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Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

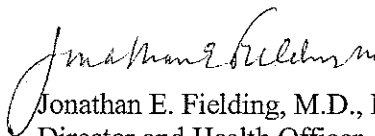
RE: Docket FDA-2012-P-0818

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. Concomitantly, overdose deaths involving opioids have nearly quadrupled since 1999 and now exceed deaths involving heroin and cocaine combined. Between 2004 and 2008, the number of emergency department visits for opioid misuse more than doubled nationwide. In California, over 15 million prescriptions for hydrocodone were filled during the 2011-2012 fiscal year. Locally, in Los Angeles County, there were 4,912 opioid-related treatment admission episodes to publically funded substance abuse treatment facilities between 2005 and 2010. Furthermore, from 2004 and 2009, there were 1,102 opioid-related deaths in Los Angeles County. Despite the lack of evidence supporting the efficacy and safety of opioid therapy for chronic, non-cancer pain, among the seven leading indications for opioid analgesics, non-cancer pain accounts for 50% of the U.S. opioid market. Adopting the label changes called for by PROP is an important strategy to mitigate the serious problem of opioid overdose, misuse and dependence that we are witnessing in Los Angeles County.

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, I 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,

  
Jonathan E. Fielding, M.D., M.P.H.  
Director and Health Officer

JEF:jmb