CLAAD Center for Lawful Access and Abuse Deterrence

September 29, 2014

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

Dear Secretary Burwell:

The undersigned organizations write to express our support for Food and Drug Administration (FDA) Commissioner Margaret Hamburg and the agency's demonstrated commitment to reducing prescription drug diversion and abuse under her leadership.

We are diverse organizations whose missions align around the dual goals of reducing prescription drug abuse and advancing consumer access to high-quality care for pain, addiction, anxiety, and other health conditions. We support balanced policy measures, such as improving public awareness, educating prescribers and patients, and employing prescription monitoring programs with privacy protections. We also include the development and adoption of abuse-deterrent medications among our priorities.

We are in the midst of two public health crises, prescription drug abuse and inadequately treated pain.[1] Addressing one problem without simultaneously seeking to reduce the other will yield greater, not less, human suffering and public expense.

The Obama Administration has committed to advancing policies that balance the dual public health aims of reducing drug abuse and providing access to care.[2] The FDA is the only entity that is authorized and qualified to evaluate, approve, and regulate the commercialization of medications in the United States.[3] In exercising these authorities, the FDA has consistently demonstrated a commitment to the Obama Administration's balanced policy approach.

Under Dr. Hamburg's leadership, the FDA has rightly relied on sound science to reduce prescription drug diversion and abuse while enhancing patient access to pharmaceutical treatments. To do otherwise would endanger the lives of people who live with pain and other conditions that can require controlled substances. For example, a recent survey by the National Fibromyalgia & Chronic Pain Association found that nearly 40 percent of people with chronic pain and without access to pain medication have considered suicide.[4]

In January 2013, the agency issued *Draft Guidance for Industry: Abuse-Deterrent Opioids — Evaluation and Labeling*, helping to provide greater regulatory clarity to spur research and innovation into abuse-

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[1] *Prescription Drug Abuse*, OFFICE OF NAT'L DRUG CONTROL POLICY, (last visited Sept. 25, 2014); Press Release, Am. Pain Soc'y, News from 32nd Annual Scientific Meeting of the American Pain Society, (May 10, 2013), http://www.americanpainsociety.org/about-aps/Press-Room/pain-research-funding-inadequate-in-the-face-of-soaring-incidence-and-treatment-costs.html.

[2] *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, OFFICE OF NAT'L DRUG CONTROL POLICY, (2011), http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf.

[3] *How Drugs Are Developed and Approved*, FDA (last updated Mar. 13, 2014), http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/.

[4] Rae Marie Gleason, et al., *Current Access to Opioids—Survey of Chronic Pain Patients*, PRACTICAL PAIN MGMT. (Mar. 1, 2014), http://www.practicalpainmanagement.com/treatments/pharmacological/opioids/current-access-opioids-survey-chronic-pain-patients.

deterrent technology.[5] Once guidance is finalized, branded pharmaceutical manufacturers will have a road map to develop medications that can effectively treat health conditions like pain and addiction, and reduce medication abuse and related overdoses and deaths. We have urged the FDA to expedite this final guidance and to issue similar guidance for generic manufacturers.[6]

Under Dr. Hamburg's leadership, the FDA approved a hand-held auto-injector that allows family members and caregivers to administer single, emergency doses of naloxone to reverse opioid overdoses.[7] The agency also recently approved a second opioid analgesic with abuse-deterrent properties.[8] Using a combination of oxycodone and naloxone, which is commonly used to reverse the effects of an opioid overdose or block the euphoric effects of opioids, the product is expected to be less desirable for purposes of abuse.[9] The naloxone becomes active when crushed and then snorted or injected, but not when the pill is swallowed whole.[10] The FDA has adopted an incremental approach to the development of medications with abuse-deterrent properties. A logical next step is to require all Schedule II controlled substances to convert to abuse-deterrent medications by a specific deadline. A transition of the market to today's abuse-deterrent medications will fund needed research and development of more effective, next-generation abuse-deterrent products.

In late October, the FDA will hold a two-day, public meeting to discuss the development, assessment, and regulation of abuse-deterrent formulations of opioid medications with patients, health care providers, the pharmaceutical industry, academics, researchers, and other governmental entities.[11] This meeting is another marked step toward achieving clear guidance and ultimately incentivizing the development of opioid medications with progressively better abuse-deterrent properties.[12]

In July 2012, the FDA approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications.[13] The REMS address the growing problem of prescription drug abuse and misuse. The REMS introduces safety measures to reduce risks and improve safe use of ER/LA opioid medications, while continuing to provide access to these medications for patients in pain.[14] Furthermore, following a Citizen Petition to the FDA to limit access to opioid treatment for chronic pain, the agency responded by adjusting safety labeling for extended-release/long-acting (ER/LA) opioid analgesics to "more effectively communicate to prescribers the serious risks … thus encouraging better prescribing, monitoring, and patient counseling practices involving these drugs."[15]

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[5] *Draft Guidance for Industry: Abuse-Deterrent Opioids—Evaluation and Labeling*, FDA (Jan. 2013), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.
[6] Letter Michael Barnes, Executive Director of the Ctr. for Lawful Access & Abuse Deterrence, et al., to the FDA, (June 11, 2013), http://claad.org/wp-content/uploads/2013/09/CLAAD-Citizen-Petition-130610-FINAL-1.pdf
[7] News Release, FDA, FDA Approves New Hand-Held Auto-Injector to Reverse Opioid Overdose (Apr. 3, 2014), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm.
[8] News Release, FDA, FDA Approves New Extended-Release Oxycodone with abuse-Deterrent Properties (July 23, 2014), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm406407.htm.
[9] *Id.*
[10] *Id.*
[11] Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting, 79 Fed Reg. 56810 (Sept. 23, 2014).
[12] *Id.*
[13] *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids*, FDA (last updated Aug. 26, 2014), http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm.
[14] *Id.*
[15] Letter from Janet Woodcock, Director, Ctr for Drug Evaluation & Research to Andrew Kolodny, President of Physicians for Responsible Opioid Prescribing, (Sept. 10, 2013), http://www.regulations.gov/contentStreamer?objectId=09000064813ecf6b&disposition=attachment&contentType=pdf.

Under Dr. Hamburg's leadership, the FDA recommended the rescheduling of commonly-abused hydrocodone combination products, such as Vicodin.[16] The change from Schedule III to Schedule II, which will increase the controls on these products, will go into effect next month.[17] Not all of the cosigners of this letter support this move, thereby signaling the difficulty of balancing oftentimes competing or conflicting public health priorities. Nevertheless, it demonstrates the FDA's commitment to using its authority to reduce opioid and other controlled substance abuse. Even given substantive disagreements with the FDA, our support for its authority and leadership is strong.

The FDA has also been careful not to exceed its interstate commerce authority. States play a pivotal role in reducing prescription drug abuse through their authority to regulate the practice of medicine and pharmacy. States at the forefront of prescription drug abuse reduction policy, such as Kentucky and Florida, have enacted mandatory standards for prescribing controlled substances,[18] and 49 out of 50 states have implemented prescription monitoring programs.[19] The FDA acknowledges that health care professionals must receive adequate, proper, training, and education to minimize prescription drug diversion and abuse[20] and has worked with industry to implement a thorough prescriber education program for ER/LA opioids. This program supports state-led efforts to improve prescribing without usurping state authority.

Together, federal and state policy makers, regulators, and stakeholders are rising to the occasion and creating a landscape with better systems to ensure safer, healthier communities. As we move forward, the solution to opioid diversion and abuse, as stated in a recent op-ed published in *The Hill*, must be "one that recognizes the legitimate treatment need for such opioid medications by millions of Americans living with chronic pain."[21]

To date, the efforts of policy makers and countless health and safety organizations have contributed to a reduction in non-medical use of opioids in at least 10 states,[22] and a nationwide reduction in non-medical use of prescription drugs among young adults aged 18 to 25.[23] This month, the Centers for Disease Control and Prevention (CDC) reported that while overdose-related deaths climbed by 18 percent each year from 1999 through 2006, they only rose by only three percent from 2007 through 2011.[24]

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[16] *Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research*, FDA (Oct. 24, 2013), http://www.fda.gov/Drugs/DrugSafety/ucm372089.htm.

[17] Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49661, 49661 (Aug. 22, 2014) (to be codified at 21 C.F.R. Part 1308).

[18] FLA. STAT. ANN. § 456.44 (2011); 201 KY. ADMIN. REGS. 9:260.

[19] Kistin Finklea, et al., *Prescription Drug Monitoring Programs*, CONG. RESEARCH SERVS. (Mar. 24, 2014), http://fas.org/sgp/crs/misc/R42593.pdf.

[20] *FDA Provides Facts About Zohydro*, FDA (Apr. 30, 2014), http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm395456.htm.

[21] Christopher Gharibo, *Prescription Drug Abuse Epidemic Demands Mandatory Physician Education*, THE HILL (Sept. 22, 2014), http://thehill.com/blogs/congress-blog/healthcare/218368-prescription-drug-abuse-epidemic-demands-mandatory-physician.

[22] Comparisons of combined 2009 and 2010 data with combined 2010 and 2011 data showed that nonmedical use of prescription pain relievers among persons aged 12 or older decreased in 10 States (Kentucky, Louisiana, Massachusetts, Mississippi, New Hampshire, New York, Ohio, Oklahoma, Rhode Island, and West Virginia), and did not increase in any State. *State Estimates of Nonmedical Use of Prescription Pain Relievers*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Jan. 8, 2013), http://www.samhsa.gov/data/2k12/NSDUH115/sr115-nonmedical-use-pain-relievers.htm.

[23] News Release, Substance Abuse & Mental Health Servs. Admin., National Survey Shows Reduction in Non-Medical Prescription Drug Use Among Young Adults (Sept. 24, 2012), http://www.samhsa.gov/newsroom/advisories/1209244622.aspx.

[24] Melanie Eversley, *CDC: Prescription Painkiller Deaths Slowing Down*, USA TODAY (Sept. 16, 2014), http://www.usatoday.com/story/news/nation/2014/09/16/prescription-painkiller-overdose-cdc/15694831/.

The FDA has made significant strides in addressing the prescription drug abuse epidemic, including advancing the innovation of abuse-deterrent medications, implementation of the REMS, changes in labeling of medications, and the rescheduling of hydrocodone combination products. Secretary Burwell, we urge you to join us in expressing your public support for Dr. Hamburg and her colleagues at the FDA.

Sincerely,

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