

Wilkin, Jonathan K

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ACUTANE

From: Julie Beitz 301-827-3159 FAX 301-827-3159
Sent: Friday, July 27, 2001 11:38 AM
To: Bull, Jonca; O Connell, Kathryn A; Wilkin, Jonathan K; Walling, Maryjane
Cc: Trontell, Anne E
Subject: Re: Celgene Presentation Notes

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Sensitivity: Confidential

Jonca and others,

You may recall a slide we showed at the DODAC meeting last year. We estimated the rate of congenital anomalies in Accutane-exposed pregnancies resulting in births to be as follows:

- 1) from adverse event reports - 42%
- 2) from the literature - 25%
- 3) from the Slone Survey - 13%

We believe that the truth lies somewhere between 13% and 42%. This is analogous to the reported rate of congenital anomalies associated with thalidomide use.

This concern was the basis for our inclusion of Option 5 - a program analogous to the STEPS program as it was configured at the time.

As you suggest, unlike with thalidomide, Accutane has enjoyed nearly two decades of physician (and patient and pharmacist) complacency. The ease of obtaining therapeutic abortions in the 80's and 90's has kept awareness of retinoid anomalies at a minimum. I believe what we are trying to develop now is a corrective campaign on several fronts that attempts to equal the playing field.

Julie