

Congress of the United States
Washington, DC 20515

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

September 22, 2014

Dear Secretary Burwell:

Heroin and prescription opioid overdose is reaching record levels in many parts of our country, devastating the lives of individuals, families, and communities. Unlike other diseases, such as cancer or Alzheimer's, those suffering from addiction often have greater barriers to access to all available treatments. The Department of Health and Human Services (HHS) can and must play a central role in improving the treatment of opioid addiction by improving access to all medicines approved by the Food and Drug Administration (FDA).

To help reverse the increasing incidence of opioid addiction, misuse, overdose, and death – and the many other social ills associated with the spread of opioid addiction – HHS, working with the Substance Abuse and Mental Health Services Administration (SAMHSA), must examine and evaluate its existing strategies for addressing the opioid crisis in our country. HHS should direct SAMHSA to use its existing authority to review current regulations, remove outdated regulatory constraints, and update regulations to incorporate and promote new FDA-approved treatments as they become available.

Right now, the medication a patient is prescribed depends almost entirely upon whether they seek treatment in an Opioid Treatment Program (OTP) or an Office-Based Opioid Treatment Program (OBOT), rather than on the specific clinical needs of that individual patient. Patients who seek treatment at an OTP – also known as a methadone clinic – will almost always be placed on methadone, while patients who seek treatment at an OBOT will almost always be placed on buprenorphine. This treatment limitation exists because these were the only two FDA-approved medications for the treatment of opioid dependence at the time the current regulations were created.

Consequently, regulations have fallen behind as newer FDA-approved medications for treating opioid dependence have become widely available. One extremely important component of a comprehensive response to this crisis requires updating the current regulations governing the treatment of opioid addiction in OTPs and OBOTs so that these settings offer all currently available treatments consistent with the modern practice of medicine. These regulations should be updated to keep pace with medical advances and ensure that patients, working with their health care professionals, are prescribed the most appropriate medication based upon their individual needs rather than the treatment setting they happen to enter. It is important for patients and their physicians to have even-handed access to all available treatments to ensure that patients' unique needs can be addressed.

Unfortunately, while the number of patients treated in OTPs and OBOTs has increased significantly in the past ten years, the problem of opioid addiction has grown in parallel. It is well recognized that relapse is a contributing factor to the current overdose epidemic, and evidence shows that after patients terminate treatment in OTPs and OBOTs, the rate of relapse to the illicit use of opioids is extraordinarily high. If we are to attempt to reverse incidence of opioid dependence and the increasing numbers of opioid overdoses and opioid-related deaths associated with opioid addiction, it is important that patients have access to all FDA

approved treatment options. As an initial step, SAMHSA should issue changes to existing regulations and guidance governing OTPs and OBOTs, such that:

- 1) OTP and OBOT practices are required to develop individualized treatment plans for all patients that ensure access to, and treatment with, the most appropriate FDA-approved medication based upon an assessment of that individual patient's clinical needs;
- 2) Training requirements for OBOT practitioners are updated to enable physicians in these practices to prescribe and administer all FDA-approved opioid treatment medications, thereby allowing the most appropriate treatment for each patient in their care; and
- 3) All OTP or OBOT practices are required to develop a relapse prevention plan for each patient completing treatment and be capable of administering continued counseling and medication with a focus on the long-term prevention of relapse to opioid dependence.

It is time to move beyond recognition of the problem and actually *treat* opioid addiction as a disease and the national priority it is. We have a higher number of effective treatment interventions available today than ever before, and the trend leading to so many tragic consequences can, and must, be reversed. HHS, working with SAMHSA, must modernize its regulations to ensure access to all FDA-approved opioid treatment medications, based on the clinical needs of the patient, and train practitioners to treat this devastating disease in a manner consistent with the treatment of other serious life-threatening illnesses or chronic conditions.

We respectfully request your written response to this letter no later than Friday, November 14, 2014. Additionally, upon receipt of your formal response, we look forward to scheduling a staff briefing to discuss a pathway forward on this important issue.

Sincerely,



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Member of Congress



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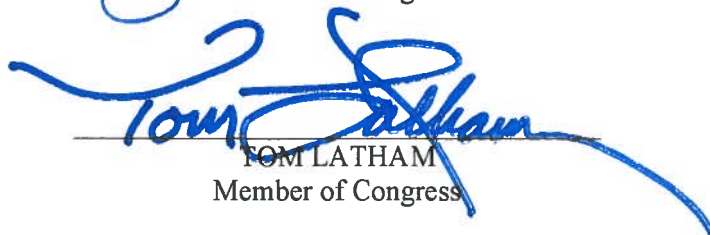
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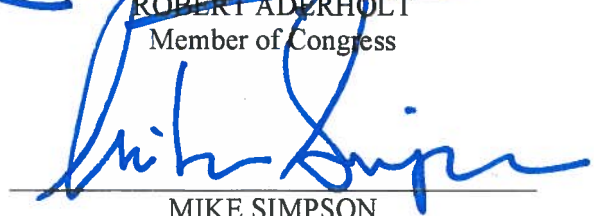
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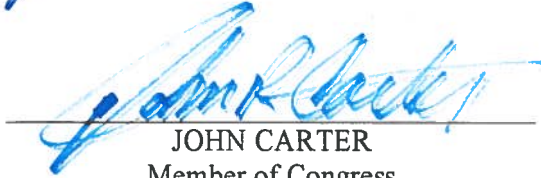
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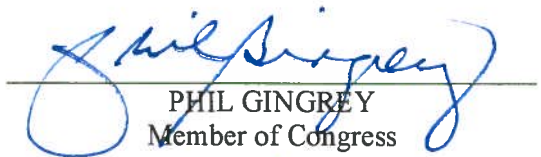
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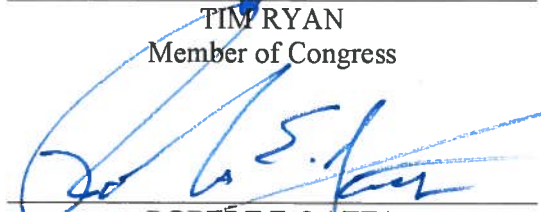
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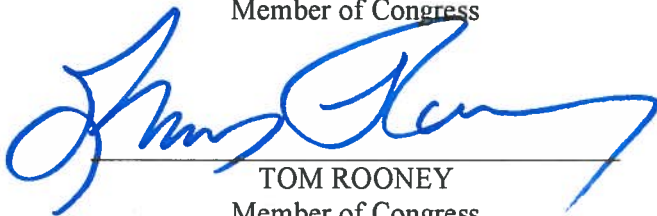
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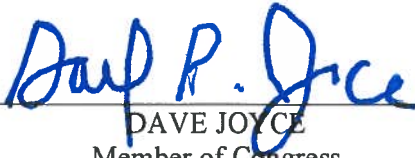
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