American Society of Addiction Medicine

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Treat Addiction. Save Lives.

September 13, 2012

Margaret A. Hamburg, MD
Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Thank you for considering the July 25, 2012 petition from researchers and health officials to regulate labeling of opioid analgesics. I, as Acting President of the American Society of Addiction Medicine (ASAM), was one of the many signatories. While ASAM stands by the recommendations offered in the petition, it has come to our attention that the intent of our recommendations may not be clear. We would like to take this opportunity to elaborate on the aforementioned proposals.

ASAM's physician members are keenly aware of the rise in opioid prescription misuse, addiction and overdose. For many of our opioid-addicted patients, the genesis of this disease can be traced to chronic pain therapy. While chronic opioid therapy is safe and highly effective at managing severe pain for many chronic, non-cancer pain patients, it can lead to adverse outcomes (i.e., addiction) for others. The recommendations put forward in the July 25 petition are intended to both help prevent unintended prescription opioid addiction and mitigate the negative patient and public health consequences of uninformed and/or over-prescribing of opioid analgesics.

The relabeling proposals are not intended, in any way, to limit a chronic pain patient's access to clinically appropriate opioid pain therapy or to impinge upon a pain specialist's ability to make individual decisions regarding the most effective therapy for their legitimate pain patient.

It is a priority of the American Society of Addiction Medicine to contribute to the work of the many public health and public safety stakeholders addressing the issue of prescription drug abuse. To that end, we have published our public policy statement,

cosponsored the FDA REMS education proposals of the CORE Collaborative, and supported the many NIH prescription addiction screening, treatment and physician education initiatives.

We hope that the relabeling recommendations add to the ongoing efforts of the Food and Drug Administration, the National Institutes of Health and the many public and private stakeholders to find the right balance between allowing access to life-saving pain therapies and limiting prescription drug misuse and diversion.

Sincerely,

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