

HAROLD ROGERS  
5TH DISTRICT, KENTUCKY

COMMITTEE ON APPROPRIATIONS  
CHAIRMAN



Congress of the United States  
House of Representatives  
Washington, DC 20515-1705

PLEASE RESPOND TO:

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January 28, 2013

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

Dear Dr. Hamburg;

I write to urge the Food and Drug Administration (FDA) to take immediate action on the recent recommendations of the Drug Safety and Risk Management Advisory Committee (DSaRM) regarding the scheduling of hydrocodone combination drugs.

As you are aware, hydrocodone is the most prescribed drug in the United States, with approximately 131 million prescriptions issued in 2011. Due in part to their widespread availability, hydrocodone combination products remain some of the most frequently diverted and abused prescription-based controlled substances. Unfortunately, I have born witness to the devastation that the misuse of these medications can wreak on rural communities, and, with prescription drug overdose deaths now eclipsing those caused by heroin and cocaine combined, the Centers for Disease Control (CDC) has characterized prescription drug abuse as a national epidemic. As co-founder and co-chairman of the Congressional Caucus on Prescription Drug Abuse, I have advocated for some time that the Drug Enforcement Administration (DEA) and FDA should collaborate to develop restrictions on the prescription of hydrocodone combination drugs to conform more closely with other opioid-based painkillers.

I was pleased to learn that the FDA responded to DEA's request to reschedule hydrocodone combination drugs by hosting a public meeting of the DSaRM to discuss the risks and benefits of these products. I understand that at this meeting, a number of scientific studies were presented which clearly demonstrate that chronic use of hydrocodone is associated with morphine-like tolerance, dependence and addiction – and that there is no data to support the notion that substances which are added to hydrocodone combination products negate the reinforcing effects of the active drug. At the conclusion of the two-day affair, DSaRM members voted to implement tighter restrictions on the prescription of these medications, and I whole-heartedly support this proposal. I urge FDA to swiftly adopt the recommendations of the advisory panel and move quickly to implement the necessary regulatory changes.

Dr. Hamburg, today, the FDA has an opportunity to make a tangible, positive impact in our Nation's struggle against prescription drug addiction and abuse, and I encourage you to use the full gamut of your authority as Commissioner to take this critical step forward. If you have any questions or concerns, please feel free to contact Megan O'Donnell of my staff at (202) 225-4601. I look forward to your response.

Sincerely,

A handwritten signature in blue ink that reads "Hal Rogers". The signature is written in a cursive, flowing style.

HAROLD ROGERS  
Member of Congress

CC: Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services