State Joins $125 Million Multistate Antitrust Settlement with Cephalon For Efforts to Delay Provigil Competition

Consumers who purchased Provigil could receive settlement funds

Attorney General George Jepsen announced today that Connecticut has joined 48 other states and the District of Columbia in a $125 million settlement with biopharmaceutical company Cephalon and its affiliated companies, including Teva Pharmaceutical Industries, Teva Pharmaceuticals USA and Barr Laboratories. The settlement resolves allegations of anticompetitive conduct by Cephalon concerning its drug, Provigil. The conduct at issue is referred to as "pay for delay", where a branded drug company sought to unlawfully maintain its exclusive rights by paying the would-be generic competitor to delay entry into the market and thus keep prices at artificially high levels.

Modafinil, the active ingredient in Provigil, is approved by the Food and Drug Administration (FDA) to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder.

As the patent for Provigil neared expiration in 2001, Cephalon intentionally mislead the United States Patent & Trademark Office (PTO) in order to secure an additional patent for the purpose of preventing competition. By misleading the PTO, Cephalon was able to obtain FDA exclusivity for modafinil until June 2006, and extend patent exclusivity until April 2012. A court subsequently deemed the additional patent invalid and unenforceable, but prior to that ruling, Cephalon was able to delay generic competition for over a decade by filing patent infringement lawsuits against all potential generic competitors.

Cephalon later settled lawsuits with its generic competitors in 2005 and early 2006 by paying them to delay the sale of their generic versions of Provigil until at least April 2012 - six years after expiration of FDA exclusivity but three years before patent expiration. The delayed entry cost consumers, states and others hundreds of millions more for Provigil than if generic versions of the drug had launched by early 2006, as expected.

"All consumers deserve the advantages of a fair and competitive marketplace; efforts to impede competition within the generic drug market are a serious concern," said Attorney General Jepsen. "Cephalon's conduct to 'pay-to-delay' generic competition of Provigil, as well as their intentional efforts to defraud the government and consumers is unacceptable. I'm pleased that Connecticut's Medicaid program will recover taxpayer funds expended and Connecticut consumers will be eligible for restitution through this settlement."

Connecticut's total recovery will be approximately $1,686,650. Of those settlement funds, $962,740 will be returned to the state's Medicaid program and $150,000 will go to support the state Department of Consumer
Protection's Prescription Drug Monitoring Fund. The remainder of funds will be deposited in the state's General Fund.

In addition, certain Connecticut consumers will be eligible for approximately $525,942 in restitution payments through this settlement.

This multistate settlement was facilitated by a suit brought against Cephalon by the Federal Trade Commission (FTC). The FTC settled its suit in May 2015 and required Cephalon pay $1.2 billion into an escrow account. The funds of the account can be used to pay off any settlement or judgment of a related case.

Assistant Attorneys Rachel Davis and Michael Cole, chief of the Antitrust and Government Program Fraud Department, assisted the Attorney General with this matter.

Please click here to view settlement document.

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