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United States Senate

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The Honorable Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Edith Ramirez
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Commissioner Califf and Chairwoman Ramirez:

According to a recent report in the L.A. Times¹, Purdue Pharma, L.P., the manufacturer of OxyContin — and well established as a leading culprit in the current opioid and heroin overdose epidemic — continues to make false and misleading claims about the longevity of OxyContin's pain-relieving properties that may be driving the ongoing development of opioid dependency and addiction. I am writing to urge the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to investigate these claims and take action to protect patients and consumers from harm caused by Purdue Pharma's deceptive marketing materials.

Drug overdoses fueled by prescription opioid painkillers like OxyContin are now the leading cause of accidental death in the United States, far surpassing motor vehicle accidents. When obtaining legal forms of prescription drugs becomes too difficult, many individuals with a physical dependency on prescription opioids turn to related, illicit heroin. Combined, prescription opioid painkillers and heroin have led to the deaths of nearly 30,000 people across the country in 2014 alone.

Purdue Pharma has maintained in its marketing and prescribing information that OxyContin is specially formulated to release the active ingredient, oxycodone, for a full 12 hours, despite knowing that the drug wears off much sooner in many patients. Doctors faced with complaints from patients that their pain returns much sooner than 12 hours instruct patients either to take the drug more frequently or prescribe higher doses. Both of these activities can lead to increased dependency among patients prescribed OxyContin.

According to the L.A. Times, since OxyContin debuted in 1996, Purdue Pharma has known that its drug does not provide 12 hours of relief, and has frequently instructed doctors to prescribe stronger doses instead of more frequent ones. Research shows that the more potent the

¹ <http://static.latimes.com/oxycotin-part1/#nt=oft12aH-11a1>

dose of an opioid like OxyContin, the greater the chance of dependency, overdose, and death. According to an analysis of nationwide prescription data conducted for the L.A. Times, more than half of long-term OxyContin users are on doses that public health officials consider dangerously high. Furthermore, as the CDC Guidelines for Prescribing Opioids for Chronic Pain indicate², to avoid adverse risks associated with taking opioids, the lowest possible dosage should be used.

In 2007, Purdue Pharma's parent 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. As a result, 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. Despite these actions, however, Purdue continues to make questionable claims about the longevity of its drug. These claims impact prescribing decisions, may cause serious adverse impacts on patients, and may continue to fuel the ongoing epidemic of opioid misuse and abuse.

I urge the FDA and FTC to immediately take action that would prevent the dissemination of misleading or false information about OxyContin's duration to those making prescribing decisions and to patients. The FDA and FTC should also proactively warn prescribers, patients, and the general public about the dangerous impact of using higher or more frequent dosing to compensate for OxyContin's failed claims.

Sincerely,



Edward J. Markey
United States Senator

² <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>