



## Accutane

Air Date: February 6, 2001

Producer: Christian Côté | Researcher: Colman Jones

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Accutane is a wildly successful acne drug. It's number one with Canadians, who spent close to \$40 million on it last year.

Doctors call the drug a miracle. But there can be dangerous side effects.

Women taking Accutane are warned not to get pregnant while on the drug. It can cause birth defects. There is another dangerous connection, about which little has been said in Canada: mood swings, depression, even reports of suicide.

Last fall, American lawmakers listened to people for

There have been a couple of important changes in Health Canada's position on Accutane since this story first aired on Marketplace.

Patients must now sign a consent form in Canada before they receive Accutane.

Health Canada has updated its Web site information on the drug.

whom Accutane was not a miracle drug: a teenager related her tale of depression and suicidal thoughts; parents broke down as they described how their children took their own lives.

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"My downfall started the moment I took the first pill," teenager Amanda Callais of Louisiana told the Congressional hearing. "I found myself feeling sad and I often cried for no reason. I hated myself more and more each

day and I began to cut my hands with razor blades."

Callais' family is one of several in the United States now suing



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Hoffman LaRoche, the makers of Accutane. There has been legal action in Canada as well. In 1995, an Edmonton medical student sued Hoffman LaRoche for more than \$10 million.

The suit claimed Accutane is a "...dangerously defective product"...that allegedly caused the student to fly into sudden and dramatic rages...[and to have] psychotic-like depression, and thoughts of suicide. As a result, the medical student claimed she had to quit school, and be committed to a psychiatric hospital. Hoffmann LaRoche denied any of this could be linked to Accutane. The company insisted the drug is "...a safe and efficacious product when used as directed."

The medical student recovered and returned to school. The lawsuit was settled out of court last June. The terms of the settlement forbid anyone involved from speaking publicly. But others are speaking out.

### Accutane-depression link?

Erin Daines of Richmond, Ontario, was an angry, frustrated teenager in 1998. Life hadn't been easy for her family since her father's death ten years earlier. At 16, Erin was also dealing with the problems of adolescence and severe acne.

"It was frustrating cause it wouldn't go away," Erin told Marketplace. "I'd use a lot of makeup and it just wouldn't, you could still see it, like it...wasn't good enough. So I had to find some way to get rid of it."

Erin began taking Accutane and it was working well. However, five weeks into the therapy, something went wrong. She said she had a sore leg — so she took 15 Tylenol pills. Erin was rushed to hospital and treated for an overdose.

Months later, Erin's mother Nancy Daines came across a story about Accutane in the Ottawa Citizen. She came away from that story wondering whether there was a link between Accutane and Erin's overdose.

### Manufacturer says no link between Accutane and psychiatric problems

Hoffmann LaRoche says there is no causal relationship between Accutane and depression or suicide. Experts point out that no one factor causes suicide and that a high percentage of Accutane users — teens and young adults — are already more likely to get depressed. But some doctors say there's plenty of evidence to support a link between Accutane and depression and suicide.



Nancy Daines of Richmond, Ont., believes Accutane is linked to her daughter's depression which led to overdose of pills. Erin Daines recovered.



Media coverage of possible link between Accutane and depression caught the attention of Daines.



Hoffman LaRoche maintains that Accutane is a safe, effective treatment for problem acne, when used as directed.

Some say evidence of the link dates back to Arctic explorers of the 19th century. Diaries tell of how some sailors suffered polar madness. Experts today say it was from eating polar bear liver, which is full of vitamin A. In large doses Vitamin A can cause brain toxicity seizures and behavioural changes.

Accutane is a derivative of vitamin A.

More recently there have been dozens of cases of people using vitamin A derivatives — including Accutane — who reported suffering psychiatric side effects.

There is also compelling evidence from Hoffman LaRoche's own trials of Accutane. As many as 26 people out of a total of 600 tested reported psychiatric side effects.

Dr. Elgin Duke calls Accutane a wonder drug. He's a dermatologist who has been treating patients from his Ottawa office for the past thirty years. While he's convinced of the drug's effectiveness, he's also very cautious, because of what he has seen.

"I've had three or four patients who I have no doubt in my own mind that they developed psychiatric manifestations," Duke told Marketplace. "It's a pretty rare phenomenon, but still a very real phenomenon and it has to be watched."

Health Canada has been monitoring Accutane. From 1983 — when the drug arrived on the Canadian market — until 1997, Health Canada received 8 reports of depression and other psychiatric reactions associated with the use of Accutane.

In the last three years, those numbers have more than doubled. Since 1998 there have been twenty reports of psychiatric side effects including delirium; suicidal tendencies; and one suicide. Many researchers believe the numbers may be significantly higher because adverse drug reactions are under-reported.

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"I've had three or four patients who I have no doubt in my own mind that they developed psychiatric manifestations." Ottawa dermatologist Dr Elgin Duke, who also stresses that Accutane is a wonder drug.



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### American Accutane rules tightened

The numbers in the United States are more dramatic. More than 1,300 psychiatric side effects and as many as 66 suicides have been reported since Accutane arrived on the market. The numbers prompted the Food and Drug Administration to take another look at Accutane.

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The FDA has changed its rules regarding the drug so that American doctors must now get patients to sign a consent form. The form is produced by Accutane's maker, Hoffman LaRoche. It says the patient understands all the risks associated with Accutane, including depression and suicide. Pharmacists must also hand out a detailed warning brochure from the FDA, called a Medguide. Accutane is one of just three drugs in the United States that has ever been required to come with a Medguide.

The rules in Canada are not nearly as stringent. In 1998, Hoffmann LaRoche sent out a letter to dermatologists and updated the drug monograph for doctors which warned that reports of depression, psychotic symptoms and — in rare cases — suicide attempts and suicide have been reported in patients treated with Accutane. Information designed for **patients** didn't include that warning until a year and a half later.

A brochure put out by Accutane's maker, designed for patients, still makes no mention of the reports of depression or suicide, although it cautions those who feel depressed or suicidal to contact their doctor.

Marketplace invited Hoffmann LaRoche to speak with us on camera. They refused. But in a letter to Marketplace they explained their product information "...is approved and regulated by Health Canada."



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## Health Canada information out of date

So what does Health Canada tell consumers about Accutane? [Its website includes information that is more than eleven years old.](#) There is no warning about the reports of depression or suicide.

Dr. Brian Gillespie, Health Canada's senior medical advisor, says there are plans to update the information on the website. The department, he says, is also in the process of determining whether Hoffman LaRoche will have to strengthen the warnings on Accutane sold in Canada.

"We're examining that issue, and as to whether or not in the Canadian context it would enhance adherence to the warnings and precautions that are in the Accutane prescribing information," Gillespie told Marketplace. "At the present time we have not made any decision, it is still under review."

Ottawa dermatologist Dr. Elgin Duke says it's ultimately up to doctors who prescribe Accutane to make their patients aware of the risks.

"As far as the depression is concerned, I discuss it with the patient, but I now ask a member of the family to be present when we discuss it," Duke explained. "I want a father, brother, mother, somebody to be aware that a personality change and depression may occur. It's an extremely rare risk and it's not a reason to not take the drug, but if they notice any change then we would stop the drug and look for something alternative."

Duke believes dermatologists in Canada are warning their patients. But he's not so sure about the increasing number of family doctors who are prescribing Accutane.

Marketplace conducted a small survey of Toronto area doctors who prescribe Accutane to find out what kinds of warnings they are giving their patients.

Of ten doctors, only one said he warned patients about the link to depression and suicide. Some said they weren't aware of such a link and others did not think it was that serious. (For Canadian Medical Association response to the Marketplace survey of doctors, [click here.](#))

Nancy Daines says doctors should know better. She wants Health Canada and Hoffmann LaRoche to offer the same warnings to Canadians now being given Americans.

"Some kids could die," Daines told Marketplace. "Depression I



"At the present time we have not made any decision, it is still under review." Dr. Brian Gillespie, Health Canada's senior medical advisor on whether Canada will strengthen Accutane warnings.



"I think that people should know about it. Like that's why I'm doing this, because I don't want people to make the same mistake I did." Erin Daines, who overdosed on Tylenol while on Accutane treatment.

think...runs high with teens on a normal basis, so if they do happen to be taking this medication, they should definitely be very cautious about it."

Her daughter Erin agrees.

"I think that people should know about it," Erin said. "Like that's why I'm doing this, because I don't want people to make the same mistake I did."

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## Accutane Warnings

Accutane is described as a powerful, yet safe, drug for the treatment of severe acne, when used as directed.

However, there are several well-documented side effects — and others that are suspected.

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Recently, in the United States, Accutane warnings were strengthened to reflect concerns that the drug may be linked to depression and thoughts of suicide in some people.

Warnings for Canadian consumers of the drug have not changed. [Health Canada's website contains information on Accutane](#) that dates back to 1989.

Below are excerpts from two Accutane warning publications given to patients when they pick up their prescription. The first one is for Americans, the second for Canadians.

Possible serious side effects of taking Accutane include *birth defects* and *mental disorders*

**2. Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives. There were reports that some of these people did not appear depressed. No one knows if Accutane caused these behaviours or if



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they would have happened even if the person did not take Accutane.

The above excerpt is from the [Accutane Medication guide](#), published by the US Food and Drug Administration, January 23, 2001. It is in addition to the patient insert that comes with the medication.

**SPECIAL SYMPTOMS YOU SHOULD TELL YOUR DOCTOR ABOUT:**

If you feel or become depressed, have thoughts of suicide, are unable to sleep and have mood swings while taking 'Accutane', tell your doctor as soon as possible. These feelings, although they do not happen very often, may occur when you are taking 'Accutane' or after you have stopped taking 'Accutane'. It has not been established whether or not these symptoms might be related to 'Accutane'. However, it is important to tell your doctor as soon as possible, if you have such feelings.

The above excerpt is from the product insert (Information for the Patient) provided by Hoffman LaRoche with every prescription of Accutane in Canada. The insert was issued in April of 2000.

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Accutane pamphlet available in Canada makes passing reference to depression and/or mood swings.



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### Accutane Facts

Accutane has been available through prescription as a treatment for severe acne since 1983. It is currently available in about 80 countries.

It is expensive. The drug costs from \$500 to \$600 for a standard first treatment of about 16 weeks. Most drug plans cover the drug — they will usually place some limits on coverage.

Canadian spent approximately \$38.5 million on Accutane prescriptions last year. Pharmacists filled 291,000 Accutane prescriptions in 2000.

In 1995, 71.8 per cent of all Accutane prescriptions were issued by dermatologists. General practitioners issued 25.1 per cent of Accutane prescriptions. By last year, prescriptions issued by dermatologists accounted for 60 per cent of the total. General practitioners issued 35 per cent of all Accutane prescriptions. (Source: IMS Health, CompuScript 2000)

This slight shift in who is prescribing Accutane raises some concerns in light of Marketplace's mini-study of Toronto-area doctors. Only one of ten general practitioners we spoke with said they warned patients of the possible risk of depression and suicidal thoughts. (For Canadian Medical Association response to the Marketplace survey of doctors, [click here.](#))

Other known side effects of Accutane:

- dryness of the skin, lips, mouth and lining of the nose
- facial or body rash, flaking of the skin, itching, peeling of the palms and soles
- increased sensitivity to the sun
- inflammation of the lips, mild nose bleed
- bleeding and inflammation of the gums
- aches and pains in the joints



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- increased fatigue
- decreased night vision

People on Accutane are also warned to avoid excessive exposure to the sun and not to use vitamin preparations or health food supplements that contain vitamin A.

Patients are also advised to avoid waxing for 5-6 months after taking Accutane — because of the risk of scarring.

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- [New Accutane Medication Guide \(U.S.\), January 22, 2001](#) [Roche Laboratories, Inc.] (PDF Format)
- [Revised Informed Consent Form \(U.S.\), January 22, 2001](#) [Roche Laboratories, Inc.] (PDF Format)
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- ["New Safety Information about Accutane"](#) Updated information from MedWatch Program, U.S. Food and Drug Administration dated 26 February 1998
- [U.S. Congressman Bart Stupak's Accutane site](#)
- [FDA's Dermatologic and Ophthalmic Drugs Advisory Committee](#) meeting on isotretinoin (Accutane), September 18, 2000 (background info on pregnancy, psychiatric events risk management issues)
- [Comments of Larry D. Sasich, Pharm.D., M.P.H., FASHP](#) Public Citizen's Health Research Group before the FDA
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