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Addiction Medicine

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July 10, 2017

Mary Gross
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 51, Rm. 6178
Silver Spring, MD 20993-0002

RE: Docket No. [FDA-2017-N-1094]

Dear Ms. Gross,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty society representing more than 4,500 physicians and allied health professionals who specialize in the treatment of addiction, I would like to thank you for the opportunity to provide comments on the Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward.

ASAM has long contended that mandatory education of physicians and all other health professionals licensed to prescribe, dispense, or administer prescription medications is an essential component of a comprehensive response to our current epidemic of misuse of and addiction to scheduled medications. This education should include the general principles of prescribing medications that are commonly associated with misuse, dependence, and addiction, as well as how to recognize and appropriately intervene in the case of such findings.

We have consistently seen increases in the rates of opioid misuse, addiction, and overdose deaths over the last decade despite increased awareness and education about opioids' risks. Clearly, the current strategy of voluntary education is insufficient to change prescribing patterns in a meaningful way. Moreover, our assessments indicate that prescribers who completed the extended-release long-acting opioids risk evaluation and mitigation strategy (ER/LA REMS) training program implemented changes in their practice as a result. These findings indicate we need to reach all prescribers with this type of education to see such changes on a systemic level.

However, ASAM believes that mandatory education should cover all classes of controlled substances and be tied to clinicians' registration with the Drug Enforcement Agency (DEA) to prescribe controlled substances. Further, ASAM believes that such a mandate should provide clinicians with many options or pathways to meet its requirements, such as a menu of courses or a test-out

11400 Rockville Pike Suite 200 Rockville, MD 20852

Phone: 301-656-3920 | Fax: 301.656.3815

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option. **Accordingly, ASAM does not recommend that FDA exercise its authority to make the ER/LA REMS program mandatory for prescribers of ER/LA opioids.** This approach is too limited and does not allow clinicians sufficient flexibility to meet training requirements efficiently.

Thank you again for the opportunity to provide comment on this important topic. ASAM looks forward to continuing to work with FDA and our CO*RE collaborators to deliver high-quality and impactful voluntary education on safe opioid prescribing to all health care providers.

Sincerely,

A handwritten signature in cursive script that reads "Kelly J. Clark".

Kelly Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine