



**JAMES L. MADARA, MD**  
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org  
t (312) 464-5000

December 20, 2017

Ms. Kathleen Davies  
Regulatory Counsel  
Office of Medical Products and Tobacco  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Building 1, Room 2310  
Silver Spring, MD 20993

RE: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments;  
Docket Number FDA-2017-N-5608

Dear Ms. Davies:

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 Opioid Policy Steering Committee (OPSC). 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 epidemic of opioid-related misuse, overdose, and death. We were pleased to take part in the May 2017 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.

I. Assessing Benefit and Risk in the Opioids Setting

The OPSC asks how the FDA should modify its approach to assessing opioid drugs to ensure that it gives adequate consideration to risks associated with the labeled indication and risks associated with potential abuse and misuse. The AMA recommends that the FDA work to strike the right balance in evaluating the benefits and risks of opioid analgesics. It is clear that the pendulum swung too far in one direction, that there was too little attention to the risks of opioid misuse and opioid use disorder, and this helped to fuel the current epidemic. It would, however, also be a mistake to view opioid analgesics only in terms of these risks and not consider their benefits in alleviating pain associated with acute injury or painful conditions, serious illness, surgery, trauma, and palliative care.

The AMA also encourages the FDA to consider the full array of potential treatment strategies for pain, including opioids and non-opioid analgesics as well as non-pharmacologic options, instead of viewing opioids in isolation. The agency should consider the benefits and risks of non-opioid analgesics in treating pain (without the risk of opioid use disorder), just as it should consider the risk to patient safety and public health from opioid analgesics.

The OPSC also asks whether there are specific public health considerations other than misuse and abuse that the FDA should incorporate into its current framework for benefit and risk assessment as a way to reduce opioid morbidity and mortality. The AMA recommends that, as it evaluates drug applications, the FDA should consider the potential for overdose deaths to occur from use, potential benefits in treating opioid use disorder and opioid-related overdose, as well as potential reductions in the risk of opioid use disorder.

## II. Steps to Promote Proper Prescribing and Dispensing

The OPSC asks whether the FDA should consider adding a recommended duration of treatment for specific types of patient needs to opioid analgesic product labeling, or whether it should work with prescriber groups to develop expert guidelines on proper prescribing by indication. The AMA agrees that the FDA should work with specialty medical societies to develop expert guidelines on prescribing for different indications, but has concerns about modifying product labeling based on these guidelines.

The Centers for Disease Control and Prevention (CDC) guidelines for use of opioid analgesics in managing chronic pain include the following statement: “Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient’s clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.”

Since their publication in March 2016, however, a number of state governments, pharmacy chains, and health insurance plans have used these guidelines to justify across-the-board limits on coverage and dispensing of opioid analgesics. The limits have in turn made it more difficult for some patients to obtain medications prescribed to them for the treatment of pain, and they have contributed to an increase in the stigma associated with patients who benefit from opioid analgesics prescribed by their physicians. While these new policies will likely have the intended effect of reducing opioid supply, there is no data to suggest that these policies are improving patient outcomes related to improved pain care. In the absence of such critical information, the AMA has grave concerns that incorporating new guidance into the labeling of opioid analgesics could increase confusion and exacerbate these problems.

At the same time, it is clear from surveys of physicians about their educational needs related to opioids that many of them would welcome additional guidance and education specific to the conditions they manage in their own patients. While we have concerns about adding additional information to the product labels, we agree that it could be beneficial for the FDA to work with specialty societies to help develop some more indication-specific guidelines on appropriate prescribing. The AMA would be pleased to assist the agency in convening the appropriate organizations and experts to undertake this type of review.

## III. Requirements for Prescriber Education

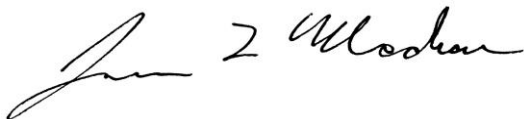
The FDA seeks comments on whether the agency should require some form of mandatory education for health professionals to ensure that those prescribing opioid analgesics are informed

about appropriate prescribing and pain management recommendations. The information presented at the FDA's May 2017 workshop showed that a wide array of strategies have been deployed in various settings to improve pain management while decreasing the risk of opioid use disorder. These strategies include education on safe prescribing and multimodal biopsychosocial pain management, increasing use of non-opioid and non-pharmacologic strategies for pain management and breaking down insurance and other barriers to these therapies, treating pain as a condition instead of a symptom, utilizing academic detailing, mentoring, and team-based approaches to coordinate care, and providing data and feedback to physicians on their practice patterns.

Over a recent two-year period, 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, including specialty societies, and state medical societies. An AMA survey found that what physicians feel is lacking and what they need most is opioid-related education that is tailored to their own specialty and patient population. The AMA is working to provide this information through a new microsite – [www.end-opioid-epidemic.org](http://www.end-opioid-epidemic.org) – that has more than 300 state- and specialty-specific education resources. We do not believe that a federally mandated one-size-fits-all program would help to reverse the opioid epidemic. We instead encourage the FDA to work to increase information about, use of, and dissemination of all of the effective strategies for treating pain and reducing the risk of opioid use disorders.

We look forward to continuing to work with the FDA and other federal agencies to stem the tide of the opioid epidemic. If you have any questions, please feel free to contact Sandy Marks, Assistant Director, Federal Affairs, at [sandy.marks@ama-assn.org](mailto:sandy.marks@ama-assn.org) or 202-789-4585.

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