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## Suits Allege Lilly Failed To Warn of Darvocet's and Darvon's Health Risks

Former users of Darvocet and Darvon are suing manufacturer Eli Lilly & Co. in federal court, claiming it failed to warn them that the painkillers carried the risk of serious heart problems.

Charles Toutant

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Former users of Darvocet and Darvon are suing manufacturer Eli Lilly & Co. in federal court, claiming it failed to warn them that the painkillers carried the risk of serious heart problems.

The drugs were taken off the market in November 2010 at the request of the Food and Drug Administration, but it was too late to prevent the plaintiffs' injuries, according to nine suits filed Monday and Tuesday in Trenton.

The plaintiffs include Mark Lopez of Trenton, who underwent a double bypass due to heart damage, and Steven Ayling Sr. of Hamilton, who suffered from angina, arteriosclerotic heart disease and mitral regurgitation.

The other plaintiffs are from Pennsylvania, Texas, California, Mississippi, North Carolina and South Carolina. Two are suing on behalf of deceased users of the drugs. Minnie Fowler of Zebulon, N.C., died of cardiac arrest, and Thomas Wilson, of Ewing, N.J., died of ischemic cardiomyopathy.

The suits charge that propoxyphene, the active ingredient in Darvocet, Darvon and generic versions of the drugs, is only marginally effective for pain relief and that any benefit was outweighed by the risk of cardiovascular problems.

A public interest group petitioned the FDA to recall propoxyphene drugs in 1978 but the agency declined after Eli Lilly promised it would educate doctors and patients about the hazards.

However, the Indianapolis-based company's educational program was turned into a program to market Darvon and Darvocet, the suit claims. When the FDA was petitioned a second time to recall the drugs, Eli Lilly made false and misleading statements to refute the claims, according to the suit.

The FDA called for an investigation into the safety concerns and in 2009 ordered that prescribers and patients be given warnings about the drugs' dangers. But the defendants failed to fully comply with the FDA orders, according to the suits.

The nine suits were filed by Kevin Hart of Stark & Stark in Princeton. Besides Eli Lilly, they name aaiPharma Inc., of Wilmington, N.C., and Xanodyne Pharmaceuticals of Newport, Ky.

Eli Lilly introduced propoxyphene in the United States in 1957 and owned the rights to Darvocet and Darvon — similar to Darvocet but with acetaminophen — until 2002, the suits say. That year, Lilly sold the rights to the two drugs to aaiPharma, but continued to take a role in their manufacture and marketing. In 2007, aaiPharma sold the rights to the two drugs to Xanodyne.

Also named as defendants are two dozen related entities, subsidiaries or others involved in the testing, manufacture, labeling, marketing and sales.

Six other suits against Eli Lilly, Xanodyne and aaiPharma were filed on behalf of Darvon and Darvocet users in federal court in Newark last September by Christopher Placitella of Cohen, Placitella & Roth in Red Bank.

The Judicial Panel on Multidistrict Litigation consolidated and transferred that on Oct. 12 last year to the Eastern District of Kentucky after defendants opposed a plan by plaintiffs to consolidate the cases in various venues.

About 175 similar cases are pending in the MDL, says Hart, who expects his cases to be moved to Kentucky as well. The first trials are at least two years away, says Hart.

Although cardiac problems are the drugs' primary negative side effects, FDA documents indicate some users were driven to suicide because of the drugs' addictive nature, and others suffered seizures, says Hart. Darvon and Darvocet were taken off the market in Great Britain in 2005 and in the European Union in 2009, says Hart.

"One positive here is the fact that the FDA recalled the drug and ultimately made the determination that the side effects were more dangerous than the utility. From the plaintiff's perspective, that can't be a bad thing. Certainly, I don't think that would help the defendant," says Hart.

Eli Lilly spokeswoman Keri McGrath-Happe said in a statement, "The health and safety of patients is Lilly's number one priority. Lilly sold its US marketing rights to Darvon, Darvocet or any and all propoxyphene pain products in 2002 and the claims against Lilly in this case are without merit, which our defense in court will prove."

Xanodyne did not respond to requests for comment, and aaiPharma spokesman Joe Poulos declines comment.