



May 31, 2022

U.S. Food and Drug Administration
Attn: Dockets Management Staff
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No: FDA-2022-N-0165, "Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments"

To Whom it May Concern:

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 thank you and your colleagues at the U.S. Food and Drug Administration (FDA) for your ongoing efforts to reduce opioid abuse in the United States. AAOMS appreciates the opportunity to comment in support of your proposed modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that mail-back envelopes be dispensed and education on safe disposal be provided with opioid analgesics dispensed in an outpatient setting.

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 pain to lead productive lives and recover more comfortably from surgical procedures; however, 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 and its members are very aware of the risks associated with exposure to opioids. AAOMS is constantly addressing the opioid epidemic with education of our membership, which has resulted in a significant reduction in OMS opioid prescribing patterns throughout the country. Because many of our patients are undergoing their first surgery and first experience with post operative pain, OMSs are committed to using the most effective means of managing pain with the least amount of harm.

Proper disposal of opioids to avoid the risk of diversion and potential abuse by nonpatients is also very important to OMSs. AAOMS encourages its members to promote the U.S. Drug Enforcement Administration's (DEA) National Prescription Drug Take Back Days to their patients and created a [Safe Use and Disposal of Prescription Medication handout](#) for OMSs to provide to patients regarding options for safe at-home disposal.

Mail-back programs are an additional tool to keep unused opioids out of the hands of those who may misuse them. As the FDA points out in the proposal, mail-back envelopes are free and particularly useful for homebound or rural patients who are unable to travel to a pharmacy or other designated drop off site to return their medication. Mail-back programs also may alleviate concerns by some patients that throwing medications in the garbage will have a negative impact on the environment. AAOMS agrees with the FDA's approach to require opioid manufacturers to provide the postage-paid envelopes and develop educational literature for patients so as minimize the logistical burden and financial expense associated with this requirement on outpatient pharmacies and other dispensing entities.

AAOMS's primary concern with a mail-back program is the possibility of tampering and diversion. Specifically, that individuals, including mail carriers, could identify the contents and intercept the package for personal use or sale instead of safely returning them to the designated location for final disposal. The FDA proposal, however, indicates that mail-back programs have existed for many years and that envelopes offered through the OA REMS program would comply with long-standing U.S. Postal Service and DEA regulations to ensure the drugs are safely and securely transported to a DEA-registered facility. As such, AAOMS believes the benefits of a mail-back program outweigh the low-risk potential for diversion.

Thank you for the opportunity to comment on this important issue. AAOMS is pleased to offer its support of the agency's proposal to amend the OA REMS program to require mail-back envelopes and education be offered to patients upon dispensing in the outpatient setting. Please contact Jeanne Tuerk, AAOMS Director of Government Affairs, at 800-822-6637, ext. 4321, or jtuerk@aaoms.org with questions or if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "J. David Johnson Jr. DDS". The signature is fluid and cursive, with the initials "J.D.J." clearly visible at the end.

J. David Johnson Jr., DDS
AAOMS President