

Subcommittee on Oversight and Investigations
***The Denial Playbook: How Industries Manipulate Science and Policy from
Climate Change to Public Health***
February 26, 2019

Response for Democratic Members by Ryan Hampton

1. For the most part, they told me that the success by sales representatives to get physicians to forget their conventional medical training and believe opioids were safe rested on the premise they wouldn't knowingly hide or ignore risks that hurt or kill people. No rational person would do that—so these doctors took their word at face value that opioids were safe. It's normal to assume that a whole industry wouldn't want to knowingly harm people. The hundreds of thousands of deaths from opioids prescribed under false pretenses is proof that there can be malicious groupthink. What I learned from this is that my personal welfare as an individual didn't matter when enough money was on the line.
2. Addiction Policy Forum is an organization funded by the Pharmaceutical Research and Manufacturers Association (PhRMA). It is led by lobbyist Jessica Nickel. According to Politico, "PhRMA's biggest single contribution was \$3.9 million to the Addiction Policy Forum, according to the drug lobby's newly released IRS Form 990 tax filing. It also gave \$2.2 million to the nonprofit Addiction Policy Leadership Action Network, which is listed on its tax filing as sharing an address. The Addiction Policy Forum was thrust into the spotlight earlier this year over questions about its ties to the drug industry. PhRMA president and CEO Stephen Uhl sits on the Forum's advisory board, along with the top executives of Alkermes and Indivior, which make opioid addiction treatments. Addiction Policy Forum's CEO Jessica Nickel was a lobbyist for Alkermes when the group was founded." This group's contribution to the misinformation tactics were well reported by the New York Times as follows: *As Minnesota lawmakers prepared to push a proposed tax on opioid sales in November, the pharmaceutical industry lobbyists who opposed the bill set up a meeting with its sponsors, and they brought an unusual guest: Jessica Hulsey Nickel, a prominent anti-addiction advocate in Washington. Ms. Nickel told the lawmakers that she took no position on the tax and was simply offering her group's resources to help fight the state's drug epidemic. But her presence along with five representatives from the industry's trade group raised eyebrows among the Minnesota lawmakers, who believed that drug companies needed to be held accountable for the prescription opioid crisis — not embraced as an ally. "She was insisting that she was totally independent and they hadn't put any strings on her," said State Senator Chris Eaton, one of the bill's sponsors. "I wasn't buying it." Two weeks later, Ms. Nickel's ties to the industry grew even deeper when her advocacy group, the [Addiction Policy Forum](#), announced in mid-December that it had accepted funding from the trade group, the Pharmaceutical Research and Manufacturers of America, known as PhRMA.*
3. In a recent report, 60 Minutes exposed evidence that the FDA bent to the will of Purdue Pharma when it changed the label for Oxycontin so that it could be used for long-term pain management—without science to back it up. In November 2018, the FDA approved Dsuvia, an opioid painkiller that is 10 times more potent than fentanyl—despite outrage

from members of their own opioid advisory committee and advocates around the country. In December 2018, the FDA shelved Brixadi, a recovery medication that was tentatively approved, for two years because of an exclusivity ruling that was shrouded in secrecy. I suspect that Big Pharma is behind these last two instances as well.

From what we've seen, Big Pharma has significant influence over the FDA. However, we don't even know the extent to which this is the case. There's a complete lack of transparency and accountability. We don't know who sits on these advisory committees or the Exclusivity Board. We don't know what their qualifications are, and we don't know if they understand patient needs or the greater context for public health emergencies like the opioid crisis.

So yes, I do believe that the pharmaceutical industry has too much influence on the science and data being presented as fact on behalf of the federal government. But until the FDA is held accountable and we are provided insight into the administration's inner workings, we will never be sure of the full extent to which the FDA has allowed misinformation to spread at the level of the public's health and wellbeing.

4. When it comes to public safety, the only information that can be trusted is from disinterested qualified third parties.
5. The denial and orchestrated lies by the pharma industry have resulted in the deaths of more than half a million people from overdoses related to or started by OxyContin. Some were my close friends. I almost died. If you think for one second that any industry with billions of dollars at stake won't manipulate in the same way—then I believe there will be millions more lost. When money is at stake, public safety and profits are divergent interests. I speak from experience.
6. The absolute best answer to this question comes courtesy of my colleague, Dr. Andrew Kolodny: *In 1986 a paper describing the treatment of 38 chronic pain patients concluded that OPRs could be prescribed safely on a long-term basis. Despite its low-quality evidence, the paper was widely cited to support expanded use of opioids for chronic non-cancer pain. Opioid use increased gradually in the 1980s. In 1996, the rate of opioid use began accelerating rapidly. This acceleration was fueled in large part by the introduction in 1995 of OxyContin, an extended release formulation of oxycodone manufactured by Purdue Pharma. Between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants and launched a multifaceted campaign to encourage long-term use of OPRs for chronic non-cancer pain. As part of this campaign, Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups, and other organizations. In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs. For example, in 1995, the president of the American Pain Society introduced a campaign entitled "Pain is the Fifth Vital Sign" at the society's annual meeting. This campaign encouraged health care professionals to assess pain with the "same zeal" as they do with vital signs and urged more aggressive use of opioids for*

chronic non-cancer pain. Shortly thereafter, the Veterans' Affairs health system, as well as the Joint Commission, which accredits hospitals and other health care organizations, embraced the Pain is the Fifth Vital Sign campaign to increase the identification and treatment of pain, especially with OPRs. Similarly, the American Pain Society and the American Academy of Pain Medicine issued a consensus statement endorsing opioid use for chronic non-cancer pain. Although the statement cautioned against imprudent prescribing, this warning may have been overshadowed by assertions that the risk of addiction and tolerance was low, risk of opioid-induced respiratory depression was short-lived, and concerns about drug diversion and abuse should not constrain prescribing. Prior to the introduction of OxyContin, many physicians were reluctant to prescribe OPRs on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence. To overcome what they claimed to be "opiophobia," physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with "physical dependence." They described addiction as rare and completely distinct from so-called "physical dependence," which was said to be "clinically unimportant". They cited studies with serious methodological flaws to highlight the claim that the risk of addiction was less than 1%. In addition to minimizing risks of OPRs, the campaign advanced by opioid manufacturers and pain organizations exaggerated the benefits of long-term OPR use. The CDC and some professional societies now warn clinicians to avoid prescribing OPRs for common chronic conditions. Although increased opioid consumption over the past two decades has been driven largely by greater ambulatory use for chronic non-cancer pain, opioid use for acute pain among hospitalized patients has also increased sharply. A recent study found that physicians prescribed opioids in more than 50% of 1.14 million nonsurgical hospital admissions from 2009 to 2010, often in high doses. The Joint Commission's adoption of the Pain is the Fifth Vital Sign campaign and federally mandated patient satisfaction surveys asking patients to rate how often hospital staff did "everything they could to help you with your pain" are noteworthy, given the association with increased hospital use of OPRs.

Response for Republican Members by Ryan Hampton

1. Nobody assisted, advised, or counseled me in the preparation, drafting, or submission of my responses.
2. I have no professional experience for questions A., B., C., or D.
3. Yes, the jurisdiction of the committee was explained to me by the Democratic staff.

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