



April 29, 2024

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
H-232
U.S. Capitol
Washington, D.C. 20515

The Honorable Charles Schumer
Majority Leader
U.S. Senate
S-221
U.S. Capitol
Washington, D.C. 20510

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
H-204
U.S. Capitol
Washington, D.C. 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
S-230
U.S. Capitol
Washington, D.C. 20510

RE: Please prioritize drug shortages in the 118th Congress

Dear Speaker Johnson, Majority Leader Schumer as well as Minority Leaders McConnell and Jeffries:

On behalf of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which represents more 9,000 oral and maxillofacial surgeons (OMSs) in the United States, I urge you to pass legislation to address the nation's ongoing drug shortages before the 118th Congress adjourns.

OMSs are surgically and medically trained dental specialists who treat conditions, defects, injuries and esthetic aspects of the mouth, teeth, jaws, neck and face. After earning a dental degree from an accredited four-year dental school, OMSs complete a minimum of four years of hospital-based oral and maxillofacial surgery residency training, which includes rotations in such areas as general surgery, anesthesia, and clinical research.

As the surgical branch of dentistry – and the bridge to medical colleagues – OMSs provide vital services that are urgent, emergent and outpatient in nature. Most OMS offices function as small, independent operatories with OMSs who diagnose and treat conditions related to the maxillofacial complex. They provide office-based sedation and anesthesia on a daily basis to patients who would otherwise not tolerate treatment outside a hospital operating room.

OMSs are particularly prone to pharmaceutical shortages given their unique skillset and largely independent practice status. OMSs need access to pharmacologics but have experienced shortages of anesthetics, analgesics, antibiotics, antiemetics, emergency medications (e.g. epinephrine, ephedrine, glycopyrrolate, atropine, adenosine) and saline, just to name a few. When such medications are unavailable – or available at significantly elevated prices, as is typical during shortage periods – OMSs cannot offer the same high level of care to patients, significantly impacting the healthcare system.

As you are aware, drug shortages are due to many factors, including regulatory issues with the FDA, manufacturing delays, production quality concerns, shipping issues (both domestic and international), company mergers and lack of profitability to produce. Reduced access to these vital pharmaceuticals has a significant impact on patient care, as alternative drugs may be more expensive or produce other untoward side effects.

Despite past congressional action, the number of ongoing and active shortages has reached a new all-time high.¹ Therefore, Congress needs to prioritize the passage of additional legislative solutions.

While a number of bills have been introduced in the 118th Congress to address drug shortages, AAOMS particularly supports the RAPID Reserve Act (S 2510/HR 6802). This bipartisan bill seeks to incentivize American-based generic drug manufacturers to increase domestic production, build reserves for potential health crises, and boost production capacity to prevent shortages. The bill is endorsed by the American Hospital Association and the American Society of Health-System Pharmacists, among others.

AAOMS also supports other proposed legislative measures to alleviate or prevent shortages, including: establishing a comprehensive database to track the entire pharmaceutical supply chain (S 2364/HR 6992); requiring manufacturers to notify the FDA of heightened demand for crucial medicines that could lead to shortages (S 2362/HR 3008); implementing reimbursement models to incentivize the production of generic injectables and extending expiration dates for life-saving medications (S 2586).

AAOMS also requests consideration of these other potential solutions:

- Require enhanced coordination between the Department of Health and Human Services and the Department of Justice to increase production quotas and remove regulations that make it difficult for manufacturers to adapt to market shifts.
- Mandate a congressional study on the impact of establishing a nonprofit entity to assist office-based professionals in securing pharmacologics during shortages, similar to Civica Rx, which is currently serving several hospital systems. Civica Rx identifies drugs that have been on shortage lists in the past, or that have had substantial price increases because of the competitive marketplace dynamic and manufactures those drugs to offset market inadequacies.

¹ American Society of Health-System Pharmacists. <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly>. Accessed April 2024.

Patients should not have to wait any longer for access to life-saving medications and those that enable providers to deliver optimal care. Please contact Jeanne Tuerk, AAOMS Director of Government Affairs with any questions at 800-822-6637, ext. 4321 or jtuerk@aaoms.org.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Egbert, DDS, FACS". The signature is written in a cursive style with a large, stylized initial "M".

Mark A. Egbert, DDS, FACS
AAOMS President