

Daniel's Law Ohio
To the State of Ohio Legislators
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For Immediate Release

The State of Ohio vs Big Pharma: Urgent Allegations of the Lawsuit

Why did the State of Ohio file a lawsuit? The following are direct and unedited urgent allegations made by the State of Ohio in its legal battle against Big Pharma.

COLUMBUS, Ohio (November 22, 2017) In its recent lawsuit against Big Pharma, the State of Ohio has made some power statements against the Defendants. These are public disclosures that the state's legislature and citizenry urgently need to be made aware of, as we seek an end to the devastating effects of prescription opioids, which is currently at catastrophic proportions. Time is of the essence with deaths reaching over 190 patients daily.

The following are unedited statements taken directly from the lawsuit as made by The State of Ohio:

IV. FACTUAL ALLEGATIONS

34. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

B. Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.

87. To convince doctors and patients in Ohio that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive,

1. Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

88. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed;

90. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

91. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’

97. **Third**, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

98. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

Defendants grossly overstated the benefits of chronic opioid therapy.

109. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.” In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later

112. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

134. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

137. When compared to previous drug overdose epidemics in Ohio, the current prescription drug epidemic is responsible for considerably more deaths.

141. The overprescribing of opioids for chronic pain caused by Defendants’ deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Ohio who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome.

Statements from the Introduction:

6. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant’s misrepresentations has been confirmed by the U.S. Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA (“2016 CDC Guideline”).

In Conclusion

How can the State of Ohio file a lawsuit against Big Pharma, make these statements, then continue down this road of destruction? The State of Ohio, its State Medical Board, and its State Pharmacy Board, continue to allow its citizens to be exposed to unsafe, lawfully prescribed medical opioids for long-term use.

Ohio's legislature has the opportunity, the ability, and ethical duty, to step forward and become the leader in stopping this runaway train of prescription opioid deaths, both at home and across the nation.

How many more Ohioans will die needlessly? In the words of the great parliamentarian Edmund Burke, "The only thing necessary for the triumph of evil is for good men to do nothing."