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The Honorable Sylvia Mathews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell,

We are writing to you on behalf of a coalition of organizations on the front line of the opioid addiction epidemic. On September 28th we will convene the 2nd FED Up! Rally on the National Mall followed by a march to the White House. Thousands of people from across the country will join us in calling for an urgent and coordinated federal response to the worst drug addiction epidemic in our nation's history. At the rally we will express our concern about the slow and tragically ineffective response to this public health crisis by some federal agencies.

We are especially frustrated by the Food and Drug Administration's (FDA) continued approval of new, dangerous, high-dose opioid analgesics that are fueling high rates of addiction and overdose deaths. After careful consideration we have come to believe that without new leadership at FDA the opioid crisis will continue unabated.

Last October FDA approved Zohydro, an easily crushed, high-dose hydrocodone product, despite an 11-2 vote by its scientific advisory committee to keep the drug off the market. This action led to urgent pleas from public health officials, consumer advocacy organizations, addiction treatment providers, medical experts, Members of Congress, several governors and attorneys general from 28 states, for FDA to reconsider its decision. Even Attorney General Eric Holder reported that he was "a little baffled" by the decision to approve Zohydro.<sup>1</sup>

In defending approval of Zohydro, Dr. Hamburg argued that new opioids are required to meet the needs of "100 million Americans living with severe chronic pain."<sup>2</sup> Dr. Hamburg's support for using opioids to treat chronic non-cancer pain (CNCP) is squarely at odds with efforts by the

<sup>1</sup> Comment by Eric Holder on April 4, 2014 in response to a question by Chairman Hal Rogers at the House budget hearing for the Department of Justice Fiscal Year 2015

<sup>2</sup> Speech by Margaret Hamburg on April 22, 2014 at the Rx Drug Abuse Summit in Atlanta, Georgia available at: <http://www.fda.gov/newsevents/speeches/ucm394400.htm>. The claim that 100 million Americans suffer from severe chronic pain has been contested by experts, including the researcher whose study the estimate is based on. See: John Fauber, *Chronic pain statistic called exaggerated, misleading*, Milwaukee Journal Sentinel (June 25, 2014), available at: <http://www.jsonline.com/watchdog/watchdogreports/chronic-pain-statistic-called-exaggerated-misleading-b99287713z1-264515601.html>

Centers for Disease Control (CDC) to discourage this widespread practice. The director of the CDC, Dr. Thomas Frieden, has been asking the medical community and the public to avoid opioid use for CNCP, warning that the “risks far outweigh benefits”.<sup>3</sup> In the midst of public health crisis, Department of Health and Human Services (HHS) agency heads should not be delivering contradictory messages to the public.<sup>4</sup>

Just last month FDA approved another extended-release opioid called Targiniq, which contains a high dose of oxycodone combined with naloxone. Although the addition of naloxone may deter misuse by injection and snorting, it cannot exert its effect when taken orally.<sup>5</sup> This means that when chewed, extended-release Targiniq tablets will immediately release the entire dose of oxycodone and the naloxone will have no effect. It is likely that FDA’s scientific advisory committee would have voted against Targiniq approval because it contains the same active ingredient found in OxyContin but unlike OxyContin, which was reformulated to be crush-resistant, Targiniq can be easily chewed for release of the full dose.

FDA approved Targiniq without convening a scientific advisory committee meeting. The decision by FDA to bypass the advisory committee violated its own policy. According to the *Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings*, “if the matter at issue [is] of significant public interest” or “if the matter at issue [is] controversial” an advisory committee meeting should be convened.<sup>6</sup> The decision to approve Targiniq clearly met both of these criteria. We believe that FDA bypassed its advisory committee because it wanted to avoid the same controversy it faced after approval of Zohydro. Yet it is precisely when approval of a drug is controversial that scientific advisory committee meetings are called for.

The United States, with about 5% of the world’s population, is now consuming 84% of the world’s oxycodone supply and 99% of the hydrocodone supply.<sup>7</sup> According to the CDC, overprescribing of opioids has led to skyrocketing rates of addiction and overdose deaths. Yet, FDA’s analgesic division continues to approve new opioids and, in violation of the Federal Food, Drug and Cosmetics Act (FD&C Act), allows them to be marketed for conditions where evidence of safety and effectiveness is lacking.

The director of FDA’s Division of Anesthesia, Analgesia, and Addiction Products, approved Zohydro and Targiniq. These decisions reflect a long-standing pattern of putting the interests of analgesic makers ahead of the public’s health. Last October, The Washington Post and The Milwaukee Journal Sentinel reported on the division

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<sup>3</sup> Dr. Thomas Frieden, *CDC Telebriefing on Deaths from Prescription Painkiller Overdoses Rise Sharply Among Women* (July 2, 2013), available at: <http://www.cdc.gov/media/releases/2013/t0702-drug-overdose.html>

<sup>4</sup> The contradiction between FDA’s opioid positions and that of other federal agencies was the subject of a recent Associated Press story *Federal Views Diverge on Proper Use of Painkillers* by Matthew Perrone (June 10, 2014), available at: <http://bigstory.ap.org/article/federal-views-diverge-proper-use-painkillers>

<sup>5</sup> Oral administration of naloxone lacks systemic bioavailability due to marked hepatic first pass metabolism.

<sup>6</sup> *Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings*, available at: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651>

<sup>7</sup> United States hydrocodone and oxycodone consumption statistics as reported by the International Narcotics Control Board in 2012.

director's relationship with pharmaceutical companies.<sup>8</sup> According to these news stories, he served on the steering committee of a private organization that charged high fees to pharmaceutical companies for the opportunity to attend closed-door meetings with him. At these private meetings FDA's clinical trial methodologies for analgesics were changed, making it easier for companies to release new opioids on the market. Emails obtained by a Freedom of Information Act (FOIA) request, referred to these private meetings as a "pay-to-play process." Despite learning of this arrangement, Dr. Hamburg has permitted the division to continue approving new opioids.

In the wake of Zohydro approval, governors, state health officials and state legislators in Massachusetts, Vermont, Maine, New Hampshire, Connecticut, Rhode Island, Pennsylvania and Ohio, attempted to ban Zohydro, limit its use and/or seek its removal from the market. In addition, bi-partisan legislation was introduced in both the United States Senate and in the House of Representatives to reverse Zohydro's approval. Policymakers took these unprecedented actions because they understood that in the midst of an epidemic caused by opioid overprescribing, the last thing our country needs are dangerous, new high-dose opioids. These efforts to ban an FDA-approved drug demonstrate a loss of confidence in FDA to make approval decisions that are scientifically informed and free of industry influence.

Since 1999, we have lost more than 150,000 Americans lives to opioid overdoses and millions more now struggle with the disease of opioid addiction. FDA's failure to cooperate with other federal agencies, its approval of a steady stream of new opioids, and its failure to limit marketing to conditions where benefits of use are likely to outweigh risks (as required by the FD&C Act), have contributed to a public health crisis. Rather than recognizing its mistakes and reversing course, FDA has made it perfectly clear that it intends to continue approving new opioids.

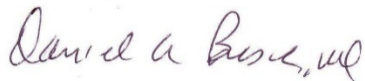
We are urging you to intervene. Pleas from across the country for FDA to respond to the opioid crisis by properly exercising its authority and responsibility have fallen on deaf ears for too long. We urge you to seek new leadership for FDA; leadership that will work in a coordinated fashion with the CDC and other federal and state agencies, leadership willing to re-examine past decisions, and leadership that will consistently put the public's health ahead of industry interests.

Sincerely,

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<sup>8</sup> Peter Whoriskey, *Pharmaceutical firms paid to attend meetings of panel that advises FDA, e-mails show*, Washington Post (Oct 6, 2013), available at: [http://www.washingtonpost.com/business/economy/pharmaceutical-firms-paid-to-attend-meetings-of-panel-that-advises-fda-e-mails-show/2013/10/06/a02a2548-2b80-11e3-b139-029811dbb57f\\_story.html](http://www.washingtonpost.com/business/economy/pharmaceutical-firms-paid-to-attend-meetings-of-panel-that-advises-fda-e-mails-show/2013/10/06/a02a2548-2b80-11e3-b139-029811dbb57f_story.html)

John Fauber, *Emails point to 'troubling' relationship between drug firms, regulators*, Journal Sentinel (Oct 6, 2013), available at: <http://www.jsonline.com/watchdog/watchdogreports/emails-point-to-troubling-relationship-between-drug-firms-regulators-b99113286z1-226692641.html>



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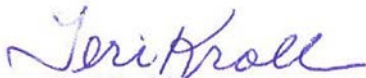
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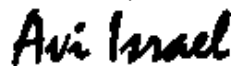
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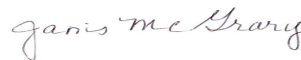
Gene DiGirolamo  
House Human Services Committee  
Majority Chairman  
PA House of Representatives  
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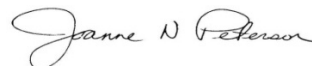
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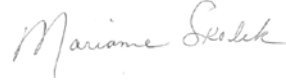
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