

United States Senate

WASHINGTON, DC 20510

July 20, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 314-G
Washington, DC 20201

Dear Acting Administrator Slavitt,

We are deeply concerned about the inappropriate use and abuse of opioid prescription painkillers that has led to unprecedented numbers of overdose deaths across the United States. In 2013 alone, approximately 16,000 people died of prescription painkiller overdoses.¹ It is estimated that 30 percent of opioid-related prescription drug overdose deaths involve methadone, even though methadone accounts for only two percent of opioid pain reliever prescriptions.² Despite the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the American Academy of Pain Medicine (AAPM), and the American Society of Interventional Pain Physicians (ASIPP) recommending that methadone not be a drug of first choice for chronic noncancer pain, most state Medicaid programs have designated methadone as a preferred drug for managing pain. These state Medicaid policies may be inadvertently contributing to opioid overdose deaths. We are therefore writing to request that the Centers for Medicare and Medicaid Services (CMS) investigate the role of methadone prescribed for the treatment of pain in overdose deaths in the Medicaid population and issue guidance to State Medicaid directors recommending the removal of methadone for pain from preferred drug lists.

Methadone, an evidence-based treatment for opioid dependence, has been increasingly prescribed for chronic pain. This increased use has been the primary contributor to the rise in methadone-associated overdose deaths.^{2,3} While methadone can be an effective, FDA-approved pain therapy, its unique pharmacologic properties distinguish it from other opioid drugs. Methadone's long half-life can increase the risk of overdose if doses are taken too closely together. Accidental overdose, respiratory problems, heart rate abnormalities, and cardiac deaths

¹ The Centers for Disease Control and Prevention. Specific Drugs Involved in Drug Poisoning Deaths 1999-2013 http://www.cdc.gov/nchs/pressroom/heroin_deaths.pdf

² The Centers for Disease Control and Prevention. (2012). Vital Signs: Risk for Overdose from Methadone Used for Pain Relief—United States, 1999–2010. *Morbidity and Mortality Weekly Report*, 61(26), 493-497 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm>

³ U.S. Government Accountability Office. (2009). Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them. GAO-09-341 <http://www.gao.gov/new.items/d09341.pdf>

have been reported in patients receiving methadone for the treatment of noncancer pain.⁴ Despite these health risks, methadone is widely prescribed, in part, because of its low cost and status as a preferred pain reliever in most state Medicaid programs. The life-threatening adverse effects have raised serious concerns regarding the appropriateness of the widespread use of methadone for the treatment of chronic pain, particularly given the availability of alternatives that have been associated with less risk of overdose.⁵

In 2006, the FDA issued a public health advisory about the dangers of methadone in response to the sharp rise in unintentional overdose deaths attributed to the increased use of methadone for pain management.⁶ Consequently, the FDA added a “black box” warning about the drug’s risks on its labeling and increased the recommended dosing interval from every 4-6 hours to every 8-12 hours.⁷ Given the risks of addiction, abuse, and misuse with opioids, FDA indicated methadone should be used for chronic pain only when alternative treatments are inadequate to provide sufficient management of pain.⁸ Similarly, in 2012 CDC found that methadone contributed disproportionately to opioid pain reliever overdoses and recommended that insurance formularies should not list methadone as a first line therapy for the treatment of chronic noncancer pain.² Additionally, two of the leading medical specialty societies representing pain medicine providers, AAPM⁹ and ASIPP⁵ have both stated that methadone should not be utilized as a first line therapy for pain relief. In fact, ASIPP guidelines specify that methadone should be limited to a third line therapy for chronic pain only “if absolutely necessary” after other opioid medications have failed. AAPM’s position is that methadone should not be designated by any public or private payer as a preferred analgesic. Despite these recommendations and the disproportionate risk of overdose associated with the use of methadone for pain, there exist 30 state Medicaid programs that continue to list methadone as a preferred first line drug for chronic pain.^{9,10}

⁴ Ray, W.A., Chung, C.P., Murray, K.T., Cooper, W.O., Hall, K. & Stein, C.M. (2015). Out-of-Hospital Mortality Among Patients Receiving Methadone for Noncancer Pain. *JAMA Internal Medicine*, 175(3), 420-427.

⁵ American Society of Interventional Pain Physicians. (2012). Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance, *Pain Physician*, 15, S67-S116.
<http://painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf>

⁶ U.S. Food and Drug Administration. (2006). Public Health Advisory: Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat.
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm124346.htm>

⁷ Clark, H.W. (2006) <http://www.dpt.samhsa.gov/pdf/DearColleague-Methadone-lbl.pdf>

⁸ U.S. Food and Drug Administration. (2014). Medication Guide for Methadone Hydrochloride Oral Solution.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/090707Orig1s003lbl.pdf

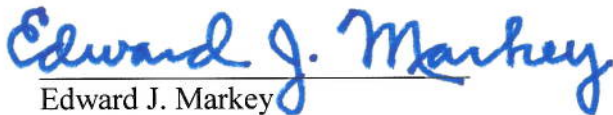
⁹ The American Academy of Pain Medicine. (2014). The Evidence Against Methadone as a “Preferred” Analgesic: A Position Statement from the American Academy of Pain Medicine.
<http://www.painmed.org/files/the-evidence-against-methadone-as-a-preferred-analgesic.pdf>

¹⁰ As of August 2014 fact sheet authored by the PEW Charitable Trusts, 33 state Medicaid programs listed methadone as a preferred drug for the treatment of chronic pain. The fact sheet can found here:
<http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2014/08/prescription-drug-abuse-epidemic>
Recent communication with PEW has indicated that 3 states (Alaska, Indiana and Missouri) have recently removed methadone from their preferred drug list. NOTE: In addition to recommendations by the CDC, FDA, AAPM and ASIPP, experts at The PEW Charitable Trusts have also recommended that State Medicaid programs reconsider the use of methadone and remove it from preferred drug lists in light of the availability of alternatives that can more safely alleviate pain for Medicaid patients.

State Medicaid agencies play a significant role in providing access to quality health services for low income families and should continue to ensure the safe, appropriate, and effective use of medications among the Medicaid population. We urge CMS to examine the role of methadone for pain in overdose deaths in the Medicaid population and release guidance to State Medicaid directors consistent with FDA and CDC recommendations to remove methadone from preferred drug lists.

Thank you for your consideration of this very important matter. Please provide your response no later than August 10, 2015. If you have any questions or concerns, please contact Dr. Chisina Kapungu or Dr. Avenel Joseph in my office at (202) 224-2742.

Sincerely,



Edward J. Markey
United States Senator



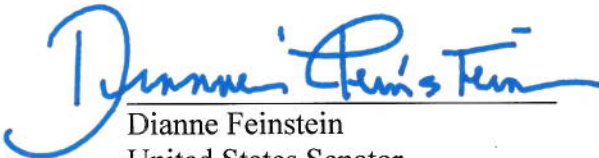
Kelly Ayotte
United States Senator



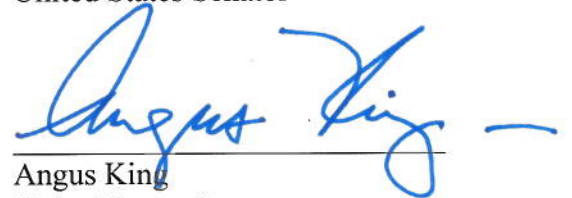
Tammy Baldwin
United States Senator



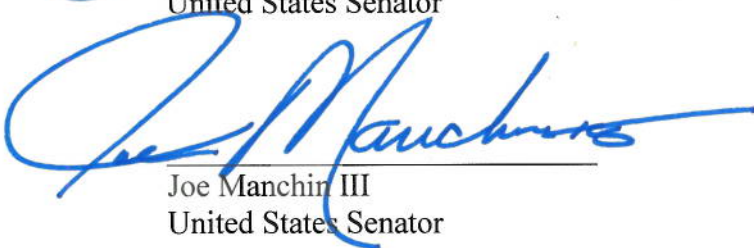
Shelley Moore Capito
United States Senator



Dianne Feinstein
United States Senator



Angus King
United States Senator



Joe Manchin III
United States Senator



Patty Murray
United States Senator