The Rise of Big Generic: Why Knockoff Prescriptions Now Cost $1,200

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Not that long ago, the generic drug industry was the ugly stepchild of the Big Pharma family - the uncomely domain of penny pills and piffling profits. The big names in pharma preferred to hawk Prozac, Viagra and other brand-name elixirs at five and 10 dollars a pop, leaving smaller firms that had all the prestige of Kmart to scramble over the nickels and dimes to be had off generics. It was, however, a good era for anyone who needed a cheap generic, as a majority of Americans did (and still do) each year. But times have changed, and decidedly not for the better.

the largest in the FTC's history - with Teva Pharmaceuticals over shady trade practices. The size of the settlement was only part of the news. The other part was that Teva responded with the corporate equivalent of a shrug, even declaring itself "pleased" with the deal, which might have been taken for bravado but for the concurrence of Teva's investors, who kept the company's stock price steady as could be. It's not news that a billion dollars is chump change to Big Pharma. The news is that Teva isn't Big Pharma. Teva is a generics maker - Mid Pharma at best. But such has been the consolidation in the generics trade that even its players are now behemoths, and this is where the danger lies.

Teva has been a consolidator (http://www.reuters.com/article/2015/04/22/us-teva-pharm-ind-acquisitions-idUSKBN0ND1JC20150422) among consolidators, hoovering up half a dozen companies in the last 15 years at a cost of more than $30 billion. Headquartered in Israel, Teva does most of its business in the West. In the United States it employs 7,500 people and fills 1.5 million prescriptions a day, more than half a billion a year. In Europe it fills nearly twice that. All of which makes it the biggest seller of generics in both America and the world. Teva has plans to grow bigger still and has cast an acquisitive eye on, among other companies, its nearest rival in the generics field, Mylan (which has so far resisted Teva's overtures). By one slightly hyperbolic assessment (http://www.forbes.com/sites/stephenbrozak/2015/04/22/tevamylanperrigo-merger-mania-in-pursuit-of-generic-margins/), if the Mylan purchase were to go through, "Every man, woman and child in the U.S. will eventually take a pill manufactured by the new entity." This is not good news for any man, woman or child - unless she or he holds stock in Teva.

Consolidation Results in Skyrocketing Prices

As Big Generic has consolidated, competition has of course dropped, and makers of generics have raised prices flamboyantly (http://abcnews.go.com/Health/generic-drug-prices-skyrocketing-lawmakers-warn/story?id=27060992). In October 2013, a month's supply of doxycycline, a widely used antibiotic that has been available in generic form for three decades, cost hospitals $1.20. Just six months later, it cost $111.00, an increase of 9,150 percent. In July 2013, a month of tetracycline, another antibiotic long generically available, cost pharmacies $1.50, but a year later it was $257.70, an increase of 17,080 percent. These are extreme instances, but they are not aberrant.

coincidence, the most frequently prescribed generics were among the more dramatic risers. One report (http://genericpharmafinance.com/generic-drug-prices-continue-to-soar/) found that in 2010, the 50 most popular generics cost an average of $13.14 per prescription, but by 2014, it was $62.10, a 373 percent spike. Big Generic is wont to point out that although the prices of half of all generics have gone up, half have gone down. Less often do they point out that the increases have far outpaced the declines. They are like the grocer who advertises the dime knocked off his cauliflower while quietly trebling the price of bread.

Naked price-gouging is indisputably behind the price hikes, but to give the pharmaceutical devils their due, it is not always the only thing behind the hikes. Shortages of raw materials, subcontracted factories that fail inspection, surges in demand due to unexpected outbreaks, backlogs at the Food and Drug Administration in processing applications by would-be manufacturers and other circumstances can contribute to high prices. But which circumstance is responsible for what part of the price of any given drug is mostly unknown because manufacturers rarely release the data that would tell us.

When Sen. Bernie Sanders, the Democrat of Vermont now running for president, held a hearing (http://www.sanders.senate.gov/newsroom/recent-business/senate-hearing-on-generic-drug-prices) on the scandalous price of generics last fall, three manufacturers of some of the most appallingly priced drugs refused to testify. Teva, which makes doxycycline and tetracycline, was one of them. What can be said with certainty is that, even setting aside rank greed, consolidation in the industry makes all of the above challenges worse. The closure of a single factory or the disruption of a single supply line doesn't much matter when six or eight companies make a drug. It's a different story when only two or three do.

It may, then, come as a surprise to those familiar with oligopolistic pricing to learn that Teva's share of the US generics market in recent years has ranged from just 13 to 22 percent. Second-place Mylan has held a mere 8 to 13 percent. The four biggest generics manufacturers combined control only 40 to 50 percent. Those numbers don't have the ring of oligopoly, but the generic market is different from most, chiefly because even the biggest manufacturers can make only a modest fraction of the thousands of generic drugs in existence. Teva and Mylan, for example, make 400 or so each, many overlapping. Other manufacturers make but a few dozen. The industry used to combat severe daytime sleepiness caused by debilitating illnesses like narcolepsy, sleep apnea and idiopathic hypersomnia. Idiopathic hypersomnia can keep sufferers perpetually groggy or, worse, asleep for up to 20 hours a day, and modafinil is the only drug that helps some sufferers. But modafinil is perhaps best known as a "smart drug" (http://www.newyorker.com/magazine/2009/04/27/brain-gain) used by students, with varying degrees of legality, to stay alert when cramming for exams. (Recent research (http://www.futurity.org/modafinil-drug-creativity-803372/), by the way, has cast a dubious light on the efficacy of modafinil for enhancing one's studying.)

Cephalon held the exclusive patent to modafinil and had been selling it since 1998, but the patent was set to expire in 2006. Teva wanted a piece of the action when it did expire. Cephalon, however, wasn't ready to give up its monopoly, so in 2005 and 2006, it paid more than $300 million to Teva and three other makers of generics to stay out of the market until 2012. That only four firms wanted to sell one of the world's most lucrative pills speaks to the industry's consolidation - and the four have since been reduced to three because Teva bought one of them. Teva's target Mylan is one of the other two survivors.

Tricks of the Trade

Generic firms love "pay to delay" deals, as they are known in the trade, because of the guaranteed profit. Name-brand firms of course love the extension of their monopoly. In certain narrow circumstances, the deals are legal, the key being that consumers don't get fleeced. But after buying off its competitors, Cephalon's profits on Provigil took on a fleece-like texture. In 2005, when the first deal was struck, annual US sales of the drug were $475 million. Just two years later, they topped $800 million. By 2011, the last full year of Cephalon's monopoly, they reached $1.1 billion.

The growth was only partly due to an increase in prescriptions. It is the vulgar norm in the pharmaceutical industry to raise the price of a drug that is about to go over the patent cliff, and Cephalon was vulgarly normal. In 2004, a month's supply of Provigil cost about $166 (drug prices vary from pharmacy to pharmacy), but by 2007 it was $272, by 2009 it was $409, and by the last year of Cephalon's patent in 2012 it was $1,001. The gross take - an altogether apt phrase - during the extra years of Provigil's monopoly came to about $5 billion, not a shabby return on $300 million in drug approaches the patent cliff is to develop a new drug to replace the old one, often by making the merest of tweaks, like putting an extended-release coating on an immediate-release tablet. Sometimes the benefits are more substantial, but even then they may be outweighed by new side effects or may be helpful only to a small subpopulation of patients.

Regardless, the drug maker will tout its new pill - often spending millions, even tens of millions, to herald its improvements (and minimize its flaws) - and a lot of doctors and patients will be swayed. Those who aren't swayed may migrate to the new drug anyway because the price of the old one has been jacked up so high, as Cephalon did with Provigil, that even the spendy new drug is a bargain. The value of all this is not just the short-term profiteering but getting a base of doctors and patients hooked on the new drug before the old one turns generic. Most doctors and patients don't care to fix what ain't broke, so if the new drug works OK, they're less likely to use the old drug even after it goes generic and its price plummets.

This was essentially Cephalon's strategy for Provigil and its lightly tweaked replacement, Nuvigil. Trouble was, in 2005, Cephalon was running behind in getting FDA approval for Nuvigil. By buying off Teva and the rest, Cephalon was buying time to get the drug approved and market it to doctors and patients. Nuvigil finally arrived in pharmacies in mid-2009 (priced at $269 a month, compared to Provigil's jacked-up $409) and grossed $39 million over the remainder of the year. By 2012, when Provigil went generic, annual sales of Nuvigil had reached $437 million. In all, Cephalon took $1 billion from Nuvigil during the extra years of its Provigil monopoly and along the way established a solid base of doctors and patients from which to wring future profits.

At first, the FTC's investigation into these shenanigans encompassed all the firms involved. But when the FTC brought suit in 2008, it declined to prosecute Teva and the other generics makers that Cephalon bought off and instead sued only Cephalon, the fattest of the mischievous cats. Why, then, does Teva now have to cough up $1.2 billion to the FTC? The answer is that, so promising was Cephalon's growth, Teva bought the company in 2011 (at a price of $6.8 billion).

Teva is thus in the unusual position of having to pay the feds for fixing prices with itself - yet another testament to the consolidation of the industry. It is also a harbinger of the future because generics firms, flush with their oligopolistic profits, are getting into the name-brand game, while name-brand firms, themselves

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