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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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To: Members of the Senate Finance Committee
From: Senator Chuck Grassley, Chairman of the Senate Finance Committee
Senator Ron Wyden, Ranking Member of the Senate Finance Committee
Date: December 16, 2020
Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities

Dear Colleagues:

As the nation continues to respond to the COVID-19 pandemic, we want to bring your attention back to another concerning public health matter: our nation's opioid epidemic. Opioid overdoses claimed more than 450,000 lives in the United States from 1999 to 2019, and preliminary data from the Centers for Disease Control and Prevention (CDC) suggests drug overdose deaths, including those attributed to opioids, have accelerated since the pandemic began.¹ Indeed, COVID-19 has increased risk factors associated with substance-use disorders (SUDs) and opioid-use disorders (OUDs) like feelings of anxiety, depression, loneliness, and an ongoing sense of uncertainty.² For individuals suffering from these diseases, COVID-19 has even presented additional barriers to treatment and social support services as people are urged to stay-at-home and social distance.³ We are concerned that this will only worsen as our country continues to battle COVID-19 and as social isolation and lack of access to SUD and OUD treatment persists.

As the opioid epidemic and its impact on programs within the Finance Committee's jurisdiction shows no signs of abating, we write to provide you with an update on the

¹ *Opioid Overdose, Data Analysis and Resources*, CTNS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugoverdose/data/analysis.html> (last viewed Dec. 10, 2020).

² Alex Edelman, *Overdose deaths appear to rise amid coronavirus pandemic in U.S.*, NBC NEWS (Oct. 20, 2020), <https://www.nbcnews.com/health/health-news/overdose-deaths-appear-rise-amid-coronavirus-pandemic-u-s-n1244024>; Jon Kamp and Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL ST. J. (Sept. 8, 2020), <https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401>.

³ Jon Kamp and Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL ST. J. (Sept. 8, 2020), <https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401>. See also DEP'T OF HEALTH AND HUMAN SERVS., OFF. OF INSPECTOR GEN., OPIOID TREATMENT PROGRAMS REPORTED CHALLENGES ENCOUNTERED DURING THE COVID-19 PANDEMIC AND ACTIONS TAKEN TO ADDRESS THEM (Nov. 2020), https://oig.hhs.gov/oas/reports/region9/92001001.asp?utm_source=web&utm_medium=web&utm_campaign=covid-A-09-20-01001.

Committee’s ongoing investigation into the financial relationships between opioid manufacturers and tax-exempt organizations. To date, the Committee has identified approximately \$65 million in payments that opioid manufacturers and related companies have made to tax-exempt entities, which suggest that manufacturers view these organizations as helpful extensions of their sales and marketing efforts.

The Committee’s Long-Standing Interest in the Opioid Epidemic

The opioid epidemic has directly impacted Federal health care programs under the Committee’s jurisdiction, and has been a long-standing interest of its members.⁴ The increased use of opioid drugs for long-term chronic non-cancer pain in the 1990’s dramatically increased the number of Medicare and Medicaid patients admitted to hospitals for “opioid overuse.”⁵ By 2017, Medicare and Medicaid covered approximately 73% of 974,000 opioid-related inpatient hospital stays.⁶ Furthermore, earlier this year, and before the COVID-19 pandemic, the Office of Inspector General at the Department of Health and Human Services (HHS OIG) reported that 267,000 Medicare Part D beneficiaries received high amounts of opioids in 2019, and 209,000 beneficiaries received medically assisted treatment.⁷ And, while the HHS OIG found that opioid use in Medicare Part D had decreased in 2019 (when compared to the past 3 years) due to the efforts of the Department of Health and Human Services (HHS) and others, it stressed the critical need to remain diligent, especially during the COVID-19 pandemic.⁸

Over the past eight years, we have used our leadership positions to seek greater transparency into the financial relationships between opioid manufacturers and tax-exempt organizations. Our work reveals that opioid manufacturers have maintained extensive financial relationships with tax-exempt organizations, including pain advocacy groups, professional provider groups, and medical associations. In turn, these groups have sought to influence opioid prescribing practices and related Federal policy connected to opioid use and pain care that directly affects Medicare and Medicaid. Given these ongoing concerns, on June 28, 2019, we sent letters to 10 tax-exempt organizations and requested information about their financial relationships with opioid manufacturers.⁹ These groups included:

⁴ Senator Grassley, in his capacity as Ranking Member of the health subcommittee, co-chaired the Committee’s first hearing on the opioid epidemic in 2012. *Prescription Drug Abuse: How are Medicare and Medicaid Adapting to the Challenge?*, Hearing Before Subcomm. On Health of the S. Fin. Comm. 112th Cong. (2012), <https://www.finance.senate.gov/hearings/prescription-drug-abuse-how-are-medicare-and-medicaid-adapting-to-the-challenged>.

⁵ The number of combined hospital inpatient stays among Medicare and Medicaid beneficiaries increased from 126,500 in 1993 to 437,800 in 2012. See *Hospital Inpatient Utilization Related to Opioids Overuse Among Adults 1993-2012*, AHRQ Table 2 (Aug. 2014), <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf>.

⁶ *HCUP Fast Stats – Opioid-Related Hospital Use*, AHRQ, <https://www.hcup-us.ahrq.gov/faststats/OpioidUseMap> (last viewed Nov. 25, 2020).

⁷ DEP’T OF HEALTH AND HUMAN SERVS., OFF. OF INSPECTOR GEN., OPIOID USE IN MEDICARE PART D CONTINUED TO DECLINE IN 2019, BUT VIGILANCE IS NEEDED AS COVID-19 RAISES NEW CONCERNS (Aug. 13, 2020), <https://oig.hhs.gov/oei/reports/OEI-02-20-00320.asp>.

⁸ *Id.*

⁹ Press Release, Grassley, Wyden Press for Answers on Financial Relationships Between Opioids Manufacturers and Tax-Exempt Organizations (July 1, 2019), <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-press-answers-financial-relationships-between-opioid-manufacturers>.

1. American Chronic Pain Association
2. American Pain Society
3. American Society for Pain Management Nursing
4. American Society of Pain Educators
5. Center for Practical Bioethics
6. Federation of State Medical Boards
7. The Joint Commission
8. American Academy of Physical Medicine and Rehabilitation
9. Alliance for Patient Access
10. International Association for the Study of Pain

We requested complete Internal Revenue Service (IRS) Form 990s filed for each year between 2012 and 2019, as well as a detailed accounting of all payments and transfers including, but not limited to, contributions, grants, advertising, program scholarship, and other revenue and remuneration.¹⁰ In a separate, but related inquiry, Senator Wyden also requested information from the U.S. Pain Foundation and the American Academy of Pain Medicine.¹¹

The goal of our requests was to identify these groups' largest pharmaceutical donors and to ascertain whether these payments influenced the organizations' activities in any way, especially as they pertain to opioids and opioid prescribing practices. This investigation also built on work the Committee began in 2012, when then-Chairman Max Baucus of the Senate Finance Committee and then-Ranking Member Chuck Grassley of the Senate Judiciary Committee examined Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson's financial relationship with tax-exempt medical groups, and included questions about payments made to physicians who specialize in pain management.¹² Ranking Member Wyden subsequently sent letters to Secretary Burwell,¹³ Secretary Price,¹⁴ Secretary Azar¹⁵ and the National Academy of Medicine,¹⁶ raising concerns about conflicts of interest of various members of Federal advisory

¹⁰ *Id.*

¹¹ Letter from Senator Ron Wyden to Dr. Jianguo Cheng, President, American Academy of Pain Medicine (Mar. 12, 2019), <https://www.finance.senate.gov/imo/media/doc/031319%20Wyden%20letter%20to%20AAPM.pdf>; Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018), <https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20the%20U.S.%20Pain%20Foundation.pdf>.

¹² Press Release, Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups (May 8, 2012), <https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups>.

¹³ Letter from Senator Ron Wyden to Sylvia Burwell, Secretary, Department of Health and Human Services (Feb. 5, 2016), <https://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS%20Opioid%20Conflicts.pdf>.

¹⁴ Press Release, Wyden Asks Price to Delay Federal Opioid Workshop Until Industry Conflicts are Examined (May 8, 2017), <https://www.finance.senate.gov/ranking-members-news/wyden-asks-price-to-delay-federal-opioid-workshop-until-industry-conflicts-are-examined>.

¹⁵ Press Release, Wyden Reveals Opioid Industry Ties on HHS Task Force, Probes Advocacy Group's Finances (Dec. 19, 2018), <https://www.finance.senate.gov/ranking-members-news/wyden-reveals-opioid-industry-ties-on-hhs-task-force-probes-advocacy-groups-finances>.

¹⁶ Press Release, Wyden Concerned by National Academy Ties to Opioid Manufacturers (July 5, 2016), <https://www.finance.senate.gov/ranking-members-news/wyden-concerned-by-national-academy-committee-ties-to-opioid-manufacturers>.

panels who were financially linked to industry or industry-backed groups that are the subject of this investigation.¹⁷

2012: The Investigation Begins

The financial information collected during the Committee’s 2012 inquiry showed that Purdue Pharma, L.P., (Purdue), Endo Pharmaceuticals (Endo), and Johnson & Johnson maintained strong financial ties to tax-exempt organizations and, in some cases, paid millions of dollars to them.¹⁸ For example, Purdue reported to the Committee that it had made payments to a handful of tax-exempt organizations totaling more than \$18 million. Between 1997 and 2012, these payments included approximately \$3.6 million to the (now-defunct) American Pain Foundation, \$3.6 million to the Center for Practical Bioethics, and \$3 million to the American Pain Society, which filed for bankruptcy in 2019.¹⁹

These payments were part of a broad strategy Purdue took to fund tax-exempt groups. Between 2006 and 2010, an internal presentation showed that the company spent \$24.5 million on education grants and donations, funding hundreds of requests annually.²⁰ The company also met with and closely tracked encounters with pain societies, professional associations, and professional licensing boards and “developed message points for internal and external stakeholders.”²¹ (The same internal presentation shows that the American Pain Foundation, American Pain Society, American Academy of Pain Medicine, the American Board of Pain Medicine, and the American Society of Pain Educators,²² were organizations with close ties to Purdue at the time).²³

Such deep cooperation was on display at the American Pain Foundation—a now-defunct, but once-influential non-profit. According to the American Pain Foundation’s 1998 business plan, “most pain sufferers are under-medicated” and “many [physicians] are reluctant to prescribe opioids because they mistakenly think their patients will become addicted to the drug or because they fear investigation and sanctions by regulatory bodies.”²⁴ The American Pain

¹⁷ Ranking Member Wyden’s letters were based in part on information contained in CMS’s Open Payments database created by the Physician Payment Sunshine Act that Chairman Grassley championed in the Senate.

¹⁸ Letter from Theodore Hester, Counsel, King & Spalding, on Behalf of Purdue Pharma, to Senator Baucus and Senator Grassley (June 8, 2012); Letter from Raymond V. Shepherd, Counsel, Venable, on Behalf of Endo Pharmaceuticals, to Senator Baucus and Senator Grassley (June 15, 2012); Letter from Daniel Donovan, Counsel, King & Spalding, to Senator Baucus and Senator Grassley (June 8, 2012); SFC00000001; JJ-SFC-00000001-10.

¹⁹ SFC00000001. *See also* Appendix A and B.

²⁰ SFC00002172, at SFC00002193.

²¹ *Id.* at SFC00002175-76, SFC00002179, SFC00002220, SFC00002186.

²² The American Society of Pain Educators was founded in 2004. It operated as a tax-exempt organization from 2004 until 2012, when the IRS revoked its status. ASPE’s activities included providing tests that certified providers as “pain educators,” and public tax records show it was involved in a number of medical communications activities. ASPE is closely associated with Aventine Co., a medical communications firm based in New Jersey, which has done business as *PainWeek*, a conference and communications franchise that features presentations from many people with professional and financial ties to opioid manufacturers. *PainWeek* was purchased by an Irish media company in 2015 in a multi-million acquisition. Purdue was one of several pharmaceutical companies that maintained “corporate memberships” with ASPE. *See* ASPE_000029-30.

²³ SFC00002172, at SFC00002175-76, SFC00002179, SFC00002220, SFC00002186.

²⁴ American Pain Foundation’s 1998 Business Plan, at 3-2. Emphasis added.

Foundation’s goal at the time was to reduce the “percentage of Americans who agree that it is easy to become addicted to pain medicine.”²⁵

Purdue was the American Pain Foundation’s largest funder during the organization’s early years of existence, and the company repeatedly sent the organization checks exceeding \$100,000, as well as other financial assistance such as underwriting “challenge grants.” Documents also show that as the foundation solicited funds from Purdue, it provided the company’s top executives frequent and detailed updates, including to its president, Richard Sackler.²⁶ The accomplishments memo sent to Mr. Sackler highlighted multiple initiatives, including state and Federal lobbying efforts, and a public relations efforts to fight “misconceptions about [o]pioids in the [p]ress,” noting that it had sent background materials to 1,200 health journalists.²⁷

Similarly, in 2007, Purdue and the American Pain Foundation worked closely to draft talking points for use during the Pain Care Forum, a coalition of drug manufacturers and other advocacy groups that met monthly to discuss opioid-related issues. According to these talking points:

Overly restrictive regulatory policies impeded pain relief . . . [and] other barriers to effective pain care include . . . the public—including doctors and people with pain—often believe that opioid medications are addictive and produce euphoria. The fact is that when properly prescribed by a health care professional and taken as directed, these medications give relief – not a ‘high.’²⁸

After reviewing these draft talking points, a Purdue Pharma official wrote in track changes, “Do we want an ethical message . . . like if as a [health care provider] if you know the right thing to do and you don’t do it . . . or the moral obligation to treat suffering????”²⁹ An employee of the American Pain Foundation wrote in a subsequent email that she amended the talking points to reflect the Purdue Pharma official’s suggestions.³⁰

In addition to its close financial relationships with the American Pain Foundation, Purdue reported paying \$2.1 million to the Joint Commission for Accreditation of Health Organizations (now known as the “Joint Commission”), a standard-setting body for the health care industry. The data produced in response to the Committee’s 2012 investigation shows that this organization also received “support for pain management activities” from Johnson & Johnson, Ortho McNeill (now Janssen), National Pharmaceutical Council, Endo, Pfizer, and Abbott Labs.³¹ This financial support occurred primarily between 2000 and 2002, when the Commission was developing a pain care guide and other materials that were distributed to providers.

The pain care guide notes that “[s]ome clinicians have inaccurate and exaggerated concerns” about addiction, tolerance and risk of death, and that “[t]his attitude prevails despite

²⁵ *Id.*

²⁶ See APF65-111, APF298-99.

²⁷ APF65-69.

²⁸ SFC00011527-29.

²⁹ *Id.*

³⁰ SFC00011511.

³¹ Letter from Mark Chassin, President, The Joint Commission, to Senators Baucus and Senator Grassley (June 29, 2012).

the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”³² The Commission’s data further disseminates these payments:

- In October 2001, Purdue funded the publication of a book for “Pain assessment and management: an organizational approach,” totaling \$58,272. The company also funded two videos in August 2000 for “Pain Management in Special Populations: Geriatric and Disease Related Pain,” totaling \$85,000.³³
- In 2001, Ortho McNeill (now Janssen) provided funding for “Pain Management: An Overview for Clinicians audioconference,” totaling \$66,000.³⁴
- The National Pharmaceutical Council paid \$155,104 between 2001 and 2002 for the Joint Commission to develop “a monograph designed as a reference for clinicians, quality professionals, researchers and others involved in performance assessment, improvement, education, and policy decisions related to pain management within health care organizations.”³⁵

Such initiatives were lumped in with other sales and marketing investments that opioid manufacturers made to expand the market footprint of their products. For example, this approach was on display in a pair of presentations created for Opana ER, an opioid drug marketed by Endo. (The company would later stop marketing in response to an unprecedented request from the Food and Drug Administration (FDA) which determined that the “benefits of the drug may no longer outweigh its risks.”)³⁶ Ten years earlier, Endo identified such a threat in a multi-year business plan for Opana ER stating: “increased awareness of Rx abuse may lead to tighter governmental oversight and new restrictions for opioid analgesics.”³⁷

Even though Endo knew of these risks, the company’s business plan for marketing Opana ER included “utilize[ing] existing and newly trained pain specialist speakers” in an effort to provide a platform for dialogue between pain specialists and the pain care physician community to discuss the features and benefits of Opana ER.”³⁸ The business plan goes on to cite two physicians who served as speakers, including Bill McCarberg, a physician who Endo reported paying more than \$45,000 from the company for honoraria, sales support, and pain education from 2001 to 2006.³⁹ McCarberg, who at one point led the American Academy of Pain Medicine,⁴⁰ has received over \$700,000 from pharmaceutical manufacturers since 1998, including opioid makers Johnson & Johnson, Purdue, Pfizer, Collegium Pharmaceuticals and

³² Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J. (Dec. 17, 2012), <http://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

³³ Letter from Mark Chassin, President, The Joint Commission, to Senator Baucus and Senator Grassley (June 29, 2012); Attachment A.

³⁴ *Id.*

³⁵ *Id.*

³⁶ Press Release, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse>

³⁷ SFC-00025042, at SFC-00025056.

³⁸ *Id.* at SFC-00025072-75.

³⁹ SFC00000001.

⁴⁰ SFC-00025042, at SFC-00025079.

Janssen Pharmaceuticals.⁴¹ Open Payments data further underscores the importance manufacturers' place on these relationships. Endo has provided more than \$28 million to physicians, as well as sponsored research and development initiatives since 2013.⁴² Similarly, Purdue provided \$89 million to physicians and sponsored research during the same period.⁴³

Endo also heavily invested in tax-exempt organizations focused on pain issues during this period. Endo reported that it made payments of \$5.9 million to the American Pain Foundation, \$4.2 million to the American Pain Society, \$1.3 million to the American Academy of Pain Medicine, and \$369,000 to the Federation of State Medical Boards between 1998 and 2012.⁴⁴ An internal presentation created for Endo's scientific affairs team in 2011 describes the company's interest in such investments, and the importance of developing "strategic partnerships . . . that further advance the coordination of the professional, patient, gov't and community advocacy efforts."⁴⁵ The presentation also highlighted efforts to advocate for tamper resistant opioids and the company's "strategic third party partnerships" with the American Pain Society, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, American Academy of Pain Management, Advanced Pain & Spine Institute, the Arthritis Foundation, National Council on Aging, and its membership in 17 State Pain initiatives.⁴⁶ It further notes that the company was "indisputably recognized as leader by the Pain Community and primary care for all pain therapeutic areas," citing its role in mobilizing a "rapid response" to an FDA proposal related to acetaminophen, securing an author for a white paper in the journal *Pain Medicine*, and leading in development of Risk Evaluation and Mitigation Strategies or REMS.⁴⁷

Endo's business plan likewise noted the value of collaborating with tax-exempt organizations, their executives, and their board members. It identified conferences, and articles in their publications as components of a multi-channel marketing strategy to increase prescription volume.⁴⁸ For example, a pocket card for managing pain—and, endorsed by the American

⁴¹ Johnson & Johnson reported to the Committee that it paid McCarberg more than \$109,000 from 2003 to 2010 for promotional speaker fees, advisory board work, and honoraria. Purdue Pharma reported paying McCarberg nearly \$51,000 from 1998 to 2005 for lecture programs, consulting fees, and clinical research. Open Payments data further shows that McCarberg was paid more than \$504,000 from pharmaceutical manufacturers from 2013 to 2019, including tens of thousands of dollars while he was head of the American Academy of Pain Medicine. *Open Payments Data, Physician Profile for Bill McCarberg*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/117086> (last viewed Dec. 2, 2020).

⁴² *Endo Pharmaceuticals, Inc.*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/company/100000000285> (last viewed Nov. 25, 2020).

⁴³ *Purdue Pharma, L.P.*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/company/100000005432> (last viewed Dec. 2, 2020)

⁴⁴ Endo Pharmaceuticals, Inc. payments to organizations.

⁴⁵ SFC-00057051, at SFC-00057069.

⁴⁶ *Id.* at SFC-00057069, SFC-00057071. Data collected by the Committee in 2019 shows that Endo's relationship with the organizations continued. The company paid the American Academy of Pain Medicine \$149,950 from 2013 to 2016 for corporate memberships, and various advertising at annual meetings. Endo also paid the American Academy of Physical Medicine and Rehabilitation \$30,000 to maintain a seat on the organization's industry relations council from 2012 to 2014, and \$8,500 to sponsor Risk Evaluation and Mitigation Strategies (REMS) at a 2012 annual assembly.

⁴⁷ *Id.* at SFC-00057069.

⁴⁸ SFC-00025042.

Society of Pain Educators⁴⁹—was among a list of “valued added initiative[s]” that “Endo sales representatives perceived as adding higher value than competitive representatives.”⁵⁰ During the two years leading up to the business plan presentation, Endo made contributions and grants to the American Society of Pain Educators totaling at least \$45,000⁵¹ and maintained a corporate membership with the organizations, which involved paying the organization at least \$25,000.⁵² That same year, the American Society of Pain Educators made over \$175,000 in payments to other pain advocacy organizations, including the American Association for Pain Management and the American Pain Society.⁵³

These industry-developed materials and talking points frequently downplayed or distracted from the addictive nature of prescription opioids. At the same time, companies sought to increase brand allegiance among prescribers, and adherence among patients. Meanwhile, prominent pain experts acknowledged that “much remains unknown about the number or types of chronic pain sufferer who will become addicted as a result of medical care,” and an FDA spokesperson said “the risk of addiction to chronic pain patients treated with narcotic analgesics has not been well studied and is not well characterized.”⁵⁴ These efforts directly influenced the medical community, causing them to widely believe that there was a low risk for addiction among patients with chronic pain—a false narrative promoted by opioid manufacturers to increase use of their opioid products.⁵⁵

2019: Senator Grassley and Senator Wyden Expand Their Investigations

In 2019, the Committee broadened its investigation to examine the financial relationships between a wider range of companies and non-profit organizations. We requested and received IRS Form 990s, grant contracts, and financial audits. These data were then compiled to assess each organization’s financial relationship to drug manufacturers that marketed opioids and opioid-related products such as therapies to treat opioid use disorder, opioid overdoses or opioid-induced constipation. Committee staff further analyzed the data to understand the timing and purposes of these payments.⁵⁶ We also sought presentations and other internal documents, which

⁴⁹ In 2016, the National Academies of Sciences, Engineering, and Medicine removed an ASPE board member from a panel studying prescription painkillers, following conflict of interest concerns raised by Ranking Member Wyden. Andrea McDaniels, *Painkiller panel drops experts linked to pharma industry*, BALTIMORE SUN (July 8, 2016), <https://www.baltimoresun.com/health/bs-hs-fda-pain-panel-20160708-story.html>. See also Press Release, Wyden Concerned by National Academy Committee Ties to Opioid Manufacturers (July 5, 2016), <https://www.finance.senate.gov/ranking-members-news/wyden-concerned-by-national-academy-committee-ties-to-opioid-manufacturers>.

⁵⁰ SFC-00025042, at SFC-00025106.

⁵¹ ASPE_001510. (On file with the Committee).

⁵² ASPE_000025-26; ASPE_000027-28.

⁵³ ASPE Form 990 (2007). (On file with the Committee).

⁵⁴ Barry Meier, *The Delicate Balance of Pain and Addiction*, NEW YORK TIMES (Nov. 25, 2003), <https://www.nytimes.com/2003/11/25/science/the-delicate-balance-of-pain-and-addiction.html>.

⁵⁵ Peter Whoriskey, *Rising painkiller addiction shows damage from drugmakers’ role in shaping medical opinion*, WASHINGTON POST (Dec. 30 2012), http://www.washingtonpost.com/business/economy/2012/12/30/014205a6-4bc3-11e2-b709-667035ff9029_story.html.

⁵⁶ These data were categorized for each type of donor (i.e. pharmaceutical company, biotech company, device company, government, hospital, foundation, etc.), and the product developed by that donor (i.e. opioids, opioid-related drugs, non-opioid pain drugs, other drugs, or devices). Categories were also created to systematically label each program type across all organizations. For example, donations were labeled as: “program”, “conference”,

the Committee used in combination with publicly available materials, to review and evaluate the types of activities pursued by organizations that received large sums of money from opioid manufacturers.

Based on payment data collected for this investigation, between 2012 and 2019, drug manufacturers that marketed opioids or opioid-related therapies paid almost \$30 million to these organizations.⁵⁷ As the money rolled in, these organizations conducted activities similar to the ones that Purdue and Endo’s internal documents previously identified as helpful to their respective businesses. Data collected by the Committee show that Teva Pharmaceuticals (Teva), Pfizer, Inc. (Pfizer), and Purdue were among the largest funders of these organizations. Teva led the way, having paid over \$4.8 million, the largest beneficiaries of which included the American Chronic Pain Association, the International Association for the Study of Pain, the American Academy of Pain Medicine, the American Pain Society, and the U.S. Pain Foundation. Pfizer made payments of roughly \$4.1 million, the largest share of which went towards funding programs at the International Association for the Study of Pain and the American Academy of Pain Medicine. Purdue paid \$2.8 million, with the majority going to the American Association for Pain Medicine, the American Academy of Physical Medicine and Rehabilitation, and the American Chronic Pain Association. Other major funders included Daiichi Sankyo, which made payments of nearly \$2 million, Endo, which made payments of almost \$1.8 million, and AbbVie, which made payments of more than \$1.6 million. In all, the Committee found that the tax-exempt organizations had received money from more than 40 pharmaceutical companies that market opioids or opioid-related products.

The data also shows that fees for opioid and opioid-related work is one of the biggest sources of revenue for some of these organizations. Together, Alliance for Patient Access, the American Academy of Pain Medicine, the American Chronic Pain Association, International Association for the Study of Pain, and the U.S. Pain Foundation received \$23 million—millions of which came in the form of grants from drug and device manufacturers for opioid and opioid-related work. For example, the International Association for the Study of Pain received more than \$4 million in funding from opioid manufacturers between 2012 and 2019. The Alliance for Patient Access came in at a close second, receiving \$4.2 million.

By contrast, the American Society for Pain Management Nursing, Center for Practical Bioethics, and The Joint Commission all received less than \$600,000 in payments for opioid and opioid-related work between 2012 and 2019. The Federation of State Medical Boards is the only organization that did not report receiving any funding from drug or device manufacturers between 2012 and 2019, opting instead to adopt a policy which precludes its acceptance of any grants or funding from pharmaceutical companies.⁵⁸ The Federation of State Medical Boards appears to have changed its policy shortly after the Committee’s 2012 inquiry which showed that, between 2007 and 2012, the organization received approximately \$1.3 million from Purdue,

“membership fees”, “grant”, “advocacy”, “advertising” and “education/lecture”. When possible, all payments were cross-referenced with 990 forms and other financial statements to eliminate duplicate observations. [hereinafter “payment data”]

⁵⁷ See Form 990s and accompanying Schedule Bs. (On file with the Committee).

⁵⁸ Letter from Humayun Chaudhry, President and CEO, Federation of State Medical Boards, to Senator Grassley and Senator Wyden (July 29, 2019).

Johnson & Johnson, and Endo.⁵⁹ The American Pain Society filed for bankruptcy the day it received our June 28th letter due to legal costs related to opioid litigation.⁶⁰

The American Chronic Pain Association

The American Chronic Pain Association (ACPA) provides a clear example of how a tax-exempt organization benefited from opioid manufacturers funding its activities. The organization received funding from opioid makers, medical device manufacturers, and companies that market therapies for opioid-related conditions. These payments funded materials that appear to help sell products sold by opioid manufacturers, discussed opioid therapy while sidestepping the addictive nature of the drugs, and attributed responsibility for overdoses to people who misuse opioids.

For example, in recent years, the ACPA has received funding for videos that promote “abuse-deterrent formulation” opioids. Daiichi Sankyo, which sells an opioid with an abuse-deterrent label called MorphaBond (morphine sulfate),⁶¹ paid the ACPA \$75,000 to support the organization’s abuse deterrent activities in 2018. The payment appears to be connected to a survey and video the company funded one month earlier.⁶² The video that was subsequently posted on the ACPA’s website opens with the host saying “pharmaceutical companies that make opioid medications now offer versions of these drugs that are more difficult to misuse,” before moving to a series of questions and answers with a pain doctor who, for the most part, hews closely to warnings on the drug’s FDA label.⁶³ (It’s important to note that abuse-deterrent formulations have not been proven to be any less addictive than other types of opioids).⁶⁴ The doctor (Ajay Wasan, now president of the American Academy of Pain Medicine) has received \$26,000 in payments from opioid manufacturers.⁶⁵ At one point in the video, Dr. Wasan appears to downplay the risk of addiction for patients using abuse-deterrent opioids:

It is possible to get addicted to abuse-deterrent formulations. It's *unusual*, but one way is if someone takes an opioid and immediately feels a high. That is one possibility that can lead to addiction. The other possibility is if someone misuses

⁵⁹ Letter from Raymond V. Shepherd, Counsel, Venable, to Senator Baucus and Senator Grassley (June 15, 2012); SFC00000001; JJ-SFC_00000001.

⁶⁰ Alia Paavola, *American Pain Society files for bankruptcy as legal costs mount*, BECKER HOSPITAL REVIEW (July 1, 2019), <https://www.beckershospitalreview.com/pharmacy/american-pain-society-files-for-bankruptcy-as-legal-costs-mount.html>.

⁶¹ Press Release, Daiichi Sankyo, Daiichi Sankyo, Inc. and Inspirion Delivery Sciences LLC Announce U.S. Licensing Agreement for MorphaBond™ Formulated with SentryBond™ Abuse-Deterrent Technology (Oct. 26, 2016), https://www.daiichisankyo.com/media/press_release/detail/index_3394.html.

⁶² SFC_ACPA_0006. (On file with the Committee). *See also* SFC_ACPA_0221-39.

⁶³ *Abuse Deterrent Formulation*, AMERICAN CHRONIC PAIN ASSOCIATION at 0:27 to 0:34, <https://www.theacpa.org/abuse-deterrent-formulations/> (last viewed Nov. 27, 2020).

⁶⁴ *Abuse-Deterrent Opioids Analgesics*, FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics> (last updated June 11, 2019). (Here the FDA acknowledges that ADFs are not addiction proof, and highlights that it is requiring manufacturers with ADF labeling claims to conduct post-market studies to determine the real world impact of their products). *Id.*

⁶⁵ *Open Payments Data, Physician Profile for Steven Feinberg*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/1272772/general-payments> (last viewed Nov. 27, 2020).

their medications and takes extra medications over and over again. That can also lead to addiction.⁶⁶ (Emphasis added).

In the February letter to Daiichi Sankyo, Penny Cowan, President of the ACPA, notes that the manufacturer's money would support an anonymous survey done on people with pain in order to "investigate general population knowledge, attitudes, beliefs and behaviors as it relates to opioids and [abuse-deterrent formulation]."⁶⁷ She goes on to explain that the survey will inform the video content by "address[ing] the misconceptions and help them understand what they need to know about [abuse-deterrent formulations], so they are used, stored and dispose[d] of properly."⁶⁸ She further states "this video will communicate all aspects of [abuse-deterrent formulations] and the importance of their use," and would be posted to ACPA's website as well as turned into a DVD for distribution to health care professionals, at medical conventions, for patient education, and would be incorporated into all of ACPA's presentations.⁶⁹ The ACPA estimated that around 50,000 people will view the video.⁷⁰

While much of the ACPA's funding came from opioid manufacturers, companies that have a financial stake in opioid-based pain treatment also contributed heavily to the organization. In turn, the organization produced programming and materials that hewed closely to the company's business interests, including at least one instance in which products were referred to in the material.⁷¹ AstraZeneca, which markets Movantik (naloxegol),⁷² a drug used to treat opioid-induced constipation, heavily funded the ACPA's opioid-induced constipation programming. In 2014, the same year that Movantik received FDA approval,⁷³ AstraZeneca was one of ACPA's corporate members that paid the organization tens of thousands of dollars annually to maintain its status. In addition, the company paid ACPA \$215,000 in a two-year span to fund programming related to opioid-induced constipation.⁷⁴ (During the same time period, ACPA's expenses related to opioid-induced constipation was \$207,000, according to a financial

⁶⁶ *Abuse Deterrent Formulation*, AMERICAN CHRONIC PAIN ASSOCIATION at 2:21, <https://www.theacpa.org/abuse-deterrent-formulations/> (lasted viewed Nov. 27, 2020).

⁶⁷ SFC_ACPA_0221-39.

⁶⁸ *Id.* at SFC_ACPA_0221.

⁶⁹ *Id.* at SFC_ACPA_0229.

⁷⁰ *Id.* at SFC_ACPA_0233.

⁷¹ *See Opioid Induced Constipation*, AMERICAN CHRONIC PAIN ASSOCIATION, at 4:22. <https://www.theacpa.org/pain-management-tools/surveys/oic/> (last viewed Nov. 27, 2020). In this video, the narrator states that, if over-the-counter medication and increasing hydration is not enough, patients should consider methylbuprenorphine or naloxegol, as these are "easier to take" than other treatment options. *Id.* It's important to note that naloxegol is manufactured under the trade name MOVANTIK™ by AstraZeneca. *See* Press release, AstraZeneca, FDA approves MOVANTIK™ (naloxegol) tablets C-II for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain (Sept. 16, 2014), <https://www.astrazeneca.com/media-centre/press-releases/2014/fda-approved-movantik-opioid-induced-constipation-chronic-non-cancer-pain-patients-16092014.html#>.

⁷² Press release, AstraZeneca, FDA approves MOVANTIK™ (naloxegol) tablets C-II for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain (Sept. 16, 2014), <https://www.astrazeneca.com/media-centre/press-releases/2014/fda-approved-movantik-opioid-induced-constipation-chronic-non-cancer-pain-patients-16092014.html#>.

⁷³ *Id.*

⁷⁴ SFC_ACPA_0127-41.

audit).⁷⁵ One video produced by ACPA, titled “Opioid Induced Constipation,”⁷⁶ singles out AstraZeneca’s product, even though at least one study published five months prior found that a competing product, subcutaneous methyl naltrexone, “was found to perform better than other interventions for managing opioid-induced constipation.”⁷⁷

Other educational videos posted on the ACPA’s website specifically target conditions and treatments for pain. For instance, several videos are dedicated to explaining implantable medical devices like medication pumps and neurostimulators for treating pain. These videos are funded by Medtronic, a device manufacturer of pain medication pumps and nerve stimulators,⁷⁸ which donated \$100,000 for the production of a DVD and web segment on implantable devices.⁷⁹ Other videos walk the viewer through how the devices work, as well as benefits, risks, goals for treatment, what is involved in implantation procedures, what living with a pump is like, and maintenance of the pump.⁸⁰ One physician featured in the video is an anesthesiologist who received 235 payments, for a total of \$113,830, from Medtronic between 2013 and 2018.⁸¹

Alliance for Patient Access

Some tax-exempt organizations also proved to be helpful vehicles for opioid manufacturers to lobby the Federal government. One example is the Alliance for Patient Access (AfPA), an organization that describes itself as “a national network of physicians and other health care providers dedicated to ensuring patient access to approved therapies and appreciate clinical care.”⁸² In 2017, all of the AfPA’s approximately \$2 million in revenue was generated from contributions and grants, of which 90% were from pharmaceutical manufacturers.⁸³ Of these payments, three opioid makers accounted for 17% of contributions to the AfPA that year—Teva (\$225,000), Mallinckrodt (\$75,000), and Pfizer (\$40,000). Opioid manufacturers have consistently made large contributions to the AfPA. Since 2012, the AfPA has received at least \$2.1 million in payments from opioid manufacturers including AbbVie, Endo, Grunenthal, Mallinckrodt, Pfizer, Purdue and Teva.

Open Payments data further shows that opioid manufacturers’ influence at the AfPA does not stop at direct payments to the organization. Doctors who sat on the organization’s board of

⁷⁵ SFC_ACPA_0067, at SFC_APCA_0069, 0077, 0089, 00102.

⁷⁶ See also *Opioid Induced Constipation*, AMERICAN CHRONIC PAIN ASSOCIATION, <https://www.theacpa.org/pain-management-tools/surveys/oic/>.

⁷⁷ See Kannan Sridharan, Gowri Sivaramakrishnan, *Drugs for Treating Opioid-Induced Constipation: A Mixed Treatment Comparison Network Meta-analysis of Randomized Controlled Clinical Trials*, J. OF PAIN AND SYMPTOM MANAGEMENT 55(22): 468-479 (2018), <https://pubmed.ncbi.nlm.nih.gov/28919541/>.

⁷⁸ *Drug Infusion Systems*, MEDTRONIC, <https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/drug-infusion-systems.html> (last visited Nov. 27, 2020).

⁷⁹ SFC_ACPA_572, at SFC_ACPA_573-75, 593.

⁸⁰ *Intrathecal Medication Pumps*, AMERICAN CHRONIC PAIN ASSOCIATION, <https://www.theacpa.org/pain-management-tools/videos/conditionstreatments/> (last viewed Nov. 27, 2020).

⁸¹ *Open Payments Data, Physician Profile for David Provenzano*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/172676> (last viewed Nov. 27, 2020).

⁸² Letter from Sam Dewey, Counsel, McDermott Will & Emery, on behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019).

⁸³ AfPA Form 990 (2017). (On file with the Committee).

directors have received more than \$5 million in payments from pharmaceutical manufacturers and device manufacturers, of which more than \$1.9 million came from opioid makers.⁸⁴

Since 2013, Director Srinivas “Sri” Nalamachu, alone, received nearly \$1.7 million in payments from pharmaceutical companies, of which \$792,000 came from opioid makers—Purdue (\$231,000), Collegium Pharmaceutical (\$148,000), Endo (\$113,000), Insys (\$103,000), Assertio (\$81,000), Pernix Therapeutics (\$63,000) and Teva (\$53,000).⁸⁵ Similarly, Director Robin Dore received more than \$2.1 million from pharmaceutical manufacturers since 2013, including \$538,000 from opioid makers Pfizer (\$286,000), AbbVie (\$145,000), and UCB (\$107,000).⁸⁶ Opioid makers also paid Director Jack Schim \$271,000 and Howard Hoffberg \$180,000.⁸⁷ As the AfPA and its board received millions of dollars from opioid makers, the organization lobbied executive branch agencies and Congress on legislation related to opioids.⁸⁸ The AfPA also joined other organizations funded by opioid manufacturers that sought to limit restrictions on opioid prescribing while promoting expanded use of so-called “abuse-deterrent formulations.”

For example, in October 2014, Brian Kennedy, Executive Director of the AfPA, wrote to the National Institutes of Health (NIH) decrying the agency’s focus on “the deleterious effects of treating pain with opioids” and urged the agency to explore “how untreated or under-treated pain affects patients and communities.”⁸⁹ Mr. Kennedy also suggested examples of studies the NIH might consider, including how reducing access to opioid medications may lead to “consequences of restricting access for patients with legitimate medical need” and “higher rates of depression, increased risks of suicide, loss of productivity and restricted mobility that requires additional care for patients.”⁹⁰ The letter pointed to the work of AfPA’s “Pain Therapy Access Physicians Working Group,”⁹¹ arguing that “undertreated pain may result in impaired concentration, which may in turn increase the risk of falls, fractures or motor vehicle injuries.”⁹² What went unsaid is that Pfizer paid the AfPA \$125,000 to fund the working group from 2014 to 2018, and another \$25,000 in 2012 to the Prescription Drug Abuse and Diversion Education Initiative, part of more than \$300,000 the company had paid the AfPA.⁹³ The working group included Dr. Nalamachu and Bob Twillman, who held leadership positions at the American Academy of Pain Management (another group with strong ties to opioid manufacturers).

⁸⁴ The majority of these payments overlapped with directors’ time on AfPA’s board. In some instances, it was not clear when some directors joined or left the board

⁸⁵ *Open Payments Data, Physician Profile for Srinivas Nalamachu*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/158026/general-payments> (last viewed Dec. 3, 2020).

⁸⁶ *Open Payments Data, Physician Profile for Robin Kathleen Doore*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/209026/general-payments> (last viewed Dec. 3, 2020).

⁸⁷ *Open Payments Data, Physician Profile for Howard Hoffberg*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/185850/general-payments> (last viewed Dec. 3, 2020); *Open Payments Data, Physician Profile for Jack D. Schim*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/151945> (last viewed Dec. 3, 2020).

⁸⁸ AfPA_SFC_000193-241.

⁸⁹ *Id.* at AfPA_SFC_000233-34.

⁹⁰ *Id.*

⁹¹ See *Pain Management Working Group*, AfPA, <https://allianceforpatientaccess.org/pain> (last viewed Dec. 2, 2012).

⁹² AfPA_SFC_000193, at AfPA_SFC_000233-34.

⁹³ *Pfizer Medical, Scientific & Patient Education Grant Transparency*, PFIZER, <https://www.pfizer.com/purpose/transparency/transparency-in-grants> (last viewed Nov. 28, 2020).

In another example, on August 27, 2015, Dr. Nalamachu wrote to the FDA “on behalf of AfPA . . . in support of the oxycodone extended-release capsules for oral use submitted by Collegium Pharmaceuticals.”⁹⁴ Dr. Nalamachu wrote that he had been an investigator for the Collegium drug and explained that the “efficacy of oxycodone is well established,” and “further, those of us in pain medicine know how important extended-release formulations are for patients who require around-the-clock pain management.”⁹⁵ The following year, Collegium Pharmaceuticals began making payments directly to Dr. Nalamachu, who would receive more than \$148,000 from the company.⁹⁶

Again, on March 5, 2018, AfPA co-signed a letter with several opioid manufacturers, including Purdue, Grunenthal GmbH, and Collegium Pharmaceuticals, and other tax-exempt organizations funded by opioid manufacturers, raising concerns about a CMS proposal to require prior authorization and dosage limits for abuse-deterrent opioids in Medicare Part D.⁹⁷ The letter highlighted diversion (the practice of transferring legally prescribed opioids to another person for illicit use) as a driver of the opioid epidemic, while sidestepping the fact that the U.S. has significantly higher rates of opioid prescribing when compared to other countries.⁹⁸ The coalition also told CMS that “increasing the availability of [abuse-deterrent] opioids represents a critical component of drug abuse prevention efforts,” and repeatedly touted their benefits to patients even while acknowledging that “[o]pioids with abuse-deterrent properties are not abuse-proof and do not prevent or reduce the risk of addiction.”⁹⁹ The coalition went on to urge CMS to “review plan formularies to ensure adequate access to [abuse-deterrent] opioids.”¹⁰⁰ It was one of three letters AfPA sent with the coalition.¹⁰¹ (Funders of the organization, including Pfizer, Teva, and Purdue, marketed opioids with abuse-deterrent label).

Finally, the AfPA manages a coalition called the Alliance for Balanced Pain Management, which it acquired from Mallinckrodt in 2016.¹⁰² At the time of the acquisition, Mallinckrodt paid AfPA \$200,000 to support the coalition and pay for an annual summit the coalition hosts.¹⁰³ The coalition, which was previously managed by Green Room Communications,¹⁰⁴ describes its mission as advocating “for balanced pain management by supporting organizations and individuals who share a common goal to reduce pain, reduce

⁹⁴ AfPA_SFC_000193, at AfPA_SFC_000232.

⁹⁵ *Id.*

⁹⁶ *Open Payments Data, Physician Profile for Srinivas Nalamachu*, OPENPAYMENTSDATA.CMS.GOV, <https://openpaymentsdata.cms.gov/physician/158026/general-payments> (last viewed Dec. 3, 2020).

⁹⁷ AfPA_SFC_000193-97.

⁹⁸ See Karim Ladhia, et al., *Opioid Prescribing After Surgery in the United States, Canada, and Sweden*, JAMA Network (Sept. 4, 2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/> (An original investigation published in the JAMA Network, which concludes that the United States has the highest average dose of opioid prescriptions for most surgical procedures when compared to Canada and Sweden.).

⁹⁹ AfPA_SFC_000193-97.

¹⁰⁰ *Id.*

¹⁰¹ AfPA_SFC_000193-205.

¹⁰² Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019). AfPA_SFC_000001-05.

¹⁰³ Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020).

¹⁰⁴ *Greenroompr.com*, <https://www.greenroompr.com/> (last viewed Dec. 7, 2020).

medicine abuse and improve care.”¹⁰⁵ Its members include patient groups such as American Chronic Pain Foundation and the U.S. Pain Foundation, which have strong financial links to opioid manufacturers, and is led by a steering committee that includes several individuals who have received roughly \$480,000 from opioid manufacturers, according to CMS’s Open Payments data.¹⁰⁶ The AfPA also told the Committee that the coalition includes industry members, but did not identify them, and further noted that “Mallinckrodt’s representative joined periodic membership calls and had an opportunity to review the Alliance for Balanced Pain Management’s educational materials in response to a group invitation for feedback.”¹⁰⁷ However, the AfPA stated that it maintains sole discretion to determine the coalition’s “advocacy efforts, annual summit events, and educational materials.”¹⁰⁸ According to the AfPA, these efforts have explored “issues such as the value of multimodal analgesia—an opioid-sparing approach to surgical pain, technology-based solutions for treating pain in patients who’ve battled opioid addiction, and the value of non-pharmacologic interventions like physical therapy, chiropractic care, and yoga.”¹⁰⁹

International Association for the Study of Pain

Between 2012 and 2018, fifteen opioid makers paid the International Association for the Study of Pain (IASP) more than \$4 million. These funds were used to support conferences the organization hosted, such as the World Congress on Pain, the International Symposium on Pediatric Pain, the International Congress on Neuropathic Pain, special interest group meetings, and various grants for activities such as the development of a tool to connect “healthcare professionals with access to independently created online education.”¹¹⁰ During this time period, Pfizer was the largest of these contributors, making payments of more than \$1.3 million to IASP, the majority of which were made in the form of grants in 2018. Other opioid manufacturers that made major payments included subsidiaries and affiliates of Mundipharma, (making more than \$1 million in payments combined),¹¹¹ Teva (\$627,000, of which \$300,000 was made in 2018)¹¹² and Allergan (\$161,000). Two Grunenthal entities, and a third party connected to the company, also paid IASP \$601,000 during this time period.

¹⁰⁵ Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020). *About AfBPM*, ALLIANCE FOR BALANCED PAIN MANAGEMENT, <https://alliancebpm.org/events/> (last viewed Nov. 28, 2020).

¹⁰⁶ Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (Jan. 29, 2020).

¹⁰⁷ Letter from the Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of the Alliance for Patient Access, to Senator Grassley and Senator Wyden (July 29, 2019).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ IASP Submission Question 2 Attachment – Accounting Report. (On file with the Committee).

¹¹¹ IASP reported receiving payments during the 2012-2018 period from Mundipharma International (UK), Mundipharma International Ltd., Mundipharma Pte, Mundipharma Pte Limited, MundiPharma PTY (Australia), and Mundipharma Research GmbH.

¹¹² The organization reported to the Committee that it received \$147,550 in payments from Teva in 2018. However, it reported receiving \$300,230 from Teva that year on its IRS Form 990. (On file with the Committee).

Pfizer, which as noted above manufactures two extended-release prescription opioids that the FDA designated as “abuse-deterrent,”¹¹³ made payments of nearly \$4 million to various pain-related tax-exempt organizations, according to payments reviewed by the Committee.¹¹⁴ The largest share of these funds went to IASP. For example, Pfizer provided a \$527,000 education grant to the Japan chapter of the IASP in 2018.¹¹⁵ (This was the single largest payment to IASP from any company during the 2012-2018 time period). The grant was intended to fund nursing student pain education programs, publish medical school textbooks on pain, and develop a recurrent educational program for physical and occupational therapists.¹¹⁶ That grant was part of \$918,000 the organization received from Pfizer that year.

IASP’s activities also suggest that opioid manufacturers are engaging in the same pattern of behavior in Asia and Europe. One such initiative is the World Congress on Pain. Opioid manufacturers have made more than \$2 million in payments to IASP in connection with the last four conferences, which in recent years have been held in Boston, Massachusetts (2018), Yokohama, Japan (2016), Buenos Aires, Argentina (2014), and Milan, Italy (2012).¹¹⁷ The meeting is advertised as the preeminent global meeting devoted to sharing new developments in pain research, treatment, and education, and attendees are predominantly clinicians, researchers, students, and educators.¹¹⁸ Each year, opioid manufacturers have made payments to fund the World Congress events, accounting for up to 16% of the conferences’ total expenses.¹¹⁹

In addition to its global conferences, IASP has also developed region-specific programs to advance the availability and accessibility of opioids. In 2018, Pfizer made a payment of approximately \$190,000 to a program titled, “Develop, Equip, and Pilot: Guide for Multidisciplinary Pain Clinics in South East Asia Project.”¹²⁰ Other programs like “IASP Pain Management Camp” are intensive courses that are designed to provide “information targeted to the educational and organizational aspects of health-care services for pain management” for health care professionals who want to start pain services or are already working with patients with chronic pain.¹²¹ IASP’s Latin America Pain Camp received \$25,000 from Grunenthal in

¹¹³ Press Release, Pfizer, FDA Approves Abuse Deterrent Labeling For Emeda® (Morphine Sulfate and Naltrexone Hydrochloride) Extended-Release (ER) Capsules CII, (Oct. 17, 2014), <https://www.pfizer.com/news/press-release/press-release-detail/>; Press Release, Pfizer, FDA Approves Troxyca® (Oxycodone Hydrochloride and Naltrexone Hydrochloride) Extended-Release Capsules CII with Abuse-Deterrent Properties for the Management of Pain, Pfizer (Aug. 19, 2016), <https://www.pfizer.com/news/press-release/>.

¹¹⁴ Based on IASP’s Form 990s collected during this investigation. (On file with the Committee).

¹¹⁵ IASP Submission Question 2 Attachment – Accounting Report. *See also Pfizer Independent Grants for Learning & Change (IGLC)*, INTERNATIONAL ASSOCIATION FOR THE STUDY OF PAIN, <https://www.iasp-pain.org/Education/GrantDetail.aspx?ItemNumber=7756> (last viewed Nov. 28, 2020).

¹¹⁶ According to IASP, “Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.” *See Pfizer Independent Grants for Learning & Change (IGLC)*, IASP, <https://www.iasp-pain.org/Education/GrantDetail.aspx?ItemNumber=7756> (last viewed Dec. 8, 2020).

¹¹⁷ *Past Congresses*, IASP, <https://www.iasp-pain.org/Meetings/WorldCongressList.aspx> (last viewed Nov. 28, 2020).

¹¹⁸ About the IASP World Congress on Pain, IASP, <https://www.iaspworldcongress.org/attend> (last viewed Dec. 8, 2020).

¹¹⁹ IASP Form 990 (2012-2018). (On file with the Committee.).

¹²⁰ IASP Submission Question 2 Attachment – Accounting Report. (On file with the Committee).

¹²¹ *Latin American Pain Management Camp Leaves Students Smiling*, INTERNATIONAL ASSOCIATION FOR THE STUDY OF PAIN (Nov. 2014), <https://www.iasp-pain.org/PublicationsNews/IASPNewsletterArticle.aspx?ItemNumber=4009>.

2014 and, three years later, received a payment of \$87,000 from Teva to support the “independent development and execution” of the event.¹²² In a similar vein, IASP also offers “pain schools” which are held in North America and Europe, which serve as longer version of the camp program. Sponsors to the North American Pain School include Grunenthal, Eli Lilly, the Mayday Fund, and the American Pain Society.¹²³

Documents provided to the Committee also show that from 2012 to 2019, the IASP received a total of \$1 million from Mundipharma, a global affiliate of Purdue owned by the Sackler family.¹²⁴ This funding has gone towards World Congress on Pain events and special interest group meetings held all over the world.¹²⁵ Mundipharma has reportedly been distributing marketing materials for OxyContin in places like China, Australia, and Italy, and is using the same pitch that Purdue admitted was false in the U.S. more than a decade ago.¹²⁶ For instance, Mundipharma allegedly provided physicians with documents that claimed the risks of opioid addiction were “virtually non-existent and that OxyContin’s slow-release formulation made it even safer.”¹²⁷ Mundipharma is also allegedly targeting China with aggressive sales teams who provide gift cards, complementary dinners, all-expense paid trips to meetings, and compensated speaking events to push opioid prescriptions.¹²⁸

Conclusion

While we continue to evaluate the information produced to the Committee, our initial review has revealed troubling instances in which patient advocacy groups, provider groups, and other tax-exempt organizations, their officers, and their board members have engaged in initiatives that appear to echo and amplify messages to increase use of opioid manufacturers’ drugs, including abuse-deterrent opioids that have not been proven to be any less addictive than other types opioids.¹²⁹

Consumers, health care providers, and policymakers seeking unbiased information may not immediately recognize the significant industry ties these groups possess, especially when they are cited as resources on Federal health websites,¹³⁰ testify before Congress,¹³¹ and have

¹²² IASP Submission Question 2 Attachment – Accounting Report. (On file with the Committee).

¹²³ *Sponsors, Organizers and Supporters*, NORTH AMERICAN PAIN SCHOOL, <https://northamericanpainschool.com/> (last viewed Nov. 28, 2020).

¹²⁴ IASP Submission Question 2 Attachment – Accounting Report. (On file with the Committee).

¹²⁵ *Id.*

¹²⁶ Erika Kinetz, *Fake Doctors, pilfered medical records drive Oxy China Sales*, ABC NEWS (Nov. 20, 2019), <https://abcnews.go.com/Business/wireStory/fake-doctors-misleading-claims-drive-oxycontin-china-sales-67154163>.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Abuse-Deterrent Opioids Analgesics*, FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics> (last updated June 11, 2019). (Here the FDA acknowledges that ADFs are not addiction proof, and highlights that it is requiring manufacturers with ADF labeling claims to conduct post-market studies to determine the real world impact of their products). *Id.*

¹³⁰ *See Resources/References*, NIH Pain Consortium – COEPES, NIH <https://coepes.nih.gov/module/joan-pain-policy-analysis-and-advocacy/resourcesreferences> (last viewed Nov. 28, 2020).

¹³¹ *Managing Pain During the Opioid Crisis*, Hearing Before the S. Comm. Health, Education, Labor & Pension, 116th Cong. (Feb. 2019), <https://www.help.senate.gov/hearings/managing-pain-during-the-opioid-crisis>.

officers that sit on Federal advisory boards.¹³² This is why the Committee is releasing the financial information collected during the 2012 investigation, in addition to data collected over the past two years, because we remain concerned that the opioid epidemic was driven, in part, by misinformation and dubious marketing practices used by pharmaceutical companies and the tax-exempt groups they fund.

Congress must continue to shed light on pharmaceutical and medical device manufacturers' financial dealings with tax-exempt organizations. While such financial entanglements are of particular concern in regards to opioids, given their danger and addictive potential, such funding and influence is not limited to this therapeutic class.¹³³ This investigation clearly shows that such payments are viewed as key marketing and policy influencing tools, which, in the case of opioids, contributed to addiction, sickness, and death for millions of Americans. Therefore, Congress must continue to advocate for stronger safeguards within tax-exempt organizations and within the Federal government. Steps we recommend taking:

1. Expand CMS's Open Payments database to require pharmaceutical manufacturers and device manufacturers to report payments made to tax-exempt organizations.
2. Require the Secretary of HHS to develop guidelines and procedures to increase transparency among members of Federal task forces, as well as research groups and panels convened or contracted by HHS.

In the next Congress, we plan to continue our work on these important issues and we encourage my colleagues to do the same.



Charles Grassley
Chairman
Senate Finance Committee



Ron Wyden
Ranking Member
Senate Finance Committee

¹³² e.g., the FDA's advisory committee on analgesics, which evaluate the safety of opioids includes Kevin Zacharoff who sat on the ASPE board, and Lonnie Zeltzer who was the APS and APF boards. *See Anesthetic and Analgesic Drug Products Advisory Committee Roster*, FDA, <https://www.fda.gov/advisory-committees/anesthetic-and-analgesic-drug-products-advisory-committee/anesthetic-and-analgesic-drug-products-advisory-committee-roster> (last viewed Dec. 10, 2020).

¹³³ *See Drug Pricing in America: A Prescription for Change, Part II: Hearing Before S. Comm. Fin.* 116th Cong. at 70, 147, 477, 529, 716 (2019), <https://www.finance.senate.gov/imo/media/doc/37143.pdf>. *See also* Alex Ruoff, *AbbVie, Bristol-Myers Among Patient Advocacy Groups' Big Backers*, BLOOMBERG, <https://about.bgov.com/news/abbvie-bristol-myers-among-patient-advocacy-groups-big-backers/>.

Appendix A

This appendix contains payment data provided to the Finance Committee by pharmaceutical companies in response to letters sent by Senator Baucus and Senator Grassley in 2012. The data from Endo Pharmaceuticals, Johnson & Johnson, and Purdue Pharma, L.P., show payments made by the companies to tax-exempt organizations from 1997 through early 2012. In total, the companies reported paying the listed organizations more than \$36 million.

Endo/Johnson & Johnson/Purdue Payments (1997-2004)

Company/Organization	1997	1998	1999	2000	2001	2002	2003	2004
Endo Pharmaceuticals		\$35,000	\$215,055	\$237,960	\$272,853	\$283,662	\$361,850	\$627,765
American Academy of Pain Medicine			\$20,090	\$26,500	\$22,000	\$48,150	\$46,200	\$115,000
American Alliance of Cancer Pain			\$13,500					
American Geriatrics Society				\$6,500				\$750
American Pain Foundation			\$20,000	\$25,000	\$20,000	\$25,000	\$15,000	\$40,000
American Pain Society		\$20,000	\$48,665	\$55,935	\$132,400	\$152,162	\$75,650	\$393,015
Beth Israel Medical Center		\$15,000	\$75,000	\$50,000	\$5,000	\$5,000	\$182,000	
Federation of State Medical Boards				\$4,025				
Joint Commission				\$37,500	\$37,500			
University of Wisconsin			\$37,800	\$32,500	\$55,953	\$53,350	\$43,000	\$79,000
Johnson & Johnson	\$189,715	\$495,305	\$206,735	\$518,586	\$239,683	\$155,100	\$108,285	\$465,950
American Academy of Pain Medicine	\$43,500	\$14,400	\$135,140	\$74,050	\$66,764	\$43,975	\$33,000	\$35,620
American Geriatrics Society								\$259,080
American Pain Foundation								\$5,000
American Pain Society	\$146,215	\$480,905	\$71,595	\$444,536	\$158,000	\$111,125	\$75,285	\$166,250
Center for Practical Bioethics								
Joint Commission					\$14,919			
Purdue Pharma	\$172,286	\$200,441	\$764,617	\$1,003,016	\$2,261,102	\$1,795,737	\$2,161,197	\$1,930,897

American Academy of Pain Medicine	\$36,800	\$25,000	\$32,300	\$37,600	\$80,272	\$198,824	\$382,295	\$572,463
American Geriatrics Society	\$11,985	\$24,481	\$38,248	\$78,446	\$127,850	\$68,750		\$1,950
American Pain Foundation			\$250,000		\$606,500	\$15,000	\$461,056	\$250,087
American Pain Society	\$48,501	\$75,960	\$391,520	\$108,065	\$211,211	\$383,530	\$606,332	\$311,603
Beth Israel Medical Center			\$40,000	\$118,542	\$25,000	\$185,615	\$96,334	\$62,679
Center for Practical Bioethics				\$25,000	\$17,500	\$270,000	\$250,000	\$250,000
Federation of State Medical Boards			\$12,549	\$75,363	\$36,410	\$6,345	\$85,180	\$199,895
Joint Commission				\$560,000	\$981,359	\$582,649		
University of Wisconsin	\$75,000	\$75,000			\$175,000	\$85,024	\$280,000	\$282,220
Annual Total	\$362,001	\$730,746	\$1,186,407	\$1,759,562	\$2,773,638	\$2,234,499	\$2,631,332	\$3,024,612

Endo/Johnson & Johnson/Purdue Payments (2005–2012)

Company/ Organization	2005	2006	2007	2008	2009	2010	2011	2012 (Partial Year)	Grand Total 1997-2012
Endo Pharma- ceuticals	\$657,211	\$792,948	\$1,097,939	\$760,628	\$1,620,021	\$2,545,277	\$2,771,140	\$1,286,405	\$13,565,716
American Academy of Pain Medicine	\$137,000	\$237,000	\$125,000	\$155,000	\$80,000	\$80,000	\$85,000	\$135,000	\$1,311,940
American Alliance of Cancer Pain									\$13,500
American Geri- atrics Society	\$95,000	\$40,000	\$112,585		\$44,850	\$17,100	\$25,000		\$341,785
American Pain Foundation	\$5,000	\$20,000	\$138,000	\$51,000	\$671,012	\$2,116,315	\$2,080,171	\$715,173	\$5,941,671
American Pain Society	\$319,961	\$338,650	\$523,038	\$369,628	\$748,178	\$75,000	\$528,969	\$430,232	\$4,211,484
Beth Israel Medical Center	\$57,250	\$52,298	\$24,316	\$60,000	\$35,981	\$32,500	\$40,000		\$634,345
Federation of State Medical Boards		\$40,000	\$100,000	\$100,000		\$125,000			\$369,025
Joint Commission									\$75,000
University of Wisconsin	\$43,000	\$65,000	\$75,000	\$25,000	\$40,000	\$99,362	\$12,000	\$6,000	\$666,965
Johnson & Johnson	\$172,193	\$51,255	\$65,250	\$101,580	\$58,775	\$424,509	\$785,329	\$40,500	\$4,078,750

American Academy of Pain Medicine	\$21,300	\$13,375	\$42,050	\$20,000	\$5,000	\$5,000	\$9,500		\$562,674
American Geriatrics Society	\$126,383	\$1,950				\$158,209	\$20,004		\$565,626
American Pain Foundation	\$5,000		\$5,000	\$75,000	\$45,000	\$235,300	\$238,000	\$25,000	\$633,300
American Pain Society	\$19,510	\$35,930	\$18,200	\$6,580	\$8,775	\$21,000	\$17,500	\$12,500	\$1,793,906
Center for Practical Bioethics						\$5,000		\$3,000	\$8,000
Joint Commission							\$500,325		\$515,244
Purdue Pharma	\$1,682,095	\$697,895	\$823,630	\$1,165,106	\$1,185,040	\$1,000,430	\$1,785,575	\$71,626	\$18,700,690
American Academy of Pain Medicine	\$17,000	\$14,000	\$159,100	\$78,500	\$45,000	\$88,695	\$171,170	\$96,500	\$2,035,519
American Geriatrics Society			\$6,000		\$44,850		\$40,988		\$443,548
American Pain Foundation	\$251,210	\$177,037	\$231,150	\$375,000	\$275,000	\$456,500	\$368,962	-\$75,000	\$3,642,502
American Pain Society	\$154,050	\$102,858	\$80,690	\$121,430	\$149,015	\$137,190	\$149,310	\$60,000	\$3,091,265
Beth Israel Medical Center	\$447		\$4,190	\$5,000	\$70,000	\$15,000	\$120,375		\$743,182
Center for Practical Bioethics	\$250,000	\$201,500	\$100,000	\$510,176	\$525,000	\$302,800	\$934,770	\$25,000	\$3,661,746

Endo/Johnson & Johnson/Purdue Payments (2005-2012)—Continued

Company/ Organization	2005	2006	2007	2008	2009	2010	2011	2012 (Partial Year)	Grand Total 1997-2012
Federation of State Medical Boards	\$339,000	\$50,000	\$100,000						\$904,742
Joint Commission									\$2,124,008
University of Wisconsin	\$670,388	\$152,500	\$142,500	\$75,000	\$76,175	\$245		-\$34,874	\$2,054,178
Annaul Total	\$2,511,499	\$1,542,098	\$1,986,819	\$2,027,314	\$2,863,836	\$3,970,216	\$5,342,044	\$1,398,531	\$36,345,156

Appendix B

This appendix contains payment data collected by Chairman Grassley and Ranking Member Wyden from 2019 to 2020, when the Finance Committee broadened its investigation to examine the financial relationships between a wider range of pharmaceutical manufacturers, device manufacturers, and the tax-exempt organizations they fund. In total, the Committee identified \$29.7 million in payments made to these organizations by pharmaceutical companies that market or manufacture opioids or opioid-related therapies.

The Committee requested and received IRS Form 990s, grant contracts, and financial audits from the tax-exempt organizations. These data were then compiled to assess each organization's financial relationship to manufacturers of opioids and opioid-related products (such as companies that market devices to deliver opioid medication, or market therapies to treat opioid use disorder, opioid overdoses, or opioid-induced constipation). Committee staff further analyzed the data to understand the timing and purposes of these payments.

These data were categorized for each type of donor (*i.e.*, pharmaceutical company, biotech company, government, hospital, foundation, etc.) and the type of product developed by that donor (*i.e.*, opioids, opioid-related drugs, non-opioid pain drugs, other drugs, or devices). Categories were also created to systematically label each program type across all organizations. For example, donations were labeled as: "program," "conference," "membership fees," "grant," "advocacy," "advertising," and "education/lecture."

When possible, all payments were cross-referenced with IRS Form 990s and other financial statements to eliminate duplicate observations. In cases when an organization reported payments from multiple entities or affiliates of the same parent company, the payments were attributed to the parent company.

The appendix contains payments made by pharmaceutical manufacturers that market opioids and opioid-related products. It excludes the American Society of Pain Educators, and the Joint Commission, both of which reported receiving less than \$100,000 from opioid manufacturers prior to 2016. The Federation of State Medical Boards also is excluded as it reported receiving no payments from pharmaceutical manufacturers since 2012.

Alliance for Patient Access

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Abbvie			\$175,000	\$125,000	\$405,000			\$705,000
AstraZeneca	\$30,000	\$30,000	\$30,000	\$50,000		\$100,000		\$240,000
Endo Pharmaceuticals	\$10,000	\$10,000		\$5,000	\$10,000			\$35,000
GlaxoSmithKline				\$50,000	\$50,000			\$100,000
Grunenthal					\$15,000			\$15,000
Mallinckrodt Pharmaceuticals			\$25,000	\$25,000	\$450,000	\$75,000	\$40,000	\$615,000
Pfizer	\$25,000	\$35,000	\$90,000	\$25,500	\$115,000	\$40,000	\$100,000	\$430,500
Purdue Pharma	\$15,000	\$25,000	\$25,000	\$75,000	\$25,000			\$165,000
Sanofi Aventis					\$50,000	\$250,000		\$300,000
Teva Pharmaceuticals		\$50,000	\$125,000	\$50,000	\$10,000	\$265,000		\$500,000
UCB, Inc.					\$25,000			\$25,000
Annual Total	\$80,000	\$150,000	\$470,000	\$405,500	\$1,155,000	\$730,000	\$140,000	\$3,130,500

American Academy of Physical Medicine and Rehabilitation

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Actavis, Inc.	\$8,150								\$8,150
AstraZeneca						\$10,000	\$12,500	\$12,500	\$35,000
Collegium Pharmaceutical					\$3,000				\$3,000
Daiichi Sankyo					\$104,500	\$275,400	\$224,450	\$12,500	\$616,850
Depomed ¹		\$18,450	\$5,000	\$34,650	\$15,000	\$2,700			\$75,800
Egalet ²					\$88,450	\$250			\$88,700
Endo Pharmaceuticals	\$18,500	\$10,000	\$10,000						\$38,500
Forest Pharmaceuticals ³	\$2,200	\$500							\$2,700
Janssen Pharmaceuticals	\$500								\$500
The Medicines Company				\$3,300					\$3,300
Pernix Therapeutics				\$2,850	\$5,700	\$2,700	\$3,100		\$14,350
Pfizer	\$132,300	\$25,000	\$20,000	\$25,000	\$15,000	\$15,000	\$101,700		\$334,000
Purdue Pharma	\$121,860	\$107,450	\$65,000	\$145,850	\$12,000				\$452,160
Teva Pharmaceuticals				\$75,000					\$75,000
U.S. WorldMeds Solstice	\$250	\$5,300	\$100	\$4,050	\$7,400	\$250	\$10,500	\$9,300	\$37,150
Zogenix			\$3,700						\$3,700
Annual Total	\$283,760	\$166,700	\$103,800	\$290,700	\$251,050	\$306,300	\$352,250	\$34,300	\$1,788,860

¹ Changed name to Asserpio Therapeutics in August 2018.

² Changed name to Zyla Life Sciences in June 2019.

³ Acquired by Actavis in July 2014.

American Academy of Pain Medicine ¹

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
AbbVie		\$7,500	\$6,000						\$13,500
Allergan ²	\$2,750	\$17,900	\$3,000						\$23,650
AstraZeneca			\$78,750	\$84,167	\$50,000	\$25,000			\$237,917
Cara Therapeutics				\$67,000	\$60,000	\$73,625			\$200,625
Cephalon ³			\$120,000						\$120,000
Collegium Pharmaceutical					\$11,000	\$28,500	\$15,000	\$17,700	\$72,200
Daiichi Sankyo					\$52,225	\$329,510	\$161,250	\$147,000	\$689,985
Depomed	\$20,925	\$57,000	\$57,825	\$46,000	\$60,500	\$53,500	\$11,000	\$7,500	\$314,250
Endo Pharmaceuticals	\$75,000	\$10,000	\$10,000	\$6,400	\$96,920	\$26,630			\$224,950
Insys Therapeutics		\$18,000	\$19,200	\$9,725		\$5,800			\$52,725
Janssen Pharmaceuticals	\$83,475								\$83,475
Johnson & Johnson		\$7,500							\$7,500
Kaleo				\$87,000	\$75,000	\$77,500			\$239,500
Mallinckrodt Pharmaceuticals		\$17,900	\$37,021	\$8,350					\$63,271
Nektar Therapeutics		\$92,400	\$97,050	\$24,000	\$15,000	\$15,000	\$15,000		\$258,450
Novartis Pharmaceuticals		\$3,000	\$3,000					\$143,365	\$149,365
Pernix Therapeutics				\$15,000	\$82,000	\$91,000	\$76,500		\$264,500

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Pfizer	\$110,000	\$127,125	\$88,333	\$75,000	\$75,000	\$83,333	\$110,000		\$668,791
Purdue Pharma	\$185,000	\$164,250	\$171,000	\$117,000	\$83,500	\$42,500			\$763,250
Salix Pharmaceuticals	\$5,500	\$21,474	\$0	\$0	\$7,000	\$38,500	\$10,000	\$19,500	\$101,974
Shionogi				\$5,000	\$15,000	\$50,000			\$70,000
Teva Pharmaceuticals	\$30,000	\$129,900	\$138,540	\$323,185	\$281,050	\$95,500		\$19,710	\$1,017,885
Zogenix		\$95,800	\$174,000	\$84,800					\$354,600
Annual Total	\$512,650	\$769,749	\$1,003,719	\$952,627	\$964,195	\$1,035,898	\$398,750	\$354,775	\$5,992,363

¹ During the final stages of the Committee's investigation, the American Academy of Pain Medicine (AAPM) provided additional data showing millions of dollars in additional payments from opioid manufacturers to AAPM and an affiliated 501(c)(3) entity, the American Academy of Pain Medicine Foundation (the Foundation). In addition to nearly \$6 million AAPM received directly from opioid manufacturers, the organization reported \$1.1 million in revenue from the Foundation from 2013 to 2017. The additional data provided by AAPM shows that the Foundation, in turn, received \$1 million in payments from opioid manufacturers from 2013 to 2019.

² Acquired by Actavis in November 2014.

³ Acquired by Teva in May 2011.

American Academy of Pain Medicine Foundation

Company	2012	2013	2014	2015	2016	2017	2018	2019	Grand Total
Collegium Pharmaceutical						\$10,000		\$10,000	\$20,000
Daiichi Sankyo						\$167,275		\$47,425	\$214,700
Depomed	\$5,000		\$100,000	\$50,000	\$148,265				\$303,265
Egalet						\$5,000			\$5,000
Mallinckrodt Pharmaceuticals			\$191,000				\$9,600	\$58,400	\$259,000
Nektar Therapeutics		\$15,000				\$25,000			\$40,000
Pfizer				\$20,000					\$20,000
Purdue Pharma		\$75,000							\$75,000
Salix Pharmaceuticals				\$45,000					\$45,000
Teva Pharmaceuticals							\$50,000		\$50,000
Annual Total	\$5,000	\$90,000	\$291,000	\$115,000	\$148,265	\$207,275	\$59,600	\$115,825	\$1,031,965

American Chronic Pain Association

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Abbvie		\$5,000	\$5,000	\$5,000				\$15,000
AstraZeneca		\$20,000	\$65,000	\$215,000	\$40,000			\$340,000
Cephalon	\$10,000							\$10,000
Collegium Pharmaceutical				\$15,000	\$10,000	\$15,000	\$45,000	\$85,000
Daiichi Sankyo						\$10,000	\$125,000	\$135,000
Depomed			\$35,000	\$5,000	\$15,000	\$12,500		\$67,500
Egalet				\$5,000	\$27,000	\$10,000		\$42,000
Endo Pharmaceuticals	\$235,250	\$49,000	\$90,000					\$374,250
Endo Labs	\$25,000							\$25,000
Forest Laboratories ¹	\$10,000	\$10,000	\$5,000	\$5,000				\$30,000
Janssen Pharmaceuticals	\$25,000							\$25,000
Johnson & Johnson	\$30,000	\$35,000	\$25,000	\$10,000	\$10,000	\$10,000		\$120,000
Kaleo				\$5,000	\$18,000	\$65,000	\$10,000	\$98,000
Mallinckrodt Pharmaceuticals		\$25,000	\$5,000	\$25,775				\$55,775
Pernix Therapeutics					\$10,000	\$10,000	\$5,000	\$25,000
Pfizer	\$125,000	\$34,875	\$5,000	\$20,000	\$10,000	\$20,000		\$214,875
Purdue Pharma	\$206,500	\$99,970	\$35,000	\$25,000	\$20,000			\$386,470
Sanofi Aventis					\$5,000	\$5,000	\$10,000	\$20,000

American Chronic Pain Association—Continued

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Shionogi				\$10,000	\$15,000			\$25,000
Teva Pharmaceuticals	\$65,000	\$78,800	\$401,000	\$194,997	\$200,578	\$50,600	\$15,000	\$1,005,975
Tonix Pharma		\$5,000		\$5,000				\$10,000
Zogenix	\$5,000		\$60,000	\$18,950				\$83,950
Annual Total	\$736,750	\$362,645	\$731,000	\$564,722	\$380,578	\$208,100	\$210,000	\$3,193,795

¹ Acquired by Actavis in July 2014.

American Pain Society

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
AstraZeneca				\$35,000				\$35,000
Daiichi Sankyo					\$80,000	\$44,711	\$20,000	\$144,711
Depomed		\$10,000	\$10,000	\$82,500	\$61,500	\$15,000		\$179,000
Endo Pharmaceuticals	\$429,307	\$417,274	\$150,000					\$996,581
Janssen Pharmaceuticals	\$60,000							\$60,000
Kaleo				\$5,000				\$5,000
Mallinckrodt Pharmaceuticals			\$25,000	\$25,000				\$50,000
Mylan				\$9,375				\$9,375
Nektar Therapeutics	\$60,000							\$60,000
Pfizer		\$37,000	\$25,000	\$35,000	\$346,000	\$217,500	\$45,000	\$705,500
Purdue Pharma	\$108,465	\$93,480	\$85,000	\$20,000		\$20,000		\$326,945
Salix Pharmaceuticals ¹		\$5,000	\$5,000					\$10,000
Teva Pharmaceuticals	\$90,000	\$90,000	\$100,000	\$179,500	\$229,500	\$60,000	\$15,000	\$764,000
Zogenix		\$5,000	\$25,000					\$30,000
Annual Total	\$747,772	\$657,754	\$425,000	\$391,375	\$717,000	\$357,211	\$80,000	\$3,376,112

¹Salix was acquired by Valeant Pharmaceuticals in April 2015.

American Society for Pain Management Nursing

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
AccreditEd/Salix Pharmaceuticals	\$37,000							\$37,000
AstraZeneca				\$65,000				\$65,000
Collegium Pharmaceutical						\$1,500	\$7,500	\$9,000
Depomed	\$7,500	\$10,700						\$18,200
Endo Pharmaceuticals						\$10,000		\$10,000
Mallinckrodt Pharmaceuticals				\$10,000				\$10,000
Pernix Therapeutics					\$6,500	\$19,500		\$26,000
Pfizer	\$10,000		\$15,000	\$15,000	\$1,000	\$20,000		\$61,000
Purdue Pharma	\$23,700	\$92,200	\$11,000	\$35,200	\$37,500			\$199,600
Teva Pharmaceuticals			\$3,500	\$10,000				\$13,500
Annual Total	\$78,200	\$102,900	\$29,500	\$135,200	\$45,000	\$61,000	\$7,500	\$459,300

Center for Practical Bioethics¹

Company	2012	2013	2014	2015	2016	Grand Total
Endo Pharmaceuticals			\$1,000			\$1,000
Janssen Pharmaceuticals	\$3,000		\$10,000			\$13,000
Johnson & Johnson			\$5,000			\$5,000
Mallinckrodt Pharmaceuticals				\$30,000		\$30,000
Pfizer	\$1,000	\$25,000				\$26,000
Purdue Pharma	\$25,000	\$100,000	\$15,000	\$3,500	\$500	\$144,000
Teva Pharmaceuticals	\$7,000		\$105,000			\$112,000
Zogenix				\$500		\$500
Annual Total	\$36,000	\$225,000	\$136,000	\$34,000	\$500	\$331,500

¹None of the payments reported by the Center for Practical Bioethics for 2017 or 2018 were made by opioid manufacturers or other pharmaceutical manufacturers.

International Association for the Study of Pain

Company	2012	2013	2014	2015	2016	2017	2018	Grand Total
Acel Rx		\$62,500	\$18,750					\$81,250
AstraZeneca		\$63,105	\$31,105		\$45,000	\$110,000		\$249,210
Charleston Laboratories, Inc.						\$20,000		\$20,000
Collegium Pharmaceutical							\$10,700	\$10,700
Daiichi Sankyo					\$70,300			\$70,300
Eli Lilly	\$28,418	\$51,034						\$79,452
Excerpta Medical (Agency for Grunenthal)	\$40,308							\$40,308
Glenmark Pharmaceuticals				\$600				\$600
Grunenthal	\$65,943	\$215,000	\$92,000		\$10,000	\$20,000	\$120,000	\$522,943
Janssen Pharmaceuticals						\$52,903		\$52,903
Johnson & Johnson Ltd/Janssen Mumbai						\$52,903		\$52,903
Mallinckrodt Pharmaceuticals				\$2,500				\$2,500
Mundipharma	\$86,546	\$228,130	\$143,360	\$251,580	\$196,999	\$22,401	\$76,667	\$1,005,683
Pfizer	\$29,100		\$105,000	\$141,000	\$45,000	\$114,865	\$918,045	\$1,353,010
Purdue Pharma	\$9,448				\$20,000		\$5,400	\$34,848
QRx Pharma Ltd.	\$13,847							\$13,847
Sanofi Aventis				\$47,000				\$47,000
Teva Pharmaceuticals		\$71,460	\$44,497	\$30,000	\$93,800	\$87,680	\$300,230	\$627,667
Zibrant Ltd (agency for Pfizer)	\$2,001							\$2,001
Annual Total	\$275,610	\$691,229	\$434,712	\$472,680	\$481,099	\$427,850	\$1,431,042	\$4,214,222

U.S. Pain Foundation

Company	2012	2014	2015	2016	2017	2018	Grand Total
Abbvie		\$9,500		\$310,000	\$300,000	\$300,000	\$919,500
AstraZeneca		\$38,800		\$145,000			\$183,800
Collegium Pharmaceutical			\$9,500				\$9,500
Daiichi Sankyo			\$14,500	\$35,000		\$50,000	\$99,500
Egalet				\$32,500			\$32,500
Endo Pharmaceuticals		\$25,000		\$55,000	\$50,000		\$130,000
GlaxoSmithKline		\$9,500	\$9,500				\$19,000
Insys Therapeutics ¹					\$2,900,000	\$350,000	\$3,250,000
Janssen Pharmaceuticals		\$7,500					\$7,500
Johnson & Johnson	\$7,500	\$9,500	\$55,000	\$40,000	\$80,000		\$192,000
Mallinckrodt Pharmaceuticals		\$9,989					\$9,989
Pfizer	\$50,000	\$80,000	\$40,000		\$55,000	\$60,000	\$285,000
Purdue Pharma	\$25,000	\$104,600	\$120,000				\$249,600
Shionogi			\$12,500				\$12,500
Teva Pharmaceuticals	\$43,000	\$266,000	\$250,000	\$110,000		\$120,000	\$789,000
UCB, Inc.		\$25,000	\$25,000	\$45,000	\$25,000		\$120,000
Zogenix		\$21,368					\$21,368
Annual Total	\$125,500	\$606,757	\$536,000	\$772,500	\$3,410,000	\$880,000	\$6,330,757

¹ Payments from Insys were in relation to a patient assistance program (PAP) operated by the U.S. Pain Foundation. Ranking Member Wyden is continuing to investigate the U.S. Pain Foundation and the PAP. See Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018).

Appendix C

Drug Companies

Endo Pharmaceuticals

1. [Letter from Raymond V. Shepherd, Counsel, Venable, on Behalf of Endo Pharmaceuticals, to Senator Baucus and Senator Grassley \(June 15, 2012\)](#)
2. [Summary of payments made by Endo Pharmaceuticals between 1997-2012](#)
3. [2008-2012 Opana ER Business Plan, November 29, 2007 \(SFC-00025042\)](#)
4. [Scientific Affairs Overview Business Plan 2011 \(SFC-00057051\)](#)

Johnson & Johnson

5. [Letter from Daniel Donovan, Counsel, King & Spalding, to Senator Baucus and Senator Grassley \(June 8, 2012\)](#)
6. [Summary of payments made by Johnson & Johnson between 1997-2012 \(SFC00000001\)](#)

Purdue Pharma, L.P.

7. [Letter from Theodore Hester, Counsel, King & Spalding, on Behalf of Purdue Pharma, to Senator Baucus and Senator Grassley \(June 8, 2012\)](#)
8. [Summary of payments made by Purdue Pharma, L.P., between 1997-2012 \(SFC00000001\)](#)
9. [Purdue payment details 1997-2012 \(SFC000000002\)](#)
10. [Health Policy Presentation by J. David Haddox, September, 9, 2010 \(SFC00002172\)](#)
11. [Email from Pamela Bennett, Vice President, Purdue, re: Pain Care Forum, March 2, 2007 \(SFC00011511\)](#)
12. [Email from Pamela Bennett, Vice President, Purdue, re: Pain Care Forum, February 27, 2007 \(SFC00011527\)](#)
13. [Attachment re: Pain Care Forum \(SFC00011528\)](#)

Tax-Exempt Organizations

American Chronic Pain Association

14. [ACPA Financial Statements & Independent Auditor's Report 2012-2018](#)
15. [ACPA-AstraZeneca Correspondence \(SFC_ACPA_127\)](#)
16. [ACPA-Daiichi Sankyo Correspondence \(SFC_ACPA_221\)](#)
17. [ACPA-Medtronic Correspondence \(SFC_ACPA_572\)](#)

Alliance for Patient Access

18. [AfPA-Mallinckrodt Agreement, January, 2016 \(AfPA_SFC_000001\)](#)
19. [AfPA Letters to Federal Government, 2014-2018 \(AfPA_SFC_000193-AfPA_SFC_000241\)](#)
20. [Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden \(Jan. 29, 2020\)](#)
21. [Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden \(Oct. 10, 2019\)](#)

22. [Letter from Samuel Dewey, Counsel, McDermott Will & Emery, on Behalf of American's for Patient Access, to Senator Grassley and Senator Wyden \(July 29, 2019\)](#)

American Pain Foundation (Defunct)

23. [American Pain Foundation Business Plan, 1998](#)
24. [APF-Purdue Correspondence 2001-2005 \(APF65\)](#)
25. [APF-Purdue Correspondence and Checks \(2001-2004\) \(APF106\)](#)
26. [Report to Purdue on 2002 Accomplishments \(APF254\)](#)
27. [APF email re: briefing with Purdue officials \(APF298\)](#)
28. [APF Operating Plan and Budget for 2001 \(APF394\)](#)

American Society for Pain Educators

29. [Letter from Noam Fischman, Counsel, Polsinelli, on Behalf of American Society of Pain Educators, to Senator Grassley and Senator Wyden \(Nov. 11, 2020\)](#)
30. [Letter from Noam Fischman, Counsel, Polsinelli, on Behalf of American Society of Pain Educators, to Senator Grassley and Senator Wyden \(Sept. 30, 2020\)](#)
31. [Endo Corporate Membership, December 2007 \(ASPE_000027\)](#)
32. [Endo Corporate Membership, October 2009 \(ASPE_000025\)](#)
33. [Purdue Corporate Membership, February 2008 \(ASPE_000029\)](#)

Federation of State Medical Boards

34. [Letter from Humayun Chaudhry, President and CEO, Federation of State Medical Boards, to Senator Grassley and Senator Wyden \(July 29, 2019\)](#)

International Association for the study of Pain

35. [Letter from Lars Arendt-Nielsen, President, International Association for the Study of Pain, to Senator Grassley and Senator Wyden \(Aug. 28, 2019\)](#)
36. [Letter from Lars Arendt-Nielsen, President, International Association for the Study of Pain, to Senator Grassley and Senator Wyden \(July 29, 2019\)](#)

Joint Commission

37. [Letter from Mark Chassin, President and CEO, The Joint Commission, to Senator Grassley and Senator Wyden \(July 29, 2019\)](#)
38. [Letter from Mark Chassin, President and CEO, The Joint Commission, to Senator Baucus and Senator Grassley \(June 29, 2012\)](#)