



September 26, 2024

The Honorable Chairman Bernie Sanders
Senate Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ranking Member Bill Cassidy, M.D.
Senate Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

Re: September 26, 2024 Markups of S. 2305 and S. 2780.

Dear Chairman Sanders and Ranking Member Cassidy:

Thank you for holding this markup of S. 2305 and S. 2780. We strongly support the Biosimilar Red Tape Elimination Act (S. 2305) and the Medication Affordability and Patent Integrity Act (S. 2780).

The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies. Therefore, we want to highlight the bills that would have a significant impact on the practice of pharmacy.

Bills ASHP Supports:

Biosimilar Red Tape Elimination Act (S. 2305): Despite a determination by the Food and Drug Administration (FDA) that a biosimilar has "no clinically meaningful differences" between the biological product and the reference product in terms of the safety, purity, and potency of the product, redundant switching studies must be performed for a product to be determined interchangeable. These studies delay biosimilars from coming market and frustrate patients' ability to access these lower cost biosimilar products, despite FDA's determination that the product is safe and effective. The Biosimilar Red Tape Elimination Act eliminates the requirement for switching studies, making a biosimilar interchangeable with its reference product upon approval by the FDA. This will allow pharmacists to dispense these safe and effective products to patients at lower costs than their reference products.

Medication Affordability and Patent Integrity Act (S. 2780): Manufacturers are currently able to unfairly secure extensions of their market exclusivity for medications by submitting potentially inconsistent information to FDA and the U.S. Patent and Trademark Office (USPTO). The Medication Affordability and Patent Integrity Act will require manufacturers to certify that they have not made inconsistent statements to FDA and USPTO.

ASHP thanks you for your work on these bills. We look forward to continuing to work with you on this legislation as it moves forward to the Senate floor. If you have questions or if ASHP can assist the caucus in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'Tom Kraus', with a stylized, flowing script.

Tom Kraus
American Society of Health-System Pharmacists
Vice President, Government Relations