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United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

May 5, 2017

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

Dear Secretary Price:

I write to you with concern about the proposed composition of a Food & Drug Administration (FDA) workshop scheduled for May 9th and 10th in Silver Spring, Maryland, that will examine how medical providers use and prescribe opioids to treat pain. A preliminary list of organizations scheduled to participate in the workshop, "Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics – Exploring the Path Forward," includes many groups with deep financial ties to opioid manufacturers.¹

Given these financial relationships between manufacturers and the participating pain groups, I request that you delay the workshop until the Department of Health and Human Services (HHS) can conduct a full conflict-of-interest review of all proposed participants. Such a review will ensure that the workshop provides a genuine balance of views. Following this review, HHS should consider including additional groups or organizations that have both (a) worked on opioid prescriber practices, and (b) can certify they have not received funds from – and are not currently partnering with – opioid manufacturers. These steps would improve the balance of the workshop, and diminish the influence of companies that have a financial stake in loosening opioid prescriber guidelines.

As you noted in recent remarks at the National Rx Drug Abuse and Heroin Summit, the prescribing practices of medical providers treating pain has contributed to the opioid overdose crisis the nation now faces.² The Centers for Disease Control and Prevention (CDC) found that "sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014, but there has not

¹ The preliminary list of participants included 26 non-federal participants:

American Medical Association, American Academy of Physician Assistants, American Association of Nurse Practitioners, American Academy of Integrative Pain Management, American Society of Addiction Medicine, American Pharmacist Association, American Dental Association, American Osteopathic Association, American Pain Society, Federation of State Medical Boards, National Governors Association, Project Lazarus, New Mexico, Medical Board of California, Permanente Medical group Northern California, Moffitt Cancer Center, Veterans Health Administration, Department of Defense, Duke University, Indian Health Service, Pain Action Alliance to Implement a National Strategy, PatientsLikeMe, American Chronic Pain Association, National Fibromyalgia and Chronic Pain Foundation, Consumers Union, Facing Addiction

² Department of Health and Humans Services, "Secretary Price Announces HHS Strategy for Fighting Opioid Crisis," April 19, 2017, https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html

been an overall change in the amount of pain Americans report. During this time period, prescription opioid overdose deaths increased similarly." As you pointed out during the summit, this rapid rise of opioid prescriptions has had devastating consequences for millions of Americans.⁴

In addition to the human toll of opioid use disorder, overdoses and death, the rise in associated health costs has had a major impact on programs within the jurisdiction of the Senate Committee on Finance. By 2020, public and private spending on substance abuse disorder treatment is expected to reach \$42.1 billion, compared to \$24.3 billion in 2009. Medicare and Medicaid costs are expected to account for a third of this spending. The Affordable Care Act (ACA) has been an important link to care for people seeking treatment for substance use disorder. Leading health economists estimate that repealing the ACA would result in coverage losses for "about 2.8 million Americans with a substance use disorder, of whom about 222,000 have an opioid disorder." The spike in opioid use has also led to higher transmission rates of blood borne diseases such as HIV and hepatitis, adding to the costs of the epidemic.

The FDA workshop has the potential to build on the work the CDC has performed in recent years, which resulted in national guidelines that medical providers can follow when prescribing opioids. Specifically, the FDA workshop is set to discuss:

- The role of health care provider training in improving pain management and ensuring the safe use of opioids.
- How best to provide appropriate training in pain management and safe opioid use to health care providers who prescribe or are directly involved in the management or support of patients with pain.
- Issues and challenges associated with possible changes to federal efforts to educate health care providers on pain management and the safe use of opioids. 9

Unfortunately, the apparent financial relationships between opioid manufacturers and pain advocacy groups participating in the workshop raise serious conflict-of-interest concerns that could undercut efforts to curb over-prescribing. I have continued to investigate the role of opioid manufacturers spending millions of dollars to fund pain groups through arrangements like payto-play corporate councils that grant companies access to executives and membership of the organizations. The pain groups, which also receive money from the companies through

Substance Abuse and Mental Health Administration, *Projections of National Expenditures for Treatment of Mental and Substance Use Disorders*, 2010-2020, SMA-14-4883, 2014, http://store.samhsa.gov/shin/content/SMA14-4883/SMA14-4883.pdf, 30-31.

⁷ Richard G. Frank and Sherry Glied, "Keep Obamacare to keep progress on treating opioid disorders and mental illnesses," *The Hill*, January 11, 2017, http://thehill.com/blogs/pundits-blog/healthcare/313672-keep-obamacare-to-keep-progress-on-treating-opioid-disorders.

⁸ Philip J. Peters, et al., "HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014–2015," *New England Journal of Medicine*, 375:229-239, July 21, 2016, http://www.nejm.org/doi/full/10.1056/NEJMoa1515195#t=abstract

³ Centers for Disease Control and Prevention, "Opioid Overdose: Prescribing Data," https://www.cdc.gov/drugoverdose/data/prescribing.html, accessed May 5, 2017.

⁴ Supra, note 2.

[°] Ibid.

Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics-Exploring the Path Forward; Public Workshop, 82 Fed. Reg. 18300 (Apr. 18, 2017), https://www.federalregister.gov/documents/2017/04/18/2017-07821/training-health-care-providers-on-pain-management-and-safe-use-of-opioid-analgesics-exploring-the.

advertising, grants and other forms of sponsorship, have worked, oftentimes in concert with other industry-funded groups, to steer state and federal policy toward favoring opioids as a treatment for pain. For example, four of the six groups detailed in this letter co-signed a letter in 2015 criticizing the CDC's draft of guidelines on opioid prescribing practices.¹⁰

Additional information regarding the financial ties between opioid manufacturers and organizations participating in the workshop include the following:

- American Academy of Integrative Pain Management: Until recently, this group was known as the American Academy of Pain Management. 11 The name change appears to be little more than cosmetic. The content of the group's website remains largely unchanged, and the group is still heavily funded by opioid manufacturers, with a corporate council consisting of AstraZeneca, Endo, Janssen, Mallinckrodt, Medtronic, Pernix, Pfizer, Purdue and Teva. 12 Regarding the corporate council, the academy states that it "greatly values its relationships with the commercial sponsors who make the products that enable members to provide the best pain care possible. To that end, AIPM considers commercial sponsors to be an integral part of the pain care team." ¹³ In return for membership dues, corporate council members receive access to leadership and data the organization collects. ¹⁴ Similarly, the state policy arm of the organization, the State Pain Policy Advocacy Network, is sponsored by Endo, Janssen, Medtronic, Pfizer, Purdue, and Teva; the only non-opioid sponsors are the American Cancer Society and Livestrong. ¹⁵ Moreover, the Associated Press and Center for Public Integrity reported last year that the organization "receives 15 percent of its funding from pharmaceutical companies ... [and] its state advocacy project is 100 percent funded by drugmakers." Under the previous name, the organization led a letter to the Centers for Disease Control and Prevention criticizing the draft opioid prescribing guidelines.¹⁷
- American Chronic Pain Association: I previously raised concerns about this organization's participation in the HHS's Interagency Pain Research Coordinating Committee (IPRCC) because of its ties to industry. The association reports receiving corporate support from 11 companies that manufactured opioid based drugs AbbVie, Collegium Pharmaceutical, Depomed, Egalet, Janssen, Mallinckrodt, Pfizer, Purdue,

¹⁰ Pat Anson, "Chronic Pain Groups Blast CDC Opioid Guidelines," *Pain News Network*, September 22, 2015, https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines

American Academy of Integrative Pain Management, "Leading Pain Organization Changes Name, Brings Alternative Solutions to Complex Pain Challenges," June 17, 2016, http://blog.aapainmanage.org/leading-pain-organization-changes-name-brings-alternative-solutions-complex-pain-challenges/, accessed May 5, 2017.

¹² American Academy of Integrated Pain Management, "Corporate Council," http://www.aapainmanage.org/about/corporate-council/, accessed May 5, 2017.

¹³ American Academy of Integrated Pain Management, "AIPM Announces New Corporate Council Program," October 4, 2016, http://www.aapainmanage.org/announcement/academy-announces-new-corporate-council-program/, accessed May 5, 2017.
¹⁴ Ibid.

http://sppan.aapainmanage.org/supporters

Liz Essley Whyte, Geoff Mulvihill and Ben Wieder, "Politics of pain: Drugmakers fought state opioid limits amid crisis," Associated Press and Center for Public Integrity, September 18, 2016,

https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis ¹⁷ Supra, note 10.

¹⁸ Senator Ron Wyden to Health and Human Services Secretary Sylvia Mathews Burwell, February 5, 2016, https://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS Opioid%20Conflicts.pdf.

Shionogi, Teva and Zogenix.¹⁹ Its "corporate champion," which appears to be its highest corporate contributor, is AstraZeneca,²⁰ which 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 However, the organization's connections to Purdue are not limited to Haddox; every page of the website states that "Development of this new ACPA web site was made possible through an unrestricted educational grant from Medtronic Foundation and Purdue Pharma." The association also has promoted Purdue-funded initiatives such as a Spanish language website²³ and a guide for pain patients.²⁴ The association's advisory board includes four doctors who have received thousands of dollars from opioid manufacturers including Endo, Purdue, Mallinckrodt, Pfizer, Teva, Depomed and Zogenix, according to Open Payments data. 25 One of the doctors received \$75,000 in payments over three years. 26 Another advisory board member, Dr. Judith Paice, served as the second coordinator of the IPRCC critique of the CDC guidelines.²⁷

American Pain Society (APS): This organization has for years reported receiving money from opioid manufacturers, prompting an investigation by the Senate Finance Committee in 2012.²⁸ APS in 2013 reported that six pharmaceutical manufacturers contributed \$225,000 to various APS programs, ²⁹ including grants, meeting sponsorship, awards, and sponsorship of the organization's electronic newsletter. 30 Contributors to APS include Teva, Purdue, Pharma, Eli Lilly, Millenium and Zogenix. 31 The organization currently maintains a "corporate council" consisting of 11 pharmaceutical companies, most of which manufacturer opioids or opioid-related products. 32 These companies appear to have paid APS at least \$180,000, based on the minimum financial requirements advertised on the organization's website; in return for dues, companies are granted access to the organization's leadership and members.³³ As recently as April 2017,

¹⁹ American Chronic Pain Association, "Partners and Contributors," https://theacpa.org/Partners-Contributors, accessed May 5, 2017. Zogenix sold its pain franchise in May 2015.

²¹ AstraZeneca, MOVANTIKTM (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 American Chronic Pain Association, "Advisory Board," https://theacpa.org/Advisory-Board, accessed May 5, 2017.
https://theacpa.org/news/PAIN-Exhibit-Launches-Website-in-Spanish, accessed May 5, 2017.

American Chronic Pain Association, "About Partners: Helping you do more to build pain awareness," https://theacpa.org/About-Partners, accessed May 5, 2017.

American Chronic Pain Association, https://theacpa.org/Advisory-Board

²⁶ Centers for Medicare and Medicaid Services, Steven P. Stanos (Open Payments),

https://openpaymentsdata.cms.gov/physician/138667/payment-information, accessed May 5, 2017.

Supra, note 18.

²⁸ Senators Max Baucus and Charles Grassley to Catherine Underwood, May 8, 2012,

https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to %20American%20Pain%20Society.pdf, accessed May 5, 2017.

²⁹ American Pain Society, "APS Transparency of Commercial Support for 2013," http://americanpainsociety.org/uploads/getinvolved/transparency-of-support-2013.pdf, accessed May 5, 2017.

American Pain Society, "Commercial Support," http://americanpainsociety.org/get-involved/commercial-support/overview, accessed May 5, 2017.

³² American Pain Society, "Corporate Council Members," http://americanpainsociety.org/get-involved/corporate- council/members, accessed May 5, 2017. 33 Supra, note 30.

the organization presented its electronic newsletter as being funded by Purdue Pharma.³⁴ This is apparently a long-standing relationship; in 2013, for example, APS indicated that Purdue contributed \$45,000 annually to sponsor the newsletter.³⁵ Furthermore, two of the four doctors on the organization's board of directors³⁶ have received substantial payments from opioid manufacturers, according to Open Payments data.³⁷ The organization's immediate past president, Gregory Terman, was dismissed from a National Academy of Medicine panel studying opioid addiction, following conflict-of-interest concerns I raised to the academy.³⁸

National Fibromyalgia and Chronic Pain Foundation: This organization appears to receive funding from Purdue Pharma, and is closely associated with other organizations and people who have long-standing financial ties to opioid manufacturers. Purdue funded one of foundation's trademarked initiatives, "Leaders Against Pain," in 2012. 39 The organization's founder, Jan Chambers, also is a member of industry-funded groups noted elsewhere in this letter. Chambers is an advisory council member for Pain Action Alliance to Implement a National Strategy⁴⁰ (see more information below) and the State Pain Policy Advocacy Network which, as noted above, is reportedly fully funded by drugmakers. 41 The Foundation also lists a number of "affiliated organizations" that have established connections to opioid manufacturers. 42 Written products Chambers has produced also raise conflict-of-interest concerns, both because of their content and coauthors. For example, Chambers was co-author of a paper, featured in an American Academy of Pain Management publication, which criticized the Drug Enforcement Administration's decision to classify hydrocodone as a Schedule III narcotic. 43 The paper was co-authored by AAPM's president, Bob Twillman; a Utah physician, Lynn Webster, who reported receiving \$160,000 from drug makers between 2013 and 2015;⁴⁴ and three employees of Millennium Health. In the same year the paper was published, Millenium Health paid "\$256 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid and other federal health care programs for medically unnecessary

³⁴ American Pain Society, E-News, April 2017, http://americanpainsociety.org/education/e-news/2017/april/society, accessed May 5, 2017.

³⁵ Supra, note 29.

³⁶ American Pain Society, "Board of Directors," http://americanpainsociety.org/about-us/who-s-who-in-aps/board-of-directors, accessed May 5, 2017.

³⁷ Centers for Medicare and Medicaid Services, Mark Wallace, (Open Payments), https://openpaymentsdata.cms.gov/physician/64875/payment-information, accessed May 5, 2017; Centers for Medicare and Medicaid Services, Edward Michna, (Open Payments), https://openpaymentsdata.cms.gov/physician/247077/summary, accessed May 5, 2017.

³⁸ Matthew Perrone, "Painkiller panel drops experts linked to pharma industry," *Associated Press*, July 6, 2016, http://www.seattletimes.com/business/painkiller-panel-drops-experts-linked-to-pharma-industry/.

³⁹ National Fibromyalgia & Chronic Pain Association, "National Fibromyalgia & Chronic Pain Association Hosting Leaders Against PainTM National Training Event For New & Veteran Support Group Leaders and Patient Advocates in DC," *PRWeb*, September 25, 2012, http://www.prweb.com/releases/nfmcpa/09 24 2012/prweb9923245.htm, accessed May 5, 2012.

⁴⁰ PAINS Project, "Advisory Committee," http://painsproject.org/who-we-are/advisory-committee/, accessed May 5, 2017.

State Pain Policy Advocacy Network, "SPPAN Leadership," http://sppan.aapainmanage.org/leadership, accessed May 5, 2017.

⁴² National Fibromyalgia & Chronic Pain Association, "Affiliate and Education Organizations," http://www.fmcpaware.org/affiliate-organizations.html, accessed May 5, 2017.

⁴³ Jan Chambers, et al., "An Online Survey of Patients' Experiences Since the Rescheduling of Hydrocodone: The First 100 Days," *Pain Medicine*, September 16, v. 17 no. 9, https://academic.oup.com/painmedicine/article/17/9/1686/2399259/An-Online-Survey-of-Patients-Experiences-Since-the.

Survey-of-Patients-Experiences-Since-the.

44 Centers for Medicare and Medicaid Services, Lynn Webster (Open Payments), https://openpaymentsdata.cms.gov/physician/1136720/summary, accessed May 5, 2017.

urine, drug and genetic testing and for providing free items to physicians who agreed to refer expensive laboratory testing business to Millennium." The Foundation also signed on to the American Academy of Pain Management letter challenging the CDC guidelines noted above. 46

- Pain Action Alliance to Implement a National Strategy: Also known by its acronym, PAINS, this group is run by the Center for Practical Bioethics, which has received substantial donations from opioid manufacturers. The Center was one of several groups investigated by the Committee on Finance in 2012 for its links to industry and its role in promoting the use of prescription opioids.⁴⁷ The financial relationship between the Center and opioids manufacturers is ongoing. In 2013, publicly available records indicate Purdue Pharma contributed \$100,000 to the Center, making the company the second largest contributor to the group that year. 48 When Finance Committee staff reviewed the Center's website in August 2015, it listed several corporate supporters, including opioid manufacturers, among its donors between January 2014 and March 31, 2015: Janssen Pharmaceuticals, Mallinckrodt Pharmaceuticals, Medtronic, Inc., Purdue, Teva Pharmaceuticals, and Zogenix. The website has since been updated to show 2016 sponsors, which still shows Purdue among them. 49 Moreover, the leadership of PAINS, Myra Christopher and Richard Payne, have longtime financial relationships with opioid manufacturers. During Christopher's time as CEO of the Center, Purdue Pharma established a \$1.5 million endowment for that chair⁵⁰ through three \$500,000 allocations in 2008, 2009, and 2011 respectively.⁵¹ Dr. Payne, meanwhile, continues to receive money from opioid manufacturers. In 2013, Dr. Payne reportedly received \$2,000 in travel and lodging from Purdue 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.⁵² Dr. Payne also received \$7,538 from Teva in 2015. 53 Moreover, PAINS also signed onto the American Academy of Pain Management letter to CDC noted above. 54
- **Project Lazarus:** In a 2015 presentation to the FDA, this organization's founder, Frederick Brason, disclosed financial relationships with Ameritox, Indivior, Kaleo,

⁴⁵ Department of Justice, "Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians," October 19, 2015, https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic, accessed May 5, 2017.

⁴⁶ Supra, note 10.

⁴⁷ Senators Max Baucus and Charles Grassley to John G. Carney,

https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20Center%20for%20Practical%20Bioethics1.pdf

⁴⁸ The Greafer Kansas City Community Foundation makes publically available the records for the organization at http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193, accessed May 5, 2017.

⁴⁹ Center for Practical Bioethics, "Our 2016 Community Supporters," https://practicalbioethics.org/support-our-mission/community-supporters?highlight=WyJwdXJkdWUiXQ, accessed May 5, 2017.

⁵⁰ 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

⁵¹ 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
⁵² Centers for Medicare and Medicaid Services, Richard Pain (Open Payments),

https://openpaymentsdata.cms.gov/physician/1094555, accessed May 5, 2017. blid.

⁵⁴ Supra, note 10.

Purdue, and Zogenix.⁵⁵ The organization's website also shows it is partnering with KemPharm, which is developing several opioid-based drugs;⁵⁶ the Academy of Integrative Pain Management, noted above, and the American Academy of Pain Medicine. 57 Last month, Purdue Pharma touted its funding of the organization in a press release on its website. 58 The organization also has partnered with other industry-funded groups in signing the American Academy of Pain Management letter to CDC cited above. In addition to the industry relationships of Project Lazarus and its founder, a 2016 Washington Examiner article questioned the effectiveness of the organization's work, noting that after a temporary decline, opioid overdose rates in the county where the organization works, have been on the rise. ⁵⁹ The amount of money the organization has received from industry is difficult to gauge. Project Lazarus was an independent nonprofit until 2011, when the director transferred all of its assets to a religious organization that he controlled, Coastlands Ministries. 60 Publically available tax records for Coastlands Ministries show that it received a \$500,000 grant in 2012, but the donor is undisclosed.⁶¹ The group also signed onto the American Academy of Pain Management letter to CDC noted above.

The long-standing and ongoing financial relationships between opioid manufacturers and participants in the upcoming FDA workshop warrant your intervention to investigate and minimize potential conflicts of interest when addressing a matter literally of life and death. I appreciate your attention to this important issue and your consideration of my requests.

Sincerely,

Ron Wyden Ron Wyden

Ranking Member

⁵⁵ Fred Wells Brason, "Exploring Naloxone Uptake and Use Public Meeting," July 1-2, 2015, https://www.fda.gov/downloads/Drugs/NewsEvents/UCM454759.pdf, accessed May 5, 2015.

KemPharm, Inc., "Product Portfolio: Pain," http://www.kempharm.com/pages/pipeline/pain.php, accessed May 5, 2017.

⁵⁷ Project Lazarus website, https://www.projectlazarus.org/, accessed May 5, 2017.

⁵⁸ Purdue Pharma, L.P., "Purdue Pharma, Project Lazarus and Safe Kids NC Partner to Improve Public Health Outcomes in North Carolina through the North Carolina Disposal Initiative," April 5, 2017, http://www.purduepharma.com/newsmedia/2017/04/purdue-pharma-project-lazarus-and-safe-kids-nc-partner-to-improve-public-health-outcomes-in-north-carolinathrough-the-north-carolina-disposal-initiative/, accessed May 5, 2017.

Paige Winfield Cunningham, "Model program to fight drug abuse falls flat," Washington Examiner, April 3, 2016, http://www.washingtonexaminer.com/model-program-to-fight-drug-abuse-falls-flat/article/2587359.

Project Lazarus, Form 990-EZ for the year ending 2011,

http://990s.foundationcenter.org/990_pdf_archive/270/270602284/270602284_201112_990EZ.pdf, accessed May 5, 2017.

⁶¹ Coastlands Ministries, Form 990 for the year ending 2015, http://990s.foundationcenter.org/990 pdf archive/562/562087110/562087110 201512 990.pdf, accessed May 5, 2017.