

MEMORANDUM OF MEETING

January 11, 2013
11:00 am – 12:00 pm
White Oak

SUBJECT: Meeting with Physicians for Responsible Opioid Prescribing (PROP) to listen to their comments and views on the current use and marketing of opioids

ATTENDEES:

FDA: Margaret Hamburg, John Taylor, Lesley Maloney, Peter Lurie, Doug Throckmorton, Virginia Cox, Elaine Vining, Lisa Dwyer, Denise Esposito, Abigail Brandel, Candra Smith, and Michelle Williams-Ellerbe

PROP:

Andrew Kolodny, Chair of Psychiatry at Maimonides Medical Center in New York City & President of PROP

Thomas Farley, Commissioner of the New York City Department of Health and Mental Hygiene
Deborah Dowell, Director of Special Projects at the New York City Department of Health and Mental Hygiene; Advisor to Thomas Farley

Jane Ballantyne, University of Washington Professor of Education and Research, Department of Anesthesiology and Pain Medicine

Robert Nickerson, Senior Legislative Representative, Office of the Mayor, NYC; guest of Thomas Farley

BACKGROUND:

On January 11, 2013, FDA met with representatives of the Physicians for Responsible Opioid Prescribing (PROP) and the New York City Department of Health and Mental Hygiene to hear their views on the use and marketing of opioid products. The participants presented their concerns about the problems associated with abuse and misuse of opioids, including addiction and death, and asserted that opioids, as currently labeled, are not safe and effective for the treatment of chronic non-cancer pain. PROP advocates changes to the labeling of opioid products in several ways. First, PROP believes that the indication for these products for use in non-cancer pain should be limited to severe pain, instead of moderate to severe pain. Second, PROP recommends that the labeling establish a maximum daily dose for these products for use in non-cancer pain. Third, PROP advocates setting a maximum duration for continuous use of opioid products for non-cancer pain. These issues are the subject of a citizen petition that PROP submitted, which was pending with FDA as of the date of the meeting.¹ FDA listened to these presentations and asked questions as necessary. The materials that the participants presented at the meeting, as well as supplemental materials that the presenters provided following the meeting, will be added to the docket. Dr. Kolodny also asked that the following video link to be forwarded to meeting attendees in advance of the presentation:

<http://www.youtube.com/watch?v=l4Y3TQUsh4k>.

¹ See FDA Docket No. FDA-2012-P-0818.

DISCUSSION HIGHLIGHTS:

PROP's Overview: Opioid Analgesic Epidemic

- PROP presented statistical information from 1999 – 2010 showing increases in opioid sales, opioid deaths, and people seeking treatment for opioid analgesics. According to PROP, the dramatic increase in prescribing opioids is not based on research, but on a movement that started in 1996, which encouraged physicians to prescribe opioids for chronic non-cancer pain.
- PROP contends that the messages conveyed during the 1996 opioid movement were inaccurate and suggests that information contained in the opioid messaging during that time was based on the belief that physicians were allowing patients to suffer due to excessive concern about opioid addiction.
- PROP advocates limiting opioid prescribing based on research surrounding epidemiological data from the past 20 years. PROP believes that this research strongly suggests that opioids do not have proven efficacy or safety for chronic non-cancer pain at high doses or for prolonged usage. PROP stated that studies show that patients who continue with opioids for more than 90 days tend to be “at risk” patients prone to addiction. They also believe that studies reveal that when opioids are prescribed at doses greater than 100 milligrams, the pain is not responsive and there is a greater likelihood for misuse and addiction.
- PROP believes that overprescribing opioids for chronic conditions, such as unexplained low back pain, fibromyalgia, and headache, has occurred because of unrealistic expectations of benefits and a failure to appreciate harm. PROP also explained that the most common pain conditions are often made worse by the use of opioids.

PROP's Proposed Strategy for Controlling the Opioid Epidemic

- PROP asserts that drug manufacturers advertise opioids as safe and effective for chronic pain. Further, existing labels on opioid analgesics state that they are “indicated for the relief of moderate to severe pain.” PROP states that the language currently displayed on opioid labels gives the medical community the impression that FDA supports broad use of opioids for both short term acute pain and chronic non-cancer pain.
- PROP proposes changing the label on opioids in order to control what they consider to be an opioid epidemic. PROP states that changing the label on opioid analgesics would provide FDA with the opportunity to prohibit manufacturers from marketing opioids as safe and effective for chronic non-cancer pain, when according to PROP, there appears to be a lack of evidence in support of this claim.
- PROP proposes the following changes for opioid labels: strike the term “moderate” from the indication for non-cancer pain; add a suggested maximum daily dose, equivalent to 100 mg of morphine for non-cancer pain; and add a suggested maximum duration of 90 days for continuous (daily) use for non-cancer pain.

- PROP also supports prescriber education on the appropriate use of opioids and the expanded use of Prescription Drug Monitoring Program (PDMP) data in order to control this epidemic.

ACTION ITEMS/NEXT STEPS:

- On January 14, PROP provided electronic copies of handouts for inclusion in the meeting package. On January 24, PROP submitted additional documents to FDA as a follow up to the meeting. These materials will be included in the docket for PROP's pending citizen petition.
- PROP will advocate its position at the Part 15 Hearing scheduled for February 7-8, 2013, entitled, "Impact of Approved Drug Labeling on Chronic Opioid Therapy."

Michelle Williams-Ellerbe
FDA Executive Secretariat