

DEPARTMENT OF THE ATTORNEY GENERAL

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MAKERS OF PRESCRIPTION DRUG THAT TREATS OPIOID ADDICTION SUED FOR ANTITRUST PRACTICES

HONOLULU - Hawaii Attorney General Doug Chin and 35 other attorneys general today filed an antitrust lawsuit against the makers of Suboxone, a prescription drug used to treat opioid addiction, over allegations that the companies engaged in a scheme to block generic competitors and cause purchasers to pay artificially high prices.

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

Attorney General Chin said, "Helping addicts recover from the deadly effects of opioids is a top priority here and in other states. This week I had commented on the legal authority in Hawaii to prescribe Suboxone for the purpose of opioid detoxification or maintenance treatment of opioid dependence. Unfortunately, the makers of this drug have capitalized on this serious public health crisis and raked in huge corporate profits."

Reckitt Benckiser Pharmaceuticals, now known as Indivior, is accused of conspiring with MonoSol Rx to switch Suboxone from a tablet version to a film (that dissolves in the mouth) in order to prevent or delay generic alternatives and maintain monopoly profits. The companies are accused of violating state and federal antitrust laws.

According to the lawsuit, when Reckitt introduced Suboxone in 2002 (in tablet form), it had exclusivity protection that lasted for seven years, meaning no generic version could enter the market during that time. Before that period ended, however, Reckitt worked with MonoSol to create a 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, Reckitt removed the tablet from the U.S. market.

The attorneys general allege that this conduct was illegal "product hopping," where a company makes modest changes to its product to extend patent protections so other companies can't enter the market and offer cheaper generic alternatives. According to

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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 and intentionally delayed 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 laws. Counts include conspiracy to monopolize and illegal restraint of trade. 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.

Attorneys general of the following jurisdictions joined in the lawsuit: Alabama, Alaska, Arkansas, California, Colorado, District of Columbia, 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, Virginia, Washington and Wisconsin.

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