

## FDA Law Update

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### Reverse Payment Issue Continues to Sizzle

We reported recently that the issue of reverse settlement payments to generic drug manufacturers was continuing to heat up this summer. FTC Chairman Jon Leibowitz's recent comments on the issue further support this forecast. In a speech before the Center for American Progress, Leibowitz stated that the FTC "has made stopping these deals a top priority," and he urged Congress to do the same.

Reverse settlement payments occur after a brand-name drug manufacturer sues a generic manufacturer for patent infringement. In settling the case, the companies enter a "pay-for-delay" agreement, whereby the generic accepts a payment to stay out of the marketplace for a certain period of time.

In his speech Tuesday, Chairman Leibowitz articulated a strong position against these agreements. "Clearly, these are win-win deals for both companies," he said. "But they leave American consumers footing the bill." Leibowitz argued that, by conservative FTC estimates, banning these payments could lower health care costs by \$3.5 billion annually. Given that the federal government is responsible for approximately one third of the nation's \$235 billion prescription drug bill, this would mean that \$1.2 billion would be available for other federally funded programs if this estimate were accurate.

The speech coincided with the FTC's release of an interim report on authorized generic drugs and their impact on reverse settlement payments. While the report did state that retail drug prices are 4.2 percent lower when an authorized generic is marketed against the "first-filer" generic during the 180 day exclusivity period, it also noted that these authorized generics decrease the first-filer's revenue on average by 47-51 percent. As a result, first-filers are more likely to enter into pay-for-delay agreements, delaying the availability of any generic for at least 180 days. Since 2004, approximately 25 percent of final patent settlements reviewed by the FTC were the result of an authorized generic leading to a pay-for-delay agreement.

Leibowitz seemed optimistic about stopping these agreements despite a recent setback at the Supreme Court. Last Wednesday, the Court denied cert in the case of *In Re: Ciprofloxacin*, a decision from the Federal Circuit approving a reverse settlement payment. This decision would have resolved a circuit split on the legality of these payments. It is the third time the Court has declined to hear the issue.

The chairman expressed hope that the new administration and Congress would take action on the issue. He noted that legislation is working its way through Congress. In the House, H.R. 1706 passed the House Energy and Commerce Subcommittee on Commerce, Trade and Consumer Protection in June. The markup of Senate version, S. 369, was deferred last week by the Senate Judiciary Committee, but is expected to be taken up at some point before the August recess.

The full text of Chairman Leibowitz's speech can be found here:

<http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

The full text of the report can be found here:

<http://www2.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>.

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