The FED Up! Coalition
Steering Committee

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Chair, Fed Up! Coalition Steering Committee
President, Steve Rummler Hope Foundation

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Advisory Committee Member, Connect the Pieces

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Joanne Peterson
Founder and Executive Director, Learn to Cope

April J. Rovero
Founder/CEO, National Coalition Against Prescription Drug Abuse (NCAPDA)

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February 26, 2014

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

RE: New Drug Application NDA 202880, Zohydro ER

Dear Dr. Hamburg,

We are writing to echo concerns raised in letters written by Members of the United States Congress and by State Attorneys General regarding the Food and Drug Administration's (FDA) approval of Zohydro, a high-dose, single-entity hydrocodone formulation. We join them in asking you to adopt the recommendation of the FDA-appointed scientific advisory panel, which voted 11-2 against approval of Zohydro.

On behalf of consumer safety organizations, health care agencies, addiction treatment providers, community-based drug and alcohol prevention programs, professional organizations, and other groups on the front-line of our nation's opioid addiction epidemic, we ask you to put the public's health ahead of industry interests. In the midst of a severe drug addiction epidemic fueled by overprescribing of opioids, the very last thing the country needs is a new, dangerous, high-dose opioid.

If your decision to approve Zohydro was based on adherence to existing FDA policies, then surely those polices require urgent revision. FDA must take into account recent history. After the release of similar high-dose opioid analgesics, thousands of lives were lost from overdose and hundreds of thousands of medical and non-medical users became addicted. We implore you to take these painful lessons into account.

Over the past 15 years, prescriptions for opioids have skyrocketed. The United States, with about 5% of the world's population, is now consuming more than 84% of the world's entire oxycodone supply and more than 99% of the hydrocodone supply.[1] According to the United States Centers for Disease Control (CDC), the sharp increase in opioid prescribing has led to parallel increases in opioid addiction and overdose deaths. Since 1999, overdose deaths have skyrocketed, especially among middle-aged individuals prescribed opioids for chronic pain. Opioid analgesic overdose deaths have increased by 415% in women and 265% in men.[2]

Zohydro's maker has claimed that it is safer than existing hydrocodone products because it does not contain acetaminophen. Zohydro is not safer. The highest available dosage of Zohydro will contain 5 to 10 times more hydrocodone than Vicodin or Lortab. Someone unaccustomed to taking opioids could suffer a fatal overdose from just two capsules. A single capsule could be fatal if swallowed by a child. For patients unable to tolerate acetaminophen, many opioid formulations made without acetaminophen are already available. There is no need for another high-dose, single-entity opioid.

Too many people have already become addicted to similar opioid medications and too many lives have been lost. We urge you to exercise your authority and responsibility to protect the public's health by keeping Zohydro off the market.

Sincerely,

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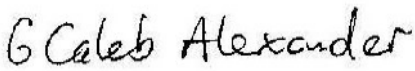
[1] United States hydrocodone and oxycodone consumption statistics as reported by the International Narcotics Control Board in 2012.

[2] CDC. Vital signs: Overdoses of prescription opioid pain relievers and other drugs among women—United States, 1999–2010. MMWR 2013; 62:537-542



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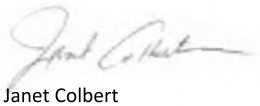

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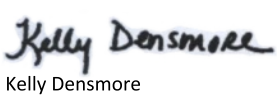

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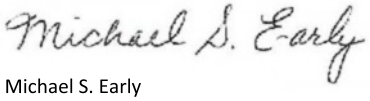

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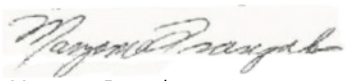

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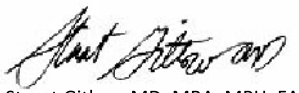

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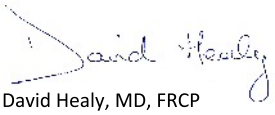

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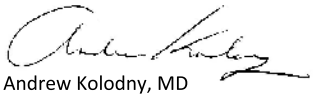

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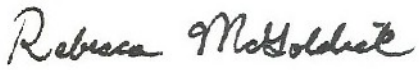

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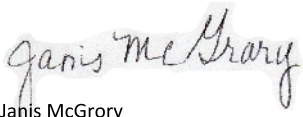

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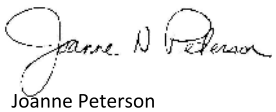

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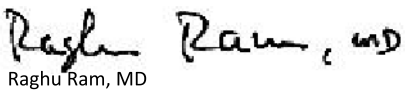

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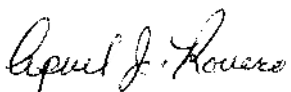

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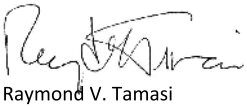

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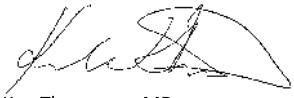

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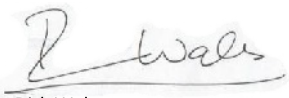

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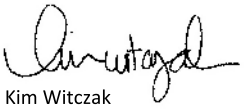

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