4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments

[Docket No. FDA-2017-N-5608]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to solicit suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, on questions relevant to FDA's newly established Opioid Policy Steering Committee (OPSC). Opioid addiction and the resulting overdoses and deaths have created a national crisis, which requires action by federal agencies that may in some instances be unprecedented in order to address the situation and attempt to turn the tide on the crisis. As a public health agency responding to the crisis, FDA seek public input as it considers how its authorities can or should be used to address this crisis. This information will help the Agency understand areas of focus important to the public and identify and address opioid product and policy issues that need clarification. FDA is especially interested in hearing from interested parties in three key areas: what more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; what steps can FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing

practice; and should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-5608 for "Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen Davies, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 1, Rm. 2310, Silver Spring, MD 20993, 301-796-2205.

SUPPLEMENTARY INFORMATION: On April 19, 2017, the Secretary of Health and Human Services announced the HHS strategy for fighting the opioid crisis. The five point strategy includes: (1) improving access to prevention, treatment, and recovery services; (2) targeting

availability and distribution of overdose-reversing drugs; (3) strengthening timely public health data and reporting; (4) supporting cutting-edge research; and (5) advancing the practice of pain management. Following that announcement, on May 23, 2017, the Commissioner of Food and Drugs announced his intention to take more forceful steps to combat the opioid crisis. An OPSC was established to explore and develop additional tools or strategies FDA can use to confront this crisis. The OPSC has a broad mandate to consider steps that FDA can take to confront the opioid crisis. FDA is seeking suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, with regard to a number of topics related to three overarching questions: (1) what more can or should FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; (2) what steps can or should FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice; and (3) should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

I. Assessing Benefit and Risk in the Opioids Setting

In a July 6, 2017, article in the *Journal of the American Medical Association*, FDA explained its approach to assessing the benefits and risks of drug products, describing a structured approach that, in the case of opioids, includes extensive additional review of the risks related to the potential misuse and abuse of these products. FDA explained that it is working to incorporate the effects of decisions on public health into its benefit-risk framework in a more quantitative manner that can supplement and enhance the strong qualitative work that the

Agency already performs (Ref. 1). In addition, in March 2016, FDA commissioned a study from the National Academies of Sciences, Engineering, and Medicine to outline the state of the science regarding prescription opioid abuse and misuse, the evolving role that opioid analgesics play in pain management, and additional actions FDA should consider to address the opioid crisis with particular emphasis on strengthening its benefit-risk framework for opioids. That report was issued in July (Ref. 2). While FDA considers the report recommendations, we would like to solicit additional feedback that will supplement those recommendations.

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. How should FDA tailor, or otherwise amend, its assessment of benefit and risk in the context of opioid drugs to ensure that the Agency is giving adequate consideration to the risks associated with the labeled indication of these drugs and the risks associated with the potential abuse and misuse of these products?
2. Are there specific public health considerations other than misuse and abuse that FDA should incorporate into its current framework for benefit and risk assessment as a way to reduce the opioid addiction epidemic? That framework includes, but is not limited to, how FDA makes regulatory decisions to approve new opioids, evaluates their use in the postmarket setting, or limits or influences their prescribing through product labeling or other risk management measures.

II. Steps to Promote Proper Prescribing and Dispensing

Proper prescribing and dispensing are critical to successfully reducing opioid misuse and abuse. A 2016 Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain* reported that, "[w]hen opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no

greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed." (Ref. 3.) And a recent analysis showed that, across six studies of patients who had undergone a variety of surgical procedures, 67 percent to 92 percent of patients reported unused opioid analgesics. Moreover, "[r]ates of safe storage and/or disposal of unused opioids were low," resulting in an "important reservoir of unused opioids available for nonmedical use…." (Ref. 4). There are clinical situations that may require a supply of opioid analgesics that exceeds current CDC guidelines and FDA wants to make sure that patients have what they need in those cases. But FDA believes there are situations in which patients are prescribed an opioid analgesic when a non-opioid pain treatment would be adequate or, when an opioid product is necessary, treatment with a shorter course of therapy would be more appropriate, and without specific requirements, variance in prescribing habits are likely to persist.

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. Should FDA consider adding a recommended duration of treatment for specific types of patient needs (e.g., for specific types of surgical procedures) to opioid analgesic product labeling? Or, should FDA work with prescriber groups that could, in turn, develop expert guidelines on proper prescribing by indication?

2. If opioid product labeling contained recommended duration of treatment for certain common types of patient needs, how should this information be used by FDA, other state and Federal health agencies, providers, and other intermediaries, such as health plans and pharmacy benefit managers, as the basis for making sure that opioid drug dispensing more appropriately and consistently aligns with the type of patient need for which a prescription is being written?

3. Are there steps FDA should take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice?

4. Are there other steps that FDA should take to help promote the prescribing of treatment durations that are appropriately tailored to a clinical patient need?

III. Requirements for Prescriber Education

Recently, the option of mandating education or training for health care professionals who prescribe opioid medications has been more widely discussed[1], and some states already are, or are considering, mandating such prescriber education. For example, as of July 1, 2017, health care professionals in New York State who are licensed to prescribe controlled substances must complete, and register their completion of, at least 3 hours of course work or training in pain management, palliative care, and addiction (Ref. 5).

Specific questions on which FDA seeks comment relating to this topic are as follows:

1. Are there circumstances under which FDA should require some form of mandatory education for health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations, understand how to identify the risk of abuse in individual patients, know how to get patients with a substance use disorder into treatment, and know how to prescribe treatment for--and properly manage--patients with substance use disorders, among other educational goals? Are there other steps FDA could take to educate health care professionals to ensure that prescribing professionals are informed about appropriate prescribing and pain management recommendations?

[1] FDA acknowledges the Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee Meeting, held May 3-4, 2016, discussed mandatory education for health care professionals (Docket No. FDA-2016-N-0820).

2. How might FDA operationalize such a requirement if it were to pursue this policy goal? For example, should mandatory education apply to all prescribing health care professionals, or only a subset of prescribing health care professionals? If only a subset, how would FDA construct a framework that focuses mandatory education on only that subset--for example, by requiring mandatory education only for those writing prescriptions for longer durations as opposed to those for very short-term use?

3. What steps should FDA take to make implementing such mandatory education efficient and more feasible? For example, should FDA work collaboratively with state public health agencies, state licensing boards, provider organizations, such as medical specialty societies and health plans, or with other stakeholders, such as pharmacy benefit managers, to integrate or avoid duplicating their educational programs or requirements? What other steps might FDA consider to make implementation less burdensome and more effective?

IV. Additional Matters for Consideration:

1. What other steps should FDA take to operationalize the above described goals?

2. Are there additional policy steps FDA should consider relating to the OPSC that are not identified in this notice?

We invite interested parties to review these questions and submit comments to the docket for the OPSC to consider. In addition, we invite interested parties to submit additional policy considerations or recommendations for actions that FDA could or should undertake to help the Agency better address the opioid addiction crisis.

V. References

1. Gottlieb, Scott and J. Woodcock. "Marshaling FDA Benefit-Risk Expertise to Address the Current Opioid Abuse Epidemic." *Journal of the American Medical*

Association. 2017;318(5):421-422. Doi:10.1001/jama.2017.9205. Available at http://jamanetwork.com/journals/jama/fullarticle/2643333. Accessed August 2017.

2. National Academies of Sciences, Engineering, and Medicine. "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (2017), Consensus Study Report." Richard J. Bonnie, Morgan A. Ford, and Jonathan K. Phillips (eds.). Available at https://www.nap.edu/catalog/24781/pain-management-and-the-opioid-epidemic-balancing-societal-and-individual. Accessed August 2017.

3. Dowell, D., T. M. Haegerich, and R. Chou. "CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016." Item 6 in "Determining When to Initiate or Continue Opioids for Chronic Pain." *Morbidity and Mortality Weekly Report Recommendations and Reports* 2016;65(No. RR-1):1-49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1. Accessed August 2017.

4. Bicket, M. C., J. J. Long, P. J. Pronovost, et al. "Prescription Opioid analgesics Commonly Unused After Surgery, A Systematic Review." *JAMA Surgery*. Published online August 2, 2017. DOI:10.1001/jamasurg.2017.0831. Available at http://jamanetwork.com/journals/jamasurgery/fullarticle/2644905. Accessed August 2017.

5. New York State Department of Health, Mandatory Prescriber Education. Available at https://www.health.ny.gov/professionals/narcotic/mandatory_prescriber_education/. Accessed August 2017.

Dated: September 26, 2017.

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