



American Association of Oral and Maxillofacial Surgeons

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June 1, 2014

Center for Drug Evaluation and Research
Food and Drug Administration
Division of Dockets Management (HFA-301)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0233

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 commend the FDA for its efforts to stem the nonmedical use and abuse of prescription opioid analgesic drugs.

We are pleased to respond in particular to the FDA's request for information on innovative packaging, storage, and disposal systems, technologies or designs that could be used to prevent or deter misuse and abuse of opioid analgesics as published in the April 9, 2014 *Federal Register*.

We absolutely agree that the nonmedical use of prescription pain relievers is a matter of significant public health concern. The AAOMS believes that approaches by concerned legislative and regulatory bodies to address opioid abuse, which focus on prescribing restrictions such as reclassification of hydrocodone-containing products, hinder access to relief for patients suffering with legitimate pain needs. On the contrary, further emphasis on the development of innovative designs for opioid analgesic packaging, storage, and/or disposal systems could significantly help prevent or deter misuse and abuse of prescription painkillers without diminishing access for patients with legitimate prescriptions. We encourage the FDA to make such a focus a primary tool in the efforts to combat prescription drug abuse/misuse and submit the following comments regarding disposal systems that could be used to prevent or deter misuse and abuse of opioid analgesics.

The AAOMS has been a strong supporter of and has educated our members on the Medicine Abuse Project (MAP), which is an action campaign that aims to prevent teens from abusing medicine by providing comprehensive resources to parents and caregivers, law enforcement officials, health care providers, educators and others to help end medicine abuse. With regard to prescription drug disposal systems, the MAP has done an exemplary job in promoting the Drug Enforcement Administration's (DEA) national drug "Take Back" programs, which are designed to help households properly dispose of unused prescription drugs. AAOMS members, in turn, have

encouraged our patients to dispose of their unused prescriptions on those “Take Back” program days. However, the DEA’s programs are not permanent or ongoing and are typically only held once or twice a year. So, while Take Back days are an innovative and highly effective way to prevent or deter misuse and abuse of opioid analgesics, patients must hold onto their unused drugs for months at a time until the next Take Back day, which increases the susceptibility of the drugs being diverted or misused.

We submit that Take Back programs should be expanded, as year-round Take Back programs would ensure that there is constant access to safe disposal of unwanted and expired medicines. One such example is already in place at the local level. In April of 2014, the city of Naperville, Illinois affixed secure prescription drug drop boxes to 10 of its fire stations, providing for the safe and anonymous disposal of unused prescription drugs on a 24-hour, seven days a week basis. This type of disposal system could help stymie one of the main origins of prescription drug abuse, which, as FDA notes, is the availability of unused prescription drugs in home medicine cabinets. We believe that at the very least, Take Back days and prescription drug drop boxes would go a long way toward mitigating opioid misuse, abuse, and addiction and limit access to medication by someone for whom it was not prescribed. We advocate that FDA work to encourage and help local communities find funding to implement similar programs in cities and towns across the country.

We welcome opportunities to work with the FDA to explore other possible solutions to curb the misuse and abuse of prescription drugs. Please contact Jeanne Tuerk, manager of the AAOMS Department of Governmental Affairs at 800/822-6637 or jtuerk@aaoms.org for questions or additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Geist". The signature is fluid and cursive, with a long horizontal stroke at the end.

Eric T. Geist, DDS
President