



Massachusetts Society of Addiction Medicine

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Martha Coakley
Attorney General
One Ashburton Place
Boston, MA 02108-1518

Dear Ms. Coakley,

As the officers of the Massachusetts Chapter of the American Society of Addiction Medicine (ASAM), we are writing in regard to the May 13, 2013 letter that was sent from the National Association of Attorney Generals to the U.S. Food and Drug Administration, to which you were a co-signer, recommending a “black box warning” on narcotic analgesic medication for use during pregnancy.

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 organizations dedicated to the prevention and treatment of addiction, substance use disorders, as well as their consequences, ASAM, its Action Group on Women and Substance Use Disorders, and the Massachusetts Chapter of ASAM share your concern about opioid exposure during pregnancy but also have grave concerns about the consequences of the “black box warning.”

The warning you support on opioid narcotic analgesic medications including opioid agonists and partial agonists used in the treatment of addiction has the potential to cause great harm to pregnant women and neonates. The recent increase in opioid exposed pregnancies is primarily the result of prescription and illicit drug misuse, or dependence 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 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.

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.

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” is 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 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.

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.

In summary, ASAM and the Massachusetts chapter 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 by the National Association of Attorney Generals. 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,

A handwritten signature in black ink, appearing to read 'J. Starer', written in a cursive style.

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