



RESEARCH  
EDUCATION  
TREATMENT  
ADVOCACY

August 8, 2012

Dr. Margaret A. Hamburg, Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

The Institute of Medicine estimates greater than 100 million Americans live with pain, a leading cause of disability and reduced quality of life.

A group of respected pain professionals with the stated important goal of reducing opioid-related harm have reviewed available clinical research and epidemiologic data and have used this largely population-based information to inform recommendations in a letter to the FDA to revise regulatory changes that will impact clinical practice. The American Pain Society (APS) strongly agrees with the intent to promote responsible opioid prescribing and reduce opioid related harm.

However, APS does not support their proposed labeling changes, as we perceive an insufficient scientific evidence base to support these recommendations. Further, we are concerned that implementation of these labeling changes which would dictate indications, dosing and duration of opioid treatment will not accomplish the intended goals, but instead have unintended negative consequences for patients including but not limited to untreated pain and loss of access to individualized care.

It is clear that there are sub-populations of patients with chronic pain for whom the risk-benefit balance is better for opioids (sometimes beyond the limits proposed by the PROP physicians) than for other available treatments; for some patients, opioids are clinically appropriate for treatment of *moderate* pain, or at doses higher than 100mg morphine equivalents per day, or for longer than 90 days or a combination of these. We strongly support additional research to better inform safe and effective practice with respect to opioids.

For patients with pain, implementation of the PROP labeling recommendation would likely shift the balance of suffering (away from the sometimes negative consequences of opioids to the negative consequences of pain), unless there were a simultaneous massive increase in availability of alternative and effective treatments for chronic pain.

The APS would like to focus the discussion on the patient. Attention to the following issues, we believe will help us achieve the critical balance between optimizing pain management and reducing harm to patients and society.

1. Like other medications, opioids achieve good pain control with minimal adverse effects for some patients but not others. At present, we lack adequate evidence to predict which patients are which. Additional research funding to support long-term studies to address these issues is needed.

2. There is a clear need for developing new pain treatments and more widely disseminating current available therapies that achieve desired levels of pain relief and increased quality of life while producing less harm to patients and society. Additional research funding is needed for fundamental discovery and treatment target development, as well as implementation research to enhance delivery of presently available but poorly disseminated treatments.
3. Efforts are needed to increase the availability of multidisciplinary care in order to provide patients with comprehensive evaluation and treatment of their pain. This will both improve pain outcomes and reduce reliance on opioids as the cornerstone of treatment for chronic pain.

Taking a regulatory approach to something that all agree is complex may be shortsighted when there are currently many initiatives in evolution that are expected to improve opioid prescribing:

- SAMHSA Physician Clinical Support Systems for Opioids has myriad resources in process of launching that to support right prescribing.
- FDA REMs education will be widely available in the immediate future; clinician participation in REMS education can be incentivized by professional credentialing organizations, state medical boards and other entities
- Several NIDA and SAMSHA initiatives aim at improving identification and treatment of addictive disorders in pain treatment populations.
- NIH Centers of Excellence in Pain Education will improve pain education across all disciplines.
- Joint programs of SAMHSA and the ONC to increase accessibility and usability of Prescription Monitoring Programs between states and within the electronic medical record.
- Provisions within the Accountable Care Act are expanding capacity for identification and treatment of addictive disorders in pain treatment settings.
- FDA ACTION program is accelerating investigation and approval of innovative pain therapies.

In addition, numerous inter-professional initiatives at both national and state levels are bringing together law enforcement, healthcare providers, licensing boards, educators, diverse state agencies and other stakeholders to implement multidimensional solutions to the broader problem of prescription drug misuse.

In the face of these promising initiatives aimed to reduce opioid related harm, in the absence of adequate evidence to support specific labeling recommendations, and with the uncertain risk of unintended health-related suffering, we believe that the FDA should not change its labeling of opioid products at this time.

Sincerely,



Roger Fillingim, PhD  
President  
American Pain Society

Additional Signature page attached

Cc: Bob Rappaport MD

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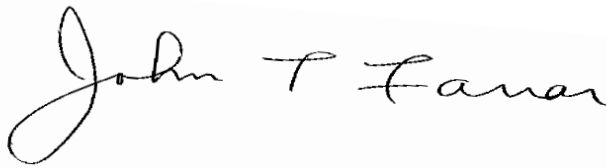


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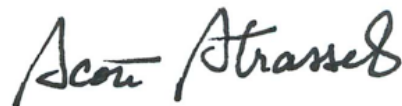
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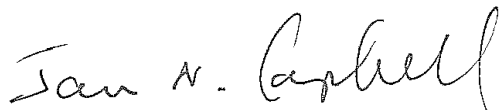
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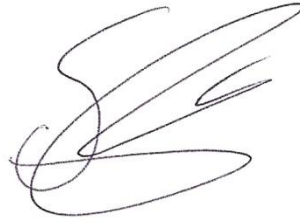
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