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March 14, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. FDA-2017-N-6502; Opioid Policy Steering Committee:
Prescribing Intervention-Exploring a Strategy for Implementation;
Public Hearing; Request for Comments**

Dear Commissioner Gottlieb:

The American College of Surgeons (ACS) is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. On behalf of more than 80,000 members of the ACS, we appreciate the opportunity to submit comments regarding topics relevant to the U.S. Food and Drug Administration's (FDA) recently established Opioid Policy Steering Committee ("Steering Committee"). The United States faces an opioid epidemic of epic proportions, and the ACS applauds the Steering Committee's efforts to obtain stakeholder input on how FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, promote the safe use of opioid analgesics.

The ACS puts the welfare of our surgical patients above all else, and we believe that surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an inevitable, but undesirable, consequence of surgery, and while opioid-based pain control for the postoperative patient is a therapy supported by numerous national medical specialty societies, these prescriptions carry risks, which include chronic usage, addiction, and overdose. In the midst of this public health crisis, surgeons have a major responsibility to understand and mitigate the risks associated with prescribing opioid analgesics and to participate in a broader solution.

As policymakers (including the Steering Committee) engage in efforts to reduce the number of individuals who improperly or unnecessarily receive opioid analgesic prescriptions, it is critical that physicians be involved in such activities. The ACS, with its 100 year history in establishing standards for the national improvement of surgical care, is committed to the implementation of a multimodal plan focused on policy, physician education, and patient/ caregiver education to address opioid abuse. In light of these priorities, we are concerned that the Steering Committee's suggested

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opioid interventions may obstruct access to medically-necessary medications and restrict physicians' treatment options. Many of the policies proposed by the Steering Committee would have a significant impact on the way surgeons can control patients' postoperative or trauma-related pain and prescribe opioid analgesics moving forward.

We provide feedback below for consideration as the Steering Committee continues its work on the challenges associated with improving pain management while addressing prescription drug misuse and addiction.

THRESHOLD DRUG AMOUNTS

The Steering Committee proposes that sponsors – such as companies, research institutions, and other organizations that are responsible for drug development – require prescribers to follow specific requirements outlined under FDA REMS authority for each opioid prescription for a quantity above a certain threshold drug amount. Under this approach, prescribers could be expected to use an electronic system in which they would document the medical necessity of the quantity of opioids prescribed for a particular patient, and key information (such as medical necessity) could be verified before the prescription is sent to the pharmacy. The Steering Committee seeks comment on the specification of threshold drug amounts for opioid prescriptions above which prescribers would be required to provide additional documentation of medical necessity. Specifically, the Committee asks for feedback on how threshold drug amounts should be determined for various clinical indications.

The ACS believes that physicians should be responsible for determining the dosage and quantity of opioids provided to patients and does not support the establishment of threshold drug amounts for opioid analgesic prescriptions at this time. The appropriate dosage and quantity of opioids for each patient will vary based on the patient's disease, intervention, the chronicity of the condition, and other health factors. Patients with different comorbidities and surgical complications cannot be addressed using a "one size fits all" approach, and the ACS wishes to remind the FDA that other patient risk factors could be more predictive of opioid abuse than the initial prescribed amount. In addition, as there is little evidence to support standardized pain control protocols for specific conditions or procedures, we are concerned that threshold drug amounts developed without fundamental data related to best practices for pain management could inappropriately limit physicians' treatment strategies and impede patient access to necessary therapies. The ACS thus opposes any actions that circumscribe physicians' ability to exercise patient-centered clinical judgement.

Restricting prescriptions through baseless regulation also invites health insurers, such as the Centers for Medicare and Medicaid Services (CMS), and licensing entities, such as the Drug Enforcement Administration (DEA), to censure physicians for prescribing opioid analgesics at the appropriate dosage for a specific patient. If

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national drug threshold amounts were specified, physicians could be forced to terminate opioid prescriptions for patients who are otherwise stable and responding positively to medication therapy or face punitive action against their participation in health insurance networks or license to prescribe controlled substances. **Rather than instituting drug threshold amounts, the ACS encourages the Steering Committee to engage the physician community in advancing opioid-sparing, multimodal pain management techniques that leverage local anesthetics, enhanced recovery after surgery (ERAS) principles, and other non-opioid treatment options.** We stand ready to work with the FDA to enhance pain management programs that allow for early intervention with non-opioid therapy (e.g., gabapentin, and high-dose non-steroidal anti-inflammatory drugs) and facilitate the frequent review of a postoperative pain control plan during a patient's hospital stay and following discharge. The ACS asks that the FDA and other Federal agencies invest resources in the evaluation of perioperative multimodal analgesia strategies to determine best practices to mitigate the risks of prescription opioid misuse and abuse across various clinical indications.

In addition, the ACS would like to offer assistance to the FDA in its efforts to identify and evaluate evidence-based practices to optimize the health of patients with pain. In the absence of data that indicates appropriate drug threshold amounts, the ACS is developing a mechanism by which to obtain real time feedback from patient to provider about patterns of medication usage. Strong for Surgery, an ACS quality program, empowers surgeons and practices to integrate checklists into the preoperative phase of clinical practice for elective operations. The checklists are used to screen patients for potential risk factors (e.g., smoking, malnutrition, diabetes, medication misuse) that can lead to surgical complications, and to provide appropriate interventions to ensure better surgical outcomes. Strong for Surgery targets areas known to be highly influential determinants of surgical outcomes. The ACS intends to release a new opioid sparing checklist, along with a web-based application to record responses and serve as a communication tool between the patient and provider, within the Strong for Surgery program mid-2018. Over time, Strong for Surgery data can be used to identify trends in prescription opioid usage, successes and challenges with patient learning, and real-time behavior feedback. Enabling surgeons to be directly involved in messaging about risk factors allows them to play a much greater role in reducing complications and treat the total health of the patient, and the ACS believes that Strong for Surgery, which has demonstrated efficacy in reducing smoking rates among preoperative patients, would be an appropriate tool to screen patients for factors that can lead to opioid abuse and a mechanism to tailor postoperative pain management programs to patients with varying levels of risk.¹ We have also created additional resources related to opioid use and surgery, which may be accessed by the public on the ACS website at <https://www.facs.org/education/opioids>.

¹ American College of Surgeons. (2017). "Strong for Surgery" program shows promise in dramatically reducing smoking rates for patients facing surgery [Press release]. Retrieved from <https://www.facs.org/media/press-releases/2017/s4s072417>

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PRESCRIPTION HISTORY DATABASES

The Steering Committee proposes to require sponsors to create an electronic system that would utilize a nationwide database intended to help physicians identify potential prescription misuse and abuse and promote safe use of opioids (e.g., real-time identification of potential harmful drug-drug combinations). The Steering Committee acknowledges that physicians generally have the capability to access state prescription drug monitoring program (PDMP) data that include patient controlled substance prescription history and prescribing patterns, but asserts that providers may encounter disparate data elements and data sharing challenges when consulting PDMPs because the systems are separately managed and maintained by individual states. In addition, the Steering Committee recognizes that review of PDMP data requires physicians to access a database that may not be integrated into their workflow.

PDMPs, which are statewide databases that collect information on the distribution of controlled substance prescriptions, can be used to track opioid prescriptions in some manner in all states except for Missouri. While the ACS has promoted the use of PDMPs to inform clinical decision-making and facilitate intervention at the point of care, we remain concerned that PDMP data are not standardized and are poorly integrated into existing workflows. Further, each state with an established PDMP has its own set of laws governing what type of drug use data are available, what type of prescriber can access the PDMP, and how the data are shared. Currently, PDMPs largely operate as outdated repositories that do not provide physicians with the real-time, actionable information needed to determine a patients' pattern of prescription drug purchase or prior therapies (such as methadone or buprenorphine prescriptions) used to treat opioid use disorders. In addition, PDMPs do not effectively share data across states, enabling patients who live near state borders to duplicate opioid prescription purchases in each state without the prescribing physician's knowledge. As a result of these inefficiencies, checking PDMPs is cumbersome, time-consuming, and may yield incomplete information.

The country's opioid crisis highlights the need for digital solutions that break down data silos and provide prescribers with comprehensive, patient-specific information. Prescription history databases, whether established at the state or national level, must interact and share information to be effective and important clinical tools that will allow surgeons to better identify patients at high risk for opioid prescription abuse and tailor their prescribing behavior accordingly. **An ongoing push toward standardized databases with the ability to share information across state borders is essential to ensuring physicians receive accurate information, and the ACS strongly believes that there must be interoperability in the data contained in PDMPs with electronic health records (EHRs) to streamline accessibility and promote patient safety.** Integration of PDMPs into the clinical workflow could greatly improve feasibility of checking patterns of patient opioid prescription purchases and thereby increase utilization, and we encourage the Steering Committee

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to explore opportunities to build upon the existing PDMP foundation and leverage health information technologies to support the functionality of PDMP data within EHRs, initiate or expand interstate data sharing, facilitate secure prescriber-pharmacy communication, and establish benchmarks to assess PDMP use.

PROVIDER EDUCATION

In 2012, the FDA approved the Extended-Release, Long-Acting (ER/LA) Opioid Analgesic REMS, which was established to ensure that the benefits of ER/LA opioid analgesics used in the outpatient outweigh the risks. As part of the ER/LA Opioid Analgesic REMS, the FDA developed the *Blueprint for Prescriber Education for ER/LA Opioid Analgesics*, which includes guidance for providers on methods to initiate therapy, modify dose, and discontinue use of ER/LA opioids.² The FDA modified the ER/LA Opioid Analgesic REMS in 2017 to incorporate immediate-release (IR) opioids, and drafted a revised version of the ER/LA *Blueprint* tool, entitled *Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain*, which includes information on acute and chronic pain management, non-pharmacologic treatments, and pharmacologic treatments.³ To supplement the FDA's updated *Blueprint*, the Steering Committee proposes to require sponsors to take additional measures to ensure that providers, patients, and caregivers are educated on safe storage and disposal and the risks of misuse, abuse, and addiction associated with prescription opioid analgesics.

The ACS believes that enhancing surgeons' knowledge of pain management techniques, including prescribed opioids and opioid-sparing multimodal strategies, could significantly reduce risks associated with postoperative opioid prescription use, and we thank the FDA for revising its *Blueprint* to include information on both pharmacologic and non-pharmacologic therapies. We encourage the development of evidence-based and comprehensive information that provide physicians with a deeper understanding of the relationship between symptoms, opioid risk assessment and addiction screening, disease management, prescribing patterns, patient education, and subsequent outcomes. However, the ACS wishes to remind the Steering Committee that physician continuing medical education (CME) requirements vary across states as well as medical specialties.⁴ While we recognize that medical specialty societies, educational institutions, healthcare organizations, and state and federal agencies are collectively responsible for physicians' understanding of different options for pain management, **the ACS does not believe that it is appropriate for the FDA to direct sponsors to institute mandatory physician education. "One size fits all" prescription opioid management education is a suboptimal approach to**

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² U.S. Food & Drug Administration. (2017). *FDA blueprint for prescriber education for extended-release and long-acting opioid analgesics*. Washington, DC: U.S. Food & Drug Administration.

³ U.S. Food & Drug Administration. (2017). *FDA education blueprint for health care providers involved in the management or support of patients with pain*. Washington, DC: U.S. Food & Drug Administration.

⁴ American College of Surgeons. (2018). *CME state requirements*. Retrieved from <https://www.facs.org/education/cme/state-mandates#viewport>



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improving physician awareness of the appropriateness and risks of prescribing opioid analgesics.

We oppose any federal mandates that specify CME requirements for physicians, and believe that medical specialty societies are best positioned to develop and provide meaningful education that is tailored to meet the needs of their members and respective patients. Surgeons are deeply committed to strengthening their knowledge about the safe and effective prescribing of opioids, and the ACS has identified a critical gap in education, practice and communications about surgical perioperative pain management, specifically a lack of education and resources aimed at the use of prescription opioids in individuals undergoing surgery. Recognizing the current opioid epidemic, we are currently engaged in the development of an educational curriculum for surgeons, titled *Opioids and Surgery: Use, Abuse and Alternatives*, which can be used to inform preoperative discussions, aid in the identification of patients at high risk for potential abuse, highlight non-opioid treatment options, and assist surgeons in adopting improved pain management strategies aimed at preventing patients from becoming victims of the opioid crisis.⁵ The ACS anticipates the *Opioids and Surgery* program will demonstrate the comparative benefit and reduction of harm associated with the use of a guided pain management program, and we intend to use this framework to establish a national standard for best intervention methods for pain control for both inpatient and outpatient procedures. Additionally, the ACS offers resources for the surgical patient to support informed choice of postoperative pain control options.⁶ We encourage surgeons and patients to use these tools to evaluate current pain management practices, and welcome federal assistance in helping to disseminate these materials.

UNIT-OF-USE PACKAGING

The Steering Committee seeks comments on how unit-of-use blister packaging might play a role in encouraging the appropriate and consistent prescribing of opioids. **The ACS supports modifications to opioid packaging and dispensing modalities that address risks related to prescription drug dependence or abuse, but does not believe that the imposition of unit-of-use packaging restrictions is an appropriate solution to enhance patient safety or facilitate consistency of opioid prescribing practices.** As noted above, we maintain that physicians should be responsible for determining the dosage and quantity of opioid analgesics provided to patients, who present with diverse pain management needs, including pain chronicity and threshold. The ACS is concerned that blister packaging may restrict access to opioids for patients in pain, whether due to increased costs shifted to patients (e.g., co-payments for return physician office visits to obtain prescription refill),

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⁵ American College of Surgeons. (2016). *American College of Surgeons launches education program on opioids and surgery: Use, abuse and alternatives* [Press release]. Retrieved from <https://www.facs.org/media/press-releases/2016/opioids103116>

⁶ American College of Surgeons. (2018). *Safe pain control: Opioid abuse and surgery*. Retrieved from <https://www.facs.org/safepaincontrol>



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geographic- or mobility-related difficulties that impede patients' ability to repeatedly visit their physician for necessary refills, or physical constraints (e.g., loss of fine motor skills, impaired vision, limited strength and dexterity) that may hamper a patient's ability to extract a tablet from the blister pack. Such restrictions are likely to negatively affect the timely and correct use of prescription medications. Further, there is little evidence to indicate that blister packaging is effective in deterring intentional opioid abuse.⁷ **The ACS encourages the Steering Committee to engage the physician and pharmacist communities, along with patient advocacy groups, to evaluate how medication packaging mechanisms may improve opioid safety, as well as any unintended consequences of utilizing these modalities, before promulgating new rules for opioid dispensing.**

ACS GUIDING PRINCIPLES TO PREVENT OPIOID ABUSE AND ADDICTION

The ACS seeks to assure that surgical patients continue to have adequate pain control and receive the proper postoperative care needed to restore their overall health and avoid prescription opioid-related complications. We believe that surgeons have a responsibility to minimize their patients' postoperative pain while addressing the societal imperative to avoid overprescribing, and in 2017 developed the following five principles to guide our efforts in preventing opioid abuse and addiction in surgical patients:

ACS GUIDING PRINCIPLES TO PREVENT OPIOID ABUSE AND ADDICTION

- 1) Promote the use of prescription drug monitoring programs (PDMPs) through the following activities:
 - Set expectation that PDMPs are fully functional and interoperable with electronic health records
 - Establish state/federal grant programs to enhance PDMPs
 - Reduce barriers to PDMP access by nonphysician licensed independent practitioners and physicians' designated agents
- 2) Support research and training, developed in collaboration with specialists in pain management, for safe prescribing practices of opioids and non-opioid analgesics through the following activities:
 - Identify patients at high risk for opioid addiction, substance use disorder, or an opioid-related adverse drug event
 - Establish guidelines for acute pain management of the opioid-addicted patient
 - Set expectations and educate patients and caregivers prior to surgery, during discharge, and throughout follow-up
 - Provide evidence-based education and evaluation training programs on opioid and non-opioid alternatives for pain management for the entire surgical team—surgeons, residents, and other health professionals
 - Strengthen postoperative surveillance by both patients and providers to expand the evidence on use, response to alternative therapies, and potential issues with long-term use in acute surgical and palliative care patients
- 3) Recognize and address issues specific to military veterans by establishing the following programs:
 - Fully functional opioid tracking system for Veterans Affairs (VA) patients
 - A system to track prescriptions issued at all federal facilities, including the VA, to outside treating providers and pharmacists
 - Expansion of the VA Opioid Safety Initiative
- 4) Change the direct relationship between provider reimbursement and patient pain control through the following efforts:
 - Detach questions regarding pain management on patient satisfaction surveys from physician reimbursement
 - Examine the impact of insurer and state-based government regulations on prescribing practices and patient experience
- 5) Support patient safety legislation that includes the following provisions:
 - Exemptions for the postoperative and/or injured surgical patients who are expected to require opioid analgesics for more than seven days
 - Exceptions from prescriber mandates for patients undergoing cancer treatment, cancer rehabilitation, and palliative care
 - E-prescribing of controlled substances to improve tracking, reduce opportunities for fraud, and limit episodes where patients in pain are without relief
 - Partial filling of opioid prescriptions
 - Disposal programs to prevent misuse or diversion of unfinished prescriptions¹⁰

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The use and abuse of prescription opioids has increased dramatically in recent years and has become a major public health concern. Addressing this crisis requires a collaborative effort among healthcare providers, insurers, consumers, and all levels of government to appropriately shift prescribing practices, enhance prescriber and patient education, improve drug dispensing mechanisms, and integrate programs that monitor patients' purchase of controlled substances into the clinical workflow. The ACS believes that the magnitude and scope of the opioid crisis warrants urgent action and we stand ready to represent the surgeon's voice as policymakers search for effective solutions to prevent further harm from prescription opioid abuse.

The ACS appreciates the opportunity to comment on the FDA Opioid Policy Steering Committee docket and looks forward to continuing dialogue on these important issues. If you have any questions about our comments, please contact Lauren Foe, Regulatory Associate in the ACS Division of Advocacy and Health Policy, at lfoe@facs.org or (202) 672-1524.

Sincerely,

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