WE WORK FOR HEALTH

Celebrating 40 Years of the Hatch-Waxman Act

In 1984, Congress enacted the bipartisan **Drug Price Competition and Patent Term Restoration Act**, otherwise known as the "Hatch-Waxman Act," which established the legal and regulatory framework that gave birth to the modern generic drug industry.

Thanks to the Hatch-Waxman Act, the United States has a thriving pharmaceutical industry that balances **innovation** with **affordability**. The law encourages companies to research and develop new, innovative medicines while creating a process for lower-cost generics with the same clinical benefit to come to market.

THANKS TO THE HATCH-WAXMAN ACT...

Hundreds of generic drugs have come to market, including chemotherapies for cancer patients, statins for patients with high cholesterol and drugs to help diabetes patients manage their blood sugar levels.

An **estimated 91% of prescriptions are filled by generics.** Prior to the law, **only 19% were**.

The U.S. healthcare system saved an estimated **$2.9 trillion** over the past 10 years due to the **availability of low-cost generics and biosimilars**.

More than **80%** of medications on the market have generic versions available.

Generic drugs often **launch immediately** after a branded drug's patents and exclusivities expire. Previously, it took 3-5 years to enter the market.

The United States has the **highest generic uptake in the world** and **access to more medicines** than anywhere else.

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PAVING THE WAY TO BIOSIMILARS

The Hatch-Waxman Act also helped lay the groundwork for the Biologics Price Competition and Innovation Act (BPCIA) by demonstrating a successful process for encouraging generic drug development.

The success of this process inspired Congress to create an abbreviated pathway for biosimilars in the BPCIA, which allows biosimilars to gain approval based on showing that they are highly similar to an existing FDA-approved biologic product.

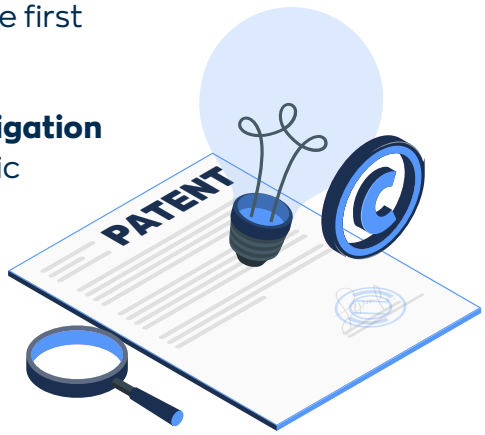
KEY PROVISIONS OF THE HATCH-WAXMAN ACT

Incentivizing Research & Innovation

- A **5-year data protection period** where a brand-name drug is protected from generic drug manufacturers utilizing the innovator's data for FDA approval.
- An **additional 3 years of exclusivity** for improvements such as a new indication or delivery method.
- **Extending patent protections** to restore some of the time the product was under FDA review.

Accelerating Broader Access to Cures

- The ability for manufacturers to **use a branded drug's safety and efficacy data** in seeking FDA approval, instead of having to fund their own costly and lengthy studies, after a period of time.
- A **"safe harbor" allowing generic manufacturers** to develop their products free from patent infringement liability.
- **180 days of exclusivity** for the first generic to enter the market.
- A **clear process for patent litigation** between branded and generic drugs, where a generic manufacturer can challenge a brand manufacturer's patents in court without risking liability for patent infringement.



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