

# Pro-painkiller echo chamber shaped policy amid drug epidemic

September 19 2016, by Matthew Perrone And Ben Wieder

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This Tuesday, Feb. 19, 2013 file photo shows OxyContin pills arranged for a photo at a pharmacy in Montpelier, Vt. For more than a decade, members of a little-known group called the Pain Care Forum have blanketed Washington with messages touting prescription painkillers' vital role in the lives of millions of Americans, creating an echo chamber that has quietly derailed efforts to curb U.S. consumption of the drugs, which accounts for two-thirds of the world's usage. (AP Photo/Toby Talbot)

For more than a decade, members of a little-known group called the Pain Care Forum have blanketed Washington with messages touting prescription painkillers' vital role in the lives of millions of Americans, creating an echo chamber that has quietly derailed efforts to curb U.S. consumption of the drugs, which accounts for two-thirds of the world's usage.

In 2012, drugmakers and their affiliates in the forum sent a letter to U.S. senators promoting a hearing about an influential report on a "crisis of epidemic proportions": pain in America. Few knew the report stemmed from legislation drafted and pushed by forum members and that their experts had helped author it. The report estimated more than 100 million Americans—roughly 40 percent of adults—suffered from chronic pain, an eye-popping statistic that some researchers call deeply problematic.

The letter made no reference to another health issue that had been declared an epidemic by federal authorities: drug overdoses tied to prescription painkillers. Deaths linked to addictive drugs like OxyContin, Vicodin and Percocet had increased more than fourfold since 1999, accounting for more fatal overdoses in 2012 than heroin and cocaine combined.

An investigation by The Associated Press and The Center for Public Integrity reveals that similar feedback loops of information and influence play out regularly in the nation's capital, fueled by money and talking points from the Pain Care Forum, a loose coalition of drugmakers, trade groups and dozens of nonprofits supported by industry funding that has flown under the radar until now.

Hundreds of internal documents shed new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse, which has claimed the lives of roughly 165,000 Americans since 2000, according to federal estimates.

Painkillers are among the most widely prescribed medications in the U.S., but pharmaceutical companies and allied groups have a multitude of legislative interests beyond those drugs. From 2006 through 2015, participants in the Pain Care Forum spent over \$740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures, according to an analysis of lobbying filings by the Center for Public Integrity and AP.

The same organizations reinforced their influence with more than \$140 million doled out to political campaigns, including more than \$75 million alone to federal candidates, political action committees and parties.

That combined spending on lobbying and campaigns amounts to more than 200 times the \$4 million spent during the same period by the handful of groups that work for restrictions on painkillers. Meanwhile, opioid sales reached \$9.6 billion last year, according to IMS Health, a health information company.

"You can go a long, long way in getting what you want when you have a lot of money," said Professor Keith Humphreys of Stanford University, a former adviser on drug policy under President Barack Obama. "And it's only when things get so disastrous that finally there's enough popular will aroused to push back."



Keith Humphreys, a professor of psychiatry and behavioral sciences at Stanford University, poses for a photo in Stanford, Calif., on Monday, Aug. 29, 2016. Regarding the political influence of pharmaceutical companies, the former adviser on drug policy under President Barack Obama says, "You can go a long, long way in getting what you want when you have a lot of money. ... And it's only when things get so disastrous that finally there's enough popular will aroused to push back." (AP Photo/Marcio Jose Sanchez)

Obama gave his first speech on the opioid epidemic last fall. In July, Congress passed its first legislation targeting the crisis, an election-year

package intended to expand access to addiction treatment. But the law includes little new funding and no restrictions on painkillers, such as mandatory training for prescribers, a step favored by federal advisory panels.

Obama administration officials say they have tried to strike a balance between controlling the harms of opioids and keeping them available for patients.

"We did not want to deny people access to appropriate pain care," said Michael Botticelli, Obama's drug czar. "We were all trying to figure out what the balance was, and that's still the case going forward."

Painkillers are modern versions of ancient medicines derived from the opium poppy, also the source of heroin. Prescription opioids were long reserved for the most severe forms of pain associated with surgery, injury or terminal diseases like cancer.

That changed in the 1990s with a surge in prescribing for more common ailments like back pain, arthritis and headaches. A combination of factors fueled the trend, including new medical guidelines, insurance policies and pharmaceutical marketing for long-acting drugs like OxyContin.

The drug's manufacturer, Purdue Pharma, pleaded guilty and agreed to pay more than \$600 million in fines in 2007 for misleading the public about the risks of OxyContin. But the drug continued to rack up blockbuster sales, generating more than \$22 billion over the last decade.

Despite having no physical address or online presence, the Pain Care Forum hosts high-ranking officials from the White House, Food and Drug Administration and other agencies at its monthly gatherings.

Purdue's Washington lobbyist, Burt Rosen, co-founded the forum more than a decade ago and coordinates the group's meetings, which include dozens of lobbyists and executives.

Purdue declined to make Rosen available for interviews and did not answer specific questions about its lobbying activities or financial support for forum participants. Purdue said it supports a range of advocacy groups, including some with differing views on opioids.



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"In practice and governance, the Pain Care Forum is like any of the hundreds of policy coalitions in Washington and throughout the nation," the company said in a statement, adding: "Purdue complies with all applicable lobbying disclosure laws and requirements."

While Purdue, Endo Pharmaceuticals and other members have maintained the forum does not take policy positions, the AP and Center for Public Integrity's reporting shows the group's participants have worked together to push and draft federal legislation, blunt regulations and influence decisions around opioids.

Opioid drugmakers say they are striving to improve the safety of their products and how they are used. They point to new harder-to-crush pills and initiatives that, among other things, allow states to share databases designed to spot "doctor shopping" by patients.

Elsewhere, experts are reevaluating the effectiveness of opioids for most forms of chronic pain, noting little long-term research.

"The biggest myth out there is that there's a conflict between reducing our dependence on opioids and improving care for patients in pain," said Dr. Caleb Alexander, co-director of Johns Hopkins University's Center for Drug Safety and Effectiveness. "It's an artificial conflict, but there are lots of vested interests behind it."

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## 'THE EPIDEMIC OF PAIN'

By spring 2014, the figure that 100 million Americans suffered from chronic pain was getting new attention: as a talking point for the nation's top drug regulator.

The head of the FDA used the statistic to illustrate the importance of keeping painkillers accessible, despite the escalating toll of opioid addiction and abuse in American communities.



In this Wednesday, July 6, 2016 file photo, Gloucester, Mass., Police Chief Leonard Campanello, joined by other members of law enforcement from around the country, talks to media outside the White House in Washington, D.C., after meeting with senior Obama administration officials to discuss the urgent need for resources to address the nationwide prescription opioid and heroin epidemic. (AP Photo/Carolyn Kaster)

In an online essay, then-Commissioner Dr. Margaret Hamburg said reducing the toll was a "highest priority," but that her agency had to "balance it with another major public health priority: managing the pain that affects an estimated 100 million Americans."

That line populated her speeches and interviews for months.

But Michael Von Korff of the Group Health Research Institute, whose



research contributed to the statistic, said the number has no connection to opioids. Instead, he said, it mostly represents "people with run-of-the-mill pain problems who are already managing them pretty well."

Von Korff's work is funded by federal, foundation and health insurance sources. He also is an officer with Physicians for Responsible Opioid Prescribing, a group that's pushing for restrictions on the drugs.

Pain Care Forum participants spent nearly \$19 million on lobbying efforts that included the legislation requiring federal research on pain and the Institute of Medicine report that first highlighted the figure.

Concerns about the use of the statistic in connection with opioids and ties between some of the report authors and the pharmaceutical industry were covered by the Milwaukee Journal Sentinel in 2014.

Nearly half the experts assembled by the Institute of Medicine to write the 364-page report had served as leaders in Pain Care Forum-affiliated groups, such as the American Pain Foundation, the American Pain Society and the American Academy of Pain Medicine—all supported by industry funding.

Hamburg said in an email that the report was "another piece of scientific literature that helped inform the broader field," which her agency had no role in producing.

The Pain Care Forum discussed the legislation that led to the report at its first meeting in February 2005, according to notes by one of the group's principal members, The American Pain Foundation. Memos from the now-defunct foundation are among hundreds of documents obtained through public information requests by the AP and the Center for Public Integrity from the city of Chicago, which accused six drugmakers of misleading the public about opioid risks in an ongoing lawsuit.



Dr. Nathaniel Katz, a former adviser to the Food and Drug Administration, and currently CEO of Analgesic Solutions, stands for a photograph at the company's offices in Natick, Mass., on Tuesday, Aug. 16, 2016. In 2010, he traveled to Washington, D.C., to implore an FDA panel to support tougher requirements to manage opioid risks. "The days of prescribers not being trained how to safely prescribe the number one medication in the United States have to be brought to an end by you today," said Katz, according to a meeting transcript. (AP Photo/Steven Senne)

In June 2006, the forum organized a Capitol Hill briefing headlined "The Epidemic of Pain in America." Briefing materials included statements like: "Appropriate use of opioid medications like oxycodone is safe and effective and unlikely to cause addiction in people who are under the care of a doctor and who have no history of substance abuse."

Attendees were asked to support a bill from then-Congressman Mike

Rogers, which would later be rewritten by the forum and reintroduced in 2007 and 2009, according to the memos. It called for the Institute of Medicine—now a part of the National Academies of Sciences, Engineering and Medicine—to develop a comprehensive report on pain in America. Parts of the legislation eventually passed with Obama's sweeping health care overhaul of 2010.

Rogers, a Republican from Michigan, received at least \$310,000 in contributions from forum groups from 2006 to 2015, which went to his campaign and to a leadership account that he could use to donate to his peers. He left office last year.

Rogers rejected the idea that he was influenced by the contributions, and said he began working on pain issues as a state senator after helping his brother through a series of back surgeries.

"I think they said, 'This guy is a champion, he's doing something we believe in and we want to support guys like that,'" he said.

Sen. Orrin Hatch, R-Utah, and former Sen. Chris Dodd, D-Conn., who together introduced the Senate version of the bill, received more than \$360,000 and \$190,000 respectively from forum participants.

Staffers for Hatch did not respond to repeated requests for comment. Dodd, who left office in 2011, said in a statement: "Sen. Hatch and I worked together to increase awareness and understanding of this serious medical condition in the hopes of providing relief to the millions of Americans who suffer from chronic pain."

Phil Saigh, the executive director of the American Academy of Pain Medicine, said he informed the Pain Care Forum years ago that his group did not consider itself a member of the coalition. Yet the academy has continuously appeared in directories of forum participants since

2006, including as late as 2013, the most recent documents available.

The academy and the American Pain Society say some of the funding they receive from drugmakers is in the form of grants used for expenses tied to educational meetings and events. Both organizations also operate separate "corporate councils," in which companies are granted meetings with physicians in exchange for annual payments up to the \$20,000 range.



Dr. Nathaniel Katz, a former adviser to the Food and Drug Administration, and currently CEO of Analgesic Solutions, stands for a photograph at the company's offices in Natick, Mass., on Tuesday, Aug. 16, 2016. In 2010, he traveled to Washington, D.C., to implore an FDA panel to support tougher requirements to manage opioid risks. "The days of prescribers not being trained how to safely prescribe the number one medication in the United States have to be brought to an end by you today," said Katz, according to a meeting transcript. (AP Photo/Steven Senne)

Jennifer Walsh, a spokeswoman for the National Academies of Sciences, Engineering and Medicine, said, "We stand by our report, the committee, and the process that produced it."

Experts who could personally profit from reports are prohibited from serving on its committees, she added. But the academies, which advise the federal government on scientific and medical topics, declined to release financial disclosure forms completed by panelists.

Those on opposite sides of the opioids debate agree that the report raised important points about pain treatment, including warnings about the risks of painkillers.

Still, some report passages called for expanding their use: "Regulatory, legal, educational and cultural barriers inhibit the medically appropriate use of opioid analgesics."

At the time, one in five U.S. patients who visited a doctor for pain already received an opioid prescription, according to national estimates.

After the report's release in June 2011, the American Pain Foundation received \$150,000 from Purdue to promote its findings through the Pain Care Forum. The foundation planned "congressional briefings and hearings" and "meetings with the leadership of various federal agencies," according to a November 2011 letter.

The foundation closed the next year. Senate investigators had asked about the nonprofit receiving nearly 90 percent of its funding from industry.

Meanwhile, a handful of lawmakers tried to draw attention to rising rates of painkiller abuse.



In 2010, then-Rep. Mary Bono, R-Calif., co-founded the Congressional Caucus on Prescription Drug Abuse, which focused on educating lawmakers about drug abuse. She clipped newspaper stories from her colleagues' home states, but recalled, "They'd just say 'Yeah, yeah, yeah,' and move on to more pressing matters."



This Oct. 14, 2015 file photo shows the Food and Drug Administration campus in Silver Spring, Md. In the last two years, the FDA has placed several limitations on opioids, including adding new warning language to immediate-release opioids such as Vicodin and Percocet. But prescriber training remains optional, even after a second FDA advisory panel again recommended the step in 2016. (AP Photo/Andrew Harnik)

Bono, whose family had dealt with opioid addiction, drafted legislation in 2010 designed to curb opioid prescribing by requiring the FDA to limit the labeling for OxyContin and related drugs to "severe pain."



OxyContin had long been marketed for a broader indication listed on the label as "moderate-to-severe pain."

According to Bono, a Purdue lobbyist visited her and threatened to pull back on its state-level funding for drug abuse initiatives.

"They were just letting it be known that if I didn't play nicer with them, they could cause some things to happen that I wouldn't like," she said.

Purdue said in a statement that it met with Bono to support "her efforts to stop prescription drug abuse." The company says it does not oppose measures that "improve the way opioids are prescribed," even when they could reduce sales. Former Rep. Bill Brewster, D-Oklahoma, a contract lobbyist for Purdue at the time, said in an email that he recalled the conversation as "cordial and constructive."

Purdue spent nearly \$800,000 on lobbying efforts that included Bono's bill and subsequent versions of it. Pain Care Forum participants gave her campaigns more than \$60,000 from 2006 through 2012.

Bono's bill, the Stop Oxy Abuse Act, never received a congressional vote or hearing, even after Republicans regained control of the House in the November 2010 elections. She lost her congressional seat in 2012.

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## 'WHAT'S A REGULATOR TO DO?'

In June 2012, a senior FDA official gave a presentation to the Pain Care Forum titled: "FDA and Opioids: What's a regulator to do?"



In this Friday, July 20, 2007 file photo, demonstrators march along Main Street in Abingdon, Va., to raise awareness about the abuse of OxyContin. From 2000 to 2016, prescription opioid abuse has claimed the lives of 165,000 Americans, according to federal estimates. (David Crigger/Bristol Herald Courier via AP)

For several years, the FDA had been developing risk-management plans to reduce misuse of long-acting opioids like OxyContin. With oversight of drugmakers and their marketing efforts, the agency seemed perfectly positioned to tackle the problem.

But the plans that the FDA laid out lacked the major reforms suggested by the agency itself in 2009, when it announced the initiative. Instead of mandatory certification training for doctors and electronic registries to track opioid prescriptions to patients, the FDA official outlined much milder steps: Drugmakers would fund optional classes for prescribers and supply pharmacy brochures to patients about opioid risks.

Over several years, the FDA seemed to have backed away from any significant restrictions.

"It was my observation that the staff at FDA had really bought into the idea that pain was greatly undertreated in the United States," said Dr. Elinore McCance-Katz, former chief medical officer with the Substance Abuse and Mental Health Service Administration, a federal health agency.

As early as December 2008, the Pain Care Forum was developing a strategy to "inform the process" at the FDA, according to meeting minutes from the American Pain Foundation.

When the FDA sought public comment on how to proceed, the forum helped generate more than 2,000 comments opposing new barriers to opioids, according to a 2010 foundation memo. Additionally, the forum produced a 4,000-signature petition opposing electronic registries for opioid prescriptions, which advocacy groups said would stigmatize patients.

Finally, in July 2010, the FDA assembled a panel of outside advisers—primarily physicians—to review its plans to manage opioid risks, including voluntary doctor training.

During a comment period, several members of the public warned it was a mistake. Dr. Nathaniel Katz, a former FDA adviser turned pharmaceutical consultant, traveled from Boston to implore the panel to support tougher requirements.

"The days of prescribers not being trained how to safely prescribe the number one medication in the United States have to be brought to an end by you today," said Katz, who had previously chaired the FDA panel, according to a meeting transcript.



This Tuesday, May 8, 2007 file photo shows the Purdue Pharma offices in Stamford, Conn. In 2007, the company pleaded guilty and agreed to pay more than \$600 million in fines for misleading the public about the risks of OxyContin. But the drug continued to rack up blockbuster sales. (AP Photo/Douglas Healey)

Ultimately, the panel voted 25-10 against the measures developed by the FDA, saying they would have little effect on opioid abuse. But the FDA put them in place anyway, one month after the agency briefed the Pain Care Forum on the plans. The FDA is not required to follow the recommendations of its advisory panels.

Agency officials said they decided that requiring certification for opioid prescribers would have been overly burdensome and disrupted care for patients.

"You can't imagine the bitter screeds we hear from the prescribing community about the paperwork involved," said Dr. Janet Woodcock, head of the FDA's drug center. She added that the opioid crisis fundamentally stems from individual prescribing decisions, saying, "We don't regulate medical practice."

In the last two years, the FDA has placed several limitations on opioids, including adding new bolded warnings to immediate-release opioids such as Vicodin and Percocet. But prescriber training remains optional, even after a second FDA advisory panel again recommended the step earlier this year. Woodcock says the agency is still weighing that recommendation.

Currently, states such as Massachusetts are imposing their own physician-training requirements, a development that Katz attributes to a lack of federal action.

"The FDA failed to make a decision that could have averted many of the thousands of deaths we're seeing per year," Katz said. "So when people continue to die and communities continue to be devastated, then others will arise to do the policing."

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## CHARTING A 'SAFER COURSE'

It was a federal agency hundreds of miles from Washington that finally sidestepped the influence of the pain care lobbyists.





In this Thursday, Feb. 27, 2014 file photo, FDA Commissioner Dr. Margaret Hamburg speaks during an event in the East Room of the White House in Washington. By spring 2014, the figure that 100 million Americans suffered from chronic pain was getting new attention: as a talking point for the nation's top drug regulator. Hamburg used the statistic to illustrate the importance of keeping painkillers accessible, despite the escalating toll of opioid addiction and abuse in American communities. But Michael Von Korff, whose research contributed to the statistic, said the number has no connection to opioids. Instead, he said, it mostly represents "people with run-of-the-mill pain problems who are already managing them pretty well." (AP Photo/Carolyn Kaster)

The Centers for Disease Control and Prevention, located in Atlanta, overcame threats of congressional investigation and legal action to publish the first federal guidelines intended to reduce opioid prescribing earlier this year.



Essentially, the agency said the risks of painkillers greatly outweigh the benefits for the vast majority of patients with routine chronic pain. Instead, the guidelines said, doctors should consider alternatives like non-opioid pain relievers and physical therapy.

For more than 15 years, CDC officials have tracked the precipitous rise in painkiller overdoses, which has been followed by a similar surge in heroin deaths. The CDC called the painkiller trend an epidemic in 2011, pushing Washington officials to do the same. The agency's director, Dr. Tom Frieden, labeled opioids "dangerous medications" that "should be reserved for situations like severe cancer pain."

When the CDC drafted its opioid guidelines, it moved quickly and quietly, initially giving outside groups just 48 hours to comment on draft guidelines distributed last September.

Opioid proponents said the guidelines were not based on solid evidence and criticized the CDC for not disclosing outside experts who had advised the effort, alleging that they included physicians who were biased against painkillers.

One pharma-aligned group, the Washington Legal Foundation, said the lack of disclosure constituted a "clear violation" of federal law. And a longtime Pain Care Forum participant—now known as the Academy of Integrative Pain Management—asked congressional leaders to investigate how the CDC had developed the guidelines. A House committee asked the CDC to turn over documents about its advisers, but staffers said the probe did not uncover any violations.

Some of the most vigorous pushback came from Pain Care Forum affiliates embedded in the federal system. Under the 2010 pain legislation backed by the forum, the NIH had created a 19-member panel to coordinate pain research made up of federal officials, civilian

physicians and pain advocates.

At the group's December meeting, panelists with connections to the Pain Care Forum called the CDC's approach "horrible" and "shocking."

Dr. Richard Payne, a former board member of the American Pain Foundation, questioned whether the experts advising the CDC had "conflicts of interests in terms of biases, intellectual conflicts that needed to be disclosed."



This Wednesday, April 26, 2006 file photo shows different brands and dosages of fentanyl patches in St. Louis. Fentanyl is a narcotic that is typically administered to people with chronic pain, including end-stage cancer patients. It is also used as an anesthetic. It is considered 80 times more powerful than morphine and can kill by inhibiting breathing. (AP Photo/Tom Gannam)

Payne himself had received more than \$16,240 in speaking fees, meals, travel and other payments from drugmakers, including Purdue, between 2013 and 2015, according to federal records.

Myra Christopher, a long-time Pain Care Forum participant, said the panel should inform the CDC that it could not support the opioid guidelines and that their release should be delayed.

Christopher holds a chair at the nonprofit Center for Practical Bioethics, which receives funding from opioid drugmakers, and her position was established through a \$1.5 million gift from Purdue. Both she and Payne also served on the Institute of Medicine panel on pain in America.

Christopher and Payne said they were thoroughly vetted before serving on the panel and disclosed their past work and activities. Federal officials who oversee the panel responded that all members met federal requirements to serve, including completing financial disclosure forms, though the NIH said those cannot be publicly released.

One week after the NIH panel's critique, the CDC said it would delay finalizing its guidelines to allow more public comment and released a list of advisers. One of 17 "core experts" advising the agency reported serving as a paid consultant to Cohen Milstein Sellers & Toll, the law firm suing multiple opioid drugmakers on behalf of the city of Chicago.

In March, the final guidelines appeared.

The first recommendation for U.S. doctors: "Opioids are not first-line therapy" for chronic pain. It was a statement considered common practice by many doctors as recently as the early-1990s, a decade before the Pain Care Forum formed in Washington.

"We're trying to chart a safer and more effective course for dealing with chronic pain," Frieden said. "We don't expect any magic. We don't expect things to be better in 15 months when it's taken 15 years to get this much worse."

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