



# American Society of Addiction Medicine

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TREAT ADDICTION • SAVE LIVES

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June 5, 2012

Dr. Throckmorton

Deputy Director

Center for Drug Evaluation and Research

Food and Drug Administration

Division of Dockets Management (HFA 305)

5630 Fishers Lane

Room 1061

Rockville, MD 20852

**Re: Docket No. FDA-2011-N-0802**

Dear Dr. Throckmorton:

On behalf of the members of the American Society of Addiction Medicine (ASAM), I am writing in support of making naloxone more widely available to reduce the incidence of opioid overdose fatalities.

ASAM is a professional medical society representing close to 3,000 physicians dedicated to increasing access and improving quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addictions.

The United States is currently facing its worst drug epidemic in 40 years. The Centers for Disease Control and Prevention (CDC) reports overdose deaths involving prescription pain medications – principally opioids – have overtaken motor vehicle crashes as the leading cause of preventable death in the United States. It will take a multifaceted public health approach and a combination of public, private, and non-profit sector efforts to address this growing epidemic. As you know, one important component of reducing overdose deaths involving opioids is naloxone, the standard of care for treatment of potentially fatal respiratory depression caused by opioid overdose.

ASAM supports the increased use of naloxone in cases of unintentional opioid overdose, in light of the fact that naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal side effects, when used at the proper dosage, for preventing the often fatal respiratory arrest which characterizes the advanced stages of prescription or illegal drug overdose. Naloxone can be administered

quickly and effectively by trained professional and lay individuals who observe the initial signs of an opioid overdose reaction.

We look forward to working with you to address the prescription drug abuse epidemic in the United States. Please reach out to me or to ASAM's Executive Vice President/CEO, Penny Mills, if we can be of further help in this or other addiction-related matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart Gitlow". The signature is written in a cursive, flowing style.

Stuart Gitlow, MD, MBA, MPH, FAPA  
Acting President, American Society of Addiction Medicine