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March 6, 2014

Dr. Margaret Hamburg
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I am writing to urge you to halt the imminent release of the new prescription painkiller, Zohydro. Bringing Zohydro to market runs the serious risk of exacerbating the prescription drug abuse epidemic that is destroying lives and tearing apart families in West Virginia and across the country.

The stated mission of the Food and Drug Administration (FDA) explicitly calls to "protect the public health by assuring the safety, efficacy and security of human drugs." There are serious questions about whether releasing Zohydro on the market meets that mission.

The FDA's own advisory council voted overwhelmingly, 11-2, not to recommend Zohydro, citing a high risk for abuse and addiction. Despite this, the FDA approved Zohydro against the recommendation of public officials, advocates, law enforcement, and medical personnel.

Recent news reports outline the dangerous potential of Zohydro. While intended for people with chronic and debilitating pain, the tremendous amount of hydrocodone found in Zohydro, ranging from five to ten times more potent than painkillers currently available to the public, leaves it ripe for abuse and overdose. Moreover, Zohydro is not available in tamper-resistant form, meaning that users will be able to crush and snort it.

Simply put, the potential costs of Zyhydro, in terms of lives lost and communities torn apart, are enormous. On top of that, U.S. Senators Joe Manchin (WV) and David Vitter (LA) recently outlined legitimate pay-to-play concerns surrounding the approval process of Zohydro. It certainly should not be released to the general public before all parties involved comply with the Senators' requests for information.

According to the Centers for Disease Control and Prevention, deaths from painkillers in the United States quadrupled from 1999 to 2010. Here in West Virginia, like many states across the country, we are all too familiar with the devastating effects of prescription drug abuse. According to a 2013 report from the Trust of America's Health, West Virginia has the highest drug overdose mortality rate in the United States, an increase of 605 percent since 1999. In McDowell County alone, twelve people die from prescription drugs every month.

These are not just statistics – they are parents, children, friends, family members, and lives torn apart.

West Virginians are working hard to combat the prescription drug epidemic. Introducing a dangerous and potentially deadly new drug into the market flies in the face of their efforts.

Last summer, I attended a town hall meeting in Wyoming County. Law enforcement, public health officials, teachers, and neighbors packed the local auditorium on a Friday night to work together toward solutions. I will never forget the heartbreaking stories of parents and school administrators who have buried far too many of our young people.

I ask you, please, work with us, not against us.

Come to West Virginia and see the consequences of prescription drug abuse for yourself. Look in the eyes of families who have lost loved ones and hear their stories. Honor the FDA mission to protect the public health and halt the release of Zohydro.

Respectfully,



Natalie E. Tennant
West Virginia Secretary of State