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Hatch-Waxman Act: Prospects for Reform

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During the last political campaign, there was significant interest in the issue of inflated pharmaceutical prices.

One solution to high drug costs is increasing competition between manufacturers of generic and brand-name drugs. Unfortunately, the regulatory process often slows the emergence of lower-priced generics. Congress appropriately is examining how to repair the regulatory process so that both the incentives to innovate and competition are protected. In addition, the Federal Trade Commission has dusted off its unique statutory power to conduct a landmark study of the industry.

The relationship between brand-name and generic firms is governed by the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417), commonly called the Hatch-Waxman Act. The act was an unprecedented attempt to achieve two seemingly contradictory objectives: making lower-cost generic copies of approved drugs more widely available, while granting extended patent protection to developers of new drugs to ensure adequate incentives to innovate.

In many respects, the act has been a success—use of generic drugs has almost doubled from about 20 percent to 40 percent of prescriptions over the last 16 years. The Congressional Budget Office estimates that this change has saved consumers between $8 billion and $10 billion a year.

In fact, the gap between the cost of brand-name drugs and their generic alternatives has skyrocketed in the last decade. In 1990, the average cost per prescription for brand-name medications was $27.16, while the average cost for generic drugs was $10.29. By 2000, the average cost per prescription reached $65.29, while the generic increased to only $19.33. Moreover, while the percentage of generic prescriptions (as a share of the entire market) increased significantly in the 1980s, in the late 1990s, it stalled at about 40 percent.

Some members of Congress have questioned whether the unanticipated problems in the regulatory process have slowed the growth of generics. This has led to efforts by the Food and Drug Administration to tinker with the regulatory process, and to antitrust enforcement actions by the Federal Trade Commission.

Now even states are instituting antitrust actions against brand-name drug makers trying to keep generics from market, as evidenced by a lawsuit brought by 15 state attorneys general who charge that two major drug companies conspired to keep a generic version of a popular heart medication off the market (9 HCPR 825, 5/21/01).

Legislative Reform Options. While regulatory reform and antitrust enforcement are necessary, they may not be sufficient. Regulatory changes are time-consuming, and are typically followed by years of litigation before they take effect. In addition, antitrust enforcement resources are limited.

Because of these constraints, consumer groups increasingly are calling for legislative reform to straighten out the regulatory system. There are several possibilities for change.

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One potential target for legislative reform involves a unique "incentive" that the act gives to generic firms to challenge the patents of the brand-name firms. The first generic to challenge the patent receives 180 days of marketing exclusivity. The provision seems to be intended to encourage the generic companies to mount expensive patent challenges, based on the belief that, without this incentive, generic firms might not have the incentive to do so.

Patent litigation is very expensive and risky, and, without this incentive, many firms may be unable or unwilling to undertake the litigation gauntlet.

However, the regulations implementing the provision have been mired in lengthy litigation challenges between generic firms, brand-name firms, and the FDA. The agency's attempts to bring guidance to the chaos in an August 1999 proposal to amend its rule governing 180-day generic drug exclusivity still awaits final action (64 Fed. Reg. 42873, 8/6/99).

Some have suggested that the most significant problem with the 180-day provision is that it allows branded and generic firms to enter "settlements" to effectively delay the entry of any generic drugs. This happens when the companies agree that the generic firm with 180-day exclusivity will not enter the market, in exchange for a payment from the brand-name firms. Settlements are typically procompetitive, and there are numerous cases attesting to the merits of settling litigation. However, some have alleged these settlements can actually delay the entry of generics.

Orange Book Listings. Another alleged flaw in the Hatch-Waxman Act involves the requirement that brand-name firms list all approved patents in the FDA's *Orange Book*, which is a sort of phone directory of patents.

Listing a patent in the *Orange Book* effectively delays generic entry for a 30-month period.

Problems arise because the FDA perceives its role as wholly ministerial, and any type of patent can be listed. Generic firms claim that brand-name firms list all kinds of add-on patents on use, packaging, and labeling, a practice that serves to further hold off competition from generics.

There are several ways to reform this practice, although each has its own attendant problems.

For example, the law could be amended to limit *Orange Book* listings to patents covering the drug product, while eliminating peripheral patents. Nonetheless, this could diminish the incentives of brand-name firms to improve those product attributes.

Another approach would be to set deadlines on listing new patents, but brand-name firms have countered that, because they have no control over when new patents are approved, the result will be an arbitrary and unfair cut-off date.

Controversy also surrounds the "citizen petition" process, in which citizens can petition the agency to question any potential regulatory action. Generic firms claim that brand-name firms file frivolous petitions challenging approval of generic drugs, leading to increased delay of generic drug approval.

In November 1999, the FDA proposed relatively modest modifications to limit the scope of citizen petitions, but FDA has now pulled back from these efforts to reform this practice.

Lack of Information. As Congress approaches the challenge of reforming the Hatch-Waxman Act, an overarching problem is the lack of information about the different types of practices available to brand-name drug manufacturers to game the system. There are plenty of anecdotes, but relatively little information about how these practices affect the primary goals of the act.

To fill this gap, the FTC has launched a major study of competition in the pharmaceutical industry (9 HCPR 633, 4/23/01). In April, the FTC subpoenaed information from more than 70 generic and brand-name drug manufacturers. The FTC study will focus on 180-day market exclusivity, the *Orange Book* listings, and the citizen petition process. FTC expects to report to Congress on the results of the study by the end of the year.

Section 6 Studies. The FTC is using its unique powers under Section 6 of the FTC Act to subpoena information for this study. Congress gave the FTC this unique power to perform studies and report to Congress, and the legislative history makes clear that Congress intended the FTC to have broad powers to serve this function.

The FTC's past Section 6 studies have led to a number of landmark regulatory enactments, including the Packers and Stockyards Act, the Communications Act of 1931, the Securities and Exchange Act, and the Public Utility Holding Company Act.

The Commission has very extensive powers under Section 6 . . . the Supreme Court has analogized its powers to that of a grand jury (see *FTC v. Morton Salt Corp.*, 338 U.S. 632, 642 (1950).

McCain-Schumer Legislation. Congress has begun to confront how to reform Hatch-Waxman. A bill (S. 812) proposed by Sens. John McCain (R-Ariz.) and Charles E. Schumer (D-N.Y.) (the Greater Access to Affordable Pharmaceuticals Act) would eliminate the automatic 30-month stay granted by FDA to brand-name firms that file suit against a generic manufacturer's patent challenge. Instead, brand-name firms would have to seek a preliminary injunction from the courts and file a bond, similar to the process in all other patent litigation.

In an effort to clarify and expedite certification, brand-name manufacturers would be required to list all of a drug's relevant patents and certify with FDA that the list is complete and accurate.

The bill also would reform the 180-day exclusivity period by creating a "use-or-lose-it" provision. If a generic firm settles litigation and decides not to enter the market, it would lose the exclusivity period to the next applicant to file an abbreviated new drug application to market a generic version of the brand-name drug.

In addition, individuals or groups filing citizen petitions would be required to certify that their petitions are factually based, warranted by existing laws or regulations, and not submitted for any anticompetitive purposes, such as to cause unnecessary delay. Any petitions that are believed to be used for anticompetitive purposes would be investigated by FTC, and any company making false statements would be subject to existing criminal penalties.

Although it is easy to engage in hyperbole, moderation and careful analysis is the right prescription for addressing these issues.

In reforming the act, Congress must be sensitive to both sides of the equation. It must fully protect the incentives of brand-name firms to innovate because new

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drugs are vital. At the same time, it must protect the incentive and ability of generic firms to enter the market.

With the value of drugs going off patent in the next five years expected to exceed $20 billion, focusing on these issues is vital to the maintenance of an affordable health care system. Writing a new prescription for pharmaceuticals is exactly what this market needs.