# DISCOUNTED DRUGS FOR CLINICAL TRIALS ACT

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**The Discounted Drugs for Clinical Trials Act** amends Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) to grant eligible researchers access to certain pharmaceutical products at a discounted price for qualified research purposes.

Pharmaceutical companies can leverage the high prices of their drugs to impede the clinical trials of competitors, slowing or preventing research into lower-cost or more effective treatment options. For example, the House Committee on Oversight and Reform's investigation into pharmaceutical pricing practices found that executives at Celgene Corporation estimated that Janssen Pharmaceuticals would be forced to spend nearly $200 million to purchase Celgene's cancer drug Revlimid for use in Janssen's own cancer clinical trials. Internal documents obtained by the Committee revealed that Celgene executives celebrated that the high price of Revlimid would "hamper" Janssen's development of new competing cancer therapies. Nearly 80% of American adults view the cost of prescription drugs as unreasonable, and one in four Americans report having difficulty affording their medications.

The Discounted Drugs for Clinical Trials Act would promote innovation by targeting an anticompetitive practice used by some brand-name companies to block access to lower-cost generics or biosimilars. Under the bill, eligible public and private researchers would be able to obtain a written order from the Secretary of Health and Human Services (HHS) to purchase an eligible drug, biologic, or combination product necessary for qualified research purposes from manufacturers at a discounted price. Once an order is granted, a manufacturer or license holder of the referenced product would be required to sell a specified quantity of that product to the researcher at a price no higher than its direct cost to manufacture. The bill would apply to all covered Medicare Part D drugs that are eligible for placement on a specialty tier or whose cost is determined by the Secretary to be prohibitive to the advancement of qualified research.

Like the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, this bill gives eligible researchers a private right of action for injunctive relief. If the researcher prevails, the manufacturer or license holder would be required to provide the product without delay at the discounted cost and award the researcher reasonable attorneys' fees and litigation costs. A court may also award damages to deter future delaying conduct. To increase transparency, the bill also requires the Secretary to annually publish information on the number and types of applications for orders submitted by researchers that are granted and denied.

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