

Oral and maxillofacial surgeons:
The experts in face, mouth and
jaw surgery®



American Association of Oral and Maxillofacial Surgeons

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The Honorable Cathy McMorris Rogers
Chair, House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20003

Dear Chair Rogers:

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, we appreciate and support your consideration of additional legislative strategies to address the nation's ongoing drug shortages.

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.

Ongoing and active shortages are the highest in a decade.¹ These shortages are due to many factors, including regulatory issues with the FDA, manufacturing delays and 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.

As you are well aware, the solution to pharmaceutical shortages is complex and requires a multifaceted approach. The Food and Drug Administration Safety and Innovation Act, comprehensive federal legislation to address drug shortages signed into law in 2012, required enhanced reporting by drug manufacturers when they anticipated a manufacturing interruption and discontinuance.² Legislation enacted last year as part of the Consolidated Appropriations Act of 2023³ also included a number of provisions to address drug shortages, which AAOMS supported.

AAOMS is pleased to see that your draft framework takes additional steps to identify and address some of the root causes of shortages, particularly among generic injectable drugs, which OMSs rely on. As you move forward, we also respectfully request the Committee consider two additional approaches:

- 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.

Thank you for your leadership on these important issues. AAOMS welcomes the opportunity to work with you to advance this important legislation. Please contact Jeanne Tuerk, AAOMS Director of Government Affairs, at 800- 822-6637, ext. 4321, or jtuerk@aaoms.org.

Sincerely,



Paul J. Schwartz, DMD
AAOMS President

¹ American Society of Health-System Pharmacists. [ASHP.org/drug-shortages/shortage-resources/%20drug-shortages-statistics?loginreturnUrl=SSOCheckOnly](https://www.ashp.org/drug-shortages/shortage-resources/%20drug-shortages-statistics?loginreturnUrl=SSOCheckOnly). Accessed August 2023.

² Food and Drug Administration Safety and Innovation Act (P.L. 112-144). <https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf>

³ Consolidated Appropriations Act of 2023 (P.L. 117-73). <https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf>