

S.4513 (Fernandez)

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BILL

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OPPOSE

The Business Council opposes S.4513 (Fernandez), which would implement new legal standards regarding patent settlements on drugs, which would run counter to the Federal Trade Commission's (FTC) role in regulating patent settlement agreements as well as current black letter common law on these patents.

In 2003, Congress mandated pharmaceutical companies to submit to the FTC certain agreements between manufacturers of new drugs and generic products. Expanded in 2018, the FTC's has broad powers to review these agreements. This bill, ignoring federal law, creates a completely new, "New York only" standard for determining the validity of settlement agreements, thus creating multiple standards and limitless confusion.

Patent settlements were created to resolve patent disputes. They most often lead to the introduction of generic drugs and biosimilar products into the market earlier than they would have had they been forced to wait until the end of a patent term; because of this, consumers benefit from earlier introduction of generic drugs and the lower prices that come with them. Modifying these standards in New York means that settlements will be less desirable and patent disputes will take longer to wind through the court system – causing delay to market of generic drugs and thus ultimately making drugs more expensive for longer periods of times for New York's patients.

The patent bargain – a trade-off between a short term "monopoly" right for invention and disclosure has been a hallmark of American innovation. Modifications to the patent system by any single state can unintentionally damage the balancing act of this grand bargain, which has allowed business to thrive and consumers to benefit. This bill does just that. In light of this, and the likelihood that this bill will have the unintended consequences of delaying to market generic drugs, The Business Council opposes S.4513 (Fernandez).