U.S. PAIN FOUNDATION

October 6, 2014
The Honorable Sylvia Mathews Burwell
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

We are writing you to express our unequivocal support for the FDA Commissioner, Dr. Margaret Hamburg, and her colleagues at the FDA who have consistently made fair, balanced and rational decisions to protect and promote the health of all Americans. FDA professionals under Dr. Hamburg's leadership have taken extraordinary steps to curb the abuse of opioid medications while at the same time protect access to these essential medications for the millions of Americans living with chronic pain who use them safely as prescribed.

The FDA is the federal agency charged with evaluating, approving and regulating medication in the U.S. and they are uniquely qualified to do so. FDA scientists spend years carefully evaluating the data on every medication before they are permitted on the market. Every medication has benefits and risks that must be weighed and considered and in the case of opioid medications, FDA has worked hard to mitigate risk in many ways. These include:

- Requiring risk evaluation and mitigation strategies (REMS) of manufacturers that include post-market risk assessments, medication guides for patients and specialized training for prescribers;
- Encouraging the development of abuse deterrent formulations with guidance for manufacturers and a planned public meeting to discuss development, assessment and regulation;
- Approving the first two opioids with abuse deterrent properties to enter the market;
- Approving a hand-held auto injector that allows the administration of emergency doses of naloxone to reverse opioid overdoses;
- Recommending the rescheduling of hydrocodone combination medications from CIII to CII thereby instituting the strictest controls on these medications;
- Toughening the labeling of these medications to remove the word "moderate" and replace it with "severe enough" to require round-the-clock treatment;
- Stipulating that the medications be reserved as a last option after failing other treatments; and
- Requiring a black-box warning on the medication- the strictest warning available.

**info@uspainfoundation.org** **Main: (800) 910.2462** **670 Newfield Street, Suite B**
**www.uspainfoundation.org** **Fax: (800) 929 -4062** **Middletown, CT 06457**

The charges leveled at the Commissioner and the agency by Fed Up are inaccurate, unfair and blatantly untrue. This group that is calling for the resignation of Commissioner Hamburg has repeatedly distorted and obfuscated the facts, blurring fact and fiction. Sadly, while a single overdose death is one too many, they and the media frequently cite that 16,600 overdose deaths were due to opioids in 2011. What is not stated is the fact that half that number were due to a combination of opioids and other licit and illicit substances including alcohol, cocaine and heroin. Furthermore, in that same year, government statistics show that there were 25,600 alcohol-induced deaths and 36,300 suicides. There are an estimated 7,000 – 10,000 deaths attributed annually to non-steroidal anti-inflammatory medications (NSAIDs) due to gastrointestinal adverse events not including those deaths due to cardiotoxic adverse events caused by NSAIDs. While the abuse of prescription drugs are of great concern, don't all these causes of preventable deaths deserve the level of investment, action and concern devoted to opioid medications? While there has been a focus on prescribers as the source of opioid problems, government statistics show that 82% of those that misuse and abuse opioids did not obtain them from a doctor themselves.

The Institute of Medicine has reported that there are 100 million Americans affected by chronic pain. An estimated ten percent of these or 10 million Americans have chronic pain so severe that they are disabled by it. Clearly chronic pain is a burden of staggering proportions and a major threat to the heath and well-being of our citizens. Uncontrolled pain devastates a person's quality of life, affecting all aspects of daily functioning including sleep, work, social activities and relationships. While opioid pain medications do not help everyone living with pain, the fact is that many require them, often in combination with other treatment modalities, to function on a daily basis and have any quality of life. When prescribed and properly administered to target populations with pain severe enough to require these medications, the incidence of abuse and addiction is extremely low.

Careful consideration of medical and scientific evidence rather than media hype and political considerations should govern access to medications that are critical for enabling a large portion of pain sufferers to be productive members in our society. Further restricting access to necessary treatment for people with pain will do little to address the problem of preventing, identifying, and treating individuals with addiction disorders. People with addiction disorders need more resources for treatment of the disease of addiction, coordinated follow-up and continuing support.

There are many things that can and must be done to minimize abuse and addiction such as the many steps FDA has responsibly taken. We stand in support of Commissioner Hamburg and her colleagues at FDA and urge you to support her as well.

Sincerely,

US Pain Foundation
National Fibromyalgia and Chronic Pain Association
Power of Pain Foundation
Center for Medicine in the Public Interest
Center for Lawful Access & Abuse Deterrence
Reflex Sympathetic Dystrophy Association
Massachusetts Pain Initiative
Wisconsin Pain Initiative
Pain Action Alliance to Implement a National Strategy (PAINS)
Global Healthy Living Foundation
Pain Connection
State Pain Policy Advocacy Network
Interstitial Cystitis Association
TxPAIN

**info@uspainfoundation.org**
**www.uspainfoundation.org**
**Main: (800) 910.2462**
**Fax: (800) 929 -4062**
**670 Newfield Street, Suite B**
**Middletown, CT 06457**

Professionals for Rational Opioid Monitoring and Pharmacotherapy (PROMPT)
Foundation for Ethics in Pain Care

CC: Margaret A. Hamburg, M.D., Commissioner, Food and Drug Administration
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs

**info@uspainfoundation.org**
**www.uspainfoundation.org**
**Main: (800) 910.2462**
**Fax: (800) 929 -4062**
**670 Newfield Street, Suite B**
**Middletown, CT 06457**