

## Chairman Dingell at the Subcommittee on Commerce, Trade, and Consumer Protection hearing entitled "H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007"

Statement of Congressman John D. Dingell, Chairman  
Committee on Energy and Commerce

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION HEARING ENTITLED "H.R. 1902, PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2007"  
May 2, 2007

Let me begin by commending Chairmen Rush and Waxman for introducing H.R. 1902, the "Protecting Consumer Access to Generic Drugs Act of 2007". It is sorely needed. Consumers no longer receive the full benefits that Congress intended when it passed the Hatch-Waxman Act in 1984. It appears that, in certain instances, drug companies may be making deals that thwart the goals of Hatch-Waxman and cost consumers billions of dollars in intended savings.

When Congress passed Hatch-Waxman, it appreciated the growing importance of pharmaceuticals for treating a host of physical and mental conditions. The statute struck a careful balance between drug innovation and drug affordability.

On the one hand, it extended the patent protection for pharmaceuticals to encourage "branded" manufacturers to research and develop new drugs, given the lengthy Food and Drug Administration (FDA) approval process. On the other hand, it crafted incentives to induce generic manufacturers to enter the market sooner to make lower-cost alternatives available to consumers. Among those incentives, the legislation encouraged generic companies to challenge potentially dubious patents and withstand infringement litigation by a branded company.

The legislation has been successful. Consumers Union estimates that in 2006 the appearance on the market of new generic drugs as alternatives to just five "blockbuster" drugs saved consumers over \$6 billion dollars.

For some years now, however, we have learned that instead of continuing litigation, some generic entrants are accepting cash payments and other transfers of value to settle and stay out of the market. These settlements, called "exclusionary payments" or "reverse payments," are a sweetheart deal for both brandeds and generics. Generics get paid even when they bring no product to the market. The brandeds pay less to the generics than the revenues they would lose when competing against a lower-cost rival.

These settlements are bad deals for consumers. Drug companies are essentially pocketing the savings that Hatch-Waxman intended for consumers.

Let's focus on some of the consumers left behind by these deals.

One is the taxpayer. Through programs such as Medicare and Medicaid, the Government spends billions on drugs every year. In 2006, Government expenditures for prescription drugs were estimated to be \$68 billion. By 2016, these estimates rise to more than \$200 billion.

Other consumers include employer health plans sponsored by U.S. industry. Government and industry would save enormous sums if more generics were made available earlier in the marketplace, as the Hatch-Waxman Act had intended.

H.R. 1902 endeavors to fix this problem. It will prevent exclusionary payments and restore Hatch-Waxman's goal of putting generic drugs on the market more quickly.

Chairman Rush, I look forward to working with you as this legislation moves through the Committee and the Congress.

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