



January 14, 2021

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

Docket FDA-2019-N-1845 for “Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain

Dear Sir/Madam:

On behalf of the American Association of Oral and Maxillofacial Surgeons (AAOMS), the professional association that represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States, I would like to offer comments on the Food and Drug Administration’s reopening of the comment period for the May 31, 2019 notice, entitled “Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain; Establishment of a Public Docket; Request for Comments.” The notice described the potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that certain solid, oral dosage forms of immediate-release (IR) opioid analgesics commonly prescribed for treatment of acute pain be made available in fixed-quantity unit-of-use blister packaging for outpatient dispensing.”

Oral and maxillofacial surgery is the surgical specialty of dentistry. As such, management of our patients’ pain following invasive procedures is an important aspect of providing the best quality patient care. As lawful prescribers, we know, when used appropriately, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from surgical procedures. We also recognize, however, that pain medication prescribed following oral and maxillofacial surgery is frequently the first exposure many American adolescents have to opioids, and roughly 6.4 percent of all immediate-release opioid prescriptions in the United States are related to dental procedures.<sup>1</sup> Dentists, including OMSs, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

AAOMS is committed to educating our membership about the potential for opioid abuse. We have, for example, developed opioid prescribing recommendations for the management of acute and postoperative pain for the OMS patient that urge non-narcotic pain management – rather than opioids – be utilized as a first-line therapy to manage a patient’s acute and post-surgical pain. We also routinely provide information and resources about opioid abuse to our membership, which have been used to

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<sup>1</sup> Gupta N, Vujicic M, Blatz A. Opioid prescribing practices from 2010 through 2015 among dentists in the United States. *JADA*. 2018; 149(4): 237-245.

educate patients and parents of adolescent patients on the use of non-narcotic, postoperative pain remedies. These education efforts appear to be working. AAOMS conducted a survey of a random selection of OMSs over a three-year period beginning in 2017, and the surveys showed a decline in the number of opioids being prescribed, with more than 93 percent of respondents prescribing less than a 3-day supply of opioids following third-molar extractions.

With respect to blister packaging, AAOMS representatives participated in one of the FDA's listening sessions on the topic in April 2020 and a number of our questions and concerns were discussed – most notably that all opioids might only be available in blister packs in fixed quantities. We were pleased to learn the FDA recognizes that prescriber judgement remains an important part of providing quality patient care, and thereby, the agency is not requiring blister packs to be the only packaging available for these products.

As a result, AAOMS supports the concept of utilizing blister packs for 5, 10 and 15 count increments as one of many means of encouraging appropriate prescribing. While many OMSs already prescribe within this range for various levels of procedures, blister pack amounts can provide guardrail reminders for OMSs when considering the appropriate amount. AAOMS also agrees with the FDA that blister packs have the opportunity to reduce serious – and potentially deadly – accidental exposure that may occur if a child is able to get access to the medication, because it is harder for a child to accidentally access and ingest more than one pill at a time in a blister pack when compared to a bottle.

AAOMS requests the FDA to consider the following issues as it moves forward with this topic:

- Some dental payers will not allow providers to prescribe more than 3 pills if utilizing a long-acting, local anesthetics such as Exparel®; therefore, AAOMS encourages FDA to consider requiring 3-count blister packs be made available for prescription.
- Blister packs may be more expensive to manufacture and AAOMS is concerned that such increases may be passed onto the patients, which would deter providers from prescribing them.
- Patients may believe that because blister packs are frequently utilized for z-packs in which they are instructed to take the full package. As a result, patients may incorrectly assume they need to take the entire contents of the package instead of only taking what is necessary. The larger packaging provides an opportunity for enhanced messaging; therefore, AAOMS encourages the FDA to require manufacturers of blister packs to include such educational messaging.
- Similarly, AAOMS also encourages blister pack labeling to remind patients to appropriately dispose of any unused medication. Patients may not associate the need to appropriately dispose of medication in a blister pack like they would a pill bottle.

Thank you for the opportunity to provide input on this important issue. Please contact Jeanne Tuerk, manager of government affairs, with any questions. Ms. Tuerk can be reached at 847-233-4321 or [jtuerk@aaoms.org](mailto:jtuerk@aaoms.org).

Sincerely,



B.D. Tiner, DDS, MD, FACS

AAOMS President