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Patients Seek to Force FDA to Release Records Showing US Distribution of Thalidomide

Attorneys representing a group of U.S. citizens suffering from severe birth defects they believe were caused by the drug thalidomide have filed a lawsuit in federal court to compel the FDA to release records they believe will show the drug was widely distributed in the United States.

The suit, filed on November 15, 2011, in the United States District Court for the Western District of Texas, seeks to compel the FDA to respond to a number of Freedom of Information Act (FOIA) requests by attorneys representing the patients, some filed more than a year ago. Under Federal law, the FDA has 20 business days to respond to a FOIA.

Thalidomide is a drug marketed throughout Canada and Europe during the late 1950s and early 1960s that caused thousands of deaths and extreme, disfiguring birth defects when used by women during pregnancy.

The drug was never approved for use in the United States, but newly uncovered documents show that hundreds of women in the US may have taken the drug as part of a marketing scheme conducted by Richardson-Merrell, a US drug distributor now owned by Sanofi-Aventis (NYSE: SNY), according to a lawsuit filed by Hagens Berman. The company gave physicians across the US as many as 2.5 million doses of the drug, the lawsuit claims.

According to court documents filed by the attorneys, the FDA archives contain lists of the physicians who were part of the marketing efforts.

"The conventional wisdom in this case has been that information about thalidomide is readily available, when in reality, the FDA is withholding key information and documents," said Steve Berman, managing partner for Hagens Berman. "These documents may prove what we have believed for some time; that thalidomide was given to pregnant women throughout the United States."

The FOIA lawsuit was filed by Kay Gunderson Reeves, co-counsel with Hagens Berman, who filed a lawsuit on Oct. 25, 2011, against Sanofi-Aventis, GlaxoSmithKline, Grunenthal GMBH and Avantor Performance materials on behalf of alleged U.S. victims.

Hagens Berman's lawsuit claims that new medical advances have changed scientists understanding of how thalidomide interacts with the body. Previously, the drug was believed to operate through a neural mechanism, causing only bilateral injuries. New cancer research demonstrates that the drug may primarily impact the vascular system, allowing it to cause unilateral defects.

Hagens Berman is representing several alleged thalidomide victims with such injuries who were previously unaware that thalidomide could have been the cause.

"We think there may be hundreds of people across the United States who have serious birth defects but were told that thalidomide could not be the cause," said Berman. "Many may have suffered for years believing they were victims of poor luck, when in fact thalidomide caused their injuries."

"I would think the FDA would be driving the effort to inform, rather than block the efforts of thalidomide victims to find the truth," Berman added.

More information about Hagens Berman's cases on behalf of alleged thalidomide victims can be found at www.hbsslaw.com/thalidomide.

About Hagens Berman

Seattle-based Hagens Berman Sobol Shapiro LLP represents workers, whistleblowers, investors and consumers in complex litigation. The firm has offices in Boston, Chicago, Colorado Springs, Los Angeles, Minneapolis, New York, Phoenix, San Francisco and Washington, D.C. Founded in 1993, HBSS continues to successfully fight for investor rights in large, complex litigation. More about the law firm and its successes can be found at www.hbsslaw.com. Visit the firm's class-action law blog at www.classactionlawtoday.com.

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