GENERIC SUBSTITUTION NON-INTERFERENCE ACT



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Brand-name pharmaceutical companies employ numerous tactics to delay or block access to lower cost generics or biosimilars. One tactic employed by some brand-name pharmaceutical manufacturers is called a "dispense as written" (DAW) campaign. This practice aims to encourage the continued prescription of expensive brand-name drugs, in order to suppress generic or biosimilar competition as branded drugs lose market exclusivity.

States generally either permit or require that pharmacists substitute brand-name drugs with generic equivalents if all prescribing conditions are met. However, doctors can expressly prohibit generic substitution by writing "dispense as written," "DAW," or other similar notation on a patient's prescription.Drug companies' DAW campaigns deploy targeted marketing to persuade doctors to write such prescriptions for their brand-name products, suppressing the uptake of generics and increasing prescription drug spending in the Medicare program and across the health care system. One study estimated that eliminating DAW could save the health system \$7 billion per year.

Documents uncovered as part of the Committee on Oversight and Reform's three-year investigation into rising prescription drug prices revealed that leading pharmaceutical companies such as Pfizer, Novartis, and Teva used DAW campaigns to limit the uptake of generic competition in anticipation of losing market monopolies on their blockbuster drugs.

The Generic Substitution Non-Interference Act would preserve physician autonomy and block this anticompetitive tactic by prohibiting drug companies from providing any item, such as a pre-printed notepad marked with "DAW" or similar notation, or service for the purpose of aiding or assisting a health care provider to request that a drug be dispensed "as written" or "brand name only" when a generic drug or biosimilar biological product is available, or directing that a health care provider write "dispense as written" or another similar notation on a prescription. The bill would make any violation an unfair method of competition under Section 5 of the Federal Trade Commission (FTC) Act and would grant both the FTC and state attorneys general enforcement powers.

The bill specifies that this prohibition does not impact the provider from exercising the provider's own medical judgment.

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