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Lawsuits: Acne drug dangerous

Families of suicide victims target maker of Accutane

By Deb Price / Detroit News
Washington Bureau

WASHINGTON -- Joining forces, families of suicide victims plan to file lawsuits beginning today in federal courts around the country against the maker of the controversial acne drug Accutane.

Seeking unspecified damages, the first two of what's expected to be a string of lawsuits accuse Accutane maker Hoffmann-La Roche Inc. of failing to investigate thoroughly during clinical trials whether the drug could cause suicide and then later failing adequately to warn physicians and the public of potential suicidal reactions in some users.

The Nutley, N.J., drug maker maintains its top-selling product available since 1982 is safe and points out that suicide is common among teen-agers.

As of June 30, the Food and Drug Administration had received reports of 83 suicides in United States and 42 foreign suicides among users of Accutane.

"There is no scientifically proven relationship between the use of Accutane and suicide," Roche's chief Accutane spokeswoman Melissa Ziriakus said. "The reports are anecdotal and not scientific in nature. We don't comment on lawsuits."

At a congressional hearing in December, a top FDA official said data "remains



Bart Stupak Jr., left, and Chad Ohse were both taking the acne drug Accutane when they committed suicide. Ohse's family is suing.

Accutane facts

- * Product is considered the most effective treatment for the severe, scarring form of acne.
- * Went on the market in 1982, is top-selling Hoffmann-LaRoche product.
- * FDA has received reports of 83 U.S. and 42 foreign suicides among Accutane users.
- * FDA panel said "no evidence" exists showing link between Accutane and suicide.
- * Congress plans to scrutinize drug again in hearings this fall.

Related Web sites:

FDA: www.fda.gov

Hoffmann-LaRoche: www.roche.com

Rep. Stupak page:
www.house.gov/stupak/accutane.htm

Accutane litigation:
www.accutanelitigation.com

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(updated April 17,
2000).

inconclusive" about whether Accutane could lead to suicide and other psychiatric disorders. That hearing followed the announcement two months earlier by Michigan Rep. Bart Stupak that he believed the drug caused his teen-age son to kill himself.

The FDA in 1998 required Roche to add to its warning labels that suicide was a potential, rare side effect. But the lawsuits charge that the drugmaker and doctors have downplayed the alleged dangers and that not all prescriptions have even contained the updated warnings.

"Roche failed to warn the public of the dangers of Accutane when they knew that it could cause suicide," charged Paul Smith, a lawyer in the Austin, Texas, area who specializes in pharmaceutical litigation. He is coordinating the series of lawsuits being filed in the federal court system.

"At one point, they were advertising that the product had psychiatric benefits -- if your acne got better, you'd be less depressed -- when in fact the FDA was requiring that they warn specifically that Accutane could cause depression or suicide in some users. Roche made a product that was defective and unreasonably dangerous," added Smith, who predicts the number of similar lawsuits in the federal system will reach about 100 within the next year.

Smith said the lawsuits being filed today won't specify how much compensation the plaintiffs are seeking, although he estimates plaintiffs' attorneys arguing each case ultimately will ask for millions in damages.

The lawsuits do not ask that the drug be taken off the market, a step that can be taken only by the FDA. An FDA advisory panel issued a report last September that "no evidence" exists showing a link between the drug and suicide or other severe psychiatric disorders. But Rep. Stupak, several other lawmakers, and many survivors of suicide victims maintain that no thorough studies have been done investigating the alleged link.

Stupak said he was dumbfounded when his 17-year-old son, Bart Stupak Jr., also known as B. J., killed himself. B.J. was president-elect of the student council at Menominee High School, and, according to his parents, showed no signs of depression before he shot himself in May 2000 during a sleep-over party with school pals that he hosted at his family's home.

Rep. Stupak, D-Menominee, who hasn't decided yet whether he will sue over his son's death, says that as a father he wants the drug taken off the market. He sits on the House Commerce Committee, which is expected to hold a second round of hearings about suicide and the drug this fall.

"I hope the lawsuits will bring more attention to Accutane," Stupak said. "It is not safe. Personally, I think it should be off the market. But as a legislator, I want further information. Maybe we should pull the drug until we at least get some studies done."

Stupak's Accutane Web site has received hundreds of e-mails from family members around the world who believe their loved ones killed themselves because of Accutane.

Lawyers representing Accutane clients are adopting a strategy used in litigation over the antidepressant Prozac and over Sulzer hip implants known as "multi-district litigation." This allows them to request the right to gather information from the drugmaker as a group in one federal court, rather than separately.

During this process, other people who believe they or their loved ones became

severely depressed or suicidal can join in. Once Roche answers all questions about the drug and any possible link to depression and suicide for the group of litigants, the individual cases would be fought out in separate court actions.

Smith, the Texas lawyer, also played a key role in litigation against Eli Lilly & Co. of Indianapolis over its popular anti-depressant Prozac. In one case, families alleged that the drug drove a Kentucky man to open fire in an office and kill eight people and wound 12 others. Ultimately, the jury rejected the claim, but not before the parties had agreed to a secret settlement.

According to lawyers, the first two cases filed today involve:

* Chad Ohse, a Yorkville, Ill., youth who loved bass fishing and baseball and worked in his family's landscaping business. When he disappeared from work May 8, 2000, his father went home and found Chad, 19, in his bedroom dead from a self-inflicted shotgun blast to the head. He had been taking Accutane for three months.

"(My son) would be alive today," said Bill Ohse (pronounced O-C). "I want it off the market."

* Ryan Pitts, an 18-year-old high school senior in Sumter, S.C., who shot himself Sept. 9, 2000, two months into his use of Accutane. Ryan, a high school football star, had planned to go dove hunting with a friend on the morning he killed himself.

How will plaintiffs' attorneys try to link the drug to suicides when suicide is the third-leading cause of teen deaths?

"You prove it by the consistency of the stories -- every family tells the same story," said Bob Foote, an Illinois lawyer who is handling the Ohse case.

"Generally you have a normal teen-ager and no warning and no bad events that would precipitate suicide other than the prescription for Accutane. We will have expert testimony from psychiatrists and doctors who will say that in any particular case, the suicide was caused by a reaction to the Accutane."

As a result of the congressional hearings in December, the FDA since February has required Accutane users to sign an "informed consent" sheet saying they understand the possible side effects, including suicidal thoughts, and to receive a "Medication Guide" at the pharmacy that explains possible adverse reactions.

Also, Roche has agreed to fund research looking into possible links between Accutane and psychiatric disorders.

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