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CDC Meeting: 03/26/1997 Minutes and Agenda Regarding Thalidomide

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Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

OCT 17 2003

October 3, 2003

Rachel M. Johnson
FOI Services, Inc.
11 Firstfield Road
Gaithersburg, Maryland 20878-1704

Dear Ms. Johnson:

This letter is in response to your Freedom of Information Act (FOIA) request of August 14.

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Lynn Armstrong
CDC/ATSDR FOIA Officer
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Enclosures

03-0850

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CDC 0.1227 Rev. 5/2001

**PREVENTING BIRTH DEFECTS
DUE TO THALIDOMIDE EXPOSURE**

**Sheraton Colony Square Hotel
Atlanta, Georgia**

March 26, 1997

**Birth Defects and Genetic Diseases Branch
Centers for Disease Control and Prevention**

**Denise Webster
writer/editor**

PREVENTING BIRTH DEFECTS DUE TO THALIDOMIDE EXPOSURE

Sheraton Colony Square Hotel
Atlanta, Georgia
March 26, 1997

Dr. Dixie Snider, Associate Director for Science, CDC, welcomed the participants.

Dr. Snider gave a synopsis of the history of Thalidomide and the role it played in changing the way drugs are approved for use in the United States. He stated that Thalidomide is used currently for the treatment of certain autoimmune disorders such as systemic lupus, rheumatoid arthritis, HIV, and for leprosy. There is concern over the use of Thalidomide in Brazil, where it is readily available as an over the counter drug, since there appears to be little evidence that its use is discouraged in pregnant women.

Dr. Snider stressed that if thalidomide is approved for use in the U.S., there must be strategies in place to reduce the risk of exposure of pregnant women to the drug. The goal is to avoid and/or reduce birth defects from all teratogenic drugs.

After this meeting, CDC will publish its written guidelines in the Morbidity and Mortality Weekly Report (MMWR) sometime this coming fall. Today's participants will have the opportunity to review those guidelines, and comment on them, prior to publication.

Assessment of Roche's Accutane Pregnancy Prevention Program - Dr. Allen Mitchell, Professor of Epidemiology and Pediatrics, Boston University

In the Fall of 1988, Roche Laboratories developed and implemented a Pregnancy Prevention Program for physicians, and women who were taking the drug Accutane. This education program included an information package for physicians, a comprehensive patient consent form, and a blister pack with an explicit warning against taking the drug while pregnant. Patients were strongly encouraged to participate in a voluntary survey, to judge compliance with the program.

Enrollment opportunities are provided through physicians, the medication package, and a toll-free telephone number, and women are paid \$10 upon enrollment. Follow-up interviews are conducted by phone and mail. Study results were published in the New England Journal of Medicine in Fall of 1995.

Survey results showed that the understanding of the need to avoid pregnancy while on Accutane, and the understanding of birth defects caused by Accutane, were high. The observation that 78% of women waited for the results of pregnancy tests before taking Accutane prompted a change in the package warnings, and subsequently 85% reported waiting for test results prior to starting the drug. The self-selected participants tended to be well educated, and it is unclear whether they are

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