December 11, 2012

Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket ID # FDA-2012-P-0818

Endo Pharmaceuticals Inc. (Endo) opposes the citizen petition submitted to the United States Food and Drug Administration (FDA or the Agency) by the organization Physicians for Responsible Opioid Prescribing (PROP), and urges the FDA to reject the petition. The petition fails to offer credible scientific evidence that the specific actions requested by PROP will reduce prescription drug abuse. Endo shares PROP's concern with the misuse and abuse of prescription opioids, but Endo is concerned that the recommendations put forward by PROP will have a significantly negative impact on the lives of patients' who live with pain.

In the petition, PROP requests three specific changes to the labels of opioid analgesics: 1) strike the term "moderate" from the indication for non-cancer pain; 2) add a maximum daily dose, equivalent to 100 milligrams (mg) of morphine for non-cancer pain, and 3) add a maximum duration of 90 days for continuous (daily) use for non-cancer pain. The PROP petition also relies on a series of supposed scientific statements as the basis for the petition.

Endo believes PROP has failed to present a case based on robust scientific data from dedicated research routinely required for labeling changes. The absence of rigorous data is especially alarming because PROP is asking FDA to make a labeling change impacting an entire class of opioid analgesics. The petitioners fall well short of providing substantive scientific data necessary for such a significant label change, instead relying on supposition without good clinical underpinnings. PROP reaches broad and misleading conclusions based on their selective use of referenced studies and establishes arbitrary thresholds for dosing and duration that are not based on credible evidence or a conclusive body of data.

Importantly, PROP fails to account for the harmful impacts their request imparts on patients' who rely on opioid analgesics to manage their pain. Patients with chronic pain must endure daily struggles with the debilitating condition that affects their quality of life. Today, many patients with pain are finding it more difficult to access their medications because of the heightened sensitivity surrounding prescription drug abuse. PROP's recommendations will exacerbate the problem and make it even more difficult for pain patients to receive the medications that allow them to function.

Endo aligns with PROP's objective of reducing prescription drug abuse, and leads a range of efforts to ensure that our products are appropriately used by patients and to reduce the potential misuse or abuse of any of our medicines.

Endo's commitment to the safe use of our products is demonstrated in our reformulation of Opana® ER. Opana ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Manufacturing of the original formulation of Opana ER ended in February 2012, after Endo voluntarily applied for and received FDA approval for a new Opana ER formulation designed to be crush-resistant. Endo launched the reformulated Opana ER, designed to be crush-resistant, in March 2012.

Endo was excited to announce in November 2012 that early surveillance data indicate that the introduction of the reformulated Opana ER reduced rates of abuse. The data follow abuse rates for Opana ER, from the third quarter of 2011 through the third quarter of 2012, and show that the reported rate of abuse of the reformulated Opana ER was reduced by 59 percent, based on the total number of prescriptions dispensed, versus the rate observed for the non-tamper-resistant formulation of Opana ER, which is no longer being manufactured by the company.

The treatment of chronic pain is complex and cannot be advanced by arbitrary, far-reaching and simplistic "solutions" as put forward in the PROP petition. Further research, dialogue, and education are best suited to improving complex problems where all aspects of the issue are discussed in order to find answers. Endo looks forward to participating in the dialogue with other interested parties, including PROP, to address the prescription abuse problem while ensuring access to medicines for those suffering with chronic pain.

Regards,

Frank Casty, MD
CMO & SVP Clinical Development & Medical Science
Endo Health Solutions