INTRODUCTION

Health care and legal blogs have been abuzz in recent months over a Senate bill to restrict pharmaceutical companies from “pay-for-delay” patent settlements that stall generic introductions. On October 15, 2009, the Senate Judiciary Committee voted 12–7 to approve the Preserve Access to Affordable Generic Drugs Act (S. 369), which would prohibit the practice whereby a generic drug company that has challenged a brand-name company’s patent accepts payment from that company in exchange for delaying its generic entry to the market.

Pay-for-delay, or “reverse payment,” settlements have been around for awhile. The first known pay-for-delay deal was in 1994 when Bristol-Myers Squibb paid $290 million to Schein Pharmaceutical to delay the sale of a generic version of the Bristol-Myers anxiety drug buspirone (Buspar).

As Pharmalot blogger Ed Silverman points out, S.369, if passed, would not completely ban the practice. However, he says, it would allow drug makers to strike a deal only if they provide ‘clear and convincing evidence’ that an agreement doesn’t stymie competition. . . . [Senator] Herb Kohl, the Wisconsin Democrat who introduced the bill, opposes any attempts to lower the threshold of evidence, although the bill was originally tougher—it would have banned these deals entirely.

The bill did indeed start out as a per se ban, making all pay-for-delay agreements illegal. However, because the Senate was unable to pass it as such, S.369 was amended to include this compromise provision. The Senate listed five competitive factors that could be used to determine whether settling parties have met that clear and convincing burden. These include the length of time remaining until the end of the life of the relevant patent, compared with the agreed-upon entry date for the Bristol-Myers’ anxiety drug buspirone (Buspar).

As Miriam Reisman notes, the author is a medical writer living near Philadelphia, Pennsylvania.

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The fate of H.R. 573, which is almost identical to the bill Representative Emerson introduced during the last congressional session, remains uncertain as it has yet to be scheduled for a vote.

Meanwhile, the question of what to do about pay-for-delay and authorized generics is as complex as it is controversial. In fact, a recent FTC Interim Report examining the effects of authorized generics on competition found that the use of these products may actually help drive down drug prices.7 According to the FTC report, retail drug prices, on average, are 4.2% lower, and wholesale prices, on average, are 6.5% lower when an authorized generic drug competes with another generic during the 180-day exclusivity period than when an authorized generic does not enter the market.

However, the FTC report also notes that authorized generics substantially decrease the first-to-file generic company’s revenue, on average, by 47% to 51% during the marketing exclusivity period. As a result, generic firms are more likely to agree to defer their market entry and enter into pay-for-delay agreements, delaying the availability of any generic drug— independent or authorized—for at least 180 days. Such brand–generic deals appear to be more common now than in the past, according to the Interim Report. From 2004 to 2008, approximately 25% of final patent settlements reviewed by the FTC were the result of an authorized generic leading to a pay-for-delay agreement.7

Brand–generic agreements that delay introducing generic brands, concludes the FTC report, can harm consumers in two ways:7

- These products would not be available to consumers as soon as they otherwise might, which would force consumers to pay higher overall prescription drug costs.
- Consumers would be deprived of the benefit of price discounts from authorized generic competition during the 180-day marketing exclusivity period.

CONCLUSION

The importance of these findings looms even larger in an increasingly contentious health care debate. True, legal experts have been arguing the pros and cons of pay-for-delay settlements for a while, but health care reform has re-energized the debate. And now that the Judiciary Committee has approved a restrictive ban, and with billions of dollars at stake, both brand-name and generic companies are expected to lobby hard against it. Lawmakers also support a curb on authorized generics, but evidence that these products might actually reduce drug prices could end up keeping a provision banning these generics out of health care reform legislation.

There is no question that everyone has a stake in how health care reform turns out and how it will affect issues such as these. Certainly, as the health care bill now moves from the House to the Senate, all sides will be watching closely.

REFERENCES