Hatch-Waxman:
America's pathway for low-cost generics and incentives for innovation

The Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, is a landmark legal framework that shaped America's world-leading innovation ecosystem.

Enacted in 1984, the law created the balance between innovation and affordability, giving U.S. patients more choice than anywhere else in the world.

Hatch-Waxman balances:

- **INNOVATION** by providing incentives for innovative biopharmaceutical companies to research and develop new treatments and cures.
- **AFFORDABILITY** by creating a clear, predictable patent litigation framework and regulatory approval pathway providing access to lower-cost generics.

The Hatch-Waxman Act has worked. Key components of the framework include:

- Creating a clear legal process and **timetable for generic manufacturers to challenge brand drug patents listed in FDA's Orange Book in court.** When a patent lawsuit is filed on time, FDA approval is generally paused for up to 30 months so courts can sort out whether the generic infringes the innovator's patents. This helps avoid a scenario where a generic launches and then has to be pulled off the market and be liable for damages if it loses the case.
- Offering a **180-day exclusivity period** for the first generic to challenge brand patents and market a low-cost generic to incentivize faster generic access for patients.
- Allowing generic manufacturers to **rely on brand manufacturers' clinical trial data** in FDA applications to expedite approval and dramatically reduce costs. Before Hatch-Waxman, generic manufacturers had to conduct their own lengthy and costly trials.
- **Creating a "safe harbor" allowing generics to develop and test products** in preparation for FDA review without infringing—so they can conduct this research early even though it would otherwise be considered patent infringement.
- Granting patent term restoration **to restore some of the patent term lost during FDA review**, allowing up to five years of extension (subject to statutory caps) and limited to one patent per product.
- **Providing a five-year exclusivity period** during which generic manufacturers cannot rely on the innovator's approval and data as the basis of seeking FDA approval of the generic. This is intended to recognize brand companies for the time, cost and risk involved in generating the clinical data needed to prove a new drug is safe and effective.
- Establishing a three-year exclusivity period **for certain approved changes to brand drugs that require new clinical studies**, during which the FDA cannot approve generic applications referencing those changes.

BEFORE HATCH-WAXMAN:

- A mere 19% of prescriptions in the United States were filled with generics.[1]
- Only 35% of top-selling pharmaceuticals had generic competitors after their patents expired.[2]
- It took three to five years for generics to enter the market after the patents on brand-name pharmaceuticals expired.[3]

TODAY:

- Nearly 90% of prescriptions in the United States are filled with generics that have an average copay of under $7.[4]
- More than 80% of approved pharmaceuticals have generic versions available.[5]
- Generics often enter the market immediately upon patent expiration and are often adopted rapidly; some capture as much as 90% of the market within three months of becoming available.[6]

Hatch-Waxman is Critical for American Leadership:

U.S. leadership in biopharmaceutical innovation is the result of decades of regulatory stability and smart policy choices that have fueled our robust brand and generic medicine pipelines. But for the first time in decades, that leadership is on the line as countries like China have dramatically scaled up their research and development.

Leadership is a choice, and if the U.S. wants to continue to lead, it must preserve the critical policy frameworks, like Hatch-Waxman, that fuel it.

[1] https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway
[2] https://itif.org/publications/2025/02/03/a-bipartisan-success-celebrating-40-years-of-the-hatch-waxman-act/
[3] https://phrma.org/blog/40-years-of-hatch-waxman-how-does-the-hatch-waxman-act-help-patients
[4] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023
[5] https://itif.org/publications/2025/02/03/a-bipartisan-success-celebrating-40-years-of-the-hatch-waxman-act/
[6] https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff

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