



October 31, 2012

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Dockets Management
Food and Drug Administration
5630 Fishers Lane
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Rockville, MD 20852

RE: Docket FDA-2012-P-0818

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On behalf of Denver Public Health, I am writing to express my strong support for the Citizen Petition filed by Physicians for Responsible Opioid Prescribing (PROP) in Docket FDA-2012-P-0818. The marketing and use of prescription opioids to manage pain has increased dramatically over the past 20 years in the United States. The Colorado Prescription Drug Monitoring Program is showing increases in prescriptions filled for oxycodone and hydrocodone. The Denver Metro area reports higher non-medical use of narcotic analgesics than either Colorado or the United States. Emergency Department visits for narcotic analgesics tripled from 2004-2009 in Denver, with oxycodone accounting for 44% of the visits in 2010. Hospital discharges for all opiates increased 76% from 2003 to 2011. Treatment admissions for opiates have increased and in 20011, females constituted more than half of prescription opioid treatment admissions in Denver. Adopting the label changes called for by PROP is an important strategy to mitigate the serious problem of opioid overdose, misuse, dependence and diversion that we are witnessing in our jurisdiction.

The FDA has the authority and responsibility to ensure that a drug is safe and effective for its intended use and to dictate labeling of drugs for treatment purposes according to scientific evidence. Therefore, we urge the FDA to adjust the industry's labeling as suggested in the petition to help assure the safe and proper use of opioids for pain management, restrict overly broad marketing claims and address the harms associated with the opioid national epidemic.

Thank you for your consideration of our comments.

Sincerely,

William Burman, M.D.

Director, Denver Public Health

FDA-2012-P-0818

William Burner, M.D.



Denver Public Health

Promotion • Preparedness • Prevention • Protection

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