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July 6, 2017

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

RE: Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Request for Comments; Docket Number FDA-2017-D-2497

Dear Commissioner Gottlieb:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am pleased to offer our comments to the U.S. Food and Drug Administration (FDA) on the FDA-created May 2017 “Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics” (FDA Blueprint). At a threshold level, the AMA strongly supports the FDA’s efforts to help ensure the safe and appropriate prescribing of opioid analgesics as a critical component of reversing the nation’s opioid epidemic. We were pleased to take part in the recent FDA Workshop on *Training for Opioid Analgesic Prescribers—Exploring the Path Forward*, and we are committed to enhancing physicians’ education that is meaningful and relevant to their practices and patient population. Our comments below follow the organization of the FDA Blueprint.

In Section 1, “The Basics of Pain Management,” the FDA Blueprint provides an extensive discussion of pain, yet it is often difficult to understand whether FDA has made distinctions for acute or chronic pain, including whether pain might be associated with active cancer, cancer-related or hospice or palliative care. While some of the areas contained within Section 1 may be applicable to all pain-related conditions, the physiologic and psychological factors that may be part of different types of pain have a direct effect on the treatment considerations for them. This includes patient assessment, where an emergency physician will commonly be faced with different considerations than an oncologist or surgeon. Thus, although the FDA has recommended nine important elements for an initial pain assessment, different sites of care—and different patient indications—may require different types of assessment. We therefore recommend the FDA include language in this section acknowledging that some of these assessment recommendations may not be applicable in all situations.

In Section 2, “Creating the Pain Treatment Plan,” the FDA Blueprint also would be well-served by distinguishing when it is referring to treatment plans for acute or chronic conditions, including whether pain is associated with cancer-related, hospice, or palliative care. The AMA supports the view that treatment plans should take activities of daily living into account and that treatment plans address functional goals as well.

On the whole, the AMA appreciates that in Section 2 the FDA Blueprint attempts to provide a comprehensive set of considerations for the health care professional. We agree that “it is important to establish a set of goals early in the course of treatment” to establish expectations for both the patient and the health care professional. This recommendation, however, appears more tied to the treatment of chronic pain. In addition, the AMA strongly supports having the health care professional consider the most effective interventions, including non-opioid and non-pharmacologic options. One point that was made by many during the FDA Workshop, however, is that these options often are not available to patients due to a lack of insurance coverage or inadequate supply of certain health care professionals in insurance networks. For example, if a physician wants to refer a patient with lower back pain to a physical therapist, the insurance company may subject the patient to a high-dollar co-pay that is prohibitive. Or, if a physician wants to refer a patient to a neurologist for recurrent migraine headaches, the insurance network may be so restricted that the waiting time for an appointment could be weeks or months. In those situations, the physician and the patient are placed in an untenable situation. This is in contrast to systems such as, the Department of Defense or Kaiser Permanente, which have the internal structure and resources to refer patients to a wide range of specialists. And while we recognize that the FDA Blueprint is not the proper document to advocate for policy changes, the AMA urges FDA to recognize that it may be recommending specific actions for physicians and other health care professionals that simply are not obtainable under the priorities of our current health care system.

Similar to our support of multi-modal therapies that incorporate non-pharmacologic treatment where appropriate and available, the AMA also supports multidisciplinary care with biopsychosocial elements to treat, for example, a patient’s psychiatric or behavioral health care needs. Yet, similar to the discussion above, the AMA is concerned that health insurers and other payers—as well as pharmacy benefit managers—have placed highly restrictive utilization management restrictions around these alternatives, which serve as a barrier to care. For example, the AMA has heard from physicians that some local anesthetics (e.g., lidocaine patches) often are denied or subject to strict prior authorization and delays under a plan formulary, even though they may be the preferred treatment for a patient instead of an opioid analgesic that does not require prior authorization. We have heard that patients have considerable challenges in accessing necessary mental health care services because of inadequate insurance networks, or excessive prior authorization requirements. We would argue that the cost of the nation’s epidemic of opioid overdose deaths far exceeds any savings that insurance plans are realizing from these types of utilization management policies. While the AMA agrees with the general approach of the FDA Blueprint to support non-opioid therapies where appropriate, we are concerned that the FDA Blueprint assumes that all modalities are equally available when, in fact, physicians and patients often face considerable barriers to access effective pain management.

The AMA also wants to comment on the “paradigm shift in opioid prescribing” for two important reasons. First, we agree that there has been such a shift. For several years, the AMA and our AMA Opioid Task Force issued multiple national calls to action for physicians to be more judicious in their prescribing patterns. Specifically, then-AMA President Steve Stack, MD, urged physicians to

- AVOID initiating opioids for new patients with chronic non-cancer pain unless the expected benefits are anticipated to outweigh the risks. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred.
- LIMIT the amount of opioids prescribed for post-operative care and acutely-injured patients. Physicians should prescribe the lowest effective dose for the shortest possible duration for pain severe enough to require opioids, being careful not to prescribe merely for the possible

convenience of prescriber or patient. Physician professional judgment and discretion is important in this determination.

This was part of a state, regional, and national communications campaign by the AMA that has contributed to reduced opioid prescribing in every state. From 2013-2016, opioid prescriptions in the United States decreased by 43 million—a nearly 17 percent decrease nationally. And to help better inform physician decision-making, the AMA and the AMA Opioid Task Force have strongly encouraged physicians to use state prescription drug monitoring programs (PDMPs), which has contributed to a 121 percent increase since 2014, with PDMPs being checked more than 136 million times in 2016. We support the FDA Blueprint's recognition of the role that judicious prescribing habits and PDMPs can play, and encourage FDA to acknowledge the progress to date on both fronts.

At the same time, however, the decreases in prescribing and increases in PDMP use have not led to decreases in opioid-related mortality. During roughly the same time frame that opioid prescribing began to decrease and PDMP use began to increase, deaths from prescription opioids have continued to increase, from 11,134 in 2012 to 12,728 in 2015—a 14.3 percent increase, according to the U.S. Centers for Disease Control and Prevention. Deaths attributed to heroin, during the same time-frame, increased from 5,925 in 2012 to 12,957 in 2015—a 119 percent increase. And deaths attributed to synthetic opioids, including fentanyl, increased from 2,628 in 2012 to 9,549 in 2015—a staggering 263 percent increase.

There are several potential explanations for the increases in heroin and fentanyl-related mortality, including the possibility that as prescription opioids become increasingly more difficult to obtain, there is a shift to less-expensive heroin and other illicit drugs. Whether future research confirms that possibility or not, it is clear that public policy interventions (e.g., restricting prescribing, mandating PDMP use, mandating continuing education) focused on reducing the supply of prescription opioids will not be sufficient to address the rising use of heroin and fentanyl. Rather, there is a great need for public health interventions and investment to more comprehensively support access to multimodal, evidence-based treatment for substance use disorders as well as for pain. In addition, while nearly all states now have broad public policies supporting access to naloxone, there must be a sustained effort to ensure enhanced access to this life-saving medication. If it were not for naloxone, it is likely that tens of thousands more would be dead due to an opioid-related overdose.

We further note that the decreased opioid supply does not appear to have resulted in improved pain care. There was much discussion at the FDA Workshop about the need to reduce the nation's opioid supply, but we note that multiple patient advocates testified to losing access to pain care. The best way to reduce the demand for opioid analgesics to treat chronic pain is to manage acute pain effectively and to use multimodal approaches for the management of chronic pain. The AMA strongly supports implementation of the National Pain Strategy (NPS) for this reason, but this strategy has yet to receive the type of attention or funding necessary to achieve its goals. To the extent that FDA is able to support the NPS, the AMA would gladly assist in those efforts. In addition, the AMA again points to the work cited at the FDA Workshop by the Department of Defense and others where physician-to-physician academic detailing, mentoring, and coordination have resulted in improved pain care. This type of effort also was featured at the AMA House of Delegates Annual Meeting where a physician from the University of Chicago highlighted the hospital's internal efforts to identify variations in pain care and prescribing and to use that data to make physician-specific interventions and institute, as needed,

corrective plans to help ensure best practices. This type of data-informed intervention is highly preferable to a one-size-fits-all proposal.

Our final comment on Section 2 focuses on the broad educational areas recommended by FDA. Throughout Section 2, the FDA Blueprint suggests a wide breadth of areas for physicians' knowledge. The AMA generally agrees that these areas highlight important considerations, including drug-to-drug interactions, special populations, co-prescribing of naloxone to patients at risk of overdose, and considerations for caring for patients with chronic pain. But it is not clear from the FDA Blueprint whether all of the elements suggested would be comprised of a new continuing medical education (CME) course, or be recommended for medical student or graduate medical education, or some other training mechanism. A key part of our commitment is supporting enhanced education, training, and resources for physicians and other health care professionals across the continuum of medical education to ensure that they have the resources they need to make informed prescribing decisions.

In the past two years, more than 118,000 physicians have taken educational courses related to opioid prescribing, pain management, substance use disorders, and related topics offered by national organizations, as well as medical specialty and state medical societies. This has been the direct result of collective efforts by the AMA Opioid Task Force and the nation's medical societies, which recognize the urgency to reduce opioid-related harms, prevent diversion, and provide access to treatment for opioid use disorder, while maintaining a clinical practice environment that enables physicians to manage an individual patient's pain and suffering in the most effective and safe manner. The AMA has collected nearly 300 educational resources addressing these objectives and regularly promotes them to physicians through a new AMA microsite: www.end-opioid-epidemic.org

The AMA strongly supports efforts to enhance education, but believes that it should occur at the state level to avoid creating confusion and unnecessary federal overlap with existing state law. In addition, given that many current state requirements have only been recently enacted and others have existed for several years, it is unclear whether educational mandates in the form of CME have led or will lead to reductions in opioid-related mortality and other harms and improve pain care. Current data shows an increase in educational mandates, but a simultaneous increase in opioid-related mortality. And as noted above, opioid-related mortality is shifting to heroin and illicit fentanyl. Because of this lack of correlation between CME mandates, which also may be imposed by state medical boards, and drug poisoning death rates, it is not clear from the FDA Blueprint how FDA would go about implementing or requiring the broad range of suggestions in the FDA Blueprint. Rather, it will be important to determine and evaluate how such policy goals can be met without practice disruption and/or unintended consequences for patients.

For all of these reasons, we believe it is imperative that efforts to enhance physician education come from within the profession. And as noted above, we believe those efforts are not only underway, but have been embraced throughout the medical community. While we understand that some would like to impose further mandates on physicians, we once again note that there is no evidence that policy mandates have reduced mortality, and they may have unintended consequences. We also urge the FDA to consider that the new requirements in the FDA Blueprint may conflict with new state laws, payer policies, and the new Federation of State Medical Boards (FSMB) Guidelines for the Chronic Use of Opioid Analgesics, which were adopted by FSMB in April of this year.

Scott Gottlieb, MD

July 6, 2017

Page 5

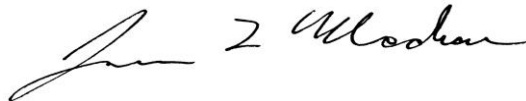
The AMA supports the goal that all physicians—starting in medical school and throughout their professional careers—seek to enhance their education and training on effective pain management, which includes opioid prescribing, recognizing signs of a potential substance use disorder, and overdose prevention and treatment options. As discussed above, we also have actively worked to enhance the education of all physicians who prescribe opioids to help mitigate the current public health epidemic. Yet, we are acutely aware that as FDA and many others adopt new guidelines, recommendations, laws and regulations, it is becoming increasingly confusing for physicians and other health care professionals to know what is right for their patients. Thus, if the federal government proposes a specific type of educational requirement on safe opioid prescribing, it is important that such an effort be undertaken as a health care initiative and not a law enforcement program. It is also critical that any new federal education initiatives be developed collaboratively with physician experts. The AMA stands ready to work with FDA as it continues to develop ways to help reverse the nation's opioid epidemic.

AMA-specific efforts

In conclusion, in addition to the work of the AMA Opioid Task Force to gather and promote state- and specialty-specific education that is meaningful and relevant to physician practices, we would like to highlight two additional efforts where we have supported enhanced physician education. First, the AMA has been a collaborative partner in the Providers' Clinical Support System for Opioid Therapies (PCSS-O) initiative. Given the progressive intersection between opioid prescribing, opioid use disorders, and the resurgence in heroin use, more specific attention should be given to educational resources on this topic. Second, as part of our deliverables for the most recent PCSS-O grant from the Substance Abuse and Mental Health Services Administration, the AMA has developed a CME primer on opioid-related harm that includes an important focus on this topic. Additionally, and given that each state is confronted with a different set of dynamics in addressing opioid morbidity and mortality, we partnered with two states, Rhode Island and Alabama, to develop a state-specific educational toolbox as a pilot, which we are hopeful can be adapted by other states. We are working with Oregon and Indiana on additional state-specific toolboxes that we hope to release later this year.

We look forward to continuing to work with the FDA and other federal agencies to stem the tide of the opioid epidemic.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD