Expanding Access to Low-Cost Generics Act of 2019

Senator Tina Smith (D-MN)

High prescription drug prices are hurting patients across the U.S. Nearly three in ten Americans report that they did not fill a prescription because it was too expensive.[1] Generic drugs are an affordable alternative to brand-name prescription drugs. In 2018, 93 percent of generic drug prescriptions cost twenty dollars or less.[2] When one generic product comes to market, prices drop 51 percent[3], and when multiple generics are available, prices drop 85 percent.[4]

Anti-competitive behavior between brand name and generic drug manufacturers is delaying timely access to low-cost generic drugs. "Parking" is a practice that can occur when a brand name manufacturer agrees not to sue the first company that submits an application to create a generic version of that drug—a so called "first filer"—as long as the generic company agrees to delay bringing that generic drug to market. This anti-competitive "parking" behavior creates a bottleneck in the number of generic products available on the market and drive up costs.

Recent reports confirm this is the case. Out of 76 patent settlements involving "first-filer" generics in 2016, 48 settlements—over 60 percent—occurred because a brand-name company decided not to sue a generic company for patent infringement, so long as the generic company agreed to "park" its product and delay market entry.[5] Based on 5 years of FTC reports, out of 771 settlements, 653 involved delayed entry.[6]

Senator Smith's Expanding Access to Low-Cost Generics Act would solve this "parking" problem. Specifically, this legislation would:

- Fix an unintended flaw in the Hatch-Waxman Act, which awards 180-days of market exclusivity to "first filers." Senator Smith's bill would allow generic companies that win their litigation against a brand-name company's patent the ability to share market exclusivity with the first filer.
- Change the incentive structure for generic companies seeking timely approval of their products. With the opportunity to receive sole 180-day market exclusivity for beating brand-name patents, and with evidence that these patents are weak and easily beat[7], Senator Smith's bill would encourage "first-filers" to rush to come to market rather than to "park" their products.
- Stop the bottleneck of generic products waiting to come to market. Senator Smith's legislation would encourage the 48 generic products who delayed their market entry due to arrangements with brand-name companies to instead come immediately to market and deliver real relief to Americans.

Senator Smith's bill would bring low-cost generic products to market, increase generic competition on a timely basis, and help patients access their medications. If you have any questions or would like to support this bill, please contact Kripa Sreepada in Senator Smith's office at Kripa_Sreepada@smith.senate.gov.

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[1] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
[2] https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report
[3] https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf
[4] https://www.fda.gov/drugs/generic-drugs/generic-drug-facts
[5] https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf
[6] *Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition before the House Committee on Energy and Commerce*, 116th Cong. (2019) (testimony of Michael Carrier).
[7] 89% of patents in settled litigation are secondary patents (not on the active ingredient), for which the brand wins only 32% of time.