the AMERICAN ACADEMY of PAIN MEDICINE
the voice of pain medicine

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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket Number: FDA-2017-D-2497

Dear FDA Officers:

The American Academy of Pain Medicine (AAPM), representing the specialty of pain medicine, writes to offer guidance on the draft revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids.

AAPM believes that updating the REMS blueprint is necessary and appropriate. The proposed revision is relatively complete and represents a marked improvement over the original blueprint.

We note that these blueprints, and indeed the REMS themselves, would likely be unnecessary were it not for the abysmal level of pain-related education in undergraduate and graduate medical education. While recognizing that space in medical schools' curricula is jealously guarded by those departments which currently have access to it, we believe that the field of pain and related treatments is critically underrepresented with attendant harms to society resulting from poorly educated physicians. The need for comprehensive education strategies at the undergraduate, graduate, and continuing professional levels cannot be emphasized enough.

Several specific comment about the draft blueprint are offered:

- The classification of pain into acute vs chronic and neuropathic vs non-neuropathic may be overly simplistic, even for a document intended for non-specialists.

- Treatments are divided into pharmacologic and nonpharmacologic. The latter makes no mention of regional anesthesia / neuroaugmentation.

- Remarkably, there is no mention of the limited evidence of effectiveness of long-term opioid therapy and the evidence of diminished effectiveness over time.

- The mention of risks of combining opioids with benzodiazepines (and other sedatives) is understated, as it only alludes to "concerns" and fails to point out the presence of evidence of lethality and the absence of evidence of benefit of long-term benzodiazepine treatment.

- We recommend changing "benzodiazepines and other central nervous system depressants" to "benzodiazepine and/or alcohol and other central nervous system depressants" to emphasize the increased risk in patients combining alcohol and opioids, since alcohol consumption is so widespread.

- The warning about methadone should be stronger: "Methadone should only be prescribed and managed by HCP's familiar with its unique side effect and safety profile."

- There were several concerns regarding the "Managing Patients on Opioid Analgesics" section. Specifically:

    - The phrase, "When is an opioid necessary?" might better be expressed as "When is an opioid a reasonable option?"

    - The reference to dosing as needed vs. around-the-clock (ATC) erroneously implies that there is a role for ATC dosing acutely, which is dangerous, especially in opioid naïve patients.

    - Acute treatment includes reference to "avoiding ER/LAs when pain is not expected to be present for an extended period of time…" This is inappropriate, as acute pain should never be treated with ER opioids.

- The recommendation that "HCPs should prescribe and discuss the use of naloxone…." might better be phrased, "HCPs should consider prescribing naloxone….."

- The document should note that not only opioids but also non-opioid medications convey risks which should be assessed when planning and managing treatment.

- It indicates that "HCPs should be aware of and use the Patient Counseling Document and Medication Guide as part of discussion with patients and caregivers when prescribing opioid analgesia." This document is minimal (190 words), does not mention risks of combining other drugs with opioids, and only applies to patients on ER/LA opioids. It should be expanded if it's to be referenced here.

- There is concern that, as with all documents recommending strategies for treating pain, there is emphasis on interventions that largely do not exist for many patients, either because of geography or reimbursement. The generation of demand for which there is no supply may be futile.

- The document should note that there are risks of *not* treating pain, that include suffering, loss of function, and even loss of life.

Respectfully submitted,

American Academy of Pain Medicine

About AAPM
The American Academy of Pain Medicine is the premier medical association for pain physicians and their treatment teams with some 2,000 members. Now in its 35th year of service, the Academy's mission is to optimize the health of patients in pain and eliminate pain as a major public health problem by advancing the practice and specialty of pain medicine through education, training, advocacy and research. Information is available on the Academy's website at www.painmed.org.