American Society of Anesthesiologists®

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March 16, 2018

via online submission: www.regulations.gov

The Honorable Scott Gottlieb
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: *Opioid Policy Steering Committee: Prescribing Intervention—Exploring Strategy for Implementation: Public Hearing: Request for Comments* ***(FDA-2017-N-6502)***

Dear Commissioner Gottlieb:

On behalf of the American Society for Anesthesiologists (ASA) and our 52,000 members, we are writing in response to the Food and Drug Administration's (FDA) recent request for comments, *Opioid Policy Steering Committee: Prescribing Intervention—Exploring Strategy for Implementation: Public Hearing: Request for Comments (FDA-2017-N-6502).* We are pleased to see FDA's efforts to address the critically important issue of opioid abuse and addiction, and we look forward to serving as a resource as the discussions ensue.

As the nation comes together to tackle the opioid crisis, physicians play an important role in ensuring the responsible prescribing of opioid medications. The specific role that physician anesthesiologists play in the delivery of care makes these specialists uniquely positioned to help curb inappropriate use and abuse of opioids throughout the perioperative period and upon discharge. These specialists not only have extensive experience with the intricacies of short-term pain management such as following a surgical procedure or minor injury, but they also focus on long-term pain management related to chronic conditions like arthritis or low back pain. While certain pain can be managed very effectively with non-opioid treatments, other types of pain requires the use of opioids. Physician anesthesiologists partner with patients and families to manage expectations around pain treatment, educate patients on the safe use, storage and disposal of opioids, and the prevention of opioid misuse and abuse post discharge. ASA's membership experiences inform the responses to the questions posed by the FDA and are addressed below.

ASA opposes rigid limits on, or interventions for prescriptions above a specified threshold.

Despite the need for aggressive action to combat opioid abuse, ASA members are concerned about patient care and their access to necessary pain treatment therapies. Physician anesthesiologists receive specialized training and education and any policy or mandate that impacts patient care or the physician's ability to practice medicine is problematic. Physician anesthesiologists address the unique clinical needs of their patients, managing acute pain before,

during and after surgery, as well as those patients suffering from chronic pain. Although physician anesthesiologists are proponents of multimodal analgesia, which enable patients to undergo procedures with fewer opioids and less reliance on opioids after surgery— it is inevitable that opioids remain critical for patients following invasive or complicated surgeries or procedures. Artificial prescribing limits will impact these patients negatively. There is no rigid, one-size-fits all opioid limit that can apply to every individual patient's diagnoses and circumstance.

Physician anesthesiologists are already engaging in efforts to implement best practices for pain management and promote minimizing opioids in the perioperative period. One example of ASA's work in this area is the development of the Perioperative Surgical Home (PSH), which is a patient-centered, physician-led, interdisciplinary and team-based system of coordinated patient care. This encompasses the entire experience from decision of the need for any invasive procedure—surgical, diagnostic, or therapeutic—to discharge from the acute-care facility. PSH collaboratives currently function in almost 60 large and small health care institutions across the country. Through work with the PSH, ASA has developed protocols to optimize the perioperative use of opioids by relying on multimodal, opioid-sparing analgesic regimens versus the traditional unimodal intravenous and/or oral opioids.[1]

ASA recommends that any policy or recommendation regarding opioid prescriptions be based on evidence-based guidelines; we urge the FDA support the efforts of national professional and medical societies to develop these guidelines. ASA welcomes the opportunity to work with the agency and other stakeholders to develop educational materials and guidelines on opioid prescribing, non-opioid alternatives, pain management and substance abuse prevention and treatment. Specifically, a program or public-private partnership that supports collaboration and consensus among the medical specialties and societies would increase consistency in education, as well as medical and clinical practice.

ASA supports a well-designed and implemented National Prescription Drug Monitoring Database.

ASA members have seen the benefits of select state-based prescription drug monitoring programs (PDMPs) and supports the implementation of a national PDMP under certain circumstances. Such a program, if properly designed, could reduce unnecessary or inappropriate opioid prescribing as well as facilitate consistent reporting and tracking across the country. Almost every state has its own PDMP, but those programs tend to differ significantly from one state to another, and there are marked differences in how states set up agreements with other states to share the data. Another significant problem is a lack of physician access to information about what prescriptions patients have filled in other states, as data sharing across state lines is not always possible. Additionally, health care providers accessing PDMPs experience other challenges caused by slow or unstable technology and barriers created by multiple systems that do not work together.

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[1] Vetter, Thomas; Kain, Zeev. (2017). *Role of the Perioperative Surgical Home in Optimizing the Perioperative Use of Opioids*. International Anesthesia Research Society; https://journals.lww.com/anesthesia-analgesia/Abstract/2017/11000/Role_of_the_Perioperative_Surgical_Home_in.33.aspx, accessed on 3/1/2018.

A national PDMP, with providers participating in the Medicare and/or Medicaid programs to start, could address many of the shortcomings of inconsistent state PDMPs and eventually create a uniform resource that reduces gaps in care, enables prescribers to effectively monitor patients and help prevent substance use and abuse. However, the rollout of a national system should be carefully implemented to ensure that clinicians are not overburdened by reporting to both state and national systems. Over time, the national PDMP should either replace or incorporate state-based efforts to streamline reporting and effectiveness.

ASA is confident that clear benefits can be derived from a national PDMP. If a national PDMP were implemented, ASA recommends that it include the following features:

- Designed so providers can easily access information and delegate authority to an agent;
- Capacity to integrate with the major electronic health IT systems used by physicians and other providers;
- Provides timely and reliable data in an easily digestible format; and
- Aligned with education, prescription monitoring and enforcement efforts.

If properly designed and implemented, a national PDMP can be an effective tool in curbing inappropriate prescribing and can help address the opioid epidemic. Encouraging consistent use also is a critical part of its implementation, so ASA supports incentive programs, such as pay for performance and quality reporting, to encourage physician reporting.

ASA encourages support for educating healthcare providers, patients, caregivers and family members on safe storage and disposal, and the risks of misuse, abuse and addiction associated with opioid analgesics.

ASA strongly supports the use of culturally sensitive and linguistically appropriate patient and caregiver education on safe storage and disposal of opioids and the risks of misuse, abuse and addiction associated with opioid analgesics. Effective patient education can be a powerful prevention tool and is especially important for extended or ongoing prescriptions. Because they are suffering from pain, anxious or distracted, patients do not always hear the information the first time they receive it. To address this issue, it's important for patients and their caretakers to receive this education at both the physician's office as well as again at the pharmacy. The FDA, Centers for Disease Control and Prevention (CDC) and other entities can be supportive in this area by participating in the ongoing validation of evidence-based guidelines and conducting research on the effectiveness of various types of interventions, communications and messaging. However, the most effective patient education efforts are undertaken at the local level, and FDA should refrain from being excessively prescriptive in this area. Individual physicians and local health systems and pharmacies should be given the authority to implement educational initiatives that are appropriate for their own patient populations.

Effective physician education is reinforced throughout the continuum of medical education, including residency training, clinical experiences, and continuing education for practicing physicians. Information on safe storage and disposal and discussing the risks of misuse, abuse and addiction associated with opioid analgesics with patients should be integrated into these educational efforts. ASA supports vigorous efforts to improve education across the health care professions in both pain management and substance abuse prevention and treatment. Professional

education and training must assure clinical competence in pain care, including, but certainly not limited to, the prescribing of controlled substances. Clinicians should be trained and demonstrate competencies in pain, controlled substance prescribing and substance abuse prevention.
ASA is pleased that the FDA is already in the process of significantly revising its Risk Evaluation and Mitigation Strategy (REMS) training materials to better reflect pain management, cover additional medication classes, and support training of non-physician professionals involved in pain management in clinical settings. We believe this will have a very positive impact.

ASA recommends that educational initiatives should be targeted at all prescribers, not just opioid prescribers. Initiatives focused only on opioid prescribing or only on Schedule II drugs, and that permit prescribers to avoid education simply by opting out of prescribing certain drugs, would likely lead to prescribing other controlled substances that also have abuse potential.

ASA encourages sound FDA policies around unit of use packaging, patient storage and handling of opioids, and requirements that sponsors create mechanisms by which patient could return unused pills.

ASA encourages the FDA to take a broad approach to developing end-to-end policies around opioid distribution— from packaging to distribution to patient storage to disposal. Policies that support best practices and harm reduction can identify potential gaps and vulnerabilities and provide system improvement opportunities.

ASA is committed to promoting the safe storage and disposal of opioids and other medications. In April 2017, in partnership with the American Medical Association (AMA) Opioid Task Force, ASA released recommendations to promote the safe storage and disposal of medications.[2] This has become an important resource to help the membership communicate with patients on these issues and may offer FDA additional guidance on this topic.

<u>Unit of Use Packaging and Patient Storage/Handling</u>

Improving patient storage practices and enhancing the secure handling of opioids through improved packaging of products can reduce accidental exposure to opioids by reducing instances of young children and others accessing and consuming opioids. Although this effort may not be as effective in deterring adults from using opioids for non-medical reasons, we believe it is an important step to safeguarding against the accidental use or distribution of opioid medications by individuals other than the patients for whom the prescription was intended.

<u>Disposal of Unused Pills</u>

Safe disposal of unused pills is especially important to reduce the stockpile of excess opioid medicine in homes, which pose a greater risk of abuse or misuse. ASA strongly supports the Drug Enforcement Agency (DEA)'s decision in 2014 to permit consumers to return unused prescription medications like opioid painkillers to pharmacies through an amendment to the

[2] https://www.asahq.org/advocacy/federal-activities/regulatory-activity/pain-medicine accessed on 3/1/2018

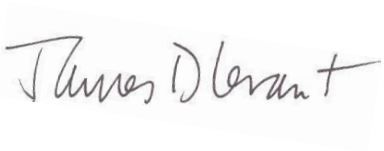
Secure and Responsible Drug Disposable Act of 2010 ("Disposable Act"). Previously, drugs could be disposed of only by the consumer (typically flushed down the toilet) or surrendered to law enforcement. Drug take-back programs not only encourage and facilitate safe disposal, but they also offer reduce the amount of prescription medications entering sewage systems, lakes and rivers.

ASA encourages the FDA to explore policies that can increasingly expand drug take-back programs. While ASA acknowledges that empirical evidence on the impact of ongoing drug take-back programs may be lacking, we believe that it is important for FDA to explore the development of mechanisms to support these initiatives. However, investments in expanding these programs should be coupled with monitoring and tracking to assess their effectiveness, and also include tools to minimize the security risks and other barriers that may inhibit the ability to offer such programs in low-security settings like the physician office.

ASA recommends that drug take-back programs be expanded with industry support. In 2016, Massachusetts became the first state to require drug companies to safely dispose of unwanted medications as part of a comprehensive drug abuse prevention strategy (H. 4056, An Act Relative to Substance Abuse, Treatment, Education and Prevention).[3] ASA believes that it would be a natural and effective partnership for sponsors, pharmacies and local communities to invest together in these efforts, The Society encourages the FDA to develop policies that reduce barriers to the implementation of these initiatives and enhance messaging to patients about drug disposal to increase awareness of existing and new programs.

Thank you for your leadership in addressing the opioid epidemic in communities across the nation. We appreciate the opportunity to provide our comments to the FDA, as the agency continues to address this issue. Please do not hesitate to contact Ashley Walton, J.D., ASA's Pain Medicine and Federal Affairs Manager, via email at a.walton@asahq.org or by telephone at (202) 289-2222 if we can be of further assistance.

Sincerely,



James D. Grant, M.D., M.B.A., FASA
President

[3] The 190th General Court of the Commonwealth of Massachusetts, https://malegislature.gov/Bills/189/House/H4056 accessed on 3/1/2018