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American Association of Oral and Maxillofacial Surgeons

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March 12, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Request for Comments; Docket No. FDA–2013–N–0124; Federal Register Vol. 78, No. 29, February 12, 2013, page 9928

Dear Sir or Madam:

On behalf of the 9,500 fellows and members of the American Association of Oral and Maxillofacial Surgeons (AAOMS), I thank you for the opportunity to provide comments to the FDA regarding drug and biological product shortages and the Drug Shortages Task Force strategic plan.

Oral and maxillofacial surgeons (OMSs) are the surgical specialists of the dental profession. Their extensive education and training, surgical expertise and unparalleled understanding of esthetics and function uniquely qualify them to treat the conditions, defects, injuries and esthetic aspects of the mouth, teeth, jaws and face. Patients who complain of pain or problems in this area are routinely referred to an oral and maxillofacial surgeon for help. Accordingly, OMSs routinely prescribe drugs to patients that are in chronic shortage. This includes sedatives, anesthetics, analgesics and anti-inflammatory drugs. Drugs such as propofol, dexamethasone, meperidine, fentanyl, lorazepam, midazolam and morphine have been in dangerously short supply and are badly needed to help dentists manage pain, infection and anxiety in their patients.

The AAOMS submits the following in response to the request for comments published in the February 12, 2013 *Federal Register* notice.

1. New ideas to encourage high-quality manufacturing and to facilitate expansion of manufacturing capacity.

We do not submit a response to this question.

2. Incentives other Agencies can provide, separately or in partnership with FDA, to prevent shortages.

As required in the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144), we believe that it's imperative for the FDA to work in partnership with the US Drug Enforcement Agency to ensure that quota restrictions do not stand in the way of obtaining access to controlled substances that are in shortage. We encourage the FDA to recognize the process for such collaboration in its strategic plan.

3. Are there changes to existing tools that FDA can make to improve their utility in managing shortages? Are there other actions that FDA can take under its existing authority to address impending shortages?

We urge the FDA to continue to allow importation from additional non-US drug manufacturers when shortages occur, at least until sufficient supplies are restored to meet demand.

4. Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to FDA's public shortage Web sites that would help enhance their utility for patients, prescribers, and others in managing shortages?

We support FDASIA's requirement that the FDA establish a mechanism for health care providers to report evidence of a drug shortage. A third-party reporting system may help identify shortages that have previously gone unreported by manufacturers and may help FDA expedite the resolution of a particular shortage. We encourage the FDA to make this system accessible and as user-friendly as possible to so as to facilitate participation by all parties.

Additionally, concurrent with the announcement of anticipated shortages, the FDA should provide information about available alternatives, including the drug regimen for specific scenarios, e.g., procedural sedation, ICU.

5. What impact do drug and biological product shortages have on research and clinical trials? What actions can FDA take to mitigate any negative impact of shortages on research and clinical trials?

We do not submit a response to this question.

6. What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

As the FDA provides opportunities for stakeholder input perhaps through a formal advisory committee process, the AAOMS encourages the FDA to allow for adequate participation by the dental community, in particular the oral and maxillofacial surgery community, as we've been uniquely affected by the increasing shortage of drugs.

Thank you again for allowing AAOMS the opportunity to submit the above comments on drug shortages. If you have questions or wish additional information, please contact Ms. Jeanne Tuerk, manager of the AAOMS Department of Governmental Affairs, at 800/822-6637, ext. 4321 or jtuerk@aaoms.org.

Sincerely,

Miro A. Pavelka, DDS, MSD
President