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August 1, 2019

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
317 Russell Senate Office Building  
Washington, D.C. 20510

The Honorable Charles E. Schumer  
Minority Leader  
U.S. Senate  
322 Hart Senate Office Building  
Washington, DC 20510

Dear Majority Leader McConnell and Minority Leader Schumer:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, wrote to you and your fellow senators on July 18 urging you to oppose S. 1895, the Lower Health Care Costs Act, unless the legislation is amended to exclude sections 211 and 213.<sup>1</sup> We also want to draw specific attention to another concerning provision in S. 1895 — section 207 (Biological product innovation) — that would threaten patient safety by excluding biologic medicines from the requirement that all medicines marketed in the U.S. adhere to quality standards established by the United States Pharmacopeia (USP). We therefore urge you to oppose the legislation unless it is amended to exclude this section, in addition to sections 211 and 213.

USP standards for decades have been, and should remain, a foundational element in the framework ensuring that medicines in the U.S. are produced in accordance with the highest quality standards in the world. As the USP explained in its June 11 letter to the Senate Committee on Health, Education, Labor and Pensions,<sup>2</sup> adherence to quality standards that are public and transparent gives health care practitioners, patients and others confidence in biologic medicines. USP's public quality standards are developed by over 1,000 scientific experts from the practitioner, industry, academic, public health, and regulatory communities and are well-established and broadly trusted.

If section 207 is adopted, public quality standards would not be required for a broad range of biologic medicines, including insulin, jeopardizing medicine uniformity and quality, and threatening the health of patients who have a wide range of conditions, including diabetes, cancer, hepatitis, and autoimmune disorders. It also would remove independent scientific experts from the standards process and allow quality standards for these vital biologic medicines to be kept secret by the government.

For these reasons, we urge you to oppose S. 1895 unless the legislation is amended to exclude section 207, in addition to sections 211 and 213. Sections 214 and 215 would represent modest steps forward toward lowering prescription drug prices and increasing transparency, but safety need not and must not be jeopardized as legislators pursue these efforts.

Thank you for considering our views on this important public health matter.

Sincerely,

Michael Carome, M.D.  
Director  
Public Citizen's Health Research Group

cc: U.S. Senators

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<sup>1</sup> <https://www.citizen.org/wp-content/uploads/2484.pdf>

<sup>2</sup> [https://www.citizen.org/wp-content/uploads/USP-Letter-Opposing-Section-207-of-S-1895\\_June-11-2019.pdf](https://www.citizen.org/wp-content/uploads/USP-Letter-Opposing-Section-207-of-S-1895_June-11-2019.pdf)