

DEPARTMENT OF THE ATTORNEY GENERAL

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\$834 Million Order Entered in Hawai'i State Court Against Bristol-Myers Squibb and Sanofi For Failing to Investigate and Disclose Ineffectiveness of Plavix®

HONOLULU – Hawai'i Attorney General Clare E. Connors announced today the entry of an \$834 million state court order against Bristol-Myers Squibb Company and three U.S.-based subsidiaries of French pharmaceutical company Sanofi for violating the State of Hawai'i's unfair and deceptive practices laws. The substantial amount reflects the fact the Defendants earned enormous profits while engaged in deceptive conduct that spanned more than a decade.

The order arises out of the Defendants' acts in developing, marketing and promoting Plavix, a prescription drug designed to reduce the risk of serious cardiovascular events such as heart attacks, strokes and blood clots. According to evidence presented in court, the Defendants began marketing the drug to Hawai'i physicians and consumers in 1998, knowing that it was not effective for many patients, including Asian and Pacific Island patients. Defendants only began warning Hawai'i physicians and consumers about this issue in March 2010, when the U.S. Food and Drug Administration (FDA) required them to place a "black box" warning on the label accompanying the drug.

After a four week trial that ended on November 20, 2020, Hawai'i Circuit Court Judge Dean E. Ochiai concluded that Defendants deliberately withheld vital information about Plavix's efficacy from the FDA, the greater medical community and Hawai'i consumers. The Court found that, between December 1998 and March 12, 2010—when the FDA required Defendants to disclose the warning—the Defendants sold 834,012 prescriptions, refills and non-retail units in Hawai'i without including important information about the large percentage of patients who received less benefit or no benefit from Plavix due to their race and genetic makeup. Based on this evidence, the Court determined the Defendants "knowingly placed Plavix patients at grave risk of serious injury or death in order to substantially increase their profits." The Court further found that the Defendants engaged in "immoral, unethical, oppressive or unscrupulous" acts, by choosing not to warn about the risks and benefits of Plavix and instead "burying their heads in the sand." Finally, the Court found that Defendants' acts deprived consumers of the right to make informed choices about the use of Plavix, and found that

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each distribution of Plavix with its misleading package label constituted a violation of Hawai'i law. Noting that the Defendants' acts were "unfair and deceptive," the Court imposed a penalty of \$1,000 per violation, for a total of the \$834,012,000 awarded as penalties.

"Today's order vindicates seven long years of work by this Department and its attorneys to ensure that companies marketing and selling their products in Hawai'i keep the safety and welfare our people at the forefront of their business decisions," said Attorney General Clare E. Connors. "The order entered by the Court today puts the pharmaceutical industry on notice that it will be held accountable for conduct that deceives the public and places profit above safety."

The Court's order highlights Defendants' "seemingly blind refusal to accept the reality of Plavix's limitations." The Court further determined that "[t]hose limitations could potentially contribute to very significant harm, including death, to large groups of patients unable to bioactivate it, or only able to activate it partially."

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