



**American Association of Oral and Maxillofacial Surgeons**  
Oral and maxillofacial surgeons:  
The experts in face, mouth and jaw surgery®

9700 W. Bryn Mawr Ave.  
Rosemont, IL 60018-5701

847-678-6200  
800-822-6637  
fax 847-678-6286

AAOMS.org

Brett L. Ferguson, DDS, FACS  
President

Scott Farrell, MBA, CPA  
Executive Director

December 19, 2017

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

Re: No. FDA-2017-N-5608 for “Opioid Policy Steering Committee;  
Establishment of a Public Docket; Request for Comments

To Whom It May Concern:

On behalf of the more than 9,500 oral and maxillofacial surgeons in the United States, we applaud the FDA for its efforts to address the country’s prescription drug epidemic. We believe it is a significant public health issue and federal resources provide critical assistance to state and local communities. Furthermore, we recognize that dentists and physicians — as prescribers — can play an important role in reducing opioid misuse. We offer the following comments in response to the Sept. 29 request for comments to the Opioid Policy Steering Committee (OPSC).

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 that when used as prescribed, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from invasive surgical procedures. We also recognize that when opioids are prescribed following oral and maxillofacial surgery, this may be the first exposure many American adolescents have to opioids. 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 surgical procedures.

AAOMS believes that it would be most valuable and efficient to work with provider groups to develop proper prescribing instructions, rather than adding a recommended duration to the product label. Trying to include indications for all patient scenarios on a product label could be burdensome to the manufacturer, overlook certain patient care scenarios as well as unnecessarily limit pain relief and hinder patient care. The more prescriptive the labeling requirement are, the greater the risk of unintended consequences, including the potential denial by an insurance company, creating an unnecessary financial burden to the patient.

The FDA should continue to partner with professional organizations, including AAOMS. Many of these organizations have begun – or even completed – the process of developing prescribing recommendations for the types of patients their members treat. Additionally, the FDA should look to other government entities such as the National Institute on Drug Abuse: Medical and Health Professionals (NIDAMED) and the Substance Abuse and Mental Health Services Administration’s

(SAHMSA), which have already developed webinars and resources that are tailored to various clinical patient needs. AAOMS, for example, worked with NIDAMED to develop an educational course to help prescribers, including oral and maxillofacial surgeons, talk to adolescents about substance use and abuse. We also helped develop and encouraged our members to participate in SAMHSA online training on “Safe Opioid Prescribing for Acute Dental Pain.”

The training received during and after their residencies implicitly qualifies OMSs to manage their patients’ pain, based on careful evaluation of the patient’s condition, treatment and severity of the procedure. AAOMS does urge our members to be aware of public health trends that may impact patient care and encourages voluntary provider participation in continuing education (CE) programs that focus on drug abuse and responsible prescribing practices. As previously noted, AAOMS worked with NIDAMED and SAHMSA to develop and promote CE content pertaining to specific prescribing scenarios. The FDA should work with these organizations, and others to educate patients and the public at large about opioid abuse and diversion. AAOMS supports such collaborative education efforts that include governmental agencies, non-profit organizations and prescriber organizations.

AAOMS believes that to be most effective, CE should be managed at the state level, where licensure is granted. Currently, 27 states require CE on the topic of opioid prescribing as part of a dentist’s overall CE requirements and more states are expected to follow in the coming years. AAOMS also believes it should be appropriately proportionate to other CE requirements and be customized so that it is relevant to each type of prescribing situation. As a credential provider of both Continuing Dental Education and Continuing Medical Education, AAOMS believes that we should be included as an accepted practitioner training organization. Finally, there remains a need beyond prescriber CE to educate patients and the public at large about opioid abuse and diversion. AAOMS supports such collaborative education efforts that include governmental agencies, non-profit organizations and prescriber organizations.

AAOMS also supports the development of prescribing guidelines. In 2017, AAOMS released the white paper “Opioid Prescribing: Acute and Postoperative Pain Management,” and we encourage all OMSs to consult this document for the management of acute and postoperative pain. As described in the document, we recommend that nonsteroidal anti-inflammatory drugs (NSAIDs) — rather than opioids — be utilized as a first-line therapy to manage a patient’s acute and post-surgical pain. AAOMS also recognizes and encourages our members who provide chronic pain management to consider the *CDC Guideline for Prescribing Opioids for Chronic Pain*. AAOMS further supports efforts that instruct all practitioners, including residents, to calculate the total morphine milligram equivalents prescribed to a patient to ensure safe prescribing. If government entities seek to develop prescribing guidelines, we encourage them to recognize the unique care provided by OMSs by involving them in the development process and to avoid a one-size-fits all approach, as pain management needs vary not only from patient to patient, but to the uniqueness of their surgical procedure.

AAOMS actively supported a provision in the recently enacted Comprehensive Addiction and Recovery Act (P.L. 114-198), which clarifies federal law to allow for patients to partially fill prescriptions for schedule II drugs, which includes opioids. This provision helps to provide patients with access to necessary pain relief while reducing the existence of unused medication in medicine cabinets, thus helping to curb the incidence of drug diversion. If appropriate, the FDA should work with stakeholder groups including the U.S. Drug Enforcement Administration (DEA), state legislative and regulatory bodies, pharmacies, and health information technology companies to remove any barriers that preclude states from fully implementing this law.

AAOMS welcomes the opportunity to dialogue with the FDA on potential solutions to the opioid abuse problem and its impact on our patients and our practice. If there is anything AAOMS can do to assist you on this issue, please contact Ms. Jeanne Tuerk of the AAOMS Governmental Affairs Department at 847-233-4321 or [jtuerk@aaoms.org](mailto:jtuerk@aaoms.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Brett L. Ferguson". The signature is written in a cursive style with a large, stylized initial "B".

Brett L. Ferguson, DDS, FACS  
President