

**SURVEY ON ACNE MEDICATIONS AND BIRTH DEFECTS
REINFORCES NEED FOR STRICTER REGULATION AND EDUCATION**

SALT LAKE CITY, UT, April 26, 2004 – PR NEWSWIRE – Pregnancy and powerful acne medicines like Accutane® don't mix. That's the message pregnancy counselors with the Organization of Teratology Information Services (OTIS) are trying to convey to pregnant women, health care providers, pharmaceutical companies, and decision-makers in the federal government.

Women who have used Accutane®, known generically as isotretinoin, within 30 days of becoming pregnant are encouraged to participate in an ongoing OTIS study by calling the North American Isotretinoin information and Survey Line (866-626-6847).

Callers will be given information on the potential effects of isotretinoin and be asked to take a brief survey about how much isotretinoin they were using when they became pregnant, how they obtained the drug, and what level of education they received when the drug was prescribed.

"Having nice-looking skin is not worth the risk of having an abnormal baby or child," stressed Debbie Banner, a Virginia mother whose son was born with brain damage as a result of Accutane® exposure during her pregnancy.

The FDA approved Accutane® in 1982 as a prescription medication for severe or cystic acne. Although the drug's label warned it was not to be taken by pregnant women, exposed pregnancies continued. It was found that Accutane® was a teratogen, meaning it can cause brain and heart defects, mental retardation, and other abnormalities.

By 1999, it was reported that nearly three out of every 1,000 American women aged 15-44 were taking Accutane®. The more recent introduction of additional forms of isotretinoin (Amnesteem®, Claravis®, and Sotret®) may further increase usage.

In late February, the Food and Drug Administration (FDA) held hearings to consider imposing stricter regulations on Accutane®, which has been shown to cause birth and developmental defects.

OTIS, a nonprofit organization that conducts research and provides education on the effects of drugs and chemicals on the human fetus, presented preliminary findings from a survey of women in the U.S. and Canada who used Accutane® at the time they became pregnant. OTIS told FDA members that only the most stringent restrictions could prevent more Accutane-exposed pregnancies.

The FDA has agreed to review recommendations by an advisory panel for manufacturers to establish a national registry system in which all patients using any form of isotretinoin would be required to enroll. For female patients, this would mean they could no longer obtain a prescription without a negative pregnancy test and written instructions by their doctor to use two forms of birth control while on the drug.

"We encourage the manufacturers of isotretinoin to implement a mandatory, nationwide registry, including required contraception counseling by trained professionals," said Dr. John C. Carey of the University of Utah School of Medicine and Medical Director of Utah's Pregnancy Risk Line, which was instrumental in obtaining the grant for the OTIS survey.

A grant by the Centers For Disease Control and Prevention has enabled OTIS and more than 20 other teratology information organizations across North America to gather critical data about exposure to Accutane® and generic isotretinoin during pregnancy. The hope is the findings will be used in future decisions about drug regulation as well as to increase and expand pregnancy prevention education.

To enroll in the survey, or find out more about birth defects caused by isotretinoin, call toll-free 1-866-626-OTIS (6847) or go to the OTIS web site at www.otispregnancy.org.

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