American Society of Anesthesiologists®

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April 19, 2016

Commissioner Robert M. Califf, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. **FDA-2016-N-0820:** Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

Dear Commissioner Califf:

The American Society of Anesthesiologists (ASA), on behalf of over 53,000 members, is pleased to comment on the Risk Evaluation and Mitigation Strategy (REMS) on opioids in advance of the May 3-4 scheduled meeting. As the medical specialty representing the largest number of practicing pain medicine physicians, ASA has significant interest in reducing the misuse, abuse, and diversion of opioid medications that have led to unintended deaths. As the Committees evaluate the extended-release and long-acting (ER/LA) Opioid Analgesics REMS program and whether it assures safe use, is not unduly burdensome to patient access, and minimizes the burden on the healthcare system, we ask that you consider ASA's recommendations and specifically, require that REMS apply to **all schedule II opioid products**.

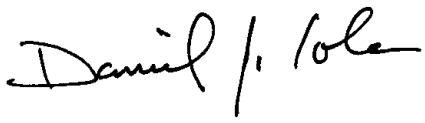
The prescription drug abuse epidemic is a serious public health crisis and the federal government, medical and professional societies, patient advocacy groups, and other stakeholders are actively seeking solutions to the epidemic. Yet, it is also well recognized that pain and the consequences of inadequate treatment represent a significant health problem for the United States. ASA is in support of efforts that reduce opioid overdose deaths but still preserve patient access to pain management therapies, and believes that REMS could be one part of the solution.

ASA recommends that REMS apply to all schedule II opioids. According to the Centers for Disease Control and Prevention (CDC), more people died from drug overdoses in 2014 than in any year on record and the majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the rate of overdose deaths involving opioids (including prescription opioid pain relievers and heroin) nearly quadrupled. Yet, ER/ LA formulations only account for a small portion of total prescriptions. According to a national retail pharmacy survey, just 9% of the total opioid analgesic prescriptions (from 2000-2009) were ER/LA prescriptions. The volume of immediate-release (IR) formulations actually increased during this same period (*American Journal of Managed Care*. 2015; 21:S177-S187). Not including IR formulations in the REMS program may give a false implication that they are safer and in fact, lead to a preference for prescribing IR formulations. ASA supports FDA's recent announcement on enhanced warnings for IR opioid pain medications but recommends that REMS apply to these opioids in order to increase physician education and appropriate prescribing practices.

ASA also recommends that the FDA work with stakeholders, including medical societies and pain medicine physicians, to update the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics (Blueprint). Any revisions to the Blueprint should incorporate concepts from the CDC Guideline for Prescribing Opioids for Chronic Pain, which provides recommendations for primary care physicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. ASA is supportive of increasing access to naloxone and co-prescribing naloxone with an opioid for patients at high risk of overdose, and we recommend that education about co-prescribing naloxone be included in the REMS program. In addition, when evaluating provider knowledge gained from the REMS program, questions should be asked more frequently throughout the program and require thoughtful, explicit answers to ensure that physicians are gaining meaningful knowledge.

ASA is pleased to comment on this matter and appreciates FDA's efforts to improve the REMS program and address prescription drug abuse and misuse. We welcome the opportunity to work with FDA to explore solutions. If you have any questions, please feel free to contact Ashley Walton, J.D., at a.walton@asahq.org or 202-289-2222.

Sincerely,



Daniel Cole, M.D.
President
American Society of Anesthesiologists