

Centers for Disease Control
Atlanta GA 30333
(404) 486-4706
February 1, 1988

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Handwritten notes:
→ Krentzky
→ Godfrey

Gerald A. Faich, M.D., M.P.H.
NCDB, FDA
Rm 15 B-39 Parklawn Bldg.
Rockville, Md. 20857

Dear Dr. Faich:

Enclosed please find copies of the latest draft of the Accutane MMWR article. I do not have a publication date yet, but it is likely to be in February.

I look forward to hearing about your meeting on February 10th to discuss the FDA review document. I would appreciate receiving a copy of that document when you can share it.

In closing, let me note that I feel a great urgency to prevent infants and children from having the serious birth defects and developmental disabilities associated with the Accutane embryopathy. As you know, the problems are as serious as the Thalidomide embryopathy and the congenital rubella syndrome and that the attack rate for serious problems after fetal exposure is 25% similar to the attack rate for congenital rubella syndrome. It is not often that we know how to prevent all cases of a particular serious birth defects or developmental disabilities. In this instance, however, we know how to prevent further cases. We simply need to remove the drug from the market.

I know that because the product is effective against cystic acne that removing the drug from the market will not be popular. On the other hand, I know that 40 infants born alive after first trimester exposure to Accutane have died as infants or children because of the developmental errors that Accutane caused. I believe that if 40 teenagers or young adults with acne had died as a result of therapy caused by this drug that the drug would have been viewed as too dangerous, even though effective, to be on the market. I do not believe that the benefits outweigh the risk and that the drug should be removed from the market as soon as possible. Drs. David Erickson and Jose Cordero and I are available to meet with you on this issue as soon as you like.

Handwritten signature: Godfrey
Godfrey P. Oakley, Jr., M.D.
Director, Division of Birth Defects &
Developmental Disabilities
Center for Environmental Health and
Injury Control
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Identical Letter sent to Dr. James Bilstad
cc: Dr. J. David Erickson