

**Fr. Joseph C. Howard, Jr.**  
**Executive Director**

*American Bioethics Advisory Commission*

**June 29, 2000**  
**8:40 a.m.**

OON-1256

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# American Bioethics Advisory Commission

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**FDA**  
**OTC Part 15 Hearing**  
**Holiday Inn Gaithersburg, MD**  
**June 29, 2000**

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*Executive Director*

Fr. Joseph Howard, Jr. M. Div.

I serve as the Executive Director of the American Bioethics Advisory Commission, a division of American Life League, Inc. in Stafford, VA. There is no financial association with any pharmaceutical companies who manufacture oral contraceptives. I speak to you today regarding the possibility oral contraceptives being made available over the counter that would not require a prescription by a physician. Because of serious side effects and complications associated with the use of oral contraceptives, it is absolutely essential that physicians maintain control of who has accessibility to them. It is therefore imperative that oral contraceptives not be made available over the counter. From a scientific perspective alone, it is clearly in the best interest of women that oral contraceptives remain available by prescription only where physicians can monitor and follow their patients accordingly.

The use of oral contraceptives is associated with increased risks of serious conditions including the following:

1. Thromboembolic disorders and other vascular problems such as myocardial infarction, thromboembolism, and cerebrovascular diseases.
2. Hepatic neoplasia
3. Ocular lesions
4. Gallbladder disease
5. Carbohydrate and lipid metabolic effects
6. Hypertension
7. Headache
8. Bleeding Irregularities

The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity, and diabetes. While it is true that many of these deleterious physiologic effects are associated with the use of oral contraceptives containing higher formulations of estrogens and progestogens, the effects of long-term use of oral contraceptives containing lower formulations of both estrogens and progestogens remains to be determined.

One grave concern that exists if oral contraceptives were made available over the counter is the predicted significant increase in STDs—particularly HIV. Large numbers of high school and college students engage repeatedly in high-

risk sexual behaviors not realizing or accepting the fact that they are candidates to contract such diseases that can have devastating consequences on their lives. Having taught high school and college biology, physiology, philosophy, and theology for the past 10 years, I am acutely aware that these young people would probably be most affected by increases in STDs because many of them are unaware or in denial that such effects are applicable to them in their lives. It is very common for both high school and college students in America to be completely unaware that at this time in America, HIV is most rapidly spreading in heterosexuals in the high school and college populations. We must not and cannot allow our youth to be exposed to such risks because they are the future leaders of our country. We must do everything that is ethically appropriate to protect them and prepare them to assume leadership positions in the United States of America. Making oral contraceptives available over the counter can only contribute to the detriment of our youth and subsequently our country. It would clearly be an unjust practice especially in regard to our young people as well as women in general. In closing, I strongly urge that the FDA not make oral contraceptives available over the counter in America.

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