US drug makers blocking generic competition to inflate prices

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1 October 2015

Last month, drug makers Concordia Pharmaceuticals and Par Pharmaceutical Inc. settled charges brought by the Federal Trade Commission (FTC) that the companies entered into an illegal agreement to avoid competition in the sale of generic versions of Kapvay, a treatment for Attention Deficit Hyperactivity Disorder (ADHD).

The two companies were the only firms with FDA approval to sell the generic drug. According to the FTC, Concordia agreed to not sell the drug in exchange for 35 to 50 percent of the net profits from Par's sales of the drug.

"When the first generic entrant is the sole seller of the generic drug product," says an FTC document analyzing the case, "it enjoys approximately double the revenues that it would otherwise make in the first six months on the market if it faced competition from an authorized generic."

The practicing of collusion among drug companies aimed at blocking generic competition, thereby increasing revenue and profits, is quite common and has contributed to significant increases in the price of a number of generic drugs in addition to rising prices for most name brands.

The latest FTC actions follow a settlement this past May in which generic drug producer Teva Pharmaceuticals, the largest generic drug manufacturer in the world, agreed to pay $1.2 billion to resolve claims that the pharmaceutical company Cephalon (acquired by Teva in 2012) blocked generic competition for the drug Provigil. Teva reached a separate settlement of $512 million in April to resolve a class action lawsuit brought by drug wholesalers and retailers over the same issue.

Provigil received FDA approval in 1999 as a treatment for narcolepsy, and the drug's approved uses were subsequently expanded to a range of sleep disorders in 2004. However, the majority of prescriptions—analysts estimated 80 percent—were made by doctors for off-label uses not approved by the FDA, in part due to Cephalon's illegal marketing practices.

In 2008, the company entered a criminal plea and paid $425 million to resolve claims by the Justice Department that it marketed three drugs, including Provigil, for off-label uses. Provigil became Cephalon's top-selling product and in 2006, the year its patents were expected to expire, had sales of $691.7 million.

According to the lawsuit initiated by the FTC in 2008, Cephalon illegally sought to stop generic drug competition by suing potential makers of generic versions who had challenged Provigil's patent. Then, in a pay-for-delay deal, Cephalon paid four potential competitors over $300 million to drop their patent challenges and forgo selling generic versions for six years.

"In this case," reports the FTC in a press release, "Cephalon agreed to pay the generics principally for active pharmaceutical ingredients and intellectual property, business deals the FTC was prepared to prove at trial made no economic sense for Cephalon except as payments not to compete."

In the 2013 decision *FTC v. Actavis*, the Supreme Court ruled that such "reverse-payment" patent settlements can violate antitrust laws, opening the door for the FTC actions this past year.

On average, generic drug prices have decreased since 2006, according to a report presented to the Senate last year by Stephen W. Schondelmeyer of the University of Minnesota's *PRIME* Institute. The prices of 227 top branded drugs, by contrast, increased substantially faster than the general rate of inflation between 2006 and 2013, and at an increasing rate. In 2013, the drug prices went up by 12.9 percent, while the rate of inflation stood at 1.5 percent.

However, Schondelmeyer reported that nearly a third (91) of 280 generic drug products widely used by older Americans saw price increases. Fifty-four of the drugs increased by 15 percent or more, while another 27 saw increases of 50 percent or higher.

Similarly, a November 2014 perspective article published in the *New England Journal of Medicine* highlighted the rising costs of a number of generic drugs.

The article pointed to the case of albendazole, a broad-spectrum antiparasitic medication that has gone off patent. However, no manufacturer ever sought generic approval because there was no financial motive to do so—the drug treats intestinal parasites, neurocysticerocosis, and hydatid disease, which primarily affect immigrants and refugees.

While the average wholesale price for a typical daily dose of albendazole in 2010 was $5.92, by 2013 the price had risen to $119.58 (an increase of over 2000 percent). The authors' analysis of Medicaid data found that spending on albendazole between 2008 and 2013 rose from less than $100,000 per year ($36.10 per prescription on average) to more than $7.5 million per year ($241.30 per prescription).

Drawing on data from the National Average Drug Acquisition Cost price file, between November 2012 and November 2013 the following generic drugs also saw substantial price hikes:

• Captopril, used to treat hypertension and heart failure, went from 1.4 cents to 39.9 cents per pill (a 2850 percent increase).

• Clomipramine, an antidepressant also used for obsessive-compulsive disorder, rose from 22 cents to $8.32 per pill (a 3780 percent increase)

• Doxycycline hyclate, a broad-based antibiotic available since 1967, went up from 6.3 cents to $3.36 per pill (a 5330 percent increase).

Around 80 percent of the prescriptions filed in the US are for generic drugs. The recent spikes in the prices of many generic drugs have followed a period of drug industry consolidation, as competitors are swallowed by larger rivals, alongside more brazen acts of illegal collusion. In the face of rising drug prices, both generic and branded, combined with stagnant wages, the health of workers in the US is being put at an ever greater risk.

According to a poll released by Consumer Reports this August, consumers have paid an average of $39 more per prescription in the past 12 months. Patients who experienced a price rise in the cost of their drugs were more likely to resort to measures that increased risks to their health. For example, skipping the filing of prescription due to cost (24 percent), skipping a dose to save money (18 percent), taking an expired medication (17 percent), or cutting pills in half to save money (16 percent).