ASPE
ISSUE BRIEF

Some Observations Related to the Generic Drug Market

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Introduction and Context

The incentive for a manufacturer of a brand-name prescription drug to undertake measures that attempt to prolong the period of marketing exclusivity for a brand-name drug is very strong. For most prescription drug products, incremental production costs are quite low—literally pennies a pill—while successful new drugs can command high prices. The period of a drug's market exclusivity is therefore a highly-profitable one, particularly in cases where the drug confers substantial clinical benefits and where patients and providers have few therapeutic alternatives. Over 30 years of experience have shown that when a generic competitor enters the market, the brand-name manufacturer typically faces a rapid and steep loss of market share and profits as patients and providers shift toward a much less expensive generic product that offers the same clinical benefits. Once several generic manufacturers enter the market, competition generally drives prices down "close to marginal cost."[1] It is not unusual for successful new drugs to have annual sales of a billion dollars or more during the exclusive sales period, so delaying the availability of an inexpensive generic alternative even for a short time can preserve enormous profits for the original manufacturer.

Brand-name manufacturers have been resourceful in responding to that powerful incentive. Litigation is one tactic that manufacturers have used to delay generic competition.[2] Another common method of delaying generic entry arising from patent litigation involves "pay-for-delay" arrangements in which a brand-name manufacturer agrees to pay a would-be generic competitor to hold its product off the market for a certain period of time. That now well-known practice can significantly harm consumer welfare.[3]

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[1] F. Scott-Morton and M. Kyle, "Markets for Pharmaceutical Products," *Handbook of Health Economics*, Vol. 2, Elsevier, 2012, chapter 12, pp. 763-823 at p. 795.

[2] New York Times, "Gaming the Drug Patent System," June 10, 2002. http://www.nytimes.com/2002/06/10/opinion/gaming-the-drug-patent-system.html (accessed April 20, 2015).

[3] See Federal Trade Commission, *An FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010, and FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002.

Litigation is not the only way that brand-name manufacturers have sought to extend market power. Another common approach to effectively extend exclusivity in sales is to develop a new product formulation of an existing brand-name drug facing impending generic competition.[4] That can be achieved several ways. For example, a new formulation, or "line extension," would have the same active ingredient and general clinical effect as its predecessor but might have a different timing of release. When an innovator manufacturer develops a new formulation of an existing brand-name drug, it typically seeks through marketing efforts to shift patients to the newer version that would be protected by its own statutory exclusivity. In such cases, the line extension product is subject to a market test in which consumers and other purchasers weigh the new product's potential improvements against its higher costs relative to a generic version of the older product. Consumers who value any improvements in the product enough to justify its price can choose the newer drug, while others who see greater value in the older, lower-cost version can realize the savings for a similar therapy.

It is within this context—a long history of various attempts by manufacturers to prolong market power in prescription drug markets—that we offer our views on the recent actions of Actavis PLC and Forest Laboratories LLC (hereinafter Actavis) concerning the product Namenda, a drug used to treat moderate-to-severe dementia from Alzheimer's disease. We understand Actavis seeks to remove its older product from the market and force patients to switch to its line extension product. We believe such actions come at a substantial cost to consumers and taxpayers.

Federal and state policies deliberately encourage the use of available generic products, as do many private payers such as insurers and Pharmacy Benefit Managers (PBMs). Because generic drugs are generally sold at much lower prices than their brand-name counterparts, the use of the generic instead of the more-expensive brand-name option generally results in substantial savings. Such savings benefit patients by reducing out-of-pocket costs and insurance premiums while enabling them to attain the same clinical benefits at a lower cost. For public payers, the savings can mean lower health care expenditures and greater value for taxpayers. As the primary source of financing for dementia care, including Namenda, the federal government in particular has a stake in the dynamics of this market. Policies aimed at steering beneficiaries of public insurance programs to generic drugs when available are important tools for addressing the enormous challenge of promoting value in health care use. We are concerned that the measures taken by Actavis undermine competition and result in excess payments by consumers and taxpayers.

Policies Intended to Encourage Generic Competition

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.[5] Its intention was to balance the dual interests of encouraging innovation and promoting competition between brand and generic drugs in order to lower drug prices. To promote innovation, the new law gave manufacturers of innovator drugs longer periods of market exclusivity for newly-approved products that increased the financial

[4] Haiden A. Huskamp, Julie M. Donohue, Catherine Koss, Ernst R. Berndt, and Richard G. Frank, "Generic Entry, Reformulations, and Promotion of SSRIs," *Pharmacoeconomics* 2008; 26(7): 603–616.
[5] Public Law 98-417 (1984).

returns for investment in drug research and development. To promote price competition, the law established a regulatory approval pathway for generic products to help ensure that generic drugs became available as quickly as possible following patent loss.

Since the passage of the Hatch-Waxman Act, there has been a rapid expansion of the role played by generic products in pharmaceutical markets, and the savings for consumers have been substantial. In 1984, the year the Act was passed, generic drugs accounted for 18.6% of prescriptions sold in the U.S.[6] A study by the Congressional Budget Office (CBO) showed that the Hatch-Waxman Act made it "easier and less costly" for generic drugs to enter the market.[7] By 2011, over 80% of prescriptions were filled with generic drugs.[8] Taken together, the Hatch-Waxman Act and other policies encouraging pharmacists to use generic instead of brand-name versions of a drug lowered the cost of medications and enhanced consumer welfare.

Summarizing experience under the Act during the 1990s, David Balto, former Policy Director of the Bureau of Competition of the Federal Trade Commission (FTC), observed that the Act worked to achieve the two "seemingly contradictory objectives" of promoting generic entry and assuring adequate incentives for investment in new drug discovery:

> "Both of these objectives seem to have been fulfilled to a significant degree. … [T]he added protections and exclusivity term for innovator firms have accompanied a tremendous increase both in the investment in, and the success of, pharmaceutical innovation. … [At the same time], [t]he industry also has seen an increase in the percentage of brand-name drugs that have a generic competitor on the market. Today, nearly 100% of the top-selling drugs with expired patents have generic versions available, versus only thirty-six percent in 1983."[9]

Shifts away from brand-name innovator products occur rapidly following the introduction of generic drugs. In the 1990s, the market penetration by generic drugs was relatively low and took several years. Since 2000, shifts in purchasing have been occurring more quickly.[10] Using data

[6] E.R. Berndt and M. Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation," National Bureau of Economic Research (NBER), Working Paper No. 16431, Oct. 2010.

[7] Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, (CBO Report).

[8] IMS Health Press Release, "IMS Health Reports U.S. Prescription Sales Grew 1.3 Percent in 2008 to $291 Billion," March 19, 2009 (http://www.imshealth.com); IMS Health Press Release, "IMS Health Reports Annual Global Generics Prescription Sales Growth of 3.6 Percent, to $78 Billion," December 10, 2008 (http://www.imshealth.com). For sales of generic drugs in 1984, see IMS Health National Prescription Audit Plans data reported in R. Frank, "The Ongoing Regulation of Generic Drugs," *The New England Journal of Medicine*, 357(20), 2007, pp. 1993-1996.

[9] D. Balto, "Pharmaceutical Patent Settlements: The Antitrust Risks," *Food and Drug Law Journal*, 55, 2000, pp. 321-341 at 324-325. The CBO study cited is CBO (1998), *op cit.* and notes that the Hatch-Waxman Act made it "easier and less costly" for generic drugs to enter (see p. xiii).

[10] Some of the older papers in this literature include the following: D. Suh, W. Manning, S. Schondelmeyer, and R. Hadsall, "Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry," *Health Services Research*, 35(2), 2000, pp. 529-547; Congressional Budget Office (CBO), *How Increased*

from IMS, Aitken, *et al.* report that in 2002 brand-name products retained 28% of their prescription volume 12 months after expiration of the patent, and this 12-month retention had dropped to 14% by 2007.[11] In fact, "sales of originator drugs drop as much as 75 percent within weeks following the entry of a generic copy into the market."[12] Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant enters the market. The generic penetration rate at that point is about 90% on average. Recent information also shows that in a mature generic market, generic prices are, on average, 85% lower than the pre-entry brand-name drug price."[13]

Generic substitution has a major impact on lowering health care costs. A study by the Congressional Budget Office in 1998 concluded that the availability of generics saved consumers approximately $8 to $10 billion annually,[14] a number that has skyrocketed as large numbers of expensive brand-name drugs have come off patent. A recent study conducted by IMS on behalf of the Generic Pharmaceutical Association found that generic medicines saved $1 trillion from 2002 to 2011 and $193 billion in 2011 alone.[15]

Given the substantial increase in the market share of generic drugs since the 1984 enactment of the Hatch-Waxman Act, the law is considered quite successful overall. At the same time, there have been unanticipated and unintended consequences for market competition. Beginning in the 1990s, allegations arose that the terms of the statute were being exploited to delay rather than expedite generic entry, and many antitrust challenges followed. Brand-name manufacturers have

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Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry, 1998; H. Grabowski and J. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," *Journal of Law and Economics*, 35(2), 1992, pp. 331-350; R. Frank and D. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy*, 6(1), 1997, pp. 75-90; D. Reiffen and M. Ward, "Generic Drug Industry Dynamics," *Review of Economics and Statistics*, 87(1), 2005, pp. 37-49; and A. Saha, H. Grabowski, H. Birnbaum, P. Greenberg, and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, 13(1), 2006, pp. 15-38.

[11] M. Aitken, E.R. Berndt and D.M. Cutler, "Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point," *Health Affairs*, Web Exclusive, pp. w151-w160 at w155.

[12] See G. Glover, on behalf of the Pharmaceutical Research and Manufacturers of America (a brand-name pharmaceutical manufacturers' trade association), Prepared Witness Testimony before the House Committee on Energy and Commerce, "Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals," June 13, 2001.

One vivid example of branded drug erosion is found in the experience of Vasotec which is described as follows: "Sales of branded drugs used to drift downward after patent expiration. Now they fall off a cliff. Within two months after the August 2000 patent expiration for Vasotec, generics grabbed 75% of the $2 billion hypertension drug's U.S. sales." G. Harris, "Back to the Lab: Merck to Shed Medco, Its Drug-Benefits Unit, In Bid to Boost Stock," *Wall Street Journal*, Jan. 29, 2002.

[13] See Federal Trade Commission, An FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010, p. 8.

[14] CBO (1998), *op cit.*, p. 35.

[15] See, Savings, $1 Trillion Dollars over Ten Years: Generic Drug Savings in the U.S. (fourth annual ed., 2012), p. 1 (http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf). Savings were calculated by computing the difference between average brand and average generic prices and attributing this difference as savings for all generic units sold (p. 8).

actively sought to delay the entry of generic competition.[16] Efforts by drug manufacturers to delay generic entry, as mentioned above, include lengthy litigation as well as pay-for-delay agreements that allow brand-name manufacturers and generic first-entrants to split monopoly profits. In 2010, the FTC found that such agreements on average delay generic entry for nearly 17 months, costing American consumers $3.5 billion per year.[17]

"Forced Switch" to Dampen Generic Competition

Actavis manufactures and markets Namenda and Namenda XR, drugs used to treat moderate-to-severe dementia from Alzheimer's disease. The drugs come in two dosage forms: Namenda, a twice-daily formulation (hereinafter, "Namenda IR"), and the more recently-developed Namenda XR, a once-daily formulation. These two products offer patients essentially the same therapeutic benefits and are currently the only ones available in their class for the target group of patients.

Actavis' period of exclusive marketing rights for Namenda IR is nearing its end. Under the usual competitive process envisioned by policymakers under current law, a generic drug manufacturer seeking to market a bioequivalent version of Namenda IR as its period of market exclusivity expired would submit an Abbreviated New Drug Application (ANDA) to the FDA, and, if the ANDA were approved, consumers would soon benefit from the availability of a lower-priced version of that therapy. In the resulting scenario, some providers and patients might opt for the newer product while others who prefer the soon-to-be-available less expensive generic option would be free to maintain existing therapy and then make a seamless switch to the generic when it becomes available.

However, Actavis devised a plan to effectively remove Namenda IR from the market prior to the availability of a generic alternative, thereby forcing patients who take this drug either to discontinue taking it or switch to the newer Namenda XR, which has exclusive sales rights until 2029. In this scenario, physicians would generally become accustomed to writing prescriptions for the newer, once-a-day product. In theory, physicians would be free to switch their patients back to a twice-daily regimen once the generic is available; in practice, such a switch could prove problematic for some patients and the providers who manage their care once patients become accustomed to the once-daily version.

This is especially significant for a drug that treats a long-term or chronic condition. The unique nature of this patient population—Alzheimer's patients with moderate-to-severe dementia—makes it likely that a switch from the twice-daily Namenda IR to the once-daily Namenda XR would be a permanent one for practical purposes, as providers, patients, and families would be reluctant to switch back to twice-a-day therapy even if they believed that it represented a better value. Recently, a federal district judge issued a preliminary injunction enjoining Actavis from implementing its plan to remove Namenda IR from the market while the court considers a challenge to the legality of Actavis' planned course of action. The court found that "[o]nce patients have switched to Namenda XR, it is very unlikely that most of them will switch to

[16] See FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, Chapter 4.
[17] Federal Trade Commission, *An FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010.

generic Namenda IR" and that "Physicians are reluctant to disrupt patients' medical routines without a medical reason to do so…Physicians can also be reluctant to switch medications because the patients and others, such as their caretakers, must be educated on how the medication is taken."[18] Furthermore, even when the twice-daily generic version becomes available, state laws would generally prohibit a pharmacist from substituting it for the once-daily brand-name product without a physician's permission.

Relying on the practical difficulties of switching Alzheimer's disease patients back to the twice-daily regimen once they begin the newer formulation, the manufacturer is attempting to blunt generic competition. By its intended behavior, Actavis seeks to avoid the normal market test in which the potential added benefits of the brand-name formulation's once-daily dose are weighed against its higher cost relative to a generic version of the IR product.

The removal of Namenda IR from the market prior to the release of any generic counterpart would result in higher market prices and some patients may also suffer from discontinued therapy due to a disruption in their treatment regimens. Such an action goes far beyond most previous attempts to minimize the impact of new competition, and its effects on consumer welfare could be far greater.

The Economic Consequences for HHS Programs

There is more at stake in this case than simply a general interest in protecting consumer welfare. The exercise of market power as described above has important consequences for HHS program spending. The retirement of the large baby-boom generation will add to existing fiscal pressures as greater numbers of Americans become eligible for the Medicare program, and the costs of treating dementia are likely to rise dramatically. According to one recent analysis, the number of individuals in the U.S. over age 65 with dementia from Alzheimer's disease was 4.7 million in 2010 and is projected to rise to 14.8 million by 2050.[19] Accordingly, efforts to contain spiraling health care costs while maintaining clinical value for beneficiaries will remain a key imperative for the federal government. Policies that encourage patients to switch to lower price generic drug products when available have played a key role is stemming health care cost growth in recent years, and will no doubt have to remain part of cost-control efforts in the years to come as the government seeks to narrow its long-term fiscal gap.

We have conducted some illustrative calculations of the expected total program and beneficiary spending impacts of generic competition and the introduction of Namenda XR over the next decade under three scenarios:

- Scenario 1 - the introduction of at least one generic version of Namenda IR without the introduction of brand-name Namenda XR;
- Scenario 2 - the introduction of at least one generic version of Namenda IR plus the introduction of brand-name Namenda XR; and

[18] *New York v. Actavis*, PLC, No. 14-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).
[19] Hebert L, Weuve J, Scherr P, Evans, D. "Alzheimer disease in the United States (2010-2050) estimated using the 2010 census", *Neurology* 2013; 80: p. 1778-1783.

- Scenario 3 - the introduction of at least one generic version of Namenda IR plus brand-name Namenda XR with brand-name Namenda IR having been withdrawn from the market.

All three scenarios assume that no generic versions of Namenda XR enter the market during the ten-year period starting in 2015. Using claims data, we estimate that total spending in Part D (Medicare's prescription drug benefit) on Namenda IR was $1.14 billion in 2012, accounting for 35 percent of all anti-dementia claims. As a baseline for the scenario estimates, we projected that in the absence of either generic versions or Namenda XR, spending for Namenda IR would be $2.2 billion by 2016 and $36.9 billion through 2024.

Assuming generic entry after patent expiration in July 2015 and a generic dispensing rate of 15 percent in the last 6 months of the year, we estimated that spending for the brand-name Namenda IR would drop by $288 million. This illustration suggested that weakening generic entry would increase spending for Namenda by about $50 million each month in 2015.

For Scenario 1 we assumed that the generic dispensing rate would reach 85 percent in 3 years, and that the generic price would drop to 20 percent of the brand-name price within 4 years. The assumptions were based on prior literature as well as on Part D trends for generic substitution and pricing in the years following the loss of the patent for other brand drugs. As displayed on table 1, we estimate that total ten year spending (2015-2024) on Namenda products would have been reduced by approximately $24 billion (from approximately $37 billion to nearly $13 billion).

Scenario 2 reflects full competition between Namenda XR, Namenda IR, and the generic versions of Namenda IR. Under this scenario, we assume 50% of the generic fills from Scenario 1 would instead be for Namenda XR and thus, the total reduction in spending would be approximately $12 billion (from $37 billion to $25 billion).

In Scenario 3, we assume that production of Namenda IR is effectively suspended prior to generic entry and thus, Namenda XR takes 75% of what would have been the generic market. Under this scenario, the total reduction in spending declines to $6 billion. Thus, at minimum, the withdrawal of Namenda IR from the market would increase spending by Medicare and its beneficiaries by $6 billion over this period.

Estimated Total Spending on Namenda and its Competitors with (1) Generic Competition and (2) Namenda XR:												**2015-24**	
ESTIMATES of Various Scenarios									**2016**		**2015-24**		
Namenda without Generic Competition													
	Namenda (Brand withOUT Generic competition)												
		Spending ($M)							2,208				
	Total Spending of the scenario ($M)										**36,951**		
Namenda with Generic Competition starting in 2015													
	Generic version of Namenda												
		Spending ($M)							828		6,842		
	Namenda (Brand POST-generic competition)												
		Spending ($M)							552		5,763		
	Total Spending of the scenario ($M)										**12,606**		
Namenda with Competition from both Namenda XR and Generic Competition starting in 2015													
	Namenda XR												
		Spending ($M)							1,104		18,475		
	Generic version of Namenda												
		Spending ($M)							414		3,421		
	Namenda (Brand POST-generic competition)												
		Spending ($M)							276		2,882		
	Total Spending of the scenario ($M)										**24,778**		
Namenda regular discontinued and replaced by Namenda XR and Generic Competition starting in 2015													
	Namenda XR												
		Spending ($M)							1,794		29,154		
	Generic version of Namenda												
		Spending ($M)							207		1,711		
	Total Spending of the scenario ($M)										**30,865**		
Source:	ASPE's estimates based on its analysis of Medicare Part D Events (PDE) data 2010-2012												
Notes:													
Projected baseline growth based on the historical 2010-12 rates of anti-dementia drugs													
Effects of generic competation based on 2010-12 data for all anti-dementia drugs													
Market share taken away from the generic competitor(s) of Namenda IR by Namenda XR is 1/2 if Namenda IR remains													
Market share taken away from the generic competitor(s) of Namenda IR by Namenda XR is 3/4 if Namenda IR exits													
prior to its generic entry													

Conclusions

The planned withdrawal from the market of Namenda IR appears designed to force a highly-vulnerable population suffering from a severe chronic illness to shift to a reformulated version of the product for the purpose of limiting generic competition and preserving monopoly profits. Actions of this type undermine consumer choice and generic competition in prescription drug markets.

If Actavis curtails production of Namenda IR, consumer welfare will suffer due to a combination of fewer choices and diminished price competition. The federal government in particular would overpay relative to what it would have paid had the generic product been permitted to freely compete with the newer reformulated product. Such practices stress public budgets and reduce the ability to promote value-based health care use. As a result, Actavis' planned conduct would exacerbate the problem of financing health care for the elderly.