



December 5, 2003

Louis Cantilena, MD, PhD
Chair, Nonprescription Drugs Advisory Committee
United States Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857-0001

Re: Docket number 01P-0075-"Switch Status of Emergency Contraceptive from Rx to OTC"

Dear Dr. Cantilena:

On behalf of the undersigned organizations dedicated to improving reproductive health care, we are writing to support over-the-counter status for Plan B, an emergency contraceptive pill (ECP). Scientific research has shown ECPs to be safe and effective for reducing unintended pregnancy and to be appropriate candidates for over-the-counter use.

Plan B meets the Food and Drug Administration's criteria for determining drugs appropriate for over-the-counter use. It treats a condition that patients can diagnose themselves; it is safe and effective when used without direct prescriber supervision; and the drug's label adequately explains potential adverse effects and conditions of use. Plan B is simple to use, is not addictive, and has no known health hazards when self-administered. There are virtually no contraindications, and side effects are minor and temporary. In sum, there is no compelling medical rationale for restricting Plan B to prescription-only use.

Moreover, over-the-counter status for Plan B is likely to have significant public health benefits. The sooner after unprotected intercourse ECPs are used, the more effective they are.^{1,2} Yet recent studies have shown that some women may have difficulty obtaining ECPs from a health care professional and/or pharmacy in a timely fashion.^{3,4}

Unintended pregnancy is a major public health issue that has negative consequences for individuals and society.⁵ In the United States, nearly half of all pregnancies are unintended.⁶ It has been estimated that if ECPs were widely available, rates of unintended pregnancy and abortion could be reduced by half.⁷ A recent analysis estimated that emergency contraception helped to avert more than 50,000 abortions in 2000-2001 in the United States.⁸ Improving access to emergency contraception will help advance the important public health goal of reducing unintended pregnancy.

On the basis of emergency contraception's suitability for over-the-counter use and its potential to decrease unintended pregnancy, a number of countries-including the United Kingdom, Portugal, Finland, Sweden, and Denmark-have simplified access to ECPs. Over-the-counter status for Plan B is appropriate and will advance the nation's public health goals. Increasing access to emergency contraception will help women in the United States reap the full benefit of this method of preventing unintended pregnancy.

Sincerely,

Abortion Access Project
American Academy of Pediatrics
American Association of University Women
American Civil Liberties Union
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
American Medical Association
American Medical Women's Association
American Society for Emergency Contraception
Arizona Family Planning Council
Association of Physician Assistants in Ob/Gyn
Association of Physician Assistants in Ob/Gyn
Association of Reproductive Health Professionals (ARHP)
Association of Women's Health, Obstetric and Neonatal Nurses
Brooklyn-Queens NOW
Catholics for a Free Choice
Center for Reproductive Rights
Clara Bell Duvall Project, ACLU-PA
Concept Foundation
DKT
Family Health Research
Family Planning Advocates of NYS, Inc.
Family Planning Council
Feminist Majority Foundation
Florida ERA Inc
GenderWatchers
Global Campaign for Microbicides
Gynuity Health Projects
Hadassah, The Women's Zionist Organization of America
Ibis Reproductive Health
Institute for Reproductive Health Access
International Consortium for Emergency Contraception
International Planned Parenthood Federation/Western Hemisphere Region
Ipas
Medical Students for Choice
NARAL Pro-Choice America
National Abortion Federation
National Association of Nurse Practitioners in Women's Health
National Council of Jewish Women
National Council of Women's Organizations
National Family Planning and Reproductive Health Association
National Latina Institute for Reproductive Health
National Organization for Women
National Organization on Adolescent Pregnancy, Parenting and Prevention, Inc.
National Partnership for Women and Families
National Women's Law Center
New York City Alliance Against Sexual Assault
New York Metro Religious Coalition for Reproductive Choice
Northwest Women's Law Center
Our Bodies Ourselves
Pacific Institute for Women's Health
Pathfinder International
People For the American Way
Physicians for Reproductive Choice and Health
Planned Parenthood Federation of America
Planned Parenthood Hudson Peconic, Inc

Population Action International
Rape and Abuse Crisis Service of the Finger Lakes
Religious Coalition for Reproductive Choice
Reproductive Health Technologies Project
Sexuality Information and Education Council for the United States
Society for Adolescent Medicine
Southern Tier AIDS Program
STOP AIDS Project, San Francisco
University of Illinois at Chicago Center for Research on Women and Gender
University of Illinois National Center of Excellence in Women's Health
Upper Hudson Planned Parenthood
Victims Assistance Services
Women's Environment & Development Organization (WEDO)
Women's Information Network

cc: Mark B. McClellan, MD, PhD, Commissioner of Food and Drugs, United States
Food and Drug Administration

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2. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet*. 1998;352:428-433.
3. Bennett W, Petraitis C, D'Anella A, et al. Pharmacists' knowledge and the difficulty of obtaining emergency contraception. *Contraception*. 2003;68(4):261-267.
4. Trussell J, Duran V, Schochet T, Moore K. Access to emergency contraception. *Obstet Gynecol*. 2000;95:267-270.
5. Brown S, Eisenberg L. *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*. Washington, DC: National Academy Press; 1995.
6. Henshaw SK. Unintended pregnancy in the United States. *Fam Plann Perspect*. Jan-Feb 1998;30(1):24-29, 46.
7. Trussell J, Stewart F, Guest F, et al. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. *Fam Plann Perspect*. Nov-Dec 1992;24(6):269-273.
8. Jones RK, Darroch JE, Henshaw SK. Contraceptive use among U.S. women having abortions in 2000-2001. *Perspect Sex Reprod Health*. Nov-Dec 2002;34(6):294-303.