WHAT IS HATCH-WAXMAN?

The Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act, is a comprehensive legal framework enacted by Congress in 1984 to streamline the process for generic pharmaceutical approvals and preserve incentives for innovation, including the creation of a procedure for patent litigation involving generic pharmaceuticals. The Hatch-Waxman Act established the legal and economic foundation for today's generic pharmaceutical industry.

HATCH-WAXMAN BALANCES:

- **INNOVATION**, by providing incentives for biopharmaceutical companies to research and develop new, innovative pharmaceuticals; and
- **AFFORDABILITY**, by creating an abbreviated path for generic manufacturers to bring lower-cost versions of pharmaceuticals to market.

For three decades, the Hatch-Waxman Act has fostered innovation, promoted competition and helped the United States remain a leader in biopharmaceutical research and development. Key components of this framework include:

- Creating a patent litigation framework with a clear process and predictable timetable where a generic manufacturer can challenge a brand manufacturer's patents in federal court without risking liability for patent infringement damages.
- Allowing generic manufacturers to reference the brand manufacturer's safety and efficacy data in their U.S. Food and Drug Administration (FDA) approval applications, rather than fund their own costly and lengthy clinical studies.
- Establishing a "safe harbor" provision that exempts generic manufacturers from patent infringement liability for development work, before the patent expires, for their own pharmaceutical approval application with the FDA.
- Incentivizing generic manufacturers to challenge patents for brand name pharmaceuticals and speeding patient access to generic pharmaceuticals by providing a 180-day market exclusivity period for the first marketed generic.
- Providing brand manufacturers with incentives to develop new pharmaceuticals through a 5-year exclusivity period during which generic manufacturers cannot submit FDA applications for new generic versions of the pharmaceutical and restoring some of the patent term lost due to the lengthy FDA regulatory approval process.
- Establishing a 3-year exclusivity period for improved versions of brand pharmaceuticals that required additional clinical studies for FDA approval during which generic manufacturers cannot gain FDA approval of their applications for generic versions of the improved pharmaceuticals.

HATCH-WAXMAN WORKS

Since Hatch-Waxman's enactment, the generic pharmaceutical industry has seen enormous growth and biopharmaceutical companies have continued to discover and develop innovative new treatments for costly, complex diseases. With the help of the Hatch-Waxman Act, the United States can remain a leader in medical innovation, while balancing innovation and affordability and promoting competition.

BEFORE HATCH-WAXMAN → TODAY

- A mere **19%** of prescriptions in the United States were filled with generics
- Only **35%** of top-selling pharmaceuticals had generic competitors after their patents expired
- It took **3 to 5** years for generics to enter the market **after** the patents on brand-name pharmaceuticals expired

- Nearly **90%** of prescriptions in the United States are filled with generics
- More than **80%** of approved pharmaceuticals have generic versions available
- 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

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