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For most Americans, generic drugs are a godsend. Prescription drug prices have become so high that many folks simply can’t afford to purchase needed medications. It’s not uncommon for some cancer and hepatitis medications to cost $1000 or more per dose. Generics, however, can cut prescription bills by 90% or more.

As much as consumers love generic drugs, big pharma hates them. Once a branded drug goes “off patent,” sales usually plummet. Most health plans, insurance companies and Medicare require physicians to dispense less costly generics.

The loss of profits can be so great when a drug goes generic that many pharmaceutical companies are now engaging in “pay for delay” tactics.

What is “pay for delay”? It is the payment by a pharmaceutical company to would-be competitors to not copy a certain medication. The results are more profits for big pharma and therefore an extension of their monopoly on pricing. The Federal Trade Commission says pay for delay costs taxpayers, insurance companies and consumers almost $4 billion per year.

Is this legal? Probably not.

Congress wanted to encourage generic manufacturers to quickly enter the marketplace and lower drug costs. In 1984, Congress passed the Hatch Waxman Act. That law encourages generic manufacturers to challenge pharmaceutical companies. The first company that seeks to make a generic of a branded drug is given an expedited review by the FDA.

Unfortunately, what started out as a law with good intentions soon turned horribly bad. Big pharma began suing the generic manufacturers for patent infringement. The pharmaceutical companies would then settle the suits and pay the generic company not to compete for a period of time, often 5 years.

A few court victories later, the pay for delay industry was in full swing.

Thankfully the Federal Trade Commission has stepped in and appears to be gaining traction. The government says that many of these pay for delay schemes violate federal anti-trust laws. In 2013, the United States Supreme Court ruled that pay for delay does automatically violate antitrust laws but still must be carefully scrutinized. (FTC v. Actavis). Georgetown University Professor Lawrence Gostin, writing for the Journal of the American Medical Association, hailed the decision and says it will save consumers and taxpayers billions of dollars.

Some may be wondering why the generic manufacturers go along with these payments. Obviously big pharma likes these settlements because they can extend their monopolies for years. Generic manufacturers find these settlements economically worthwhile too. Because the profits made on branded drugs are so large, big pharma can pay millions to the generic manufacturers and still make a profit. The smaller generic companies make just as much profit from the settlements and don’t have to produce a single pill.

The Motley Fool investigated one branded drug, Provigil, manufactured by Cephalon. The drug was due to come off patent in 2005 but Cephalon paid four generic companies $200 million to delay manufacturer of generic
equivalents until 2012. The cost of a three-month supply of Provigil? $3600. The cost after generics were finally introduced? About $5 per month according to fool.com.

With the courts and regulators finally looking hard at these arrangements, we hope more whistleblowers come forward. Under the federal False Claims Act, whistleblowers with inside information about fraud involving a government program can receive up to 30% of whatever is recovered from drug companies. To qualify for an award, whistleblowers need inside, “original source” information about the fraud.

The FTC’s Bureau of Competition concluded that of the 145 final patent dispute settlements in 2013, 29 represent potential pay for delay schemes. Recently the agency launched a hotline to help people report illegal pay for delay schemes.

Whistleblowers using the hotline should know, however, that calling the hotline does not make them eligible for a whistleblower award. To claim an award, one must first file a lawsuit in federal court.

As a law firm that has helped clients receive over $100,000,000.00 in whistleblower award payments, we want to see whistleblowers properly awarded for coming forward and reporting illegal behavior.

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