Congress of the United States
Washington, DC 20515

April 23, 2014

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

Dear Commissioner Hamburg,

We are writing to encourage the Food and Drug Administration (FDA) to take prompt action to recognize naloxone as a safe and effective over-the-counter (OTC) medication to treat and reverse an opioid overdose. According to data from the Centers for Disease Control (CDC), fatal overdoses in the U.S. involving opioids have more than quadrupled since 1999, and there were almost 17,000 opioid overdose deaths in 2010 alone. Opioid abuse has reached epidemic proportions, and we must make use of safe and available tools to prevent opioid-induced deaths as we combat this public health crisis.

Naloxone is a prescription opioid antagonist with no potential for abuse that immediately reverses an opioid overdose. Naloxone must be administered quickly, and it is often too late by the time an overdose victim is treated. Community programs that provide brief training and equip potential bystanders and emergency responders with naloxone have demonstrated large reductions in opioid related fatalities. For example, the Quincy Police Department in Quincy, Massachusetts began distributing naloxone to emergency responders in 2010, and their police officers have reversed over 200 overdoses to date. Since prevention programs first began distributing naloxone in 1996, they have reported over 10,000 overdose reversals.

These success stories have led the American Medical Association, the American Public Health Association, Attorney General Holder and former Office of National Drug Control Policy (ONDCP) Director R. Gil Kerlikowske to endorse widened access to naloxone. Unfortunately, naloxone is still considered a prescription drug, enacting large barriers to wide distribution. Multiple states have tackled this issue by implementing liability laws that increase access to naloxone. However, the only way to effectively place naloxone in the hands of all those who need it is by making it available OTC.

The only FDA approved naloxone formulation is injectable naloxone, for use as a prescription drug. We would like to commend the FDA on its efforts so far to expedite the regulatory process required for new formulations of naloxone to receive FDA approval. Formulations such as the intranasal spray are easier for a lay person to administer, and are already being used off-label with good results. In addition, we urge the FDA to consider all options to immediately give any appropriate naloxone formulations OTC drug status. While we recognize that the regulatory process must occur in a thoughtful, scientific manner, it is vital that the FDA takes into account

the public health implications of this drug. We believe there is a clear rationale for prompt OTC availability of naloxone.

Given the importance of naloxone, we would like the FDA to respond to the following questions:

1. What tools has the FDA made available to developers of naloxone formulations to expedite the regulatory process to receive drug approval and has there been an effort to enhance outreach to and communication with entities performing clinical trials for naloxone?

2. Does the FDA have all the resources necessary to quickly review a drug application that is related to new naloxone formulations and are there any existing regulatory hurdles to quickly processing such an application?

3. Does the FDA have an estimate on the time it will take to reclassify naloxone from prescription drug status to over-the-counter status, should the application and relevant clinical data be submitted?

4. Are there alternative pathways to a rulemaking process that the FDA can pursue to widen access to naloxone on a shorter time scale?

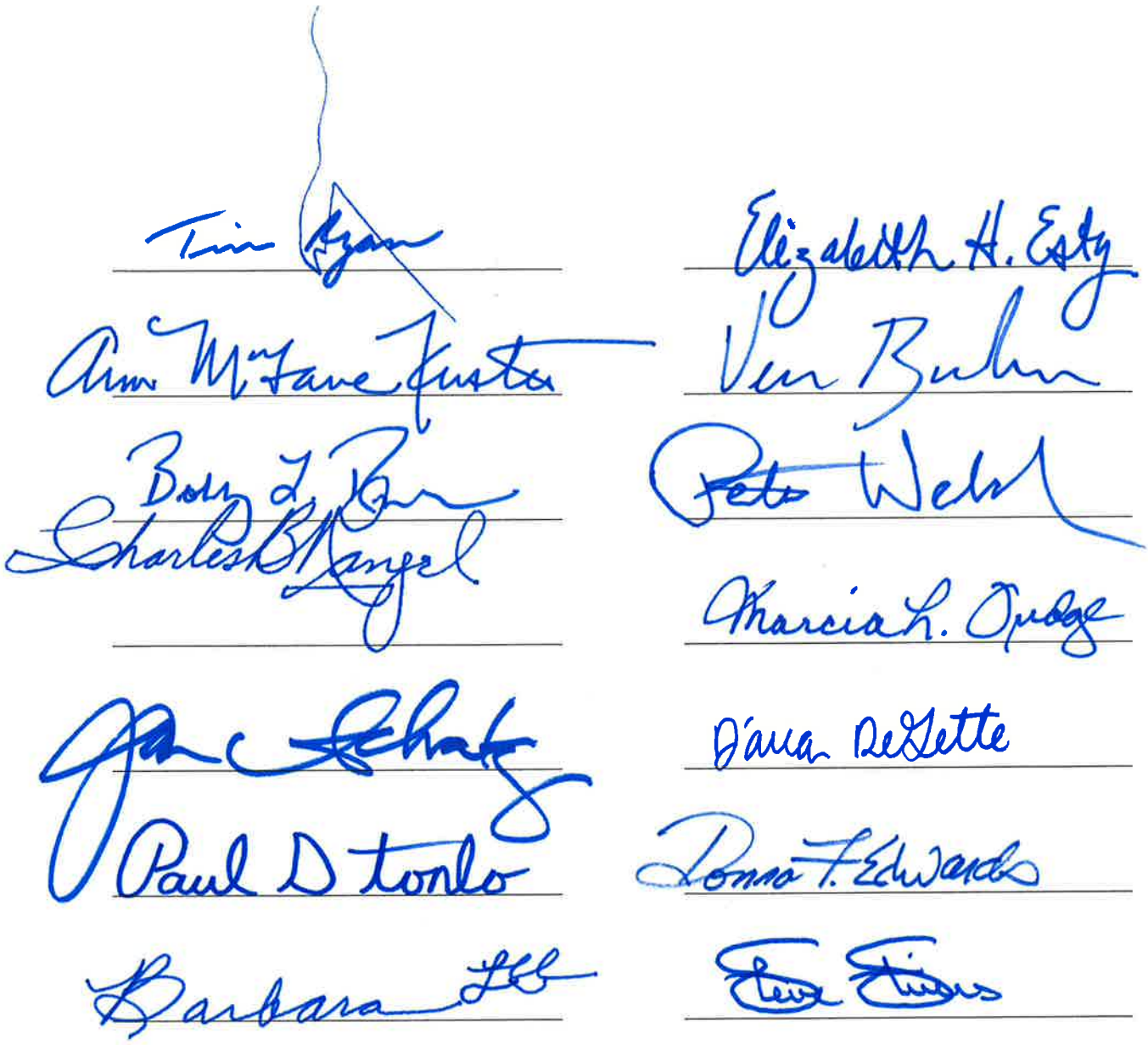
5. Can the FDA take into consideration drug safety data from countries that have already made naloxone available OTC?

Thank you for your consideration of this request. Please respond to these questions within 30 days of receiving this letter.

Sincerely,

Bill Foster
Member of Congress

Sean Patrick Maloney
Member of Congress



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