American Society of Anesthesiologists

1501 M Street, N.W. • Suite 300 • Washington, D.C. 20005 • (202) 289-2222 • Fax: (202) 371-0384 • mail@ASAwash.org

December 7, 2011

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health & Human Services
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. **FDA-2011-D-0771**; Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy; Availability; Request for Comments

Dear Commissioner Hamburg:

The American Society of Anesthesiologists (ASA), on behalf of its over 48,000 members, appreciates the opportunity to provide comments in response to the Food and Drug Administration's (FDA) November 7, 2011, Federal Register Notice regarding the draft Blueprint for prescriber education for the long-acting and extended-release (LA/ER) class-wide opioid Risk Evaluation and Mitigation Strategy (REMS). As the medical specialty representing the largest number of practicing pain medicine physicians and the recognized leaders in patient safety, ASA has significant interest in reducing the misuse, abuse, and diversion of opioid medications that have led to unintended deaths. We commend the FDA for adopting a voluntary continuing education (CE) program on LA/ER opioids without cost to physicians. Below, we offer recommendations for revising the Blueprint and reiterate concerns we identified in our June 30, 2009, comment letter to the FDA on REMS for certain opioid drugs.

ASA agrees that accredited CE providers are the only groups that should develop the education programs. CE providers will adhere to accreditation standards to provide scientifically valid, evidence-based content and to ensure balance and prevention of commercial bias in the planning and implementation of the program. Since it is specified that physicians will be able to participate in the educational programs without cost, it is critical that funding to develop the programs is available through unrestricted educational grants from the drug manufacturers and that the FDA does not consider this as inappropriate commercial support for the CE.

We are pleased that the FDA expects the CE program to be two to three hours long; however, we are concerned that the program, once developed by CE providers, may be significantly longer than two to three hours considering the amount of content in the Blueprint. In revising the Blueprint, we ask the FDA to consider all stakeholders comments, while still ensuring that the revised Blueprint can be developed into a two to three hour CE program. Ultimately, we do not want physicians to be deterred from enrolling in the program due to its length.

While the Blueprint rightly emphasizes the problem of prescription drug abuse, we believe the Blueprint should also highlight the prevalence of chronic pain and barriers patients face in accessing the opioid medications they need. In June 2011, the Institute of Medicine released *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (IOM report), finding that at least 116 million U.S. adults suffer from common chronic pain conditions. Given the prevalence of chronic pain, physicians have dual responsibilities to minimize prescription drug abuse while ensuring patient access to the medications they need. Yet research indicates that patients currently lack adequate and appropriate access to opioids. The IOM report noted that "[t]wenty nine percent of primary care physicians and 16 percent of pain specialists report they prescribe opioids less often than they think appropriate because of concerns about regulatory repercussions."[1] For that reason, the Blueprint should also address myths and fears physicians have regarding law enforcement so they are not deterred from prescribing opioids, when appropriate.

ASA urges the FDA to emphasize in the Blueprint the significant role of diversion in the misuse of prescription drugs. According to the Centers for Disease Control and Prevention (CDC), over seventy five percent of people who misuse prescription pain relievers use drugs that were prescribed for someone else.[2] In addition, primary care and internal medicine physicians and dentists, not specialists, prescribe the majority of prescription pain relievers. For that reason, all physicians must carefully screen and monitor patients for opioid therapy, and must be knowledgeable about proper prescribing practices.

We believe that physicians, prior to prescribing opioids to a particular patient, should conduct a more thorough patient selection process and risk assessment than proposed in the Blueprint. For instance, physicians should assess the patient's level of pain and conduct appropriate lab and imaging tests to establish a diagnosis. Physicians should also review and document whether the patient adequately responded to other therapies and other classes of drugs. We also encourage the routine use of an opioid agreement for anyone receiving chronic opioids and urine drug screening. It is important that physicians be educated on providing appropriate education to patients for whom opioids are prescribed, as stated in the Blueprint, and that the education include patient education materials. For patients deemed ineligible for opioid medication, physicians should be educated on alternative options for management of chronic pain.

Once physicians determine that opioid therapy is the most appropriate course of treatment, they must be knowledgeable about recommendations for quantities of opioids that should be prescribed in various situations. This will reduce the likelihood that patients have unused medications that may be inadvertently exposed to household contacts or diverted for misuse. Depending on a patient's history and behaviors, physicians may consider conducting pill counts to ensure the patient is adhering to the treatment program and to monitor for misuse and abuse.

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[1] IOM (Institute of Medicine). 2011. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, p. 144. Washington, DC: The National Academies Press (*citing* Breuer, B., R. Cruciani, and R. K. Portenoy. 2010. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: A national survey. *Southern Medical Journal* 103(8):738-747).

[2] Centers for Disease Control and Prevention, *Policy Impact: Prescription Painkiller Overdoses*, http://www.cdc.gov/homeandrecreationalsafety/rxbrief/ (last visited December 7, 2011).

ASA would also like to note that expert diagnosis and treatment often results in a successful therapeutic regimen that minimizes or avoids entirely the use of opioids. The necessary skills and knowledge to assist primary care, general, and family practitioners in managing their patients are available through pain physicians, whose specialized training and in-depth knowledge allow them to offer guidance to the generalist managing patients with pain. This guidance can consist of consulting on the appropriateness of the proposed or ongoing treatment regimen, suggesting multimodal therapies (including interventional and other non-pharmacological approaches) to decrease unimodal reliance upon opioid analgesics, and recommending outcomes to be assessed that guide ongoing therapy and support vigilance for the loss of effectiveness, inappropriate use, or need to dose-adjust opioids and all other controlled substances.

Finally, as noted in our June 30, 2009, comment letter to FDA on REMS for certain opioid drugs, ASA believes that any program meant to address the abuse, misuse, or diversion of opioids should cover all opioid classes to avoid the unintended consequences of shifting problems from one group of drugs to another and reducing the number of physicians available to prescribe necessary pain medications**.** We encourage the FDA to apply the LA/ER REMS to all opioids, including transmucosal immediate release fentanyl (TIRF) products. In addition, ASA strongly believes that the most effective approach to reducing diversion is the development of real-time, state-based, prescription drug monitoring programs that can interface with each other. We therefore, continue to reiterate our strong support for funding and implementation of the National All Schedules Prescription Electronic Reporting (NASPER) Act. We also urge the FDA to review the effectiveness of LA/ER REMS, its impact on patient access, individual practitioners, and the healthcare delivery system, and whether it creates a spike in the misuse or abuse of other drugs.

We look forward to continue working with the FDA on this important initiative. Please feel free to contact Lisa Pearlstein, J.D., Pain Medicine and Regulatory Lobbyist at l.pearlstein@asawash.org or 202-289-2222 if you have any questions or need additional information regarding this issue.

Sincerely,

Jerry A. Cohen, M.D.
President
American Society of Anesthesiologists