ENDOCRINE SOCIETY
Hormone Science to Health

August 22, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy & Commerce Committee
2125 Rayburn HOB
Washington, DC 20515

Dear Chair Rodgers:

On behalf of the Endocrine Society, thank you for the opportunity to provide feedback on the Stop Drug Shortages Act. Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, infertility, obesity, osteoporosis, endocrine tumors and cancers (i.e., thyroid, adrenal, ovarian, pituitary), and thyroid disease.

Our membership includes over 11,000 clinicians who prescribe medications that are currently in shortage or have been in shortage in recent months. The Society is particularly concerned about these shortages because of the impact they have on patients' access to standard of care therapies. Within endocrinology, there are several drugs that have been placed on the shortage list recently including GLP-1 medications approved to treat type 2 diabetes and obesity, growth hormone medications, and chemotherapies.

The lack of access to these medications creates major disruptions in care that can have a life-or-death impact on the patients we serve. The impact of shortages is even more severe in rural communities where patients must travel significant distances to receive care and may not have access to academic medical centers that may have the most abundant supply of drugs in shortage. Additionally, these shortages can impact the important work being done in clinical trials where participants are receiving these medications to determine improved courses of treatment. These reasons all point to the critical need for Congress to address this problem now. While legislative action will not end the current shortages, we are hopeful it will prevent future shortages. We appreciate your work on this legislation and your efforts to address this issue. However, drug shortages impact all Americans. Given the widespread impact these shortages have had across the country, we encourage you to work with your colleagues “across the aisle” to pass comprehensive bipartisan legislation addressing drug shortages.

The Society has discussed these shortages with both the Food and Drug Administration (FDA) Office of Drug Shortages and the manufacturers. Despite these conversations, it is unclear what is causing this problem. There are many distinct reasons for a drug shortage including increased demand, supply chain issues, or a problem at a specific manufacturing facility. Knowing the cause of a shortage will help the appropriate stakeholders resolve the problem expeditiously. For our members, having a better understanding of a shortage’s cause will help to better inform them in the treatment of their patients. Unfortunately, the legislation you have drafted does not provide FDA with additional authorities to require more robust reporting on a shortage’s cause—supply or demand, expected duration, or provide detail on the active pharmaceutical ingredients that may be included in the drug in shortage. We encourage the committee to

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add stronger manufacturer reporting requirements and guardrails to this legislation to better inform the public and prevent future shortages from occurring.

As you know, the FDA is required to post information on its website pertaining to current and resolved drug shortages. This information is reported to the FDA by the manufacturers of the medications. Manufacturers are also required to disclose the reason for the shortage, but the information provided is not actionable for providers and patients in many cases. There is also a lack of transparency provided to the public on why these shortages occur. We believe providing the FDA with authority to require manufacturers to report the information mentioned previously would allow the public to better understand why a shortage or discontinuation has occurred, potentially reducing the anxiety that many patients experience when faced with a shortage of their prescribed medications. Physicians and patients deserve to have the most up to date information to make the best decisions on an appropriate care plan.

The discussion draft includes provisions to provide flexibility and increased reimbursement to manufacturers. These flexibilities include exemptions for certain drugs from increases in rebates and exempting some generic and sterile injectable drugs from the 340B Drug Discount Program. We appreciate the committee's efforts to find novel ways to incentivize manufacturers to prevent these shortages. However, there is no requirement that these flexibilities and increased reimbursements be used to invest in improved manufacturing practices to support the production of higher quality drugs. The Society believes that any incentives provided to manufacturers should be tied to manufacturers' actions to improve the resiliency of the supply chain. Additionally, we urge you to provide the FDA with more resources to help them prevent future shortages. For example, providing funding that would support the manufacturing of high-quality drugs would be a worthwhile investment to prevent future shortages.

Thank you again for the opportunity to provide feedback on this legislation. This is a critical issue for our members, and we look forward to continuing to work with you to address this problem. If you have any questions, please reach out to Rob Goldsmith at rgoldsmith@endocrine.org.

Sincerely,

Stephen R Hammes, M.D., Ph.D.
President
Endocrine Society