US Senate report details funding of patient advocacy groups by opioid manufacturers

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Missouri Senator Claire McCaskill issued a report last week exposing the financial connections between the major opioid manufacturers and ostensibly independent patient advocacy groups.

The report, which is the outcome of a nearly year-long investigation, was released amidst the ongoing opioid epidemic in the United States where more than 600,000 people died from drug overdoses between 2000 and 2016, according to the Centers for Disease Control and Prevention (CDC). In 2016 alone, over 42,000 Americans died from opioid drug overdoses, 40 percent of which involved prescription painkillers. In other words, on average 115 Americans die every day from opioid overdoses.

Based on disclosures by the manufacturers of the five major opioid products—Purdue Pharma, Janssen Pharmaceuticals, Mylan, Depomed and Insys Therapeutics—made in response to requests by McCaskill, the report found that these companies donated nearly $9 million to 14 patient advocacy groups between 2012 and 2017. These companies paid doctors affiliated with these groups an additional $1.6 million, bringing their total funding to over $10 million.

The report did not include information on other major opioid manufacturers, such as Allergan, Pfizer, Teva Pharmaceuticals and Endo Health Solutions.

Purdue Pharma, maker of the painkiller Oxycontin, gave the greatest amount to these organizations, totaling $4,153,554. Insys Therapeutics, maker of the fentanyl product Subsys, gave more than $3 million. Both companies are known for aggressively and deceptively promoting their highly addictive products to doctors.

Not surprisingly, these patient advocacy organizations, whose policy positions are given more credibility since they are supposedly independent of drug companies, favorably promoted the treatment of pain with opioids. Only a handful of advocacy organizations working on pain-related issues do not accept donations from the drug industry.

"These groups," notes the report's executive summary, "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."

Opioid manufacturers are interested in these groups because advocacy organizations can influence health policies that impact the drug industry. According to the report, they "play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."

However, the financial relationships between the drug companies and advocacy organizations are not always transparent.

For example, one study published in the *New England Journal of Medicine* last year and cited by the report found that at least 83 percent of the 104 organizations examined received industry funding and 39 percent included a former drug industry executive on their board, but only 57 percent disclosed donation amounts (often given in ranges, rather than exact figures).

Similarly, a study published last year in the *Journal of the American Medical Association* found that while 67 percent of the 245 organizations it looked at received industry funding—12 percent received more than half their funding from industry—only 65 percent of the organizations released information on their funding from for-profit sources. Moreover, 8 percent of the respondents "reported [that] pressure to conform their organizations' positions to the interests of industry funders is of concern."

Among those patient advocacy groups receiving the

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most funding from opioid manufacturers were the Academy of Integrative Pain Management, the American Academy of Pain Medicine, the American Chronic Pain Association and the American Geriatrics Society.

Around 30 percent of the total contributions made by the major opioid manufacturers, and the largest donation category, went towards restricted grants that specify the use of their money. Non-education grants—despite the name of the category, these funds are used for initiatives related to patient and public education and scientific research—constituted 26 percent of all donations, followed by payments for advertising (18 percent) and sponsorship (14 percent).

The report also detailed payments from the opioid companies to physicians affiliated with these advocacy organizations totaling over $1.6 million. For example, based on data from CMS open payments, between 2013 and 2016 Dr. Steven Stanos of the American Academy of Pain Medicine received over $90,000 in payments, while Dr. Charles Argoff, president of the American Academy of Pain Medicine Foundation, received over $600,000.

The report notes that these groups, financially supported by opioid manufacturers, "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."

According to a complaint from the City of Chicago cited by the report, the Academy of Pain and Medicine and the American Pain Society allegedly issued guidelines to physicians in 2009 that promoted opioids as "safe and effective" for chronic pain. That same year, the American Geriatrics Society issued guidelines for patients with persistent pain recommending that they use opioids instead of aspirin or ibuprofen if acetaminophen (Tylenol) proves insufficient.

"It looks pretty damning when these groups were pushing the message about how wonderful opioids are and they were being heavily funded, by the manufacturers of those drugs," Lewis Nelson, a professor of emergency medicine at Rutgers University and expert on prescription drug misuse, told the Center for Public Integrity after the release of the report.

The advocacy groups also lobbied to defeat legislative measures that would have restricted the over-prescription of opioids and opposed the 2016 guidelines issued by the CDC recommending non-opioid therapies for chronic pain (outside of active cancer treatment and end-of-life care) and generally limiting opioid prescriptions for acute pain to three to seven days.

The report states that these groups registering opposition with the CDC "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."

This conclusion coincides with that of a 2017 article in *JAMA Internal Medicine*, which looked at more than 150 organizations that submitted comments to the draft CDC guidelines, and found that "opposition to the guidelines was significantly more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."

Some of the advocacy groups even challenged efforts by the government to hold accountable physicians overprescribing opioids and industry executives engaged in fraudulent marketing.

For example, the National Pain Foundation defended Dr. William Hurwitz after he prescribed excessive amounts of oxycodone, up to 1,600 pills in one day: "The 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."

The report concludes by quoting from a 2011 study in the *American Journal of Public Health* that "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.'"

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