Elliot
INSTITUTE

May 7, 2003

Dockets Management Branch
Food & Drug Administration
Department of Health & Human Services
Room 10-61
5630 Fishers Lane
Rockville, MD 20857

RE: Docket 01P-0075 ("Switch Status of Emergency Contraceptives from Rx to OTC").

Dear Commissioner:

I strongly oppose the reclassification of "Emergency Contraceptives" as an over the counter drug. I am also deeply concerned by the fact that this drug regimen was approved for prescription use without the normal testing that would normally be required. Instead of requiring careful testing, the FDA made assumptions about the safety and effectiveness of this regimen based on inferences from studies of birth control pills. As a result, women considering the use of this regimen may be misled about the safety, effectiveness and mode of operation of this regimen. In many cases, the latter may offend the moral and/or religious sensibilities of some women and in many cases this is being concealed from women.

I strongly recommend that BOTH the physicians prescribing "emergency contraception" AND the pharmacists filling these prescriptions should be required to obtain from the patient a signed copy of the following informed consent form.

> If you have recently engaged in sexual intercourse, the sperm from your partner may have already fertilized your ovum (egg). The human embryo created at this moment is a living, genetically unique human being.
>
> Fertilization can occur in as little as fifteen minutes after intercourse. If fertilization has already occurred, the intended effect of this drug is to harden or disturb the lining of your womb in such a way as to prevent the human embryo from being implanted in your womb. As a result, the human embryo will be expelled from your body and die.
>
> The effectiveness rate of this drug in preventing implantation, if ovulation and fertilization has already occurred, has not yet been determined.
>
> The long term effects, if any, of using this drug at this dosage level have not yet been determined.
>
> The effects of this drug, if any, on the development of an unborn child have not yet

01P-0075 C 242

Elliot Institute • Post Office Box 7348 • Springfield, IL 62791 • Voice: (217) 525-8202 • Fax: (217) 525-8212

been determined.

> The government encourages you to reflect upon the serious moral questions associated with the use of this or any other substance that may irreversibly interfere with the creation, implantation, or sustenance of your biological progeny.

Unlike the previous statements, which are absolutely necessary to fully disclose the scientific facts surrounding this treatment regimen, the last statement is not strictly required as an aspect of disclosing scientific facts. On the other hand, it is certainly appropriate and, I would argue, necessary, for complete disclosure of facts that are relevant to the reasonable patient standard for obtaining informed consent.

Since use of this drug does have moral implications—at least for a substantial number of people of particular religious faiths, such as Catholicism or Islam—it would be an act of negligence for the FDA and health care providers to fail to notify patients that use of this regimen may violate their religious norms. After all, many religious people are not fully informed about all their religion's positions on every matter, much less the specific issue of using this particular drug regimen.

The failure to address the fact that this drug regimen raises moral concerns for women of some faiths may be a direct cause of their agreeing to use this drug regimen in violation of their religious conscience, resulting in subsequent remorse, guilt, or religious censor. Furthermore, to maintain a scientific pretense that moral concerns are not relevant puts the government in the practical position of imposing a secular humanistic view on all women. (Since the Supreme Court has defined secular humanism as a form of religion, the failure to address other moral views regarding the use of this drug regimen would arguably constitute government promotion of one religious view in preference to others.)

My recommended statement is religiously neutral and is an appropriate notice, especially to those women who are religious, that religious and moral questions surrounding the use of this drug regimen exist that are beyond the competence of their physician, pharmacist, or government to answer. Many women would benefit from this portion of the disclosure by being notified that they may wish to consult with their pastor, rabbi, or other religious advisor to consider moral issues relevant to them and their religious faith before using this regimen. While other women may not need or desire to examine the moral issues involved, they are free to dismiss this portion of the disclosure. Since the latter will suffer no harm while the former will benefit, clearly this portion of the disclosure ~~it~~ should be included.

Moreover, to the question of providing adequate informed consent meeting the reasonable patient standard, the fact that even a small minority of women would consider this information relevant to their decision to forgo the use of this regimen is sufficient to demonstrate that this is a subject that a reasonable patient might properly expect to be addressed. In my opinion, the failure to disclose any of the points identified in the above disclosure is a grave violation of the patients' right to proper disclosure of information that is reasonably relevant to their decisions.

Sincerely,

Dave Reardon

David C. Reardon, Ph.D.