

Congress of the United States

Washington, DC 20515

January 9, 2004

The Honorable George W. Bush
President of the United States
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President,

We thank you for the remarkable job you and your Administration are doing during these challenging days. We are writing now regarding a very urgent and important matter that will affect the health and welfare of millions of Americans. A joint advisory panel of the Food and Drug Administration has voted to recommend the availability of the morning-after pill levonorgestrel, or Plan B, without a prescription. We urge you and the Commissioner of the Food and Drug Administration to reject this recommendation.

We are very concerned that no data is available to suggest what impact this decision will have on the sexual behavior of adolescents and the subsequent impact on adolescent sexual health. We are concerned that adolescent exposure to sexually transmitted infection will increase because of the availability of levonorgestrel over-the-counter. This availability may ultimately result in significant increases in cancer, infertility, and HIV/AIDS.

According to Food and Drug Administration documents, only the drug's safety and its effect on pregnancy were considered –without considering the significant impact over-the-counter availability of this product may have on the sexual health of adolescents and young people.

Adolescents and young adults (15-24) are the age groups at the greatest risk for acquiring sexually transmitted infections (STIs). Approximately two-thirds of all people who acquire STIs are under the age of 25 and each year 15 million new cases are diagnosed. The Centers for Disease Control states that adolescents and young adults are at greater risk of acquiring a sexually transmitted infection because of their immature physiology and immune systems; the increased probability of adolescents having multiple sexual partners, and the greater likelihood of adolescents engaging in high-risk sexual activity. ⁱ

Compared to older women, teen girls have a higher rate of chlamydia, a disease that is a common cause of pelvic inflammatory disease (PID), which can lead to infertility. At least ten percent of all sexually active teens are infected with this disease. Among women, gonorrhea rates are highest among teen girls ages 15-19.ⁱⁱ And the risk of pelvic inflammatory disease is as much as 10 times greater for 15-year-old females than for 24-year-old females. PID can result in sterility.ⁱⁱⁱ

Moreover, many STIs are difficult to treat. Herpes simplex virus infection (HSV-2) is typically asymptomatic and yet is highly contagious. Twenty two percent of the United States population age 12 and older (45 million) is infected with HSV-2.

Furthermore, age of initiation of sexual activity is a strong predictor of exposure to and contraction of a sexually transmitted infection. Anything that affects the sexual behavior of adolescents has significant public health consequences in terms of pregnancy and acquisition of sexually transmitted infections, including HIV/AIDS. The CDC estimates that 50% of all new HIV infections occur among people under 25 years old, with the majority being infected sexually.^{iv}

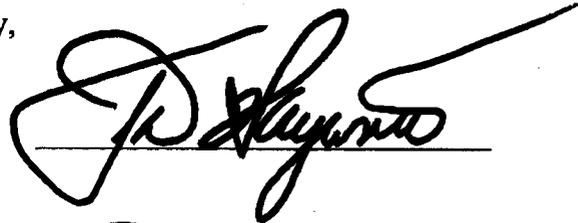
Determining how the over-the-counter availability of levonorgestrel may affect adolescent sexual health is a reasonable and minimal public health question that we feel must be determined before any decision is made. Unfortunately, this important public health information was not considered as part of the review process.

We urge you and Commissioner McClellan to reject the recommendation of the joint advisory panel. Current public efforts to inform young persons of risk have not effectively reduced prevalence of sexually transmitted disease. Moreover, data on adolescent risk-taking indicates that young people are risk-takers and will engage in risky behaviors that increase their chances of acquiring STDs, becoming pregnant and participating in drug, alcohol and nicotine abuse. We have attached a news article from the United Kingdom that indicates the over-the-counter availability of levonorgestrel as causing significant increases in STIs among adolescents.

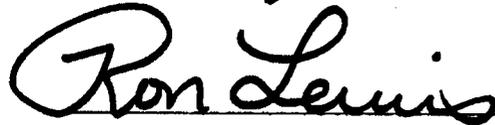
We are hard-pressed to understand how the over-the-counter availability of Plan B will enhance adolescent sexual health and reduce the incidents of sexually transmitted infection. Therefore, we urge you in the strongest of terms to reject the joint advisory council recommendation and protect the health and lives of American adolescents.

Sincerely,

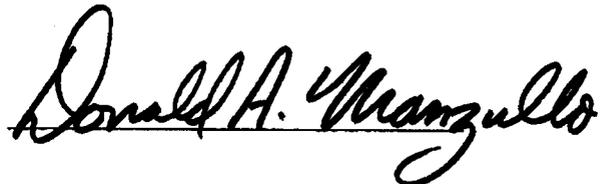












~~Brad Pitt~~

John T. Doherty

Henry Hyde

Jim DeMint

~~Kevin Brown~~

Walter B. Jones

Rob. Byrd

Thaddeus McCotter

David Vitter

John E. Sununu

W. Gooden

Rob Portman

Robin Kagan

Jeff Miller

Eric Cantor

Tom Feeney

Pete Habstra

Ann Tracy

Shirley Ann

Virgil Good

Ann Tracy

Melissa G. Hunt

Robert B. Adulmet Steve King

Mark Suda

Marilyn Musgrave

John Hortel

Mae Collins

Tom Tancredo

Jo Ann Davis

Zach Wamp

Roger F. Wicker

Pat Toomey

Sue Myrick

Chip Piling

Tim Murphy

Ernest Lambert

Wally Hergen

Quince Hunter

Cliff Starnes

Edw. Smith

Todd Tiahut

Jh. Shuman

ⁱ Division of STD Prevention. *Sexually Transmitted Disease Surveillance 1999*. Department of Health and Human Services, Atlanta: Center for Disease Control and Prevention (CDC), September 2000.

ⁱⁱ Division of STD Prevention. *Sexually Transmitted Disease Surveillance 1999*. Department of Health and Human Services, Atlanta: Center for Disease Control and Prevention (CDC), September 2000.

ⁱⁱⁱ Westrom L. Incidence, Prevalence, and Trends of Acute Pelvic Inflammatory Disease and Its Consequences in Industrialized Countries. *American Journal of Obstetrics and Gynecology*. 1980: 138, 880-92.

^{iv} Centers for Disease Control and Prevention. *HIV Prevention Strategic Plan Through 2005*. September 2000.