

Please see the following comment from Purdue Pharma on the unredacted complaint filed in Massachusetts.

### **Purdue Pharma Statement**

*Today's release of the remaining portions of the Massachusetts Attorney General's amended complaint is part of a continuing effort to single out Purdue, blame it for the entire opioid crisis, and try the case in the court of public opinion rather than the justice system.*

*Such a serious allegation demands clear evidence linking the conduct alleged to the harm described, but Massachusetts fails to show such causation and offers little evidence to support its sweeping legal claims.*

*Instead, Massachusetts seeks to publicly vilify Purdue, its executives, employees and directors while unfairly undermining the important work we have taken to address the opioid addiction crisis by taking out of context snippets from tens of millions of documents and grossly distorting their meaning. The complaint is riddled with demonstrably inaccurate allegations.*

*Among the Attorney General's most egregious mischaracterizations are:*

- *Casting in a negative light Purdue's due diligence on a potential acquisition of a drug for the treatment of addiction that was already on the market; even though the company never actually made the acquisition;*
- *Suggesting Purdue received recommendations from a leading management consultancy to circumvent restrictions on illegal drug sales by pharmacies; when the recommendations actually relate to ensuring continued access to pain medicines for appropriate patients;*
- *Portraying as craven Purdue's decision to increase the planned number of sales visits to prescribers, when Purdue planned to decrease the number of visits relating to opioid products in favor of promoting a laxative product that does not contain opioids; and,*
- *Stating that the Purdue board of directors was in possession of an independent report criticizing Purdue's innovative abuse deterrent formulation of OxyContin, when that same report explicitly recognized that the abuse-deterrent formulation had averted thousands of cases of abuse.*

*Absent from the complaint is any acknowledgement of the fact that most opioid overdoses now result from heroin and illicit fentanyl. In fact, rates of overdoses from illegal fentanyl have skyrocketed in Massachusetts between 2012-2016, according to the National Institute on Drug Abuse ([NIDA stats](#)). Instead, Massachusetts deliberately conflates illegal street drugs with legitimate prescription opioids in an attempt to assign to Purdue liability for all misuse of all opioids.*

*Purdue's opioid pain medicines represent less than 2% of total opioid prescriptions. They are approved by FDA, prescribed by doctors, and dispensed by pharmacists. The material released today once again shows Massachusetts conveniently disregarding basic facts about Purdue's prescription opioid medications including that:*

- *FDA, the scientific agency charged with approving and regulating medicines in the U.S., has approved OxyContin and other Purdue opioid medications as safe and effective for their intended use;*

- Prescription opioids are among the most tightly controlled medicines in the United States, and Purdue's OxyContin is a Schedule II controlled substance, meaning that it is in a class of medicines with the highest level of control by the US Drug Enforcement Administration (DEA);
- The first information that healthcare providers see when reading the FDA-approved label for OxyContin is a prominent "black box" warning that includes information about the risks of addiction, abuse, and overdose; and
- Purdue promoted its opioid medications based on the medical and scientific evidence in the FDA approved label and did so to licensed physicians who have the training and responsibility to ensure that medications are properly prescribed.

*And once again, the complaint omits key facts about the federal regulation of opioid medications, including:*

- In April 2010, FDA approved a reformulated version OxyContin, which Purdue developed with properties intended to deter abuse. Purdue worked for over a decade to develop the new formulation, investing hundreds of millions of dollars, and it was the first opioid FDA approved with abuse deterrent properties.
- The Massachusetts Attorney General commended the FDA for supporting abuse-deterrent formulations and later insurers in the state were required to cover them.
- FDA has directly addressed many of the scientific issues complained of in the Massachusetts complaint and has continued to determine that Purdue's opioids are safe and effective for their intended use.
- In 2016, the Centers for Disease Control (CDC) issued a new guideline for prescribing opioids for chronic pain ([CDC Guidelines](#)). Purdue immediately emailed the guidelines to over 150,000 healthcare professionals throughout the country and subsequently distributed thousands of CDC 'tear sheets' setting forth the guideline's recommendations including to doctors in Massachusetts.

*One of the most glaring omissions in Massachusetts' complaint continues to be that, in 2013, the Office of Inspector General ("OIG") of the Department of Health and Human Services determined that Purdue had fulfilled its requirements under a 2007-2012 Corporate Integrity Agreement ("CIA") relating to the marketing of its medications and released Purdue from the agreement. Furthermore, during the term of this five-year agreement, Purdue had submitted annual reports to a designated OIG monitor and had engaged an Independent Review Organization that evaluated specified elements of Purdue's compliance program on a periodic basis to assess compliance with the terms of the CIA.*

*We believe that no pharmaceutical manufacturer has done more to address the opioid addiction crisis than Purdue, and we continue to work closely with governments and law enforcement agencies on this difficult social issue. Since 2000, we have pursued more than [65 initiatives](#) in an effort to minimize diversion and abuse pharmaceutical opioid medications. For example, when Purdue learned that Oxycontin tablets could be crushed to defeat the time-release properties and extract the active ingredient, Purdue invested hundreds of millions of dollars to receive FDA approval of the first prescription opioid with abuse-deterrent properties (2010). And when the Centers for Disease Control issued new guidelines for doctors to use prescribing prescription opioids, we promptly sent that updated information to health care professionals.*

*Purdue and the individual defendants will continue to defend themselves against these misleading and deliberately inflammatory allegations. In the meantime, Purdue continues to*

*fight for balance in the public discourse so that society can simultaneously help pain patients in need and create real solutions to the complex problem of addiction.*

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