**REFORMING MEDICARE**

**Option: Prohibit Pay-for-Delay Agreements**

Brand-name pharmaceutical companies can delay generic entry into the marketplace by compensating a generic competitor for holding its competing product off the market for a certain period of time. Some proposals would prohibit brand-name and generic pharmaceutical manufacturers from entering into these “pay-for-delay” agreements.

**Prepared for the Public Policy Institute by: Avalere Health, LLC**

**Argument for:**

Proposals to prohibit pay-for-delay agreements will help get less expensive generic drugs to the market more quickly. The U.S. Federal Trade Commission (FTC)—the government agency charged with protecting consumers from anticompetitive business practices—reports that patent settlement agreements between brand-name and generic manufacturers that involve some sort of compensation prohibit generic entry for nearly 17 months longer (on average) than agreements without such payments.

Eliminating pay-for-delay agreements would also result in substantial savings for consumers and government programs like Medicare and Medicaid, as generic drugs can cost up to 90 percent less than their brand-name counterparts. The FTC estimates that ending pay-for-delay agreements would save $3.5 billion each year for patients, insurers, and government programs.

Prohibiting pay-for-delay agreements could also improve patient health. Access to generic drugs has been shown to increase medication adherence, which is particularly important for individuals with chronic health problems who rely on multiple medications to help stabilize and manage their conditions. Medicare beneficiaries who fail to take their medications as prescribed are more likely to have costly health complications, creating additional costs for the beneficiaries and the Medicare program.

**Argument against:**

Pay-for-delay agreements are an efficient and cost-effective way for pharmaceutical companies to resolve expensive patent lawsuits. Patent challenges occur when generic drug manufacturers try to gain market entry before the patent on a brand-name drug has expired. If pay-for-delay agreements are prohibited, generic drugs could actually be kept off the market for a longer period of time, since it can take years to resolve patent litigation through the court system.
Prohibiting pay-for-delay agreements could also affect generic manufacturers’ willingness to challenge brand-name drug patents, reducing the number of generic drugs that become available before their brand-name counterparts go off patent. Generic manufacturers may be hesitant to engage in patent challenges if it is unclear whether the potential gains—including the possible settlement terms—outweigh the risk of recovering nothing.

Further, there is little proof that pay-for-delay agreements prevent generic competition. In fact, a majority of pay-for-delay agreements allow generic drugs to enter the market before the brand-name patent has expired. It is also important to ensure that the innovations of brand-name drug manufacturers are adequately protected by patents. Without this security, pharmaceutical companies may be less likely to invest money in the research and development of new drugs.

*Avalere Health, LLC* is a leading advisory company focused on health care business strategy and public policy.