PHARMACEUTICAL RESEARCH AND TRANSPARENCY ACT OF 2022

INTRODUCED BY:
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The Pharmaceutical Research and Transparency Act of 2022 (the Research and Transparency Act) would amend the Public Health Service Act and the Securities Exchange Act to increase public transparency into the costs of pharmaceutical research.

Pharmaceutical companies frequently cite research and development (R&D) expenditures to justify their high prescription drug prices, despite data suggesting that companies' high prices far exceed the amounts necessary to fund R&D. The Research and Transparency Act would require drug companies to report overall R&D expenditures as well as disaggregated costs for individual clinical trials, which are not currently reported. This legislation would provide valuable data on companies' investments in pharmaceutical innovation, enable detailed evaluation of pharmaceutical industry claims about R&D, and inform policies to ensure meaningful innovation is incentivized.

The Pharmaceutical Research and Transparency Act of 2022 would direct the Secretary of Health and Human Services, acting through the National Institutes of Health (NIH), to create a publicly accessible repository of cost data, linked to clinicaltrials.gov, for applicable drug clinical trials. Each responsible party of an applicable clinical trial would be required to post cost data, disaggregated by year, within one year of completion of a clinical trial. Cost data would include: the total cost of the trial; the cost of the trial per patient; and expenditures for certain other categories—including personnel, materials and supplies, and health care services provided to trial subjects. Responsible parties would be required to certify that the data submitted is complete and accurate.

The Research and Transparency Act would also amend the Securities Exchange Act to require drug manufacturers who file with the Securities and Exchange Commission (SEC) to disclose drug research and development expenditures disaggregated by clinical trial phase in their annual reports.

The bill would require the Secretary of HHS and the SEC to propose initial regulations no later than one year after enactment of the Act, with final regulations promulgated no later than two years after enactment.

A Senate companion bill was introduced by Senators Debbie Stabenow and Tina Smith.