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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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December 17, 2014

Secretary Sylvia Burwell
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

We are writing for two reasons: first, we would like to thank you for the participation of Department of Health and Human Services agencies in the bipartisan HELP Committee working group examining prescription drug abuse in the United States; second, we write to ask that you keep the committee informed of the Department's continuing efforts to address this epidemic.

Prescription drug abuse is a public health crisis that has increased dramatically in scope during recent years. Drug overdose death rates in the United States have more than tripled since 1990. The most recent data shows that more than 16,000 lives are lost each year due to opioid-related overdoses. In 2011, almost 2 million people reported using prescription opioids non-medically for the first time—nearly 5,500 people a day.

As the Senate committee with jurisdiction over public health matters, we have been closely examining this problem and potential solutions through a bipartisan HELP Committee working group. Throughout this effort, we held numerous briefings on a broad range of topics in order to 1) learn more about the characteristics of the prescription drug abuse epidemic; 2) study what local, state, and federal governments and a range of non-governmental entities are doing to address prescription drug abuse; and 3) explore potential solutions to this problem.

While we acknowledge the crucial roles that state and local governments, the private sector, and other organizations have in combatting this epidemic, the Department of Health and Human Services (HHS) plays a key role in the federal response.

HHS supports important surveillance and research and provides key information to health professionals and the public. These surveillance and research efforts not only provide insights as to the characteristics and extent of the prescription drug abuse problem in this country, but also inform prevention, prescribing, and treatment for both pain management and addiction, including for some of our most vulnerable populations such as newborn infants or seniors suffering from dependence. We urge you to continue federal efforts to assess the epidemiology of prescription drug abuse and the changing patterns of abuse. Where your Department collects new information on patient satisfaction through surveys and other means, we urge you to closely examine whether these methods collect the information intended without creating inadvertent incentives for prescribing or other behaviors.

Preventing prescription drug abuse remains a key focus of the federal response, and prescription drug monitoring programs (PDMPs) are an important tool in preventing and detecting abuse. We encourage you to continue evaluating PDMPs and working with states and other stakeholders to maximize the usefulness of PDMPs. We also encourage you to leverage electronic health platforms to improve PDMPs where possible.

Education plays an integral role in helping to prevent and treat prescription drug abuse. It is critical that healthcare providers, patients, and families understand the dangers of prescription drug abuse, and have access to information about appropriate prescribing, dispensing, storage, use and disposal of these drugs. Your continued focus on promoting public education materials is vital. For the many Americans suffering with prescription drug addiction, there must also be appropriate education with respect to safe and effective treatment options.

Abuse-deterrent formulations are another area where technology can help with the response. In order for this technology to be fully realized in its potential to relieve pain while reducing the potential for abuse, additional guidance is needed from HHS on the standards to achieve labeling of abuse-deterrent formulation drugs, including both brand and generics, and post-market assessment. Also, we urge you to consider whether changes are needed to the existing Risk Evaluation and Mitigation Strategy (REMS) for long-acting opioids, and whether a REMS would be helpful and appropriate for short-acting opioids.

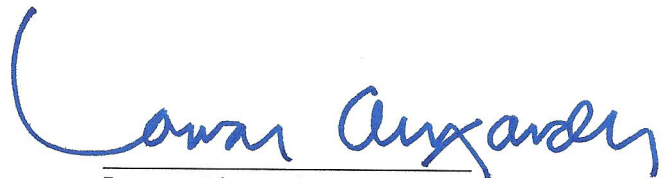
Continued training and coordination of law enforcement officials at the federal, state, and local level is necessary to appropriately combat the epidemic. HHS plays an important role in these efforts, as all response efforts must consider the full range of potential public health consequences and solutions.

We greatly appreciate your efforts to address prescription drug abuse and your continued work on ending this epidemic. With our shared goal of preventing and reducing prescription drug abuse in this country – a crisis that demands continued action – we expect that your activities in this area will continue, and we stand ready to assist you. We request that you provide updates to us early next year about your ongoing work, as we continue to explore potential solutions to this problem. Again, thank you for your commitment to this issue.

Sincerely,



Tom Harkin
Chairman



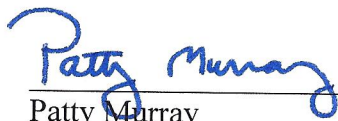
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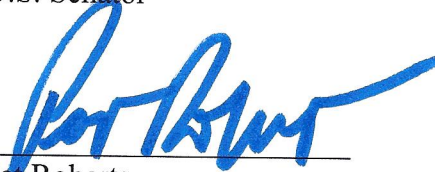
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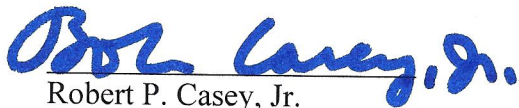
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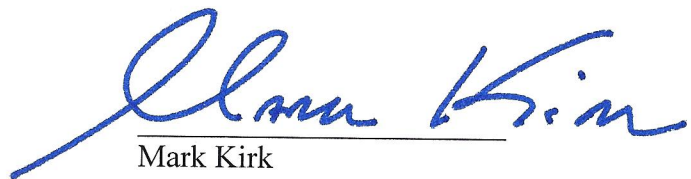
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U.S. Senator



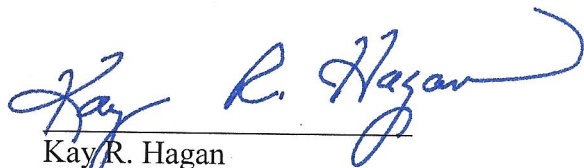
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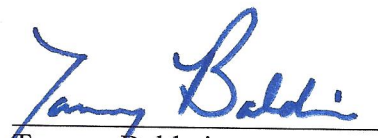
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U.S. Senator



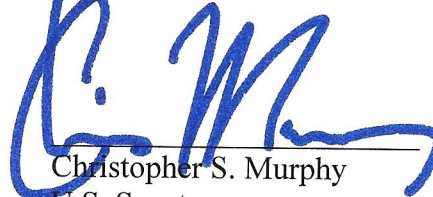
Michael F. Bennet
U.S. Senator



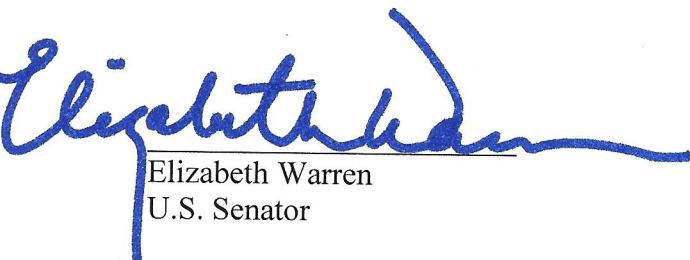
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