



Getting Access

To Generic Drugs:

A Timeline

Consumers' Access to Generic Drugs

How the Current Generic Approval Process Can Delay Competition

To market a generic version of a brand-name drug, the generic manufacturer must file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA). In its ANDA filing, the generic manufacturer must make one of four certifications regarding the patent status of the brand-name drug, based on the FDA's list of approved patents: (I) no brand-name drug patent was submitted to the FDA; (II) the relevant patent has expired; (III) the generic wants approval only after the brand-name drug patent expires; or (IV) there is a patent on the brand-name drug but the generic manufacturer claims the patent is invalid or will not be infringed by the generic.

An ANDA with the fourth type of certification, a Paragraph IV Certification, can set in motion a process that can delay consumers' access to full market competition—multiple generics competing with the brand—for three years or longer.

- Once a generic manufacturer submits an ANDA with a Paragraph IV Certification, it must notify the brand manufacturer, which has an immediate right to sue for patent infringement.
- A patent infringement lawsuit filed within 45 days of notice can delay marketing of the first generic for 30 months or longer.
- The first generic to file a Paragraph IV Certification receives 180 days of exclusivity. No other generics can go to market until 180 days after the first generic goes to market or wins the patent lawsuit.

This process is a result of the Hatch-Waxman Amendments' attempt to protect the interests of patent-holders while encouraging early marketing of generics. In practice, it has created incentives for brand-manufacturers to load up on patents, thus forcing generic manufacturers to file a Paragraph IV Certification; for brand-manufacturers to sue Paragraph IV filers to obstruct generic marketing; and for brand and generic manufacturers to make deals to keep the first generic off the market, which then blocks all subsequent generics. The result, illustrated in this timeline, can be dramatic delays in consumers' access to lower-cost generics. These delays cost consumers and other health care payers millions of dollars. For the millions of Americans with no or limited prescription drug coverage, these delays extend the time that some drugs are completely unaffordable.

More detail on the provisions of the law and related cases can be found in *Collusion and Anticompetitive Practices: A Survey of Class Action Lawsuits against Drug Manufacturers* and *Overview of Hatch-Waxman: Legislative Background*, both available from Families USA.



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Paragraph IV Certifications and Potential Delays in Market Competition

