NATIONAL PHYSICIANS ALLIANCE

March 2, 2016

Robert M. Califf, MD, MACC,
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Science Board Meeting on Opioids

Dear Dr. Califf,

The National Physicians Alliance (NPA) is pleased that FDA convened a meeting of its external Science Board to discuss the role of opioids in pain management. We greatly appreciate FDA's willingness to consider regulatory changes to reduce opioid-related morbidity and mortality.

NPA urges FDA to adopt the recommendations made at the conclusion of the meeting by Dr. Bruce Psaty, Chair of the Science Board. The recommendations by Dr. Psaty and the Science Board included the following:

1. Opioid labels should indicate a suggested maximum dose.
2. FDA should clearly communicate that use of opioid analgesics for more than 90 days may not be safe or effective.
3. FDA should overhaul the existing opioid Risk Evaluation and Mitigation Strategy (REMS).

We are writing to reinforce these recommendations because FDA's analgesic division has not followed the advice of its scientific advisors on decisions involving opioids. For example, in 2010 a scientific advisory committee voted against FDA's opioid REMS proposal, yet FDA's analgesic division proceeded with its plan. In 2011, the analgesic division did not honor concerns of experts that its proposed curriculum for prescriber education was inadequate. In 2012, an advisory committee voted 11 to 2 against approving Zohydro (extended-release hydrocodone), yet the drug was approved. More recently, the analgesic division has been bypassing external scientific review for decisions involving opioids, including the decision to approve marketing of long-term OxyContin use as safe and effective for children.

Twenty years ago an unprecedented marketing campaign led to a quadrupling of opioid prescriptions in the United States, which in turn led to parallel increases in opioid addiction and overdose deaths. The need to promote more cautious prescribing is clear. Unfortunately, many of FDA's actions and public statements suggest a belief that opioid harms are limited to individuals who "abuse" or "misuse" opioids, failing to recognize that patients who take opioids exactly as prescribed can become addicted

and suffer other adverse outcomes including accidental overdose. Approaches focused exclusively on reducing nonmedical opioid use, like the development of so-called "abuse-deterrent formulations (ADFs)" will not stem the rising tide of opioid addiction and overdose deaths.

The NPA appreciates the spirit of the new 'Opioids Action Plan' announced by the FDA on February 4, 2016. We urge you to strengthen the plan by taking the following actions: 1) FDA should convene scientific advisory committee meetings for all opioids (including ADF opioids) and committee recommendations should be adhered to; 2) revise extended-release and immediate release opioid labels in the manner suggested by the Science Board; and 3) overhaul the curriculum used in opioid REMS educational programs to explicitly clarify the lack of evidence regarding the safety and effectiveness of long-term opioid use.

NPA appreciates your willingness to reexamine the risk-benefit profile of opioid analgesic and to consider taking actions that will promote more cautious prescribing. We look forward to working with you in this effort.

Sincerely,

Lisa Plymate, MD
Co-Chair, NPA FDA Taskforce
Member, NPA Board of Directors

Joseph A. Adams, MD
NPA FDA Taskforce