Congressman Andy Levin
Testimony before the House Committee on Energy and Commerce, Subcommittee on Health
July 25, 2019

Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, Ranking Member Burgess, members of the subcommittee: thank you for allowing me to testify before you today.

I am here today to talk about drug pricing – a topic that, I know, has been a tremendous priority for this subcommittee and for our constituents. And I want to applaud the hard work Energy and Commerce has already done this year to tackle this issue.

But, as you all know, we have more work to do.

My family knows this all too well. Two of my sons live with Crohn's disease. My wife, Mary, and I would do anything to keep our kids healthy, and I know parents across this country feel the exact same way – even if it means waiting to pay another bill, or neglecting necessities for themselves, families in every community are making incredibly hard choices for the sake of their kids. They should not have to.

I came to Congress to raise the standard of living for working people and ensure the deck isn't stacked against American families. That is why I've introduced the **Stop The Overuse of Petitions and Get Affordable Medicines to Enter Soon – or "STOP GAMES" – Act**. This commonsense, bipartisan bill that I authored with Congressman Francis Rooney will help stop pharmaceutical companies from gaming the system to block competition.

There have been multiple reports of drugmakers attempting to use the Food and Drug Administration's "citizen petition" tool to keep generic competition from coming to market. While the citizen petition is meant to ensure stakeholders can flag legitimate issues with drugs awaiting

FDA approval, reports indicate that drugmakers have filed baseless petitions to protect their monopolies. In fact, in October, then-FDA Commissioner Scott Gottlieb listed the misuse of citizen petitions among "anticompetitive techniques of concern."

Even if FDA doesn't ultimately agree with a petition's argument, the agency must investigate and respond to what are sometimes unsubstantiated claims. This prevents more affordable drugs from reaching consumers quickly, forcing American families to pay more.

For example, in 2017, the Federal Trade Commission filed a complaint arguing that ViroPharma's use of the citizen petition process constituted an antitrust violation. According to the FTC, ViroPharma's "repetitive, serial, and meritless filings lacked any supporting clinical data" and "succeeded in delaying generic entry at a cost of hundreds of millions of dollars."

The STOP GAMES Act would, as the title suggests, stop these kinds of games. Our bill outlines circumstances under which the FDA can promptly reject a petition meant to delay the approval of a generic competitor and directs the Secretary of Health and Human Services to report any such incidents to the FTC.

The bill also requires drugmakers to file a petition within 60 days of learning the information it's based on—not right before a patent or exclusivity period expires and rival drugs can come to market. Finally, the bill requires enhanced reporting to keep Congress informed of efforts to game the FDA approval process.

As your subcommittee continues its important work to bring down drug prices, I urge you to consider the STOP GAMES Act and ensure the FDA's citizen petition tool can't be misused to keep prices high. I thank the members of this committee who have already cosponsored the bill –

Congressman Tonko and Congresswoman Schakowsky – and I would welcome the chance to talk with more of you about this important fix.

Again, I want to thank you all for the privilege of testifying before your subcommittee, and truly look forward to working with you on this bill and others on behalf of working families.

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