August 31, 2015

Dr. Stephen Ostroff
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Ostroff:

As governors, we commend the Food and Drug Administration's (FDA) commitment to addressing prescription drug abuse, and welcome its partnership with the states to address this public health crisis. Combatting the misuse and abuse of opioid analgesics requires a multi-faceted action plan, including risk evaluation and mitigation strategies. Therefore, we ask the FDA to build upon its recent guidance regarding labeling of opioid analgesics by acting promptly to require labeling changes for Immediate Release (IR) opioid analgesics that effectively communicate to patients and prescribers the serious risk of addiction, overdose, neonatal abstinence syndrome (NAS), and death associated with these widely used and abused opioid analgesics.

The FDA now requires the most restrictive labeling language – the "black box" warning – for Extended Release and Long-Acting (ER/LA) opioid analgesics. In making this decision, the FDA cited the higher doses of opioids in the ER/LR products and the disproportionate safety concerns of ER/LR compared to IR opioids. However, scientific studies indicate that both short and longer acting opioids put patients at risk of misuse, abuse, addiction, and overdose.

Opioid abuse can have long-lasting and often tragic consequences for individuals, especially for newborns affected by NAS. Opioid abuse also imposes significant costs on the nation's health care system. Finally, the rise in prescription opioid abuse can also be linked to a rise in heroin abuse and addiction that has led to spikes in heroin-related overdoses and deaths in communities around the county. The risks to individuals and public health are heightened by the scope of opioid analgesic prescription abuse in this country, with IR opioids being prescribed outside medical facilities at a rate almost ten times that of ER/LR formulations.

Timely action by the FDA to ensure that all IR opioid formulations include a "black box" warning comparable to warnings on ER/LR formulations can provide critical, upfront

information about the risk of IR opioid analgesics to prescribers and patients. This additional information would be an important tool in our collective efforts to combat prescription drug abuse in our region and across the nation.

Sincerely,

/o.s./
Dannel P. Malloy
Governor of Connecticut

/o.s./
Paul R. LePage
Governor of Maine

/o.s./
Charles D. Baker
Governor of Massachusetts

/o.s./
Margaret Wood Hassan
Governor of New Hampshire

/o.s./
Gina Raimondo
Governor of Rhode Island

/o.s./
Peter Shumlin
Governor of Vermont