The Honorable Mike Johnson
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Hakeem Jeffries
Democratic Leader
United States House of Representatives
Washington, DC 20515

The Honorable John Thune
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Charles E. Schumer
Minority Leader
United States Senate
Washington, DC 20510

Dear Mr. Speaker, Mr. Democratic Leader, Mr. Majority Leader, and Mr. Minority Leader:

We, the undersigned organizations, write to inform you of the need to end serial pharmaceutical patent litigation — an abusive practice that costs patients, employers, and taxpayers billions of dollars every year.

The Hatch-Waxman Act, passed in 1984, had two goals: (1) protect and promote pharmaceutical innovation, and (2) create a predictable path for lower-cost generic medicines to reach patients after brand-name drugs' patents expire. To support both goals, the law created a framework for patent disputes to be resolved in a single lawsuit within a 30-month period before an affordable generic medicine can be marketed. For decades, this system worked as intended.

Unfortunately, in recent years, some brand-name drug companies have found new ways to game the system in order to extend their market exclusivity. Rather than asserting all their patents during the initial 30-month litigation window, they strategically hold some in reserve to assert in later lawsuits. Additionally, brand companies acquire additional, weaker patents years after a drug is on the market, which they also use as the basis of future lawsuits.

By suing generics firms again and again over the same drug – inflicting expensive litigation costs, demanding lost-profits damages and market-clearing injunctions – brand-name companies bully and pressure generic manufacturers to settle the litigations by delaying generic

product entry for several years. Even when generics firms ultimately prevail in court, these lawsuits cost millions and make it harder and more expensive for affordable products to reach the market — driving up prices for patients and all health care system stakeholders.
The consequences of serial patent litigation are severe. Generic medicines typically cost 80-85% less than brand-name drugs. When brand-name companies use serial litigation to bully generic companies into delaying market entry, patients pay higher prices at the pharmacy, employers and insurers face higher costs, and federal and state governments and taxpayers shoulder billions in unnecessary spending.

Congress can stop serial patent litigation and ensure Hatch-Waxman works as intended with targeted, commonsense reforms:

- Limit the pursuit of the most severe remedies — lost-profits damages and market-clearing injunctions — in cases involving later-issued frivolous patents sought solely to keep generics from taking the brand's market share. If a generic firm prevails in an initial lawsuit over a drug's core patents, subsequent lawsuits on minor or newly obtained patents should not expose them to crippling damages.
- Add a 'use it or lose it' clause to prevent brand-name companies from strategically withholding patents from initial lawsuits so they can assert them later in repetitious intimidation lawsuits.

These reforms would protect U.S. innovation, curb serial patent lawsuits that extend monopoly pricing far beyond what Congress intended, and speed access to affordable drugs patients need.

We respectfully urge you to sponsor legislation to stop serial patent litigation and ensure that the Hatch-Waxman Act works as Congress intended.

Sincerely,

Coalition of Hematology and Oncology Practices
Crohn's & Colitis Foundation
Citizen Action Illinois
Doctors for America
Freedom Virginia
Frontiers of Freedom
Generation Patient
Hispanic Leadership Fund
Knowledge Ecology International
Labor Campaign for Single Payer
Moms for America
National Consumers League
Public Citizen
Public Sector HealthCare Roundtable
R Street
Vermont Legal Aid
Voices of Health Care Action

cc:

The Honorable Charles Grassley
The Honorable Richard Durbin
U.S. Senate Committee on the Judiciary

The Honorable Jim Jordan
The Honorable Jamie Raskin
U.S. House Committee on the Judiciary

The Honorable Brett Guthrie
The Honorable Frank Pallone
U.S. House Energy and Commerce Committee

The Honorable Bill Cassidy
The Honorable Bernie Sanders
U.S. Senate Committee on Health, Education, Labor and Pensions