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Dear Members of the United States Senate:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully urges you to oppose S. 1895, the Lower Health Care Costs Act, unless the legislation is amended to exclude sections 211 (Prompt approval of drugs related to safety information) and 213 (Modernizing the labeling of certain generic drugs). Although we appreciate the modest provisions in the legislation aimed at lowering drug prices and increasing transparency, especially sections 214 and 215, the provisions of sections 211 and 213 would weaken existing requirements for ensuring that generic drugs approved by the Food and Drug Administration (FDA) are safe and effective for their FDA-approved uses.

Regarding section 211, it is our understanding that the provisions of this section would allow the FDA to approve a generic version of a drug not blocked by any existing exclusivity (i.e., the originator reference product has already lost its exclusivity with respect to one or more of its original FDA-approved indications) but for which more expansive safety information may be available from clinical trials that qualified the drug for additional exclusivity that does not apply to the generic drug being approved and its proposed indication. For example, if a company is seeking approval of a generic drug for indication A, but there are remaining orphan drug exclusivity protections on indication B for the originator reference product, section 211 apparently would allow the FDA to approve that generic drug for indication A with product labeling that omits safety information that is derived from studies relied on for the originator reference product to receive approval for indication B.

Allowing the omission of any safety information that may relate to a drug's contraindications, warnings, precautions, dosing, administration, or other information pertaining to safety for the generic drug could undermine public health and should not be permitted. Section 211's provision mandating that the Secretary require for such a generic drug a statement in the product labeling of any appropriate safety information that the Secretary considers necessary to assure safe use is an inadequate safeguard. A much simpler and more sensible approach to protecting patients would be to exempt safety information included in the product labeling of any generic drug from marketing exclusivity protections.

Regarding section 213, we have three major objections. First, despite the rules of construction stating that this section "shall not be construed as altering the applicability of the standards for approval of an application under section 505" of the Food, Drug, and Cosmetic Act, the provisions in this section would create a new regulatory pathway for FDA approval of new indications for certain existing FDA-approved generic drugs that bypasses the far more rigorous supplemental new drug application process currently required for such approvals.

Second, section 213 would create a slow and cumbersome process for updating safety information in the labeling of generic drug products. The FDA under its current statutory authority can order generic drug manufacturers to immediately update the labeling of their

products with respect to the drugs' contraindications, warnings, precautions, dosing, administration, or any other pertinent safety information. In contrast, the process that would be authorized under section 213 would (a) require FDA notification to the holders of approved applications for a generic version of a covered drug about requested safety information changes in the drug's product labeling and the scientific evidence for those changes; (b) provide a 30-day period for the holder to respond to the FDA's notification and either agree to the requested labeling changes or notify the FDA that the holder does not believe the requested labeling changes are warranted; and (c) require the FDA to review the holder's response and, if the agency disagrees with the holder's assertion that the requested changes are not warranted, provide an opportunity for discussions between the agency and the holder to reach an agreement on whether labeling should be updated. After these steps, the FDA may order the holder to make the labeling changes. Such a process could be lengthy and would delay the implementation of important safety updates in generic drug labeling that would better protect patients.

Lastly, a pathway for updating generic drug labeling is woefully incomplete if it does not facilitate updates to safety labeling. Currently, the FDA does not allow generic drug manufacturers to initiate safety updates when they become aware of new risks, though brand-name manufacturers have long had that ability and responsibility. Although in 2013 the FDA proposed a new rule to correct that safety gap, the rule was not finalized and was later withdrawn by the current administration. We urge you to include in S. 1895 a provision instructing the FDA to re-propose and promptly finalize a rule to allow generic drug manufacturers to update safety labeling.

For these reasons, we urge you to oppose S. 1895 unless the legislation is amended to exclude sections 211 and 213. Additionally, we urge you to support amending the legislation to include a new section that would provide generic drug manufacturers the ability to promptly initiate labeling updates to warn patients and physicians of newly discovered risks.

Thank you for considering our views on these important matters.

Sincerely,

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