Senate Passes Language on Drug Shortage Issue

On June 26, the United States Senate passed the *Food and Drug Administration Safety and Innovation Act* (S. 3187) by a vote of 92 to 4. The House had passed S. 3187 on June 20. This is the final version of S. 3187 which is a compromise between House and Senate negotiators who worked out the differences between the two respective FDA bills. The President is expected to sign the bill into law.

The bill would reauthorize the ability of the Food and Drug Administration (FDA) to collect user fees which partially fund its review of drugs and medical devices. Of importance to EMS, the legislation would also make several changes to FDA regulations including language intended to address current drug shortages. Below is a summary of the provisions on drug shortages.

Section 1001 would modify existing reporting requirements for manufacturers of drugs that are life-supporting, life-sustaining, and intended for use in the prevention or treatment of a debilitating disease or condition, including those used in emergency medical care or surgery. The section would authorize the Secretary to expedite establishment inspections and review of supplements and applications that could help mitigate or prevent a "shortage," as defined in this title. It would authorize the Secretary to apply this section, by regulation, to biological products, although the Secretary must consider if the notification requirement for vaccines could be met through the CDC vaccine shortage notification program.

Section 1002 would require the Secretary to establish a task force to enhance the Secretary's response to shortages, and create a strategic plan to address stated aspects of shortages.

Section 1003 would require FDA to maintain a drug shortage list and provide patients, providers and the public with such information in order to prevent, mitigate, and manage drug shortages on the ground. The bill includes safeguards that would prevent the release of confidential business information or information that could adversely affect public health.

Section 1004 would require the Drug Enforcement Administration (DEA) to provide timely approvals or denials of increases in quotas of controlled substances in instances where such an increase could help address a drug shortage.

Section 1005 would require DEA to report annually on their efforts on drugs shortages based on the metrics set forth by Congress.

Section 1006 would allow hospitals within the same health system to repackage drugs into smaller units to alleviate drug shortages.

Section 1007 would authorize GAO to conduct a study to examine the causes of drug shortages and issue recommendations on how to prevent or alleviate a drug shortage. This provision would provide needed data on how the regulatory framework, manufacturing challenges, or other factors contribute to drug shortages, as well as recommendations to address such issues.

We will let you know when the President has signed S. 3187 into law.