

Childs, Suzanne M

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From: Bull, Jonca
Sent: Friday, August 03, 2001 4:04 PM
To: O'Connell, Kathryn A
Subject: RE: Accutane -- is the FDA putting an "anti-abortion" agenda ahead of patients?

Kathy,
I completely agree.
Jonca

-----Original Message-----

From: O'Connell, Kathryn A
Sent: Friday, August 03, 2001 11:35 AM
To: Wilkin, Jonathan K; Bull, Jonca
Subject: FW: Accutane -- is the FDA putting an "anti-abortion" agenda ahead of patients?

Something this obnoxious could only have been written by someone who could never face the horrible "choice" of an unwanted abortion or high probability of a severely deformed baby - a male.

Women who take Accutane deserve the most rigorous risk management plan that is feasible so that they are not put in this miserable position over a bunch of pimples.

If he wants a meaningful response from Janet, I suggest that he become a reformed misogynist and try a more productive, pro-woman attitude.

MTF

-----Original Message-----

From: Wilkin, Jonathan K
To: Hills, Indira
Cc: Bull, Jonca; O'Connell, Kathryn A
Sent: 8/3/01 9:42 AM
Subject: FW: Accutane -- is the FDA putting an "anti-abortion" agenda ahead of patients?

Indira, please circulate this to the working group. thanks, Jon

-----Original Message-----

From: WHWoodII@aol.com [mailto:WHWoodII@aol.com]
Sent: Thursday, August 02, 2001 9:14 PM
To: rxderm-l@ucdavis.edu
Cc: WOODCOCKJ@cder.fda.gov; DRUGINFO@cder.fda.gov; wilkinj@cder.fda.gov; BSCHWETZ@oc.fda.gov
Subject: Accutane -- is the FDA putting an "anti-abortion" agenda ahead of patients?

Assuming perfect compliance with oral contraceptive pills there is an approximate 0.005 probability of failure for one woman using them for one year.

A barrier plus foam method has a 0.2 probability of failure in one year.

We know that humans are not perfect at compliance, but assuming perfect compliance with using both methods together, and say 500,000 patient years

taking Accutane (the equivalent of one million women of child bearing age

using Accutane for 6 months), I calculate $500,000 \times 0.005 \times 0.2 = 500$ expected pregnancies taking Accutane per year. If only about 200 Accutane

pregnancies are being reported per year to the FDA in a year, dermatologists and their patients are already doing a great job (or pregnancies are not being reported). In view of this, I do not see any point at all in imposing additional bureaucratic impediments to access to treatment. If anything, what might be added to the consent is an agreement to abort any pregnancy that occurs while exposed. Of course that agreement cannot be enforced, but such agreement is important as an indicator of whether to prescribe Accutane.

Presumably, this discussion does normally occur at the time of all the other consent. If the patient or parent does not understand that an abortion would be a sad necessity, the physician might think again about whether the patient is a candidate for Accutane treatment. Anyway, special stickers on prescriptions certifying negative pregnancy testing will not do anything except make Accutane more expensive and difficult to get. That will increase the illegal "black market" -- in short, more problems will be created than will be solved. It is most unfortunate that Dr. Janet Woodcock does not respond in any meaningful way to those who oppose additional regulation of Accutane.

Earlier I sent all of you a copy of the reply I finally got from her. It was a model of how to reply without saying anything meaningful. It would have been so much better to read her thoughts on the issues and see some dialog.
Walter Wood, MD