S.296 - Preserving Access to Life-Saving Medications Act
(Brief Summary)

The purpose of the legislation is to amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration (FDA) with improved capacity to prevent drug shortages.

Section 1 – Short Title

- Preserving Access to Life-Saving Medications Act

Section 2 – Drug Shortages

- Defines the terms "drug shortage" and "shortage" as the "period of time when the total supply of all version of a drug available at the user level will not meet current demand for the drug at the user level."
- Requires notification by drug manufacturers to the FDA of a discontinuation, interruption, or adjustment to the production of a specific drug that would result in a shortage. The definition of "drug" does not include biologics.
- Requires that the manufacturer notify the secretary 6 months in advance of any discontinuation or planned interruption or other adjustment. If the interruption or adjustment is not planned, the manufacturer must provide notification as soon as practicable after becoming aware.
- Instructs the Secretary, within 180 days of enactment, to issue regulations that include civil monetary penalties for failure to comply.
- Requires public notification by the Secretary of adjustments while ensuring the confidentiality of manufacturers' proprietary information.
- Instructs the Secretary to proactively identify which drugs could potentially come into shortage. Once a drug has been identified to be susceptible to shortage, the Secretary must work with the manufacturer to establish and improve continuity of operations plans for addressing drug shortages of any medically necessary drugs.

Section 3 – Manufacturer Review

- If an establishment fails an inspection, the Secretary must conduct a re-inspection within 90 days after the establishment certifies that the issue for the failure has been corrected. The secretary will prioritize these re-inspections based on whether the establishment could be involved in a drug shortage.

Section 4 – Reports to Congress

- Once a year, the Secretary of Health and Human Services shall submit to Congress a report that describes the actions taken by such Secretary during the previous 1-year period to address drug shortages.