Congress of the United States
Washington, DC 20510

May 9, 2013

The Honorable Margaret Hamburg
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Thank you for your March 14, 2013 response letter regarding a citizen's petition to reschedule hydrocodone. While we appreciate your reply, we remain concerned about the already excessive length of time that this rescheduling process has taken. We are also disappointed that you did not provide the requested timeline for reaching a final decision regarding rescheduling hydrocodone combination drugs.

The Centers for Disease Control (CDC) have labeled the prescription drug problem ravaging our nation as an "epidemic." Recent CDC data underscores the role that opioid pain relievers, like hydrocodone combination products, play in unintentional overdose deaths. Its study demonstrated that drug overdose deaths increased for eleven straight years since 1999. Sixty percent of the drug overdose deaths (22,134) involved pharmaceutical drug products. Prescription drug products containing oxycodone, hydrocodone, methadone and others, represented three-quarters of those deaths (16,651).[1] A separate, independent analysis of autopsy reports from various coroners' offices between 2006 to 2011 conducted by the Los Angeles Times shed additional light on the role that hydrocodone plays in overdose deaths. Its analysis of 3,733 prescription drug-related fatalities in Southern California found that hydrocodone was involved in over a quarter of the deaths, more than any other prescription medication.[2]

This information underscores the scope and magnitude of the hydrocodone abuse epidemic and why we believe that it is imperative that the FDA complete its review and accept the recommendation of its Drug Safety and Risk Management Advisory Committee (DSaRM).

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[1] Jones, C., Paulozzi, L., and Mack, K. "Pharmaceutical overdose deaths, United States, 2010". Journal of the American Medical Association (JAMA), 309(7), 657-659 (2013).

[2] Glover, S., Girion, L. (2013, March 20). Bill aims to tighten restrictions on painkiller hydrocodone. *Los Angeles Times.*

The Controlled Substances Act (CSA) requires that the:

> "Evaluation and the recommendations of the Secretary [...] be made in writing and submitted to the Attorney General within a ***reasonable time***." 21 U.S.C. §811(b) [emphasis added]

It has been 14 years since the initial petition requesting that the FDA and the Drug Enforcement Administration (DEA) evaluate the proper scheduling of hydrocodone combination drugs. Not only is 14 years more than enough time, but this rescheduling process has exceeded the "reasonable time" requirement of the CSA. Your own advisory board has already approved rescheduling by a 19 to 10 vote. The American people have waited too long for action from this agency. Your previous response failed to address our request for a timeline for finalizing your review and, accordingly, we are writing a second time to respectfully request a timeline of this 14-year petition.

Let us again emphasize that rescheduling hydrocodone combination products from Schedule III to Schedule II is an important step in addressing prescription drug abuse. We respectfully urge you to accept the recommendation made by the DSaRM Advisory Committee without delay, and we look forward to your response.

Sincerely,

Joe Manchin III
United States Senator

Mark Kirk
United States Senator

John D. Rockefeller IV
United States Senator

Charles E. Schumer
United States Senator

Dianne Feinstein
United States Senator

Kirsten Gillibrand
United States Senator

Bill Nelson
United States Senator

Marco Rubio
United States Senator

Vern Buchanan
Member of Congress