HERRING AND COLLEAGUES ACCUSE SUBOXONE MANUFACTURER OF ILLEGALLY CONSPIRING TO KEEP MONOPOLY PROFITS

~ Reckitt Benckiser and Indivior are accused of illegal "product hopping" that kept prices for this important addiction treatment medication artificially high ~

RICHMOND (September 21, 2016) - Virginia Attorney General Mark Herring and 35 fellow attorneys general today filed an antitrust lawsuit in federal court against the makers of Suboxone, a prescription drug used to treat opioid addiction, over allegations that the companies engaged in a "product hopping" scheme, where small changes were made to the product to block generic competitors and cause purchasers to pay artificially high prices for this important addiction treatment medicine. Reckitt Benckiser Pharmaceuticals and Indivior are accused of conspiring with MonoSol Rx to switch Suboxone from a sublingual tablet version to a film that dissolves in the mouth. Their goal was allegedly to prevent or delay generic alternatives and maintain monopoly profits. The companies are accused of violating state and federal antitrust laws.

"For many Virginians struggling with an addiction to heroin and other opioids, Suboxone can be an important part of a treatment plan that allows them to manage their substance abuse disorder," said Attorney General Herring. "After extensive investigation, my colleagues and I have reason to believe that these monopoly practices violated the law and made this important medication more expensive and more difficult to obtain. I will continue to attack the heroin and prescription opioid crisis with every tool at my disposal and will not hesitate to take action against those who contribute to the problem, no matter who they are."

Suboxone is a brand-name prescription of buprenorphine and naloxone that is used to treat heroin addiction and other opioid addictions by easing addiction cravings. No generic alternative for Suboxone film is currently available.

According to the lawsuit, when Reckitt introduced Suboxone in 2002 in tablet form, it had exclusivity protection from the FDA that lasted for seven years. During that time, no generic version could enter the market. Shortly before that period ended, however, Reckitt worked with MonoSol to create a slightly new version of Suboxone - a dissolvable film, similar in size to a breath strip. Over time, Reckitt allegedly converted the market away from the tablet to the film through marketing, price adjustments, and other methods. Ultimately, after the majority of Suboxone prescriptions were written for the film as opposed to the tablet, Reckitt then removed the tablet from the U.S. market. When a generic version of tablet Suboxone was finally approved, there was no brand-name Suboxone tablet left on the market for which the generic could be substituted. This allowed Reckitt to maintain its monopoly over the product and get higher monopoly profits from its sales.

Attorney General Herring and his colleagues allege that this conduct is illegal "product hopping," where a company makes just modest changes to its product to extend patent protections so other companies cannot enter the market and offer cheaper generic alternatives. According to the suit, the Suboxone film provided no real benefit over the tablet, and Reckitt continued to sell the tablets in other countries even after removing them from the U.S. market. Reckitt also allegedly expressed unfounded safety concerns about the tablet version, thereby intentionally delaying
Reckitt also allegedly expressed unfounded safety concerns about the tablet version, thereby intentionally delaying FDA approval of generic versions of Suboxone.

As a result, the attorneys general allege that consumers and purchasers have paid artificially high monopoly prices since late 2009, when generic alternatives of Suboxone might otherwise have become available. During that time, annual sales of Suboxone topped $1 billion.

The lawsuit, filed in the U.S. District Court for the Eastern Division of Pennsylvania, accuses the companies of violating the federal Sherman Act and state antitrust laws. In the suit, the attorneys general ask the court to stop the companies from engaging in anticompetitive conduct, to restore competition, and to order appropriate relief for consumers and the states, plus costs and fees.

Thirty four additional states and the District of Columbia have joined the lawsuit including Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin.

Attorney General Herring has made combating the heroin and prescription opioid epidemic a top priority, attacking the problem with a multifaceted approach that includes enforcement, education, prevention, and legislation to encourage reporting of overdoses in progress, expand the availability of naloxone, and expand access to the Prescription Monitoring Program. He has supported federal efforts to improve the availability of treatment and recovery resources and recently partnered with U.S. Attorney Dana Boente to create the Hampton Roads Heroin Working Group to develop holistic, community-driven solutions to the heroin and opioid crisis.

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