

Fueling an Epidemic

REPORT TWO



Exposing the Financial Ties Between
Opioid Manufacturers and Third Party
Advocacy Groups

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EXECUTIVE SUMMARY

This report provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy. Drawing on disclosures from Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc., in response to requests from Ranking Member McCaskill, the sections below describe nearly \$9 million in payments from these manufacturers to 14 outside groups working on chronic pain and other opioid-related issues between 2012 and 2017. In addition, physicians affiliated with these groups accepted more than \$1.6 million in payments from the five manufacturers between 2013 and the present. In total, the five manufacturers have made more than \$10 million in payments to these groups and affiliated individuals since January 2012.

Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.

The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

INTRODUCTION AND METHODOLOGY

More than 42,000 Americans died from opioid overdoses in 2016, with deaths from natural and semisynthetic opioid painkillers like hydrocodone and oxycodone rising roughly 14% compared to 2015.¹ In Missouri, around 60% of the more than 1,300 drug overdose deaths in 2016 involved opioids,² and the epidemic cost the state \$12.6 billion the same year, according to the Missouri Hospital Association.³ Alarming, fatal overdoses from fentanyl and other synthetic opioids more than doubled in the United States between 2015 and 2016—“more than an exponential increase,” according to the chief of the mortality statistics branch at the National Center for Health Statistics.⁴ This surge in overdose deaths resulted in the first two-year drop in average U.S. life expectancy since the early 1960s.⁵

The necessary conditions for this crisis may have arisen, in part, due to the financial relationships between opioid manufacturers and patient advocacy groups and medical professional societies—the precise terms of which parties to these transactions rarely disclose. Patient advocacy organizations and professional societies play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public. Even small organizations—with “their large numbers and credibility with policymakers and the public”—have “extensive influence in specific disease areas.”⁶ Larger organizations with extensive funding and outreach capabilities “likely have a substantial effect on policies relevant to their industry sponsors.”⁷

Nearly all health advocacy groups accept funding from the pharmaceutical industry. According to a recent study from PharmedOut—a Georgetown University Medical Center project focused on pharmaceutical marketing practices—only “a handful of 7,865 health advocacy groups in the U.S. are completely independent of pharmaceutical industry money.”⁸ As a result, “[t]he voices of independent groups that truly represent patients and consumers are drowned out by the thousands of groups that take money from industry and push industry viewpoints.”⁹

Moreover, neither pharmaceutical manufacturers nor advocacy groups fully or routinely disclose the extent of their financial relationships. In a special report published in the *New England Journal of Medicine* in March 2017, for example, researchers found that out of 104 organizations, “at least 83% received financial support from drug, device, and biotechnologies companies, and at least 39% have a current or former industry executive on the governing board.”¹⁰ Full disclosure of these payments was limited, with only 57% of organizations disclosing amounts of donations; even then, this disclosure “was typically done with the use of broad ranges rather than exact figures.”¹¹ Moreover, only 12% of the organizations researchers examined “have published policies in place for managing institutional conflicts of interest.”¹²

A January 2017 article in *JAMA Internal Medicine* similarly examined relationships between patient advocacy organizations and the pharmaceutical industry. According to the study, more than 67% of 245 examined organizations received industry funding within the last fiscal year, with almost 12% receiving more than half of their funding from industry sources.¹³ Only 65% of organizations that provided information on their funding from for-profit sources “provided a detailed breakdown” of this funding, and a similar percentage (63.9%) of 274 responsive organizations “reported having a written organizational conflict of interest policy.”¹⁴

These financial relationships—and the lack of transparency surrounding them—have raised concerns regarding the information and initiatives patient advocacy organizations promote. In the *JAMA* study discussed above, 8% of respondents in the study “reported [that] pressure to conform their organizations’ positions to the interests of industry funders is of concern.”¹⁵ Without additional disclosure, according to David Mitchell of Patients for Affordable Drugs, “policy makers or patients are unable to make informed judgments about the motives of the information being given, and the credibility of the information.”¹⁶

On March 28, 2017, Ranking Member McCaskill issued wide-ranging requests for documents related to opioid sales and marketing efforts to five major opioid manufacturers: Purdue Pharma L.P., Janssen

Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc.¹⁷ As the requests explain, these companies manufactured the top five opioid products as measured by worldwide 2015 sales.¹⁸ Among other items, the requests required manufacturers to produce records of payments to certain advocacy groups and professional societies since 2012, including the date, amount, and purpose of each payment.¹⁹ (Many of the groups at issue appeared in a previous congressional request from 2012 and feature prominently in nationwide litigation against the opioids manufacturing industry.²⁰) In response, manufacturers produced information on payments flowing to many—but not all—of the groups listed in the March 2017 requests. To verify this information, Ranking Member McCaskill issued additional requests directly to 15 of the organizations at issue on October 5, 2017.²¹

The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies.

PAYMENTS BY OPIOID MANUFACTURERS TO PATIENT ADVOCACY ORGANIZATIONS AND PROFESSIONAL SOCIETIES

Between January 2012 and March 2017, the five opioid manufacturers featured in this report contributed nearly \$9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area. For some groups, contributions from these manufacturers—alone—constituted significant portions of their total annual contributions and grants.

In addition, the five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Physicians affiliated with these groups accepted more than \$1.6 million in payments from the five manufacturers between 2013 and the present. These same individuals received payments totaling over \$10 million from all opioid manufacturers during this time period.

Opioid Manufacturers Contributed Millions to Patient Advocacy Organizations and Professional Societies

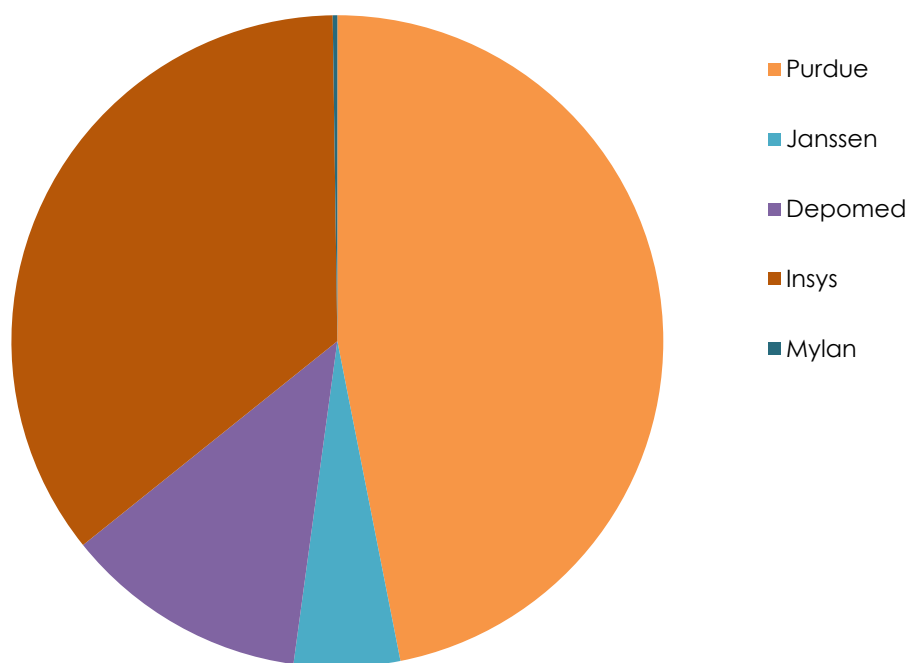
Purdue, Janssen, Mylan, Depomed, and Insys provided at least \$8,856,339.13 in funding to 14 outside groups working on chronic pain and other opioid-related issues between January 2012 and March 2017. Detailed information on these payments, including payment totals for each manufacturer and group and the contributions applicable to each relationship, appears below in Figure 1.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue ²²	Janssen ²³	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	\$1,091,024.86	\$128,000.00	\$43,491.95	\$3,050.00 ²⁴	\$0.00	\$1,265,566.81
American Academy of Pain Medicine	\$725,584.95	\$83,975.00	\$332,100.00	\$57,750.00	\$0.00	\$1,199,409.95
AAPM Foundation	\$0.00	\$0.00	\$304,605.00	\$0.00	\$0.00	\$304,605.00
ACS Cancer Action Network	\$168,500.00 ²⁵	\$0.00	\$0.00	\$0.00	\$0.00	\$168,500.00
American Chronic Pain Association	\$312,470.00	\$50,000.00	\$54,670.00	\$0.00	\$0.00	\$417,140.00
American Geriatrics Society	\$11,785.00 ²⁶	\$0.00	\$0.00	\$0.00	\$0.00	\$11,785.00
American Pain Foundation	\$25,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$25,000.00
American Pain Society	\$542,259.52	\$88,500.00	\$288,750.00	\$22,965.00	\$20,250.00	\$962,724.52
American Society of Pain Educators	\$30,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$30,000.00
American Society of Pain Management Nursing	\$242,535.00	\$55,177.85 ²⁷	\$25,500.00 ²⁸	\$0.00	\$0.00	\$323,212.85
The Center for Practical Bioethics	\$145,095.00	\$18,000.00	\$0.00	\$0.00	\$0.00	\$163,095.00
The National Pain Foundation²⁹	\$0.00	\$0.00	\$0.00	\$562,500.00	\$0.00	\$562,500.00
U.S. Pain Foundation	\$359,300.00	\$41,500.00	\$22,000.00	\$2,500,000.00 ³⁰	\$0.00	\$2,922,800.00
Washington Legal Foundation	\$500,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$500,000.00
	\$4,153,554.33	\$465,152.85	\$1,071,116.95	\$3,146,265.00	\$20,250.00	\$8,856,339.13

As shown in Figure 2, payments from Purdue account for roughly half of this funding, and the company provided donations to the most diverse array of groups—a significant majority of the organizations profiled below. Primarily due to large payments to the National Pain Foundation and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017. At the other end of the spectrum, Mylan reported only \$20,250 in payments during the same period; in correspondence with the Committee, the company has claimed a “very limited role in the opioid-containing products marketplace.”³¹

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



As shown in Figure 3 below, trends based on yearly payment totals varied between manufacturers from 2012 to 2017. Payments from Purdue, for example, fell dramatically in 2016 after remaining in the \$800,000–\$1,000,000 range between 2012 and 2015. Conversely, payments from Insys to advocacy groups rose significantly between 2012—when the company received U.S. Food and Drug Administration approval for its fentanyl drug Subsys—and 2017. As Ranking Member McCaskill noted in a recent report entitled, “Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization,” Insys revenues tripled and profits rose 45% between 2013 and 2015, and the value of company stock increased 296% between 2013 and 2016.³²

Payments from Janssen to the groups listed above dropped sharply to \$0 in 2015 from \$126,000 in 2014 (and \$99,250 and \$239,902.85 in 2013 and 2012, respectively) and remained at \$0 for 2016 and 2017. In April 2015, Janssen sold U.S. licensing rights for its major Nucynta opioid product line to Depomed for \$1.05 billion.³³ For its part, Depomed more than tripled payments to the advocacy groups featured in this report in 2015 relative to 2014, and the payments total for 2016—\$318,257.47—remained steady compared to the 2015 total.

Mylan made a single \$15,000 payment to the American Pain Society in March 2015—its first payment to the groups in this report—before making significantly smaller payments to the same group in 2016 and 2017. Also in March 2015, Mylan announced the launch of intermediate dosage strengths for its fentanyl transdermal system.³⁴ In connection with this launch, according

to the company, Mylan “engaged in marketing efforts to educate doctors about the availability of the intermediate strengths.”³⁵

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	\$824,227.86	\$973,328.00	\$812,451.95	\$935,344.00	\$558,067.52	\$50,135.00	\$4,153,554.33
Janssen	\$239,902.85 ³⁶	\$99,250.00	\$126,000.00				\$465,152.85
Depomed	\$73,080.00	\$135,300.00	\$113,600.00	\$350,000.00	\$318,257.47	\$80,879.48	\$1,071,116.95
Insys	\$14,040.00	\$68,000.00	\$34,200.00	\$530,025.00		\$2,500,000.00	\$3,146,265.00
Mylan				\$15,000.00	\$2,500.00	\$2,750.00	\$20,250.00
Total	\$1,151,250.71	\$1,275,878.00	\$1,086,251.95	\$1,830,369.00	\$878,824.99	\$2,633,764.48	\$8,856,339.13

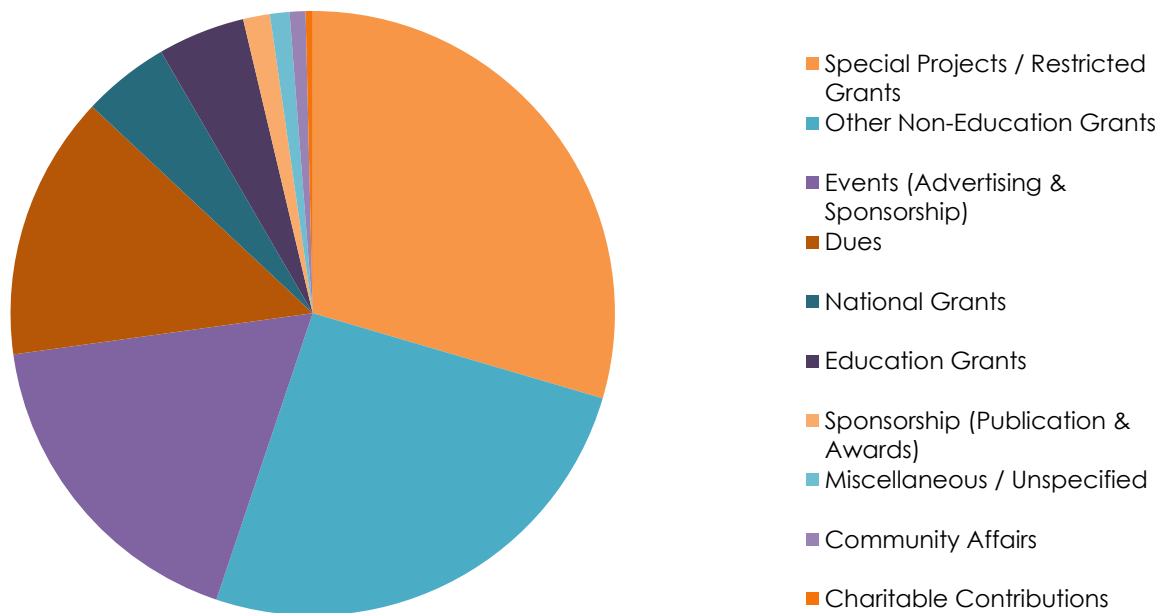
Purpose of Manufacturer Contributions

Based on the descriptions manufacturers submitted in connection with each specific reported payment, the minority staff designated broad payment categories. Payments directed to special projects and restricted grants comprise the largest category of contributions, totaling \$2,617,899 and constituting roughly 30% of total contributions between 2012 and 2017. For these types of restricted grants, donors specify a use for their contribution beyond the broad parameters resulting from the nature of the non-profit entity at issue, the environment in which it operates, or the purposes specified in its organizing documents.³⁷

Following closely behind the total for special projects and restricted grants is the amount manufacturers contributed in the form of non-education grants, which totaled \$2,269,765 and constituted roughly 26% of all contributions. According to a publicly available overview from Purdue, non-education grants provide support for healthcare-related organizations or initiatives focused on patient and public education, scientific research, and other programs.³⁸

Payments for advertising and sponsorship related to group events and dues occupy the next tier of categories, with \$1,564,215.86 and \$1,253,988 in payments and roughly 18% and 14% of the total contributions, respectively. Finally, national grants and education grants occupy the third tier of categories, with similar payments totals of \$413,154 and \$413,128, respectively, and percentages of roughly 5%. According to Purdue, an education grant “[p]rovides for healthcare professional continuing education (CE) activities designed to foster improved understanding of scientific, clinical, and other healthcare issues that help to improve patient care.”³⁹ See Figure 4.

FIGURE 4: Payment Categories as Percentages of Total Payments, 2012-2017



Payments by Organization

The U.S. Pain Foundation received the largest amount of payments during the 2012–2017 period—almost \$3 million—which includes \$2,500,000 in payments from Insys. The Academy of Integrative Pain Management, formerly the American Academy of Pain Management, received \$1,265,566.81 in donations—the second-highest total—followed closely by the American Academy of Pain Medicine with \$1,199,409.95 in payments. (The American Academy of Pain Medicine Foundation also received \$304,605 in payments from Depomed during the same period.)

FIGURE 5: Group Rankings by Manufacturer Payments, 2012-2017

U.S. Pain Foundation	\$2,922,800.00
Academy of Integrative Pain Management	\$1,265,566.81
American Academy of Pain Medicine	\$1,199,409.95
American Pain Society	\$962,724.52
The National Pain Foundation	\$562,500.00
Washington Legal Foundation	\$500,000.00
American Chronic Pain Association	\$417,140.00
American Society of Pain Management Nursing	\$323,212.85
AAPM Foundation	\$304,605.00
ACS Cancer Action Network	\$168,500.00
The Center for Practical Bioethics	\$163,095.00
American Society of Pain Educators	\$30,000.00
American Pain Foundation	\$25,000.00
American Geriatrics Society	\$11,785.00

Contributions by Selected Manufacturers as a Percentage of Overall Contributions

Based on comparisons between manufacturer contributions to groups and group reporting on contributions and grants in IRS filings between 2013 and 2015, the percentage of total contributions attributable to the five manufacturers discussed in this report vary significantly. Insys contributions to the National Pain Foundation in 2015, for example, actually exceeded total contributions the group reported on its Form 990 by \$154,800. In a less extreme example, the American Society of Pain Management Nursing received approximately 76% of its funding from Depomed, Janssen, and Purdue in 2013, although this percentage declined for 2014 and 2015. For other groups, the percentages of contributions attributable to the five manufacturers remained consistent during 2013–2015. The Academy of Integrative Pain Management and the American Academy of Pain Medicine, for example, received between 13% and 20% of their contributions from at least one of the five manufacturers during this three-year period. At the other end of the spectrum, the American Cancer Society Cancer Action Network received less than 1% of its contributions from Purdue between 2013 and 2015.

FIGURE 6: Comparison of Contributions from Selected Manufacturers and Total Contributions and Grants, 2013-2015⁴⁰

2013 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	\$319,929	\$1,624,115	19.70%
American Academy of Pain Medicine	\$201,944	\$1,071,992	18.84%
AAPM Foundation	\$50,000	\$381,738	13.10%
ACS Cancer Action Network	\$28,500	\$35,409,632	0.08%
American Chronic Pain Association	\$100,970	\$564,004	17.90%
American Geriatrics Society	\$0	\$2,709,179	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	\$161,585	\$1,271,537	12.71%
American Society of Pain Educators	\$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	\$97,950	\$129,167	75.83%
The Center for Practical Bioethics	\$101,000	Unavailable	Unavailable
The National Pain Foundation	\$50,000	\$50,100	99.80%
U.S. Pain Foundation	\$84,000	\$467,040	17.99%
Washington Legal Foundation	\$75,000	\$4,113,151	1.82%

2014 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	\$269,980	\$1,929,818	13.99%
American Academy of Pain Medicine	\$255,087	\$1,346,712	18.94%
AAPM Foundation	\$0	\$533,776	0.00%
ACS Cancer Action Network	\$40,000	\$35,288,961	0.11%
American Chronic Pain Association	\$85,000	\$558,510	15.22%
American Geriatrics Society	\$0	\$3,197,135	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	\$161,190	\$949,867	16.97%
American Society of Pain Educators	\$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	\$68,100	\$229,732	29.64%
The Center for Practical Bioethics	\$30,095	\$1,232,768	2.44%
The National Pain Foundation	\$0	\$3,100	0.00%
U.S. Pain Foundation	\$121,800	\$791,657	15.39%
Washington Legal Foundation	\$50,000	\$4,213,431	1.19%

2015 INFORMATION	Contributions from Selected Manufacturers	Contributions and Grants	% of Selected Contributions
Academy of Integrative Pain Management	\$275,098	\$1,465,067	18.78%
American Academy of Pain Medicine	\$239,941	\$1,482,707	16.18%
AAPM Foundation	\$100,000	\$451,835	22.13%
ACS Cancer Action Network	\$100,000	\$37,925,236	0.26%
American Chronic Pain Association	\$30,000	\$382,671	7.84%
American Geriatrics Society	\$0	\$4,041,760	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	\$266,020	\$660,894	40.25%
American Society of Pain Educators	\$10,000	Unavailable	Unavailable
American Society of Pain Management Nursing	\$63,810	\$171,256	37.26%
The Center for Practical Bioethics	\$3,500	\$857,788	0.41%
The National Pain Foundation	\$512,500	\$357,700	143.28%
U.S. Pain Foundation	\$129,500	Unavailable	Unavailable
Washington Legal Foundation	\$100,000	\$4,583,620	2.18%

Manufacturers Also Provided Payments to Group-Affiliated Individuals

The five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Figure 7 below lists totals for these payments between August 2013 and the present, as well as the sum of these payments and the amounts manufacturers contributed to the groups directly. In terms of total contributions, the U.S. Pain Foundation ranks first among the groups despite minimal payments to affiliated individuals, and the National Pain Foundation assumes the second-place ranking due to payments to individual physicians of over \$800,000. Notably, the nearly \$300,000 in payments to individuals affiliated with the American Society of Pain Educators significantly outweighs the relatively minor amount the group received from Purdue directly. In contrast, manufacturer payments to groups like the Academy of Integrative Pain Management, the American Academy of Pain Medicine, the American Pain Society, and the American Chronic Pain Association far exceeded payments to physicians affiliated with these organizations.

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012-Present⁴¹

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	\$2,922,800.00	\$126.20	\$2,922,926.20
The National Pain Foundation	\$562,500.00	\$839,848.84	\$1,402,348.84
Academy of Integrative Pain Management	\$1,265,566.81	\$30,223.42	\$1,295,790.23
American Academy of Pain Medicine	\$1,199,409.95	\$16,462.42	\$1,215,872.37
American Pain Society	\$962,724.52	\$95,474.56	\$1,058,199.08
AAPM Foundation	\$304,605.00	\$314,175.58	\$618,780.58
Washington Legal Foundation	\$500,000.00	N/A	\$500,000.00
American Chronic Pain Association	\$417,140.00	\$31,265.87	\$448,405.87
American Society of Pain Management Nursing	\$323,212.85	N/A	\$323,212.85
American Society of Pain Educators	\$30,000.00	\$280,765.92	\$310,765.92
The Center for Practical Bioethics	\$163,095.00	\$7,116.86	\$170,211.86
ACS Cancer Action Network	\$168,500.00	N/A	\$168,500.00
American Pain Foundation	\$25,000.00	N/A	\$25,000.00
American Geriatrics Society	\$11,785.00	\$194.13	\$11,979.13
Total	\$8,856,339.13	\$1,615,653.80	\$10,471,992.93

As shown in Figure 8 below, individuals affiliated with these groups have significant financial ties not only with the five companies at issue in this report, but also with all other opioid manufacturers. According to CMS Open Payments data, for example, the current President of the American Academy of Pain Medicine, Dr. Steven Stanos, received over \$90,000 in payments from opioid manufacturers between 2013 and 2016.⁴² Additional searches of Open Payments data also show that multiple American Academy of Pain Medicine Corporate Relations Council members made payments directly to at least one American Academy of Pain Medicine board member between 2013 and 2016.⁴³ In total, between 2013 and 2016, American Academy of Pain Medicine board members received more than \$200,000 in payments from opioid manufacturers.⁴⁴ In addition, Dr. Charles Argoff, current president of the American Academy of Pain Medicine Foundation, received over \$600,000 in payments from opioid manufacturers between 2013 and 2016.⁴⁵

Similarly, Open Payments data indicates that between 2013 and 2016, ten members of the American Chronic Pain Association Advisory Board received more than \$140,000 from opioid manufacturers, including Endo, Purdue, Mallinckrodt, Pfizer, Teva, and Depomed.⁴⁶ In another prominent example, National Pain Foundation chairman and founder Dr. Daniel Bennett⁴⁷ received over \$170,000 from Insys Therapeutics, manufacturer of the powerful fentanyl drug Subsys, between 2013 and 2016.⁴⁸ Members of the National Pain Foundation Board of Directors, which include Dr. Bennett, received more than \$950,000 from opioid manufacturers, including more than \$250,000 from Insys Therapeutics, during the same period.⁴⁹ In addition, at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council⁵⁰ have received general payments—totaling more than \$7,900,000—from opioid manufacturers between 2013 and 2016.⁵¹ Manufacturer payments to all individuals affiliated with the National Pain Foundation total more than \$8,000,000 since 2013—by far the largest total for the groups profiled in this report.

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present⁵²

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	\$8,307,243.47
AAPM Foundation	\$798,051.22
American Society of Pain Educators	\$749,564.78
American Academy of Pain Medicine	\$204,631.53
American Pain Society	\$187,699.34
ACS Cancer Action Network	\$154,578.09
American Chronic Pain Association	\$145,861.30
Academy of Integrative Pain Management	\$82,596.98
The Center for Practical Bioethics	\$16,945.88
American Geriatrics Society	\$7,548.35
U.S. Pain Foundation	\$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	\$10,654,859.85

GROUPS FAIL TO ADEQUATELY DISCLOSE MANUFACTURER CONTRIBUTIONS

Due to their classification under the U.S. tax code, the groups profiled in this report have no obligation to disclose their donors publicly; as a result, each group maintains different levels of transparency regarding its financial connections to the pharmaceutical industry. Specifically, as either 501(c)(3), 501(c)(4), or 501(c)(6) public charities, the groups discussed below have no obligation to publicly disclose the list of donors they provide to the Internal Revenue Service with their annual Form 990 filing.⁵³ Instead, these organizations have the ability to selectively disclose donors, donations, and other support—or no information at all. Importantly, no organization profiled in this report provides an online

list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017.

The minority staff reviewed disclosure policies available online for each of the groups listed in the March 28, 2017, requests. Several groups—the American Society of Pain Educators, the National Pain Foundation, and the Academy of Integrative Pain Management—provided no information concerning their policies for disclosing donors and donations. Other groups stated explicitly that they do not disclose any information concerning donor relationships. The Washington Legal Foundation, for example, states in its 2016 Annual Report: “All contributions to WLF are strictly confidential. WLF does not disclose, publish, or trade the names of its donors.”⁵⁴

Other groups simply list donors, “corporate members,” or “corporate partners” without indicating specific donation amounts or even the range of donations for each category of contributor. The website for the American Geriatrics Society, for example, states that “AGS corporate arrangements will be disclosed regularly as part of the organization’s financial reporting to the Board of Directors,” but for the public, the organization simply lists three “corporate partners” without details of the amounts donated or any related arrangements.⁵⁵ The U.S. Pain Foundation similarly lists “Platinum,” “Gold,” and “Basic” corporate members—including opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, and Mallinckrodt—without indicating the level of donations required for each classification.⁵⁶ The American Chronic Pain Association lists many of the same corporations as “Partners & Contributors” at the “Champion,” “Ambassador,” “Educator,” and “Builder” levels without specifying the applicable ranges of contributions.⁵⁷ Both the American Cancer Society Cancer Action Network and the Center for Practical Bioethics also list corporate or individual donors without including donation amounts.⁵⁸ Finally, the American Academy of Pain Medicine website lists donors between January 1, 2017, and October 31, 2017, and describes the list as including “matching gifts from companies,” but no companies appear on the list.⁵⁹

A handful of groups disclose both their donors and list the ranges of donations applicable to each category of contributor. The American Pain Society, for example, specifies that “Corporate Council” contributors donated at least \$25,000, “Executive” donors provided at least \$15,000, and “Associate” contributors donated at least \$7,500.⁶⁰ Opioid manufacturers, including Pfizer, Teva, Depomed, Purdue, and Mallinckrodt, appear at all three donor levels.⁶¹ The website of the American Society of Pain Management Nursing similarly specifies that all listed corporations contributed more than \$5,000.⁶²

GROUP ACTIVITIES CONTRIBUTING TO OPIOID OVERPRESCRIPTION AND OVERUSE

Many of the groups discussed in this report have amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Several groups have also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.

Minimizing the Risk of Addiction

Many of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain. According to a complaint from the City of Chicago, for example, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement in 1997 “which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.”⁶³ Dr. J. David Haddox, then a paid speaker for Purdue and now the Vice President

of Health Policy at the company, co-authored the statement.⁶⁴ The American Academy of Pain Medicine and the American Pain Society also allegedly issued guidelines in 2009 that “promote[d] opioids as ‘safe and effective’ for treating chronic pain, despite acknowledging limited evidence, and conclude[d] that the risk of addiction is manageable for patients regardless of past abuse histories.”⁶⁵

Similarly, the American Geriatrics Society released guidelines in 2009 for the management of persistent pain in older patients.⁶⁶ While acetaminophen remained the preferred option for the treatment of chronic pain patients, the American Geriatrics Society recommended opioids—as opposed to aspirin or ibuprofen—for those unable to gain relief from Tylenol and similar products.⁶⁷ According to the City of Chicago complaint, the guidelines included these recommendations: “All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation),” and “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”⁶⁸ The American Geriatrics Society also partnered with the American Academy of Pain Medicine and Janssen to create the 2009 patient education guide entitled, “Finding Relief: Pain Management for Older Adults,” which stated that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”⁶⁹

Lobbying to Defeat Measures to Restrict Overprescription

Advocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment for pain. In 2014, for example, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led an effort to protect a 2001 Tennessee law that made it difficult to discipline doctors for overprescribing opioids and prohibited them from refusing to prescribe opioids unless they referred the patient to another “opioid-friendly” doctor.⁷⁰

According to a joint investigation by the *Associated Press* and the Center for Public Integrity, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network have contacted legislators and other officials about opioid measures in at least 18 states.⁷¹ More broadly, the American Cancer Society Cancer Action Network reportedly maintains “about 200 lobbyists around the country opposed to opioid restrictions even in some cases where they specifically exempted cancer patients.”⁷² In an example of the general legislative reach of these groups, the U.S. Pain Foundation has “participated in more than 30 state and national advocacy coalitions, alliances, and task forces . . . [and is] actively engaged in 70 legislative bills in 20 states with the support of 250 advocates engaged in outreach to policymakers.”⁷³

Efforts to Criticize or Undermine CDC Guidelines

On March 15, 2016, the CDC issued guidelines providing prescribing recommendations for “primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.”⁷⁴ In introducing these guidelines—“the first national standards for prescription painkillers,”⁷⁵ as the *New York Times* reported—the CDC noted that opioid prescriptions per capita had increased 7.3% from 2007 to 2012, “more than 165,000 persons died from overdose related to opioid pain medication in the United States” from 1999 to 2014, and “the death rate associated with opioid pain medication” had increased “markedly” in the previous decade.⁷⁶ The guidelines explained that non-opioid therapies are preferred for chronic pain and recommended that physicians prescribe immediate-release opioids at the lowest effective dosage and evaluate the benefits and harms of continued opioid use within one to four weeks of starting opioid therapy.⁷⁷ The guidelines also noted that for opioid therapy for acute pain, “[t]hree days or less will often be sufficient; more than seven days will rarely be needed.”⁷⁸

These guidelines represented an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain in the face of an unprecedented

public health crisis. A majority of the groups described in this report, however, strongly criticized the content of the guidelines, the process by which the CDC drafted them, or the experts who assisted during their development. In fact, the *New York Times* reported that the release of the CDC guidelines ended “months of arguments with pain doctors and drug industry groups, which had bitterly opposed the recommendations on the grounds that they would create unfair hurdles for patients.”⁷⁹ As Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing, has explained, “[t]he opioid lobby has very actively blocked interventions that might result in more cautious prescribing or reduced prescribing. They’ve very clearly defended their financial stake in the status quo.”⁸⁰

In 2016, for example, the immediate past president of the American Academy of Pain Medicine, Daniel Carr, criticized the prescribing guidelines, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”⁸¹ Similarly, several advocacy groups criticized draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines.”⁸² Dr. Richard Payne, a physician affiliated with the Center for Practical Bioethics, made a similar argument, criticizing the CDC guidelines as the product of “conflicts of interests in terms of biases [and] intellectual conflicts”—while himself maintaining “financial links to numerous drug companies.”⁸³ The Washington Legal Foundation also strongly criticized the guidelines on procedural grounds, claiming CDC had developed its guidelines in an “overly secretive manner” and in violation of the Federal Advisory Committee Act, which called “into question the viability of the entire enterprise.”⁸⁴ The Washington Legal Foundation claimed, moreover, that “[s]tate governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input.”⁸⁵ When the CDC published its final opioid prescribing guidelines, Richard A. Samp, Washington Legal Foundation general counsel, reportedly believed the guidelines “were inherently biased, crafted by people who already had strong views about what opioid policy should look like.”⁸⁶

The fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging. Relatedly, in a March 2017 article published in *JAMA Internal Medicine*, researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines.⁸⁷ After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found “opposition to the guidelines was *significantly* more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry.”⁸⁸ Accordingly, a “major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline.”⁸⁹ In an extended version of their findings, the researchers are more explicit: “[O]pposition to more conservative opioid use may, at least in part, be financially motivated.”⁹⁰

Efforts to Limit Accountability

Certain advocacy groups and professional societies have also organized legal efforts to challenge government actions to punish physicians engaging in opioid overprescription and executives responsible for fraudulent marketing of opioid products. In 2005, for example, the National Pain Foundation submitted to the U.S. Court of Appeals for the Fourth Circuit an amicus brief in support of Dr. William Hurwitz,⁹¹ a doctor convicted “of 16 counts of drug trafficking, [for] prescrib[ing] massive quantities of medicine to patients in chronic pain.”⁹² Prosecutors asserted that Dr. Hurwitz “prescribed excessive amounts of Oxycodone and other dangerous narcotics—in one instance more than 1,600 pills a day—to addicts and others, some of whom then sold the medication on a lucrative black market.”⁹³ In defense of Dr. Hurwitz, the National Pain Foundation suggested that

“[t]he conviction [in the trial court] broke ground by holding that a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer.”⁹⁴ Similarly, the Washington Legal Foundation filed an amicus brief challenging the exclusion of three former Purdue executives from participation in federal healthcare programs for 12 years for their admitted failure to prevent the fraudulent marketing of OxyContin.⁹⁵ In a brief filed with the U.S. Court of Appeals for the District of Columbia Circuit, the Washington Legal Foundation argued—unsuccessfully—that the exclusion raised serious constitutional due process concerns.⁹⁶

FULL EXTENT OF INDUSTRY INFLUENCE ON GROUPS IS UNKNOWN

This report does not capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies. According to the *Associated Press* and the Center for Public Integrity, for example, opioid manufacturers “spent more than \$880 million nationwide on lobbying and campaign contributions from 2006 through 2015—more than 200 times what those advocating for stricter [opioid] policies spent.”⁹⁷

Moreover, payments between 2012 and 2017 may not fully reflect historical funding activities by manufacturers, given that several of the most prominent advocates in this space historically—the American Pain Foundation, for example—no longer operate. The fact that opioid prescribing, as measured in morphine milligram equivalents (MME) per capita, peaked between 2010 and 2012 before declining from 2012 to 2015 may also suggest more robust financing of advocacy groups in the pre-2012 period.⁹⁸

In addition, the data contained in this report may not even capture the full extent of payments between the covered manufacturers and patient advocacy groups and professional societies. This report is based on information provided voluntarily to the Committee at the request of the Ranking Member—information which certain manufacturers changed following further inquiries from the minority staff. A timeline of interactions between the Committee, manufacturers, and advocacy groups appears below as Figure 9.

As mentioned above, Ranking Member McCaskill sent requests for payments information to Purdue, Janssen, Insys, Depomed, and Mylan on March 28, 2017.⁹⁹ On April 25, 2017, Depomed provided an initial response, closely followed a response from Purdue on May 11, 2017, and a response from Janssen on June 12, 2017.¹⁰⁰ Following extensive discussions with minority staff, Mylan provided payments information on October 5, 2017.¹⁰¹

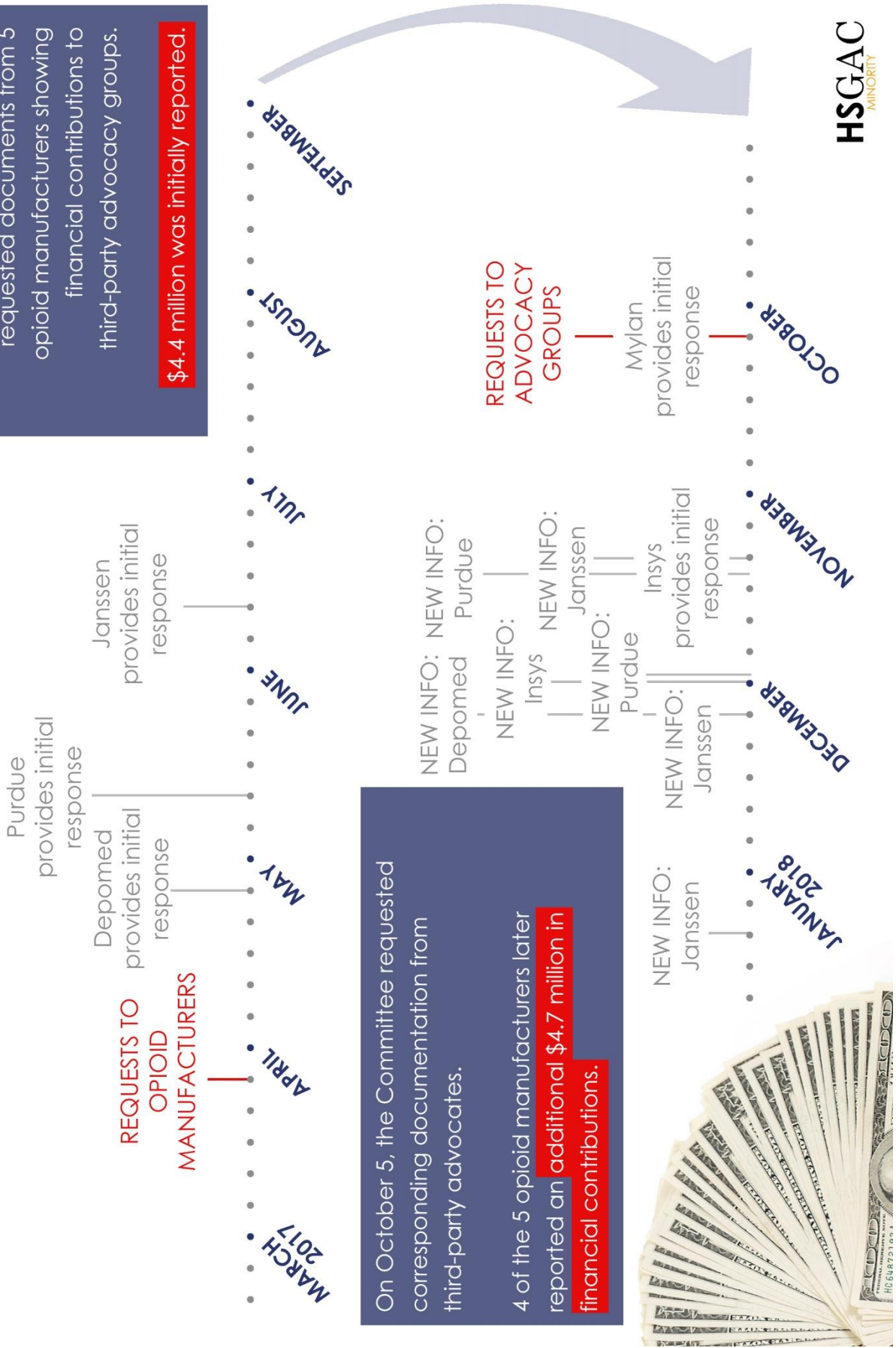
On October 5, 2017, Ranking Member McCaskill sent requests for payment information directly to 15 advocacy groups and professional societies.¹⁰² Following these letters, several manufacturers volunteered additional or revised data. After further due diligence, for example, Janssen reported an additional \$7,500 payment to the American Academy of Pain Medicine and an additional \$128,000 in cumulative payments to the Academy of Integrative Pain Management.¹⁰³ Purdue also provided updated information showing an additional \$70,552 in payments to the American Academy of Pain Medicine, \$415,574 in payments to the American Pain Society, and \$17,755 in payments to the American Society of Pain Management Nursing.¹⁰⁴ For the first time, Purdue also reported \$1,091,025 in payments to the Academy of Integrative Pain Management—the company had not searched for payments to the American Academy of Pain Management, the previous name of the organization—and \$168,500 in payments to the American Cancer Society Cancer Action Network.¹⁰⁵ Purdue additionally reported over \$91,000 in payments associated with incomplete entity names in company records.¹⁰⁶

A comparison of payments information from the five manufacturers and the information advocacy groups provided directly to the Committee revealed several discrepancies. Most significantly, Insys Therapeutics initially failed to report \$2,500,000 in responsive payments to the U.S. Pain Foundation for the “Gain Against Pain” patient assistance program.¹⁰⁷ The company also did not report \$12,500 in

FIGURE 9

TIMELINE of FINANCIAL DISCLOSURES from opioid manufacturers to the United States Senate

On March 28, 2017, minority staff on the homeland security committee requested documents from 5 opioid manufacturers showing financial contributions to third-party advocacy groups. **\$4.4 million was initially reported.**



payments the Academy of Integrative Pain Management reported receiving in 2014 and 2015 and could not confirm or deny these payments after further due diligence.¹⁰⁸ (Insys did, however, report an additional \$3,050 in payments to the Academy of Integrative Pain Management during 2012.¹⁰⁹) Purdue also failed to report \$40,000 in corporate roundtable dues to the American Geriatrics Society Health in Aging Foundation; according to the American Geriatrics Society, this foundation received all payments Purdue directed to the organization between 2012 and 2017.¹¹⁰

In addition, Depomed later reported five additional responsive payments—totaling \$17,600 to the American Chronic Pain Association and \$28,174.95 to the Academy of Integrative Pain Management—after receiving further correspondence from minority staff.¹¹¹ According to Depomed, these payments “were for advertising or promotional purposes,” and the company initially considered them outside the scope of the March 28, 2017, requests.¹¹² Finally, in response to information from minority staff, Janssen representatives also reported the company had made an additional \$68,500 in payments to the American Pain Society and an additional \$76,475 in payments to the American Academy of Pain Medicine via a third party during the 2012-2017 time period.¹¹³

CONCLUSION

The privacy the advocacy groups discussed above have guarded for their donors has come at a high price for the public debate on chronic pain and opioid use in the United States. As a 2011 study in the *American Journal of Public Health* noted, a tension exists between the status of advocacy organizations as “among the most influential and trusted stakeholders in U.S. health policy,” and the reality that their “positions closely correspond to the marketing aims of pharmaceutical and device companies.”¹¹⁴ The findings in this report indicate that this tension exists in the area of opioids policy—that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use. By aligning medical culture with industry goals in this way, many of the groups described above may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

¹ Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, NCHS Data Brief No. 294, *Drug Overdose Deaths in the United States, 1999-2016* (Dec. 21, 2017) (www.cdc.gov/nchs/products/databriefs/db294.htm); *CDC Releases Grim New Opioid Overdose Figures: “We’re Talking About More Than an Exponential Increase.”* Washington Post (Dec. 21, 2017)

(www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.79af03095271).

² *Opioid Crisis Drives Declines in U.S., Missouri Life Expectancy*, Columbia Missourian (Jan. 10, 2018)

(www.columbiainmissourian.com/news/local/opioid-crisis-drives-declines-in-u-s-missouri-life-expectancy/article_cd71e66e-f488-11e7-ac3f-d77b751b7c73.html); see also Department of Health and Human Services, Centers for Disease Control and Prevention, *Drug Overdose Mortality by State* (Jan. 10, 2018) (www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm).

³ *Opioid Crisis Cost Missouri \$12.6 Billion in 2016, Report Says*, St. Louis Business Journal (Jan. 17, 2018).

⁴ *CDC Releases Grim New Opioid Overdose Figures: “We’re Talking About More Than an Exponential Increase.”* Washington Post (Dec. 21, 2017).

⁵ *Opioid Crisis Trims U.S. Life Expectancy, Boosts Hepatitis C*: CDC, Reuters (Dec. 21, 2017) (www.reuters.com/article/us-usa-healthcare-cdc/opioid-crisis-trims-u-s-life-expectancy-boosts-hepatitis-c-cdc-idUSKBN1EF1TF).

⁶ Susannah L. Rose et al., *Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest*, JAMA Internal Medicine (Mar. 2017).

⁷ *Id.*

⁸ *Very Few Patient Groups Don’t Take Pharma Money*, Bloomberg BNA (Oct. 20, 2017) (www.bna.com/few-patient-groups-b73014471175/).

⁹ PharmedOut, *Pharma-Free Advocacy Groups* (www.pharmedout.org/pharma-free-groups.html) (accessed Dec. 7, 2017).

- ¹⁰ Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, *New England Journal of Medicine* (Mar. 2, 2017).
- ¹¹ *Id.*
- ¹² *Id.*
- ¹³ Susannah L. Rose et al., *Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest*, *JAMA Internal Medicine* (Mar. 2017).
- ¹⁴ *Id.*
- ¹⁵ *Id.*
- ¹⁶ *More Than 80 Percent of Patient Groups Accept Drug Industry Funds, Study Shows*, *New York Times* (Mar. 1, 2017) (www.nytimes.com/2017/03/01/health/patient-groups-drug-industry-money.html).
- ¹⁷ See, e.g., Letter from Sen. Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Insys Therapeutics, Inc. (Mar. 28, 2017).
- ¹⁸ *Id.*
- ¹⁹ *Id.*
- ²⁰ See, e.g., Letter from Sen. Baucus and Sen. Grassley to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012); Third Amended Complaint (Oct. 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.*, N.D. Ill. (No. 1:14 CV 04361).
- ²¹ See, e.g., Letter from Sen. Claire McCaskill to Steven P. Stanos, President, American Academy of Pain Medicine (Oct. 5, 2017).
- ²² Purdue also reported \$91,449 in payments to entities with incomplete names like "American Academy of Pain" and "American Society of." Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017)
- ²³ Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc. Letter from Daniel F. Donovan, Counsel for Janssen, to Sen. Claire McCaskill (Nov. 10, 2017).
- ²⁴ Insys was unable to account for \$12,500 in payments to the Academy of Integrative Pain Management for expenses related to the organization's 2014 and 2015 annual meetings. Brian D. Smith, Counsel for Insys Therapeutics, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017)
- ²⁵ Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017)
- ²⁶ The American Geriatrics Society reported that Purdue also provided \$40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).
- ²⁷ Payments from Janssen to the American Society of Pain Management Nursing include two payments to Rockpointe Corporation for an educational grant with signatories including the American Society of Pain Management Nursing. Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (Nov. 10, 2017)
- ²⁸ This total includes \$4,500 in reported payments from Depomed to the "American Society of Pain Management Nurses." Production from Depomed to the Senate Homeland Security and Governmental Affairs Committee (Apr. 25, 2017)
- ²⁹ The National Pain Foundation changed its name to the Global Pain Initiative in mid-2017. Email from Dr. Daniel Bennett, Chairman, Board of Directors, Global Pain Initiative, to Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 10, 2018). According to Dr. Bennett, the Global Pain Initiative board decided in the fourth quarter of 2016 not to accept contributions from pharmaceutical or device manufacturers. This decision "permits an academic 'hands off' approach, which is crucial to [the Global Pain Initiative's] public credibility and mission." *Id.*
- ³⁰ An additional payment from Insys to the U.S. Pain Foundation of \$250,000—on April 7, 2017—fell outside the scope of the March 28, 2017, requests and is not included in this total.
- ³¹ Letter from Jonathan C. Su, Counsel for Mylan, to Sen. Claire McCaskill (Sept. 15, 2017).
- ³² *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, *Wall Street Journal* (Nov. 22, 2016) (www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968); *An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain*, *Forbes* (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).
- ³³ Janssen Pharmaceuticals, Inc.: *Janssen Pharmaceuticals, Inc. Completes Divestiture of U.S. License Rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol) extended-release tablets and NUCYNTA® (tapentadol) Oral Solution to Depomed, Inc.* (Apr. 2, 2015); *DepoMed to Buy U.S. Rights to Nucynta From J&J Unit*, *Wall Street Journal* (Jan. 16, 2015) (www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503).
- ³⁴ Mylan N.V.: *Mylan Launches First and Only Available Intermediate Dosage Strengths of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr* (March 11, 2015).
- ³⁵ Letter from Jonathan C. Su, Counsel for Mylan, to Sen. Claire McCaskill (Sept. 15, 2017).

- ³⁶ Although Janssen representatives confirmed the company made a \$60,000 payment to the American Pain Society and \$75,975 in payments to the American Academy of Pain Medicine via a third party during the 2012-2017 time period, it could not provide the exact dates associated with these payments. See Daniel F. Donovan, Counsel for Janssen, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 17, 2018). According to information the minority staff received from the American Pain Society and the American Academy of Pain Medicine directly, however, all these payments occurred in 2012. See Production from the American Pain Society to the Senate Homeland Security and Governmental Affairs Committee (Oct. 9, 2017); Production from the American Academy of Pain Medicine (Oct. 16, 2017). Janssen representatives later reported an additional \$8,500 payment to the American Pain Society and an additional \$500 payment to the American Academy of Pain Medicine—both via a third party in 2012. Email from Daniel F. Donovan, Counsel for Janssen, to Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 31, 2018).
- ³⁷ Financial Accounting Standards Board, *Not-for-Profit Entities (Topic 958)* (Aug. 2016) (asc.fasb.org/imageRoot/56/92564756.pdf).
- ³⁸ Purdue Pharma L.P., *Grants and Giving Frequently Asked Questions* (July 11, 2014).
- ³⁹ *Id.*
- ⁴⁰ Data on contributions and grants are taken from line 8 of Form 990 for each group. The American Pain Foundation ended its operations in 2012.
- ⁴¹ These totals consist of payments in the Open Payments database from the five opioid manufacturers at issue to physician board members, advisory board members, advisory council members, staff members, and officers and executives of the advocacy groups listed. The totals only include payments from manufacturers to physicians since August 2013, when the first reporting period for the CMS Open Payments database began. See Centers for Medicare and Medicaid Services, *How Open Payments Works* (Sept. 2, 2015) (www.cms.gov/OpenPayments/About/How-Open-Payments-Works.html). The listed payments from manufacturers to the groups occurred between January 2012 and March 2017.
- ⁴² Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data, (openpaymentsdata.cms.gov/physician/138667/summary) (accessed Dec. 22, 2017). See also American Academy of Pain Medicine, AAPM Fact Sheet (www.painmed.org/files/aapm-fact-sheet.pdf) (accessed Dec. 22, 2017).
- ⁴³ Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data (openpaymentsdata.cms.gov/physician/138667/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Jianguo Cheng, Open Payments Data (openpaymentsdata.cms.gov/physician/163794/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Ajay Wasan, Open Payments Data (openpaymentsdata.cms.gov/physician/1272772/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Daniel B. Carr, Open Payments Data (openpaymentsdata.cms.gov/physician/202832/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Robert Hurley, Open Payments Data (openpaymentsdata.cms.gov/physician/299398/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Robert Wailes, Open Payments Data (openpaymentsdata.cms.gov/physician/233305/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Chester Church Buckenmaier III, Open Payments Data (openpaymentsdata.cms.gov/physician/1035447/summary) (accessed Dec. 22, 2017). See also American Academy of Pain Medicine, AAPM Fact Sheet (www.painmed.org/files/aapm-fact-sheet.pdf) (accessed Dec. 22, 2017).
- ⁴⁴ *Id.*
- ⁴⁵ Centers for Medicare and Medicaid Services, Charles Argoff, Open Payments Data (openpaymentsdata.cms.gov/physician/93628/summary) (accessed Dec. 22, 2017). See also American Academy of Pain Medicine Foundation, AAPM Foundation Leadership (aapmfoundation.org/leadership) (accessed Dec. 22, 2017).
- ⁴⁶ Centers for Medicare and Medicaid Services, Daniel B. Carr, Open Payments Data, (openpaymentsdata.cms.gov/physician/202832/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Edward C. Covington, Open Payments Data, (openpaymentsdata.cms.gov/physician/1008604/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Steven Feinberg, Open Payments Data, (openpaymentsdata.cms.gov/physician/308924/payment-information) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Gary W. Jay, Open Payments Data (openpaymentsdata.cms.gov/physician/1134064/payment-information) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, John D. Loeser, Open Payments Data (openpaymentsdata.cms.gov/physician/555855/payment-information) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Sean Mackey, Open Payments Data (openpaymentsdata.cms.gov/physician/406055/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Srinivasa Raja, Open Payments Data (openpaymentsdata.cms.gov/physician/72208/payment-information) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data (openpaymentsdata.cms.gov/physician/138667/summary) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Knox Todd, Open Payments Data

- (openpaymentsdata.cms.gov/physician/1052955/payment-information) (accessed Dec. 22, 2017); Centers for Medicare and Medicaid Services, Debra Weiner, Open Payments Data (openpaymentsdata.cms.gov/physician/591428/payment-information) (accessed Dec. 22, 2017). See also American Chronic Pain Association, Advisory Board (theacpa.org/Advisory-Board) (accessed Dec. 22, 2017).
- ⁴⁷ Global Pain Initiative, Board of Directors (www.globalpaininitiative.org/board-of-directors/) (accessed Jan. 2, 2018).
- ⁴⁸ Centers for Medicare and Medicaid Services, Daniel S. Bennett, Open Payments Data (openpaymentsdata.cms.gov/physician/329225/summary) (accessed Jan. 2, 2018). See also Global Pain Initiative, Board of Directors (globalpaininitiative.org/board-of-directors/) (accessed Jan. 2, 2018).
- ⁴⁹ Centers for Medicare and Medicaid Services, Daniel S. Bennett, Open Payments Data (openpaymentsdata.cms.gov/physician/329225/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Dmitry M. Arbuck, Open Payments Data (openpaymentsdata.cms.gov/physician/213597/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Joseph V. Pergolizzi, Jr., Open Payments Data (openpaymentsdata.cms.gov/physician/223423/summary) (accessed Jan. 2, 2018). See also Global Pain Initiative, Board of Directors (globalpaininitiative.org/board-of-directors/) (accessed Jan. 2, 2018).
- ⁵⁰ Global Pain Initiative, Clinical and Scientific Advisory Council (www.globalpaininitiative.org/clinical-scientific-council/) (accessed Oct. 3, 2017).
- ⁵¹ Centers for Medicare and Medicaid Services, Kenny Chantasi, Open Payments Data (openpaymentsdata.cms.gov/physician/64321/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Leonard A. Farber, Open Payments Data (openpaymentsdata.cms.gov/physician/300520/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Perry G. Fine, Open Payments Data (openpaymentsdata.cms.gov/physician/672854/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Joseph Pergolizzi, Jr., Open Payments Data (openpaymentsdata.cms.gov/physician/223423/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Steven M. Simon, Open Payments Data (openpaymentsdata.cms.gov/physician/386520/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Lisa Jo Stearns, Open Payments Data (openpaymentsdata.cms.gov/physician/41530/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Andrea Trescot, Open Payments Data (openpaymentsdata.cms.gov/physician/231857/summary) (accessed Jan. 2, 2018); Centers for Medicare and Medicaid Services, Lynn R. Webster, Open Payments Data (openpaymentsdata.cms.gov/physician/1136720/summary) (accessed Jan. 2, 2018). See also Global Pain Initiative, Clinical and Scientific Advisory Council (globalpaininitiative.org/clinical-scientific-council/) (accessed Jan. 2, 2018).
- ⁵² As with the previous figure, these totals only include payments to group-affiliated physicians since August 2013.
- ⁵³ See 26 U.S.C. § 6104(d)(3)(A).
- ⁵⁴ Washington Legal Foundation, *2016 Annual Report* (2016) (www.wlf.org/pdf/WLF2016AnnualReport.pdf).
- ⁵⁵ American Geriatrics Society Health in Aging Foundation, Guidelines for Corporate Relationships (www.healthinagingfoundation.org/support-us/become-a-corporate-partner/guidelines-for-corporate-relationships/) (accessed Oct. 18, 2017); American Geriatrics Society Health in Aging Foundation, Meet Our Partners (www.healthinagingfoundation.org/support-us/become-a-corporate-partner/meet-our-partners/) (accessed Jan. 2, 2018).
- ⁵⁶ U.S. Pain Foundation, Transparency (www.uspainfoundation.org/transparency/) (accessed Oct. 18, 2017).
- ⁵⁷ American Chronic Pain Association, Partners & Contributors (www.theacpa.org/Partners-Contributors) (accessed Oct. 18, 2017).
- ⁵⁸ American Cancer Society Cancer Action Network, Our Partners (www.cancer.org/our-partners.html) (accessed Oct. 18, 2017); Center for Practical Bioethics, Community Supporters (www.practicalbioethics.org/support-our-mission/community-supporters.html) (accessed Oct. 18, 2017).
- ⁵⁹ American Academy of Pain Medicine Foundation, AAPM Foundation Donors (www.aapmfoundation.org/donors) (accessed Oct. 18, 2017).
- ⁶⁰ American Pain Society, Corporate Council Members (www.americanpainsociety.org/get-involved/corporate-council/overview) (accessed Oct. 18, 2017).
- ⁶¹ *Id.*
- ⁶² American Society for Pain Management Nursing, Corporate Membership (www.aspmn.org/Pages/corporatemembership.aspx) (accessed Oct. 18, 2017); American Society for Pain Management Nursing, ASPMN Corporate Membership Categories (www.aspmn.org/Documents/Membership/Corporate%20membership%20information_17.pdf) (accessed Jan. 2, 2018).
- ⁶³ Third Amended Complaint (Oct. 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.*, N.D. Ill. (No. 1:14 CV 04361).
- ⁶⁴ *Id.*
- ⁶⁵ *Id.*
- ⁶⁶ *Chronic Pain Guidelines Suggest Opioids*, New York Times (May 12, 2009) (query.nytimes.com/gst/fullpage.html?res=9806E0D71E3AF931A25756C0A96F9C8B63).
- ⁶⁷ *Id.*; see also *Pharmacological Management of Persistent Pain in Older Persons: American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons*, Journal of the American Geriatrics Society (Aug. 2009).
- ⁶⁸ Third Amended Complaint (Oct. 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.*, N.D. Ill. (No. 1:14 CV 04361).
- ⁶⁹ *Id.*

- ⁷⁰ *Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis*, The Center for Public Integrity (Dec. 15, 2016) (www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis).
- ⁷¹ *Id.*
- ⁷² *Industry Uses 50-State Strategy to Weaken Drug Laws*, The Journal (Sept. 22, 2016) (the-journal.com/articles/1047-industry-uses-50-state-strategy-to-weaken-drug-laws).
- ⁷³ U.S. Pain Foundation, Annual Report (www.uspainfoundation.org/about-us/annual-report/) (accessed Oct. 3, 2017).
- ⁷⁴ Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (Mar. 15, 2016) (www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf). See also Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, JAMA Internal Medicine (Apr. 19, 2016).
- ⁷⁵ C.D.C. *Painkiller Guidelines Aim to Reduce Addiction Risk*, New York Times (Mar. 15, 2016) (www.nytimes.com/2016/03/16/health/cdc-opioid-guidelines.html).
- ⁷⁶ Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (Mar. 15, 2016) (www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf).
- ⁷⁷ *Id.*
- ⁷⁸ *Id.*
- ⁷⁹ C.D.C. *Painkiller Guidelines Aim to Reduce Addiction Risk*, New York Times (Mar. 15, 2016) (www.nytimes.com/2016/03/16/health/cdc-opioid-guidelines.html).
- ⁸⁰ *Opioid Epidemic: Ex-DEA Official Says Congress is Protecting Drug Makers*, Guardian (Oct. 31, 2016) (www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma).
- ⁸¹ Practical Pain Management, *Responses and Criticisms Over New CDC Opioid Prescribing Guidelines* (www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines) (accessed Sept. 28, 2017).
- ⁸² *Chronic Pain Groups Blast CDC for Opioid Guidelines*, Pain News Network (Sept. 22, 2015) (www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines).
- ⁸³ *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Center for Public Integrity (Sept. 19, 2016) (www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic).
- ⁸⁴ Washington Legal Foundation, *Re: Guideline for Prescribing Opioids for Chronic Pain* (Nov. 17, 2015) (www.wlf.org/upload/litigation/misc/CDCCComments-Opioids.pdf). In addition to its work related to the pharmaceutical industry, the Washington Legal Foundation has also recently challenged the validity of Consumer Financial Protection Bureau enforcement actions, raised objections to certain Department of Labor disclosure requirements, and sought to enjoin the enforcement of a local ordinance requiring health warnings in advertisements for sugary drinks, among other initiatives. See Washington Legal Foundation, *2016 Annual Report* (2016) (www.wlf.org/pdf/WLF2016AnnualReport.pdf). WLF previously maintained a relationship with the Philip Morris tobacco company during regulatory disputes with the Food and Drug Administration throughout the 1990s. See, e.g., Letter from Steven C. Parrish, Senior Vice President, Corporate Affairs, Philip Morris, to Daniel J. Popeo, Chairman & General Counsel, Washington Legal Foundation (Mar. 21, 1996) (www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=zhfw0096); Philip Morris, *REM Monthly Report* (Apr. 1994) (www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=fphm0071); Memorandum from BSMG Worldwide to Philip Morris, *Communications Plan – Supersized* (Feb. 25, 1999) (www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=xmyd0068).
- ⁸⁵ Washington Legal Foundation, *Re: Guideline for Prescribing Opioids for Chronic Pain* (Nov. 17, 2015) (www.wlf.org/upload/litigation/misc/CDCCComments-Opioids.pdf).
- ⁸⁶ *The CDC Just Told American Doctors to Rethink Pain Treatment and Opioid Addiction*, Vice (Mar. 17, 2016) (news.vice.com/article/the-cdc-just-told-american-doctors-to-rethink-pain-treatment-and-opioid-addiction).
- ⁸⁷ Dora H. Lin et al., *Financial Conflicts of Interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain*, JAMA Internal Medicine (Mar. 2017).
- ⁸⁸ *Id.* (emphasis added).
- ⁸⁹ *Id.*
- ⁹⁰ Dora H. Lin et al., *Potential Financial Conflicts of Interest and Federal Opioid Guidelines: A Cross-Sectional Study* (2017) (manuscript provided to minority staff).
- ⁹¹ Brief for Amici, The American Pain Foundation, The National Pain Foundation and The National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction (Sept. 8, 2005), *United States v. William Eliot Hurwitz*, 4th Cir. (No. 05-4474).
- ⁹² *Pain Doctor is Guilty of Drug Trafficking*, Washington Post (Apr. 28, 2007) (www.washingtonpost.com/wp-dyn/content/article/2007/04/27/AR2007042702204.html).
- ⁹³ *Id.*
- ⁹⁴ Brief for Amici, The American Pain Foundation, The National Pain Foundation, and The National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction (Sept. 8 2005), *United States v. William Eliot Hurwitz*, 4th Cir. (No. 05-4474).
- ⁹⁵ Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal (June 29, 2011), *Friedman v. Sebelius*, D.C. Cir. (No. 11-5028); *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. July 27, 2012).

- ⁹⁶ Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal (June 29, 2011), *Friedman v. Sebelius*, D.C. Cir. (No. 11-5028).
- ⁹⁷ *Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis*, The Center for Public Integrity (Dec. 15, 2016) (www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis).
- ⁹⁸ See Dr. Gery P. Guy Jr. et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015*, CDC Morbidity and Mortality Weekly Report (July 7, 2017) (www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm).
- ⁹⁹ See, e.g., Letter from Sen. Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Insys Therapeutics, Inc. (Mar. 28, 2017).
- ¹⁰⁰ Production from Depomed to the Senate Homeland Security and Governmental Affairs Committee (Apr. 25, 2017); Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (May 11, 2017); Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (June 12, 2017).
- ¹⁰¹ Production from Mylan to the Senate Homeland Security and Governmental Affairs Committee (Oct. 5, 2017).
- ¹⁰² See, e.g., Letter from Sen. Claire McCaskill to Steven P. Stanos, President, American Academy of Pain Medicine (Oct. 5, 2017).
- ¹⁰³ See Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (June 12, 2017); Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (Nov. 10, 2017).
- ¹⁰⁴ See Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (May 11, 2017); Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).
- ¹⁰⁵ *Id.* As stated above, the total for the American Cancer Society Cancer Action Network also included payments from Purdue to the American Cancer Society that could potentially apply to the Cancer Action Network.
- ¹⁰⁶ Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).
- ¹⁰⁷ See Letter from Paul Gileno, U.S. Pain Foundation, to Sen. Claire McCaskill (Oct. 5, 2017); Letter from Brian D. Smith, Counsel for Insys Therapeutics, to Sen. Claire McCaskill (Nov. 10, 2017). As stated above, one payment between Insys and the U.S. Pain Foundation related to this program—a \$250,000 payment on April 7, 2017—fell outside of the scope of the March 28, 2017, requests and is not included in this total. See E-mail from Brian D. Smith, Counsel for Insys Therapeutics, to Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Dec. 1, 2017).
- ¹⁰⁸ See Production from the Academy of Integrative Pain Management to the Senate Homeland Security and Governmental Affairs Committee (Oct. 31, 2017); Brian D. Smith, Counsel for Insys Therapeutics, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 28, 2017).
- ¹⁰⁹ Email from Brian D. Smith, Counsel for Insys Therapeutics, to Committee on Homeland Security and Governmental Affairs Minority Staff (Dec. 1, 2017).
- ¹¹⁰ Letter from Nancy E. Lundebjerg, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017). According to counsel for Purdue, the company could verify three out of four payments to the American Geriatrics Society Health in Aging Foundation. Reginald J. Brown, Counsel for Purdue Pharma, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Nov. 29, 2017).
- ¹¹¹ Email from Catherine A. Byrd, to Committee on Homeland Security and Governmental Affairs Minority Staff (Dec. 1, 2017); Letter from J. Evans Rice, Counsel for Depomed, to Sen. Claire McCaskill (Dec. 5, 2017).
- ¹¹² *Id.*
- ¹¹³ Daniel F. Donovan, Counsel for Janssen, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Dec. 11, 2017); Daniel F. Donovan, Counsel for Janssen, Briefing with Senate Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 17, 2018); Email from Daniel F. Donovan, Counsel for Janssen, to Committee on Homeland Security and Governmental Affairs Minority Staff (Jan. 31, 2018).
- ¹¹⁴ Sheila M. Rothman et al., *Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices*, American Journal of Public Health (Apr. 2011).