

Serious Psychiatric Events Due to Isotretinoin (Accutane)

	Total Psychiatric Reports*	Total Deaths*	Total Suicides*
As of 2000	N/A	60	54
As of 2004	3617	580	235

[Source: FDA]

*Reported AERS events represent between 1% and 10% of actual events.

[Source: Energy and Commerce Committee Hearing Testimony, December, 2002]

Serious Childbirth Events Due to Isotretinoin (Accutane)

	Total Number of Accutane Pregnancies Reported*	Number Choosing Abortion Reported*	Total Spontaneous Abortions Reported*	Children Born with Defects Reported
As of 2001	2,261	1,349	252	167

[Source: FDA/Boston Globe 4/11/02]

*Reported adverse events represent between 1% and 10% of actual adverse events.

[Source: FDA/Boston Globe 4/11/02]

"There probably have been between 15,000 and 18,000 pregnancy exposures to Accutane since its appearance on the market in 1982. The magnitude of fetal injury and death has been great and permanent, with 11,000 to 13,000 Accutane-related abortions and 900 to 1,100 Accutane-related birth defects." - FDA Internal Memo, 1990

[Source: Exhibit 12, Energy and Commerce Committee Hearing, December, 2002]

FDA estimated that 2000 pregnancies per year are exposed to Accutane in 2002.

[Source: Energy and Commerce Committee Hearing Testimony, December 2002]