American Society of Addiction Medicine

4601 North Park Avenue ● Upper Arcade Suite 101 ● Chevy Chase, MD 20815-4520
Treat Addiction ● Save Lives

June 19, 2013

Margaret Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing in regard to the May 13, 2013 letter that was sent from the National Association of Attorneys General to the U.S. Food and Drug Administration recommending a “black box warning” on narcotic analgesic medication for use during pregnancy.

The American Society of Addiction Medicine (ASAM) is a national medical specialty society of 3000 physicians who focus their careers on prevention, treatment, education, research and public policy addressing addiction and substance use issues. As an organization dedicated to the prevention and treatment of addiction as well as the treatment of the medical consequences of addiction and substance use disorders, ASAM and its Action Group on Women and Substance Use Disorders share the concern regarding the increase in opioid exposure during pregnancy and its potential effects on neonates, including neonatal abstinence syndrome.

Our opinion is however, that a “black box warning” on opioid narcotic analgesic medications including opioid agonists and partial agonists used in the treatment of addiction would have the potential to cause great harm to pregnant women and neonates. The recent increase in opioid exposed pregnancies is primarily the result of prescription drug misuse, abuse, or dependence, or the use of illicit opioid drugs such as heroin by pregnant women, and a “black box warning” would have little impact on the behaviors of these women.

A “black box warning” would be intended as a caution to prescribers but it could serve to reduce the number of opioid addicted pregnant women who are recommended to treatment, the mainstay of which is opioid agonist treatment. The “gold standard” for opioid dependence treatment during pregnancy is

Phone: (301) 656-3920 ● Fax: (301) 656-3815
E-mail: email@asam.org ● Website: www.asam.org

methadone maintenance treatment, as part of a comprehensive treatment program. Additionally, the emerging alternative treatment of buprenorphine has been shown to be comparable in safety and effectiveness to methadone and is promising in terms of a potentially less severe neonatal abstinence syndrome.

So despite the known risk of neonatal abstinence syndrome associated with opioid agonist treatment and the resultant requirement that such a syndrome be managed in the nursery, it is well established that the use of agonist medications improves maternal and fetal outcomes when compared to no treatment or medication assisted withdrawal during pregnancy.

We encourage all states to work towards adequate access to and insurance coverage for opioid agonist treatment including methadone and buprenorphine for all patients in need, with pregnant women receiving special priority access into treatment. Among the main barriers to treatment is lack of available care, lack of insurance coverage for treatment, and stigma. Development of supportive, patient centered treatment will be the best approach to improved outcomes for mothers, neonates, and families.

A “black box warning” on opioid analgesic medication has the potential to cause other types of harm as well. There are very few options for the treatment of pain during pregnancy, and opioid analgesics have been relied upon as the safest alternative in conditions requiring treatment for pain. Pregnant women would likely be denied adequate pain treatment if a “black box warning” were placed on these medications. This would not only be inhumane, but we also do not clearly know the impact of untreated pain during pregnancy. Untreated pain would certainly present a major stressor for the pregnant woman and her fetus, with potential adverse effects. This concern applies not only to pain throughout pregnancy but also pain during labor and delivery, where judicious use of narcotic medications is often necessary, and for which safe administration protocols have been developed by obstetricians and anesthesiologists.

We certainly support advocacy of dialogue between patients and providers in planning for pregnancy and avoiding unintended pregnancy, including among women who need treatment for opioid abuse, misuse, dependence, or addiction, which may include treatment with opioid agonist medications. We also agree that providers must consider the risk to benefit ratio when prescribing opioid analgesic medication during pregnancy. These are all critical aspects in reaching the goal of appropriate prescribing of opioid medication and reducing the number of opioid exposed pregnancies. A “black box warning” is not required to achieve these goals, however. The focus should be on screening, prevention, and early referral to treatment among opioid dependent pregnant women, as well as opioid agonist treatment as part of comprehensive prenatal care among these women. A “black box warning” will do little to achieve these goals.

Further, research is also warranted to identify evidence based practices which could minimize the risk of neonatal abstinence syndrome as well as more research on the

treatment of prescription drug abuse vis a vis the risks and benefits of opioid agonist maintenance versus medication assisted withdrawal.

In summary, ASAM supports the current labeling of opioid analgesics by the FDA and does not support changes in labeling to include a “black box warning” as is being proposed to the FDA. We do support additional educational programs for health care professionals, health professional trainees, and women of childbearing age, regarding maternal-fetal exposure to opioids and the risks inherent in non-medical use of opioids during pregnancy. Hopefully, along with the FDA, we can all work together to respond appropriately to the important public health issues that we face regarding opioid exposed pregnancies and the effect of exposure and acute abstinence syndromes on neonates.

Sincerely,

Jacquelyn Starer, MD, FACOG, FASAM
Fellow, American College of Obstetrics and Gynecology
Fellow, American Society of Addiction Medicine
Diplomate, American Board of Addiction Medicine
Chairperson, Action Group on Women and Substance Use Disorders, ASAM

Stuart Gitlow, MD, MPH, MBA, FAPA, FASAM
Fellow, American Psychiatric Association
Fellow, American Society of Addiction Medicine
President and Board Chair, ASAM

Cc:
National Association of Attorneys General
2030 M Street, NW
Eighth Floor
Washington DC 20036