



## FACT SHEET

### **Ban 'Pay- For- Delay' Collusion to Promote Drug Savings and Access**

#### **Generic drugs have saved consumers and federal programs \$734 billion.**

Generic drugs compete with brand names in the marketplace and have saved \$734 billion in the past 10 years.<sup>i</sup> The Hatch-Waxman Act of 1984<sup>ii</sup> safely sped up the approval process for generics and thereby helped increase generic drug use from just 12 percent<sup>iii</sup> in 1984 to 70 percent today. Since generic drugs cost 60 to 90 percent less than the brand name drugs they replicate, this has become the most important tool for reducing our ever-rising drugs costs.

#### **The Problem: Drug industry sweetheart deals block competition and prevent higher savings and access through generic drugs**

Brand-name drug makers have routinely tried to delay generic rivals with patent infringement lawsuits. But as a result of legal decisions in 2005, brand-name drug makers have paid generic rivals multi-million dollar 'sweetheart deals' to settle these questionable lawsuits. These settlement amounts are far more lucrative than the slim profit margin on a generic drug, and they guarantee the brand-name drug company continued profits without competition from any generic.

For example, Bayer Corp, maker of the antibiotic drug Cipro, paid three different generic drug competitors a combined \$400 million to delay any generic for six and a half years. In order to ensure that our health system remains affordable, healthy competition cannot be undermined by industry collusion that limits consumer choices and undermines patient care.

#### **"Pay-for-delay" deals shield \$29 billion in yearly drug spending from competition**

Two recent reports by the FTC have revealed how costly these settlements are to government programs, consumers, and insurers. A January 2010 FTC report revealed that nearly **\$20 billion dollars in current annual spending on brand-name drugs is unfairly protected from competition** by the 63 settlements then in effect.<sup>iv</sup> A subsequent July report<sup>v</sup> updated this information, noting that a record number of new pay-for-delay settlements – 21 in FY2010 – insulate *another \$9 billion in brand-name drug sales from competition*. January's report revealed that these sweetheart deals delay generics by an average of 17 months. But as the drug industry continues to maneuver the FTC's legal challenges into the industry-friendly 4<sup>th</sup> and 11<sup>th</sup> Circuit courts, longer, more costly delays are nearly certain. The delays prevent the 60-90 percent cost savings that lower-priced generic drugs allow, while also undermining patient care.

#### **The Solution: Provide FTC authority to challenge anti-competitive pay-for-delay deals and increase access to generics**

Generics should be allowed to come to the market as soon as possible. A ban on pay-for-delay settlements will prevent drug companies from unfairly colluding to keep generics off the market. The Senate Financial Services and General Government Appropriations Act of 2010 (S. 3677)<sup>vi</sup> provides the FTC with needed authority to protect consumers health market competition.

## Pay-for-delay ban to save consumers, health plans billions

The Congressional Budget Office has estimated, conservatively, that a ban would save the federal government \$2.4 billion on prescription drug costs over the next decade.<sup>vii</sup> The FTC, which is able to review these agreements filed under seal, estimates that the savings to consumers and our health system overall would be \$3.5 billion or more per year.<sup>viii</sup> Other experts predict even more significant savings of \$12 billion per year are likely.<sup>ix</sup>

## Access to generics drugs improves quality of care

The American Medical Association recently condemned the role these pay-for-delay settlements play in preventing affordable treatment, which can result in no treatment at all in vulnerable populations, or patients on fixed or limited incomes.

## Support for a ban on pay-for-delay settlements

President Obama has consistently supported a ban on these anti-competitive deals between drug makers. This policy has been supported by the AMA, AARP, the FTC, the Attorneys-General in 34 states, and numerous consumer, labor, and patient advocacy groups.<sup>x</sup>

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<sup>i</sup> AARP, *Rx Watchdog Report*, Vol. 6, Issue 4 (May 2009), available at

[http://assets.aarp.org/www.aarp.org/\\_cs/health/205256rxwatchdogmay09.pdf](http://assets.aarp.org/www.aarp.org/_cs/health/205256rxwatchdogmay09.pdf), last accessed 9/10/2010.

<sup>ii</sup> Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, a generic drug company can use the safety studies of the original drug. The Act also polices against bad drug patents by allowing a generic to be brought to market if the drug's patent is invalid or would not be infringed. According to a 2002 FTC study, generic manufacturers won two-thirds of the patent disputes when litigated in court.

<sup>iii</sup> Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm>, last accessed 9/19/2010.

<sup>iv</sup> FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010, available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>, last accessed 9/10/2010.

<sup>v</sup> Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Antitrust Division: Before the United States House of Representatives Committee on the Judiciary Subcommittee on Courts and Competition Policy, 11<sup>th</sup> Cong. 2d Sess. (July 27, 2010) (Statement of Jon Leibowitz, Chairman of the Federal Trade Commission). Available at: <http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf>, last accessed 9/10/2010.

<sup>vi</sup> S. 3677 PCS, The Financial Services and General Government Appropriations Act, 111<sup>th</sup> Cong., § 746, at 158 (2011).

<sup>vii</sup> CBO, "S. 369: Preserve Access to Affordable Generics Act (Updated Table)", June 16, 2010, available at [http://www.cbo.gov/ftpdocs/115xx/doc11582/S369\\_updated\\_table.pdf](http://www.cbo.gov/ftpdocs/115xx/doc11582/S369_updated_table.pdf), last accessed 9/10/2010 (revising their earlier January 2010 analysis to reflect the passage of health care reform legislation and to extend the estimates to 2020).

<sup>viii</sup> Jon Leibowitz, Chairman, FTC, speech, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (June 23, 2009), available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>. (Noting at p.8 that "[t]hese numbers were based on pretty conservative assumptions. Perfectly reasonable alternative assumptions would lead you to \$75 billion in savings for American consumers, which would work out to \$25 billion for federal programs over the next decade.")

<sup>ix</sup> Scott Hemphill, testimony, Mar. 31, 2009, before the House Subcommittee on Commerce, Trade, and Consumer Protection, at 9, at [http://energycommerce.house.gov/Press\\_111/20090331/testimony\\_hemphill.pdf](http://energycommerce.house.gov/Press_111/20090331/testimony_hemphill.pdf).

<sup>x</sup> Community Catalyst organized the support of thirty-three national and local consumer and labor organizations for a ban on pay-for-delay settlements during national health reform. <http://www.prescriptionaccess.org/2009lobbyletter20.pdf>. For a description of organizations opposing these agreements in the Courts, see <http://blog.prescriptionaccess.org/?p=807>.