

after exclusivity was lost, with brand-name prescriptions dropping another 48 percent in the month after “full” generic competition began.⁸⁵

Perhaps most important, the FDA estimates that consumers saved more than \$217 billion in 2012 alone through the use of generics,⁸⁶ with total savings of \$1.68 trillion from 2005 to 2014.⁸⁷ In the Lipitor study mentioned previously, median monthly out-of-pocket spending dropped from \$17.50 when only brand-name Lipitor was available to barely above \$5.00 for generic versions when many generics were available.⁸⁸

One might call the generic revolution a miracle, but it certainly did not occur naturally or serendipitously. To begin with, the modern system of generic entry has only been in place for about three decades. Generic drug entry is covered by the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch–Waxman Act.⁸⁹ Passed in 1984, Hatch–Waxman created a pathway to generic entry meant to incentivize the speedy introduction of generic drugs to market. Before the act, generic entry into the market was slow.⁹⁰ Would-be generic manufacturers could not apply to enter the market until after the branded company’s patents had expired, with the effect that brand-name companies enjoyed a de facto patent extension and ongoing monopoly profits as the generic awaited FDA approval.⁹¹ Brand-name drugs could face no competition for years after patent expiration. Further, few generics were entering the market to begin with. The burden of the application process, which required the generic to complete its own clinical trials, and the lack of substantial profits, deterred most manufacturers.⁹²

As discussed in more detail in the [Introduction](#), Hatch–Waxman offers generics a number of incentives to enter the market as quickly as possible, creating a complex web of regulation. First, prospective generics can submit an abbreviated new drug

⁸⁵ Jing Liao *et al.*, *Effect of Generic Competition on Atorvastatin Prescribing and Patients’ Out-of-Pocket Spending*, J. AM. MED. ASS’N. INTERN. MED. at tbl. 2 (Jun. 27, 2016), <http://archinte.jamanetwork.com/article.aspx?articleid=2530416#i0i160055128>.

⁸⁶ GENERIC PHARM. ASS’N, *GENERIC DRUG SAVINGS IN THE U.S.* 1 (2013), www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf (data supplied by IMS Health).

⁸⁷ *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Hearing before the H. Comm. on Oversight & Gov’t Reform*, 114th Cong. 1 (2016) (statement of Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin.).

⁸⁸ Jing Luo *et al.*, *Effect of Generic Competition*, *supra* note 85, at tbl. 3.

⁸⁹ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

⁹⁰ See Wendy H. Schacht & John R. Thomas, CONG. RES. SERV., REPORT R4114, *THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER*, at Summary (2011), [http://congressional.proquest.com/profiles/gis/result/pqpresultpage.gispdfhitspanel.pdf?ink/\\$2fapp-bin\\$2fgis-congresearch\\$2ff\\$2fa\\$2f7\\$2f8\\$2fcrs-2011-rsi-0151_from_1_to_20.pdf/&entitlementkeys=1234%7Capp-gis%7Ccongresearch%7CCrs-2011-rsi-0151](http://congressional.proquest.com/profiles/gis/result/pqpresultpage.gispdfhitspanel.pdf?ink/$2fapp-bin$2fgis-congresearch$2ff$2fa$2f7$2f8$2fcrs-2011-rsi-0151_from_1_to_20.pdf/&entitlementkeys=1234%7Capp-gis%7Ccongresearch%7CCrs-2011-rsi-0151).

⁹¹ ROBIN FELDMAN, *RETHINKING PATENT LAW* 159 (2012).

⁹² See Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch–Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585–90 (2003) (discussing the absence of generics on the market before the adoption of Hatch–Waxman).