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United States Senate

May 27, 2016

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The Honorable Loretta E. Lynch
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

Dear Attorney General Lynch:

I am writing to urge the Department of Justice to investigate allegations that the drug manufacturer Purdue Pharma, L.P. has made false claims that its prescription opioid drug OxyContin relieves pain for twelve hours, knowing that OxyContin wears off much sooner in many patients, and thereby exposing them to an increased risk of dependency and addiction. If after investigation these allegations are substantiated, the Department should take legal action against The Purdue Frederick Company, Inc. and its pharmaceutical subsidiary Purdue Pharma, L.P., including recouping damages sustained by federal healthcare programs that paid for excess OxyContin prescriptions that should have been unnecessary if the drug lasted for the full twelve hours Purdue claimed it did.

A prescription opioid and heroin epidemic continues to grip the nation. In 2014, nearly 30,000 people in the United States died of prescription opioid and heroin overdoses.¹ It is estimated that nearly 80 percent of the people using heroin started with opioid pain medications like OxyContin.² OxyContin's leading role in this epidemic is well-established, caused in large part by Purdue's aggressive — and illegal — marketing efforts.

In a 2007 criminal proceeding against Purdue in the United States District Court for the Western District of Virginia, the company pled guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. Purdue admitted that, to maximize its profits, it illegally marketed and promoted OxyContin by falsely claiming that it was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal symptoms than other pain medications. Purdue agreed to pay over \$600 million in civil fines, penalties, and forfeitures. Three Purdue executives also pled guilty to misdemeanor charges of misbranding OxyContin and collectively agreed to pay \$34.5 million in penalties.

¹ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

² <http://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.htm>

According to a recent report by the L.A. Times, despite that resolution of the 2007 Virginia federal court case, additional Purdue marketing misconduct has continued unabated — namely, that Purdue has for years knowingly made the false claim that OxyContin provides twelve hours of relief when in fact the medication wears off sooner. As the L.A. Times reported:

- “● Purdue has known about the problem for decades. Even before OxyContin went on the market, clinical trials showed many patients weren’t getting 12 hours of relief. Since the drug’s debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales reps and independent research.
- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin’s market dominance and its high price — up to hundreds of dollars per bottle — hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.
- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to ‘refocus’ physicians on 12-hour dosing. Anything shorter ‘needs to be nipped in the bud. NOW!!’ one manager wrote to her staff.
- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn’t last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.
- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for The Times.”³

These are serious allegations. They raise questions about ongoing deception by Purdue, harm to the public, continued costs to the United States, and the availability of further judicial recourse against Purdue under the resolution of the 2007 criminal proceeding, which included a civil Settlement Agreement between Purdue and the United States. Under the Settlement Agreement, Purdue agreed to pay just over \$100 million for putative civil claims for damage to Medicare, Medicaid, and other federal healthcare programs. If Purdue’s wrongdoing has continued and resulted in further damage to the United States, the Department of Justice should seek additional compensation.

³ <http://static.latimes.com/oxycontin-part1/#nt=oft12aH-11a1>

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I therefore urge the Department of Justice to investigate the 12-hour claim allegations, and, if warranted, take the necessary action to hold Purdue accountable, including recouping taxpayer dollars that federal healthcare programs may have needlessly and unnecessarily spent on OxyContin prescriptions.

Sincerely,



Edward J. Markey
United States Senator