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May 13, 2013

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

Dear Dr. Hamburg:

We write to you today out of concern for the health and well-being of newborn children. The opioid epidemic has taken the lives of many of our citizens and has affected nearly everyone in this nation, including newborn children. Neonatal Abstinence Syndrome (“NAS”) caused by maternal opiate use has increased at alarming levels. As you are aware, NAS is caused when infants suddenly lose their opioid drug supply at birth.

NAS includes the malfunction of the autonomic nervous system, respiratory system and gastrointestinal tract. Signs of withdrawal usually present from within 24 hours to several days after delivery and may include: abnormal sleep patterns, tremors, vomiting, high-pitch crying, irritability, hyperactivity, seizures, weight loss and failure to gain weight. Onset, duration and severity of the manifestations vary with the substance or substances used, the amount and timing of the mother’s last dose, and the rate at which the drug is eliminated from the infant’s body.

As the use of prescription opioid analgesics increases, so do the instances of NAS. We therefore believe that a “black box warning” for these medications would help ensure that women of childbearing age – as well as their health care providers – are aware of the serious risks associated with narcotic use during pregnancy. Possible content for the warning might be as follows:

WARNING: USE OF NARCOTIC ANALGESICS IN PREGNANT WOMEN MAY CAUSE NEONATAL ABSTINENCE SYNDROME

Both the human and financial costs of NAS are alarming. In a 2012 Journal of American Medical Association article, a group of physicians determined that treating a single newborn with NAS in 2009 cost approximately \$53,400, with a total estimated cost to the Nation in that year of \$720 million; Medicaid paid for 77.6% of these treatment costs. This study also found that approximately 1 infant was born every hour in the United States with NAS.

While there are NAS treatment protocols, there is still sparse scientific data as to optimal treatments for NAS in either the ante or post-partum

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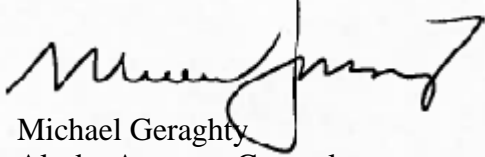
settings. The best course of action therefore is prevention. Appropriate clinical awareness and protocol would be enhanced by a “black box” warning.

Thank you for your consideration. We look forward to your response.

Sincerely,



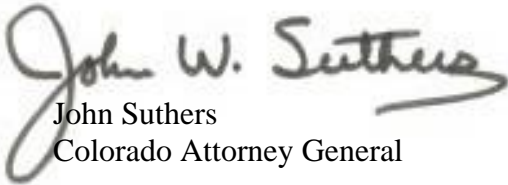
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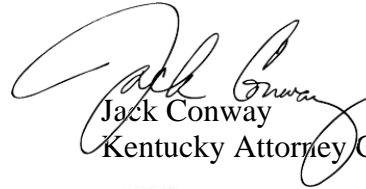
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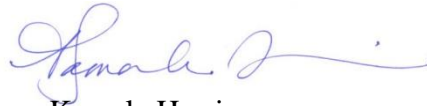
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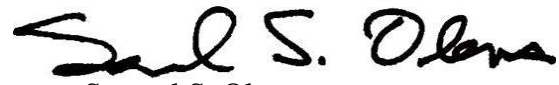
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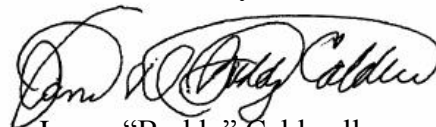
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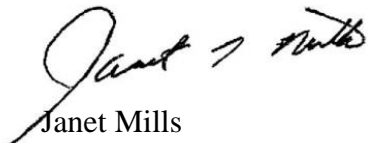
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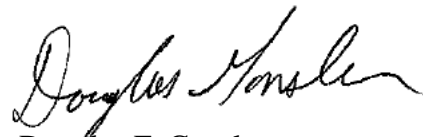



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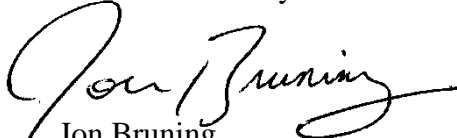

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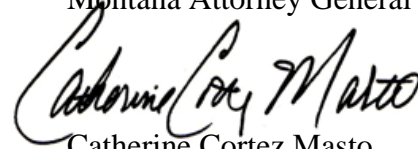

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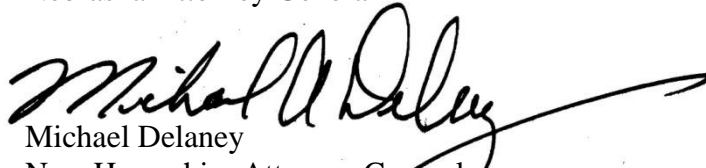

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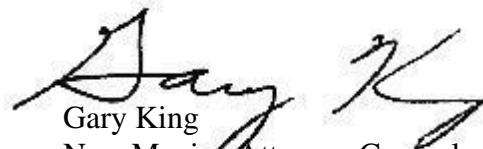

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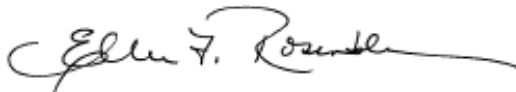

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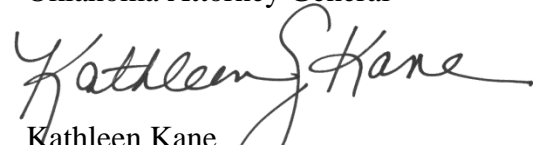

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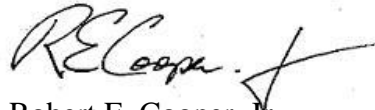

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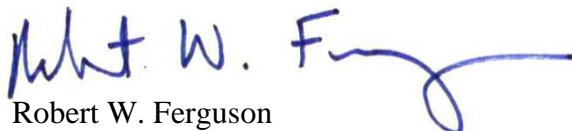

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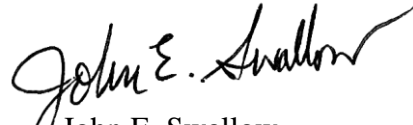

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