Concerns About The Future Of Pharmaceutical Innovation Under The Hatch-Waxman Act

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By all reports, the outlook for the brand-name pharmaceutical industry in the United States is surprisingly bleak. The pipeline for new drugs is drying up, with few new drugs expected to emerge in the future. Indeed, companies such as AstraZeneca have completely given up in some areas of drug development such as psychiatric drugs, focusing instead on more profitable areas such as cardiology and oncology. American health care providers face shortages of much needed vaccines and medications because too few manufacturers are able to sustain a presence in those markets. Eli Lilly, another giant in the industry, has slashed thousands of jobs, and consolidations and mergers among industry players is an increasingly common occurrence. The U.S. pharmaceutical industry was until very recently, however, known as one of the most robust and profitable in the world – what happened to cause this once flourishing industry to become one struggling to survive?

While a variety of factors are thought to account for the rather sudden downturn in the fortunes of brand-name pharma, one factor seldom considered as contributing to the situation is the Drug Price Competition and Patent Term Restoration Act, otherwise known after its two leading sponsors as the Hatch-Waxman Act. Enacted in 1984 and amended in 2003, the Hatch-Waxman Act is certainly coincident in time with most of the apparent decline in brand-name pharmaceuticals, but the question is whether it's more than coincidence. Ostensibly designed to facilitate the market entry of generic imitators while preserving the incentives of brand-name innovators to continue to develop new drugs, the Act appears to have been largely a success in its first goal but of questionable success in its second. This Article therefore takes a closer look at what effects the Hatch-Waxman Act may have had on pharmaceutical innovation in the last three decades and in particular, what role the Act may have played in the weakening of the U.S. brand-name pharmaceutical industry. This initial examination of the Act strongly suggests that it did indeed at least aggravate the industry's downward turn and in any event certainly did little to protect the continued vitality of the industry. We may therefore wish to reconsider the wisdom of maintaining the Act in its current form, if at all.

In particular, this Article suggests that the Hatch-Waxman Act focuses far too much on market forces – and in particular, on competition – as a way of decreasing the costs for consumers. A *sui generis* regime that focuses solely on the pharmaceutical industry because of its singular regulatory burdens and yet obvious social benefits, the Act recognizes that these regulatory burdens often serve to deter both brand-name and generic entry into the pharmaceutical market. The Act therefore compensates for those regulatory burdens in part by relieving some of that burden for generic manufacturers and in part by adjusting the effective duration of pharmaceutical patents to account for term lost meeting regulatory approval requirements. The Act ultimately fails, however,

for it grossly overshoots the mark, in large part because of its misguided emphasis on competition within the pharmaceutical marketplace.

To be sure, generic pharmaceuticals now enjoy a much greater market share than they ever have before, providing much less expensive versions of brand-name drugs. Brand-name pharma, by contrast, has not faired nearly so well. Given the incredible costs of developing and marketing new drugs, not to mention the regulatory burdens of doing so, brand-name pharma is widely believed to depend on patent protection more than other industry. Even after Hatch-Waxman and its attempts to restore patent duration to its full expected term, however, the average effective life of a pharmaceutical patent is still shorter than that for any other type of patent. This situation would in itself be bad enough, but now pharmaceutical patents have been even further weakened because Hatch-Waxman subjects them to a kind of Russian roulette that no other type of patent faces. This double-edged functional shortening of average effective patent life likely has devastating effects on the pharmaceutical industry.

Even more problematic, moreover, is the fundamental belief, running throughout the Hatch-Waxman Act, that generic competition and pharmaceutical patents are effective tools to lower the cost of drugs. Competition may be key to lowering costs in other parts of the health care system, and it may even be useful to a limited extent in lowering the cost of drugs; I make no claims to the contrary. The point I do want to make here, however is that the story is much more complex than simply the Act's narrow focus on competition and pharmaceutical patents and that, by failing to take this complexity into account, the Hatch-Waxman Act may causing great harm to the pharmaceutical industry. Indeed, despite its obvious dependence on patents, patent rights are actually a rather sloppy way of conceptualizing what drives brand-name pharma and pharmaceutical innovation. In fact, at first glance, it is somewhat surprising that brand-name pharma values its patent as much as it does. There is no correlation between whether a new drug may be patentable and the value of that patent with the costs of developing and testing that new drug for safety and efficacy, its profitability, or its potential for product liability post-development and marketing. Indeed, on closer inspection, the value of pharmaceutical patents lies not so much in the direct incentives they create to invent new drugs but rather in the ability of brand-name pharma to leverage that value to subsidize a much wider range of socially beneficial activities, including detailing and other services that generic manufacturers do not provide. And now that not only federal law but also evolving trends in both research and treatment have changed the number and nature of patent holders and other players in the pharmaceutical market, the wisdom of enacting the Hatch-Waxman Act begins to look more and more doubtful. We should therefore evaluate other approaches to the problems facing the pharmaceutical industry, such as market or data exclusivities.