

February 23, 2018

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: National Shortages of Lidocaine with Epinephrine, Lidocaine, and Other Local Anesthetics

Dear Dr. Gottlieb:

The undersigned organizations collectively treat millions of patients who are currently battling or who have fought serious, chronic, and life-threatening diseases. We write to express our concern regarding the ongoing national shortages of lidocaine with epinephrine, lidocaine, and other local anesthetics. These shortages continue to plague physicians and their patients as our members across the country have reported unavailability and difficulty obtaining needed local anesthetics. Manufacturers and suppliers are filling backorders at an unpredictable and slow pace. Physicians are running out of their stocks before they can obtain replacements. We ask that the FDA take immediate action to address these critical shortages.

We are very concerned about the adverse impact these shortages have on our patients. Lidocaine with epinephrine is used for example, in biopsies, skin cancer surgery, cataract surgery, tooth extractions, periodontal surgeries, and a variety of ear, nasal, and oral cavity procedures. Additionally, because of this shortage, physicians and dentists are having to use these drugs sparingly and are facing disrupted workflows. Physicians and dentists worry about uncontrolled intraoperative bleeding without having access to epinephrine. Increased bleeding can lead to an obscured operative site which forces physicians to delay surgeries. Intraoperative bleeding can also increase the risk of postoperative bleeding. This critical drug shortage is a threat to patient safety especially as it can lead to other costly complications when the drug is not accessible for these procedures.

The only ways to obtain any information regarding the matter are to check the FDA drug shortage website or contact the drug manufacturer or supplier directly. The resupply dates continue to be pushed back with little explanation and it is especially concerning as more and more physicians run out of their supplies. The suppliers receive unpredictable shipments of the drug from manufacturers and fill it on a first-come, first-serve basis or however they choose to prioritize customers, but are unable to keep up with the backorders. The alternatives to lidocaine with epinephrine are limited and often cost prohibitive. Given the small number of manufacturers producing the drug and that some have stopped producing it all together, we anticipate that this situation will worsen and repeat.

The undersigned organizations recognize that shortages occur for a variety of reasons such as difficulty accessing raw materials or increased demand. The undersigned organizations supported language included in the recently passed FDA Reauthorization Act of 2017, which would accelerate the approval of generic drug applications when there is a shortage. With a multifactorial issue such as drug shortages, there is still more to be done. We ask that the FDA:

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- Create incentives for manufacturers to produce lidocaine with epinephrine and other local anesthetics during a shortage;
- Allow temporary importation of lidocaine with epinephrine due to the severe backlog of orders;
- Issue a formal response to address the shortage of critical drugs such as in this case;
- Have a main point of contact for national shortages of specific drugs;
- Provide regular updates to the public regarding the status of a national shortage;
- Require manufacturers to have plans in place to deal with production issues or delays.
- Monitor the prices of generic drugs during and after a shortage

We would also like to request a call with the FDA drug shortages team in the near future to discuss this critical shortage. Provider associations frequently become aware of shortages early on, know when it escalates, and can be a resource to the FDA. Overall, there is a need for greater transparency regarding what the FDA is doing to address drug shortages. We hope that the FDA will work with the manufacturers to resolve this shortage quickly for the sake of the safety of and access for our patients. Thank you for your attention to our concerns.

Sincerely,

American Academy of Dermatology Association

American Academy of Ophthalmology

American Academy of Otolaryngology—Head and Neck Surgery

American College of Mohs Surgery

American Dental Association

American Society for Dermatologic Surgery Association

American Society for Mohs Surgery

Women's Dermatologic Society