees worth thousands of dollars. For example, one Task Force member reported receiving payments of more than \$79,000 during that time period, the majority of which came from Pfizer, Inc. (“Pfizer”), which manufactures two extended release opioid capsules. Three other members received total payments ranging from \$26,000 and \$31,000.

Another one of these panel members received a consulting payment of more than \$20,000 from Purdue Pharma, L.P. (“Purdue”) just 15 months before the Task Force was formed. Purdue, a

¹ Letter from Sen. Ron Wyden to the Hon. Sylvia Matthews Burwell, Feb. 5, 2016; Letter from Sen. Ron Wyden to the Hon. Sylvia Matthews Burwell, June 23, 2016; Letter from Sen. Ron Wyden to Victor Dzau, July 1, 2016; Letter from Sen. Ron Wyden to the Hon. Thomas E. Price, May 5, 2018.

² Press Release, Members Appointed to New Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health & Human Services (May 1, 2018), available at <https://www.hhs.gov/about/news/2018/05/01/members-appointed-new-pain-management-best-practices-inter-agency-task-force.html>.

³ Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, Sec. 101.

⁴ Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, P.L. 115-271, Sec. 6032.

manufacturer of multiple opioid products, has been subject to extensive civil and criminal prosecution for abusive marketing practices dating back more than a decade.

In this case, Open Payments data show that Purdue paid Dr. Jianguo Cheng a consulting fee of \$24,600, on March 1, 2017.⁵ This payment appears to have been the only consulting fee that Dr. Cheng received since Open Payments was implemented in 2013. The Purdue payment also is many times larger than any other payment he received from any entity for any sort of activity. Open Payments data further shows the payment to Dr. Cheng was the eighth largest stand-alone payment that Purdue reported making in 2017. Furthermore, of the more than 16,000 doctors Purdue reported paying in 2017, fewer than 25 received more in aggregate payments that year than Dr. Cheng did.

In addition to the consulting fee from Purdue, Dr. Cheng is the current president of the American Academy of Pain Medicine (“AAPM”), an affiliation that HHS does not disclose to the public on its website. The affiliation with AAPM is relevant to the consideration of financial conflicts of interest for two reasons.

First, AAPM has a long history of receiving significant funding from the pharmaceutical industry, including opioid manufacturers. The Minority Staff of the U.S. Senate Committee on Homeland Security and Government Affairs (“HSGAC”) found that from 2012 to 2017, the organization received \$1.2 million from the five largest opioid manufacturers, as measured by worldwide 2015 sales.⁶ An affiliated foundation received an additional \$300,000 from these five firms during the same time period.⁷

Secondly, AAPM is organized for tax purposes as a business league under Section 501(c)(6) of the Internal Revenue Code, which means it is seeking to improve the business of its members. Unlike a Section 501(c)(3) entity, which is organized for charitable purposes business leagues must be “an association of persons having some common business interest, the purpose of which is to promote such common interest,” and “must be devoted to improving business conditions of one or more lines of business as distinguished from performing particular services for individual persons.”⁸ In the case of AAPM, the organization represents health care providers,⁹ who also stand to benefit from potential changes to Centers for Medicare & Medicaid Services’ reimbursement schedules—one of the Task Force’s central responsibilities.

Taken together, the AAPM’s financial links to opioid manufacturers, and its status as a business league, are even more relevant since the organization was deeply critical of opioid prescribing guidelines that were issued by the Centers for Disease Control and Prevention (“CDC”) in

⁵ Centers for Medicare & Medicaid Services, Open Payments data for Jianguo Cheng, *available at* <https://openpaymentsdata.cms.gov/physician/163794/summary> (accessed Dec. 11, 2018).

⁶ Minority Office of the U.S. Senate Committee on Homeland Security and Government Affairs, “Fueling an Epidemic: Report Two,” (Feb. 12, 2018) at 3, 7, *available at* <http://goo.gl/T4qiWh> (link shortened). The firms are Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc.

⁷ *Id.*, at 7.

⁸ Internal Revenue Service, “Business Leagues,” *available at* <https://www.irs.gov/charities-non-profits/other-non-profits/business-leagues> (accessed Dec. 11, 2018).

⁹ American Academy of Pain Medicine, Form 990 for the tax year 2016, at Part III (Line 4c), *available at* http://990s.foundationcenter.org/990_pdf_archive/363/363874208/363874208_201612_990O.pdf (accessed Dec. 11, 2018).

2016.¹⁰ The organization’s criticism specifically targeted the CDC’s suggested daily dosing limits, the preference in the guidelines for use of non-opioid therapies. The AAPM also questioned the evidence on which the guidelines were based.¹¹ In 2016, Dr. Cheng was a Vice President of the organization.¹²

In addition to Dr. Cheng, three other AAPM members are on the Task Force.¹³ One is Dr. Rollin Gallagher, a current board member¹⁴ and former president¹⁵ of the organization. While Dr. Gallagher has not reported receiving payments directly from pharmaceutical manufacturers, he is a highly paid independent contractor for AAPM, which, as mentioned above, receives substantial funding from opioid manufacturers. According to tax records reviewed by staff, AAPM paid Dr. Gallagher more than \$975,000 from 2011 through 2017 for oversight of its flagship publication,¹⁶ the *Journal of Pain Medicine*, where he remains editor-in-chief.¹⁷ In that position, many of the senior editors Dr. Gallagher oversees also have received substantial payments—some in excess of \$100,000—from opioid manufacturers, according to Open Payments data.¹⁸ Prior to Open Payments being established, Dr. Gallagher disclosed working as a consultant or receiving grants from opioid manufacturers including Purdue, Endo Pharmaceuticals, Inc. (“Endo”), Janssen Pharmaceuticals, Inc. (“Janssen”), and Cephalon, Inc.¹⁹

Not all panel members are subject to Open Payments reporting. For example, one of the four current Task Force members not required to file such reports is on the staff of the U.S. Pain Foundation (“Pain Foundation”). The HSGAC report found that the Pain Foundation received \$2.9 million in payments from the five largest opioid manufacturers from 2012 to 2017, including a \$2.5 million payment from Insys for a patient assistance program the foundation helped administer.²⁰ Insys markets fentanyl and has been the subject of civil and criminal

¹⁰ Daniel B. Carr, “President’s Message: NPS Versus CDC: Scylla, Charybdis and the “Number Needed to [Under-] Treat” *Journal of Pain Medicine* (2016) 17:999–1000, available at <http://www.painmed.org/files/presidents-message-2016-volume17-06.pdf>.

¹¹ *Id.*

¹² *Supra*, note 9.

¹³ Press Release, “AAPM Members Appointed to New Pain Management Task Force,” American Academy of Pain Medicine (May 8, 2018), available at <http://www.painmed.org/files/press/members-appointed-to-pain-mgmt-task-force.pdf>.

¹⁴ American Academy of Pain Medicine, “Board of Directors,” available at <http://www.painmed.org/membercenter/board-of-directors/> (accessed Dec. 14, 2018).

¹⁵ American Academy of Pain Medicine, “AAPM Council of Past Presidents,” available at <http://www.painmed.org/membercenter/council-of-past-presidents/> (accessed Dec. 14, 2018).

¹⁶ According to Part VII, Section B, of IRS Form 990s filed by the American Academy of Pain Medicine, Dr. Gallager received \$150,000 in 2017; \$122,500 in 2016; \$160,932 in 2015; \$110,000 in 2014; \$115,000 in 2013; \$173,820 in 2012; and \$147,216 in 2011. Some of the tax returns are available publically through the Foundation Center:

- 2016 (*supra*, note 9).
- 2015 (http://990s.foundationcenter.org/990_pdf_archive/363/363874208/363874208_201512_990O.pdf)
- 2014 (http://990s.foundationcenter.org/990_pdf_archive/363/363874208/363874208_201412_990O.pdf)
- 2013 (http://990s.foundationcenter.org/990_pdf_archive/363/363874208/363874208_201312_990O.pdf)
- 2012 (http://990s.foundationcenter.org/990_pdf_archive/363/363874208/363874208_201212_990O.pdf)

¹⁷ Pain Medicine, “Editorial Board,” available at https://academic.oup.com/painmedicine/pages/Editorial_Board (accessed on Dec. 11, 2018).

¹⁸ *Supra*. According to a staff review, seven of the 12 senior editors subject to Open Payments reporting received more than \$10,000 from pharmaceutical and/or medical device manufacturers in at least one calendar year from 2013 to 2017. Three senior editors—Timothy Deer, Perry Fine and Lynn Webster—received payments exceeding \$10,000 in 2017, the most recent year for which data are available. Dr. Deer alone received \$281,000.

¹⁹ Austin American-Statesman, “Critics say pharmaceutical firms spurred the increase in prescriptions for narcotic painkillers,” (Sept. 27, 2016), available at <https://www.statesman.com/NEWS/20160927/Critics-say-pharmaceutical-firms-spurred-the-increase-in-prescriptions-for-narcotic-painkillers>.

²⁰ *Supra*, note 6, at 7.

prosecution for abusive marketing practices, some of which were examined during a 2016 hearing before the Finance Committee.²¹ The HHS Office of Inspector General and the FDA Office of Criminal Investigations participated in the federal investigation and 2017 arrest of the company's founder and majority owners in connection to these illegal practices.²²

The Pain Foundation's 2014 tax filing shows that the organization received nearly \$500,000 combined from opioid manufacturers Teva Pharmaceutical Industries, Ltd. ("Teva") (\$266,000), Purdue (\$104,800), Pfizer (\$80,000), Endo (\$25,000) and Zogenix, Inc. ("Zogenix") (\$21,368), in addition to tens of thousands of dollars more from other pharmaceutical and device manufacturers.²³ According to documents that have since been removed from the foundation's website, over 70% of the organization's funding in 2012 came from major pharmaceutical manufacturers.²⁴ That year the organization received more than \$180,000 from pharmaceutical manufacturers including Pfizer (\$50,000), Purdue (\$30,000), Teva (\$43,000), Endo (\$30,000), Johnson & Johnson (\$7,500), and the pharmaceutical industry trade group PhRMA (\$20,000).²⁵

It also has recently been revealed that the foundation faces serious legal and financial control issues regarding misuse of funds. It was reported this month that the Attorney General and Department of Consumer Protection for the State of Connecticut have opened investigations into its activities.²⁶ The organization's former CEO, who was forced to resign in May, also has reportedly spoken to the U.S. Attorney's Office, the Federal Bureau of Investigation, and the Department of Health & Human Services.²⁷ Media reports also stated that the foundation inflated its membership numbers by 600%. The foundation previously said that it had 90,000 members, but now states that it has just 15,000 members.²⁸

Given the financial influence that opioid manufacturers could exert on the above-discussed Task Force members, it is troubling that the body's first work product hewed closely to industry positions on federal policy. As one example, the Task Force's literature and policy review cast only negative light on the CDC's 2016 opioid prescribing guidelines, and its attempt to moderate their use and improve patient safety.²⁹ Likewise, the Task Force's draft gap analysis and

²¹ Examining the Opioid Epidemic: Challenges and Opportunities, Before the U.S. Senate Committee on Finance, 114th Cong. 523 (2016) (statement of David A. Hart, Assistant Attorney-In-Charge, Civil Enforcement, Financial Fraud And Consumer Protection, Oregon Department of Justice), available at <https://www.finance.senate.gov/hearings/examining-the-opioid-epidemic-challenges-and-opportunities>.

²² Press Release, "Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering," U.S. Department of Justice (Oct. 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

²³ U.S. Pain Foundation, Form 990 for tax year 2014, available at <http://www.uspainfoundation.org/wp-content/uploads/2015/12/2014-taxes.pdf>, (accessed Dec. 12, 2018).

²⁴ U.S. Pain Foundation, Form 990 for tax year 2012, available at <http://uspainfoundation.org/Docs/2012-990-taxes-signed-complete.pdf>, (accessed Jan. 28, 2016).

²⁵ *Id.*

²⁶ Pat Anson, "U.S. Pain Foundation Under Investigation," *Pain News Network* (Dec. 12, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/12/us-pain-foundation-under-investigation>.

²⁷ Pat Anson, "Ex-CEO Admits 'I Took Money From U.S. Pain,'" *Pain News Network* (Dec. 9, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/8/ex-ceo-admits-i-took-money-from-us-pain>.

²⁸ Pat Anson, "'Financial Irregularities' Found at U.S. Pain Foundation," *Pain News Network* (Dec. 7, 2018), available at <https://www.painnewsnetwork.org/stories/2018/12/7/financial-irregularities-uncovered-at-us-pain-foundation-nbsp>.

²⁹ Pain Management Inter-Agency Task Force, "3.2 Clinical Best Practices" in *Meeting Materials – Environmental Scan Report* (May 2018), available at <https://www.hhs.gov/ash/advisory-committees/pain/meetings/2018-05-30/index.html>.

recommendations appear to focus largely on chipping away at the CDC's guidelines that are designed to encourage moderation of opioid use by medical providers.³⁰

In order to better understand HHS's process for appointing members to the Task Force, please answer the following questions, and provide the requested documents:

1. Please describe HHS's process for selecting Task Force members, including the extent to which the Task Force is subject to the Federal Advisory Committee Act. Please provide any relevant policies, guidance or regulations the Department adhered to during this process.
2. Please describe HHS's conflict of interest review process in regards to its selection of Task Force members, including disclosure and recusal requirements. Please provide any relevant policies, guidance or regulations the Department adhered to during this process.
3. Was HHS aware of the potential conflicts of interest for the members detailed in this letter? Is HHS aware of any other potential conflicts of interests for Task Force members?
4. Was HHS aware of the legal and financial control issues faced by the U.S. Pain Foundation? If so, when did it become aware of these issues? Was the issue ever brought to HHS's attention by the Pain Foundation's representative on the Task Force or others?
5. Has HHS placed any restrictions on any Task Force members due conflicts of interest or the appearance of such conflicts?
6. Did HHS consult the Open Payments database maintained by the Centers for Medicare & Medicaid Services during its selection process for Task Force members? Does HHS's policies or guidelines require it to consult Open Payments as part of its review for federal advisory committees that include participants from professions subject to disclosure?
7. Section 101(c)(5) of the Comprehensive Addiction and Recovery Act sets specific criteria for the makeup of the Task Force's members. Please categorize each of the Task Force's members according to the criteria set forth by statute.
8. Please provide the Finance Committee with the ethics disclosures completed by each of the Task Force's members and any evaluations or determinations of such conflicts.
9. Dr. Cheng's and Dr. Gallagher's affiliation with AAPM was briefly mentioned during the Task Force's opening session, but no discussion of their affiliation is made on the Task Force's website. Setting aside for a moment my concerns about financial conflicts of interest, such professional affiliations are relevant to the public's understanding of the composition of this and similar advisory bodies.

³⁰ Pain Management Inter-Agency Task Force, "1.3 Review of CDC Guidelines," in *September 2018 Meeting Materials – Draft Gaps and Recommendations* (September 2018), available at <https://www.hhs.gov/ash/advisory-committees/pain/meetings/2018-09-25/recommendations-and-gaps/index.html>.

- a. In HHS's view, is there any law or policy that would prevent it or its agencies from listing these affiliations—or similar ones for other members—on its website, where it would be more readily available to the public?
- b. Does HHS feel it needs additional statutory authority to make such disclosure of professional biographical information of this panel and others it convenes?

Please provide the requested information and documents no later than January 22, 2019. If you or your staff have any questions, please direct them to Peter Gartrell on my Finance Committee staff, at (202) 224-4515.

Thank you for your attention to this matter.

Sincerely,



Ron Wyden
Ranking Member