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JOHN C. WILLKE, M.D.

President

BRADLEY MATTES

Executive Director

To: Food and Drug Administration

From: J.C. Willke, MD

Date: April 13, 2004

Re: Authorization of Plan B

I happen to be the president of the International Right to Life Federation, but also practiced obstetrics and gynecology for many years before my present position. I've recently returned from a trip to Ukraine, London and Brussels. On this trip I spoke at length to knowledgeable people on this issue. I'm sure you are aware of the fact that this drug can prevent implantation of a one-week-old human embryo and because of this is in fact an abortifacient.

The above notwithstanding, I think there are ample arguments to give pause for authorization of over-the-counter use by teenagers. I would submit the following:

- 1) Here is a teenage couple thinking of having sex. If they know that she can take a pill tomorrow morning and "prevent" pregnancy, they are substantially more likely to proceed rather than to withhold. Accordingly, I don't believe there is any question at all that this pill will promote more teenage sexual promiscuity.
- 2) Note that the pill allows intercourse without any contraceptive barrier. This being true, we would expect an increase in sexually transmitted disease, if this pill is available. Experience in the United Kingdom over the last five years amply confirms this, as the STD rate has risen steadily during this time.
- 3) Since we know that a substantial majority of sexual encounters with minor girls is being had with mature men, it also seems obvious that these guys can have the pills in their pocket, can exploit the young girl, and then merely hand her the pills. The over-the-counter availability of these pills will promote statutory rape.

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- 4) We note that in practice, many young women are confused about the dosage of these pills and repeatedly take this very large dosage, oblivious of the fact that instructions say otherwise.
- 5) I'm old enough to have prescribed and used DES back in the 50s to "prevent" miscarriage, which was then conventional wisdom. As you know, that did not prevent miscarriages and we quit using the drug. But later we found the tragic harvest of clear cell carcinoma in the vagina in the little girls conceived during that time and some genital abnormalities in the little boys. Accordingly, I do not believe this should be used for teenagers until we have substantial proof that we're not going into another disaster such as the one with DES.
- 6) It goes without saying and you have been told that this is a drug with consequences, and so it should be used only under the direction of a physician. To throw this open to the market place in the light of the above will not just be unfair to these young ladies, but probably very dangerous.

A handwritten signature in black ink, appearing to read "J. Williams". The signature is written in a cursive style with a large, sweeping initial "J" and a long horizontal stroke extending to the right.