emergency contraception
ACCESS CAMPAIGN

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 01P-0075 – Switch Status of Emergency Contraceptives from Rx to OTC

For the last two years, the Emergency Contraception Access Campaign – a coalition of over 70 public health advocates, medical and health professionals and community organizations across New York State (see attached list) – has sought to promote widespread knowledge of and access to emergency contraception (EC). The Emergency Contraception Access Campaign is committed to: educating New Yorkers about the safety, efficacy and availability of EC as a back-up method of birth control; encouraging physicians and other health care professionals to educate about and make EC more widely available; and, reducing the specific barriers to the timely availability of EC, including advocating for access through pharmacists and direct over-the-counter distribution.

Contraceptives can let any woman down. Accidents do not discriminate – they happen to single and married women; mothers and daughters; women in their 20s, 30s and throughout their reproductive years. If women had easy, timely access to emergency contraception, we could help cut the U.S. rate of unintended pregnancies in half.

Women with an unintended pregnancy are more likely to fail to receive timely prenatal care, and the child of an unwanted conception is at greater risk of being born with a low birth weight and is more likely to suffer from abuse or death during the first year of life.

There are about 3 million unintended pregnancies each year in the United States. Just over half of these happen to women who are using a regular method of contraception.[1] Plan B can reduce the risk of pregnancy by up to 89% when taken within 72 hours of unprotected or coerced sex. Recent data shows that EC use averted more than 50,000 abortions in 2000 alone.[2] Yet, barriers to access and lack of knowledge about EC preclude women from using this safe and effective back-up method – only 6% of women report ever having used EC.

Prescription status for emergency contraception is a barrier for women. Women who live in rural areas may not be able to readily access a health care provider who can prescribe EC. Women without insurance or a regular health care provider have limited or no access to the method. Even women with better access to health care may be required to visit her clinician before receiving a prescription or may encounter a pharmacist who would refuse to fill an EC prescription

[1] Henshaw SK. Unintended pregnancy in the United States. Family Planning Perspectives 1998, 30: 24-29.
[2] Jones RK, Darroch JE, Henshaw SK. Contraceptive Use Among U.S. Women Having Abortions in 2000-2001. Perspectives on Sexual and Reproductive Health 2002, 34: 294-303.

for 'moral reasons.' A study published in 2000 showed that about one in four calls to an EC hotline did not result in an appointment with a health care professional or telephone prescription for emergency contraceptive pills within 72 hours.[3]

Plan B should be available over-the-counter. Despite the many highly effective birth control options women have to choose from, none is fail-safe. There are 3 million unintended pregnancies each year in the United States and Plan B could prevent half of these, and, thereby, a significant number of abortions. Plan B meets United States Food and Drug Administration criteria for over-the-counter status and its wider use could result in significant cost savings to both Medicaid and private insurers.

Over-the-counter availability makes fiscal sense. A recent study by the Office of the New York State Comptroller Alan G. Hevesi found that easier access to EC would cut health care spending by $452 million annually in New York State.[4] The study was based on actual Medicaid and representative private health insurance data for New York and on health care spending trends and research.

The Office of the State Comptroller adjusted the 2000 pregnancy and spending figures and projected that spending in New York by all public and private sources on unintended pregnancy will total an estimated $913 million in 2003, with Medicaid representing nearly $511 million, or 56 percent of that total.

With expanded access to emergency contraception, local governments could save $66 million a year and the State $67 million, for a total of about $133 million. The federal government would save the rest of the $254 million in reduced Medicaid costs.

The indication for treatment is self-diagnosable. The condition that Plan B treats - contraceptive failure or failure to use contraception during intercourse – is readily diagnosable by the woman herself.

Plan B is effective when self-administered. Correct administration of EC relies only on knowing the time elapsed since sexual intercourse, information that is readily available to the woman. Any interaction between EC and other drugs would not be fatal and unlikely to seriously effect EC's efficacy. All patients take the same dosage of the drug.

Plan B is safe when self-administered. Side effects of EC are well known and minor. Nausea occurs in 30-66% of patients and lasts for two days or less. The incidence and severity of nausea and vomiting are decreased when antiemetic agents are taken one hour prior to the first dose.[5]

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[3] Trussel JT, et al. Access to Emergency Contraception. Obstet Gynecol 2000, 95: 267-270.
[4] Office of the New York State Comptroller. Emergency Contraception in New York State: Fewer Unintended Pregnancies and Lower Health Care Costs 2003.
[5] ACOG Committee on Practice Bulletins, Chez RA. ACOG Practice Bulletin 2001, 25: 2.

There is a low risk of abuse or overdose. In a controlled trial of more than 1,000 subjects in Scotland, women given a hormonal EC method to keep at home for self-administration were more likely to use it than were those in the control group, and not more likely to use it more than once.[6]

EC is not harmful to the woman or to the fetus if a pregnancy is already established.

Drug labeling is clear and comprehensible for self-administration. Plan B's labeling is shown to be simple, clear, comprehensive and easy to follow. In a 2002 study that simulated over-the-counter availability of emergency contraception, nearly all the subjects used the product (Plan B) appropriately and safely. The incidence of contraindicated use was extremely low (1.3%).[7]

Reducing the rate of unintended pregnancy is an important public health priority for our country. Providing direct EC treatment will, in many cases, mean the difference between a woman receiving effective pregnancy prevention or dealing with the consequences of unplanned pregnancy. Emergency contraception is a safe, effective back-up birth control method which prevents unintended pregnancy after unprotected sex. Emergency contraception is birth control, pure and simple – the sooner a woman has access to it, the better. Emergency contraception meets the Food and Drug Administration's criteria for over-the-counter status: a patient can self-diagnose need and the product is safe and effective when self-administered. By ensuring that Plan B is available over-the-counter, the FDA may prevent as many as 1.7 million unintended pregnancies and 800,000 abortions each year in the United States. The Emergency Contraception Access Campaign urges the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs to support the switch of emergency contraceptives, specifically Plan B, from prescription to over-the-counter status.

Sincerely,

Emergency Contraception Access Campaign

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[6] Glasier A. Baird D. The effects of self-administering emergency contraception. N Engl J Med 1998, 339: 1-4.

[7] Raymond EG, Chen P, Dalcbout SM. "Actual Use" Study of Emergency Contraceptive Pills Provided in a Simulated Over-the-Counter Manner. Obstet Gynecol 2003, 102: 17-23.

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Coalition Members

List in formation

AIDS Work of the Southern Tier AIDS Program
American Association of University Women – Islip Area
American College of Obstetricians and Gynecologists, District II/NY
American Jewish Congress Commission for Women's Equality
Betances Health Center
B'rith Kodesh Sisterhood
Brooklyn Pro-Choice Network
Buffalo Adolescent Pregnancy Prevention Services
Callen-Lorde Community Health Center
Capital District Women's Bar Legal Project, Inc.
Catholics for a Free Choice
Center for Reproductive Rights
Circulo de la Hispanidad
Community Healthcare Network
Community Healthcare Network – Community League Center
Coney Island Hospital
Crime Victims Treatment Center – St. Luke's Roosevelt Hospital
The Crystal Quilt
Deaconess Family Planning Center – Kaleida Health
Dominican Women's Development Center
The Door
Empire State Pride Agenda
Family Planning Advocates of New York State
Gay Men's Health Crisis
inMotion
Institute for Humanist Studies
Interfaith IMPACT of New York State
Joseph P. Addabbo Family Health Center
League of Women Voters of New York State
Life Force: Women Fighting AIDS, Inc.
Lower East Side Family Union
Medical and Health Research Association of NYC, Inc.
Mount Sinai Sexual Assault & Violence Intervention Program
My Sister's Place
NARAL Pro-Choice New York
Nassau Health Care Corporation/Community Health Centers
National Association of Social Workers of New York State
National Council of Jewish Women of New York State
National Council of Jewish Women, Rockland Section
National Organization for Women – New York State
National Organization for Women - NYC
New Rochelle Emergency Services P.C.
New York City Pharmacists Society
New York Civil Liberties Union – Reproductive Rights Project
New York Medical College - Division of Adolescent Medicine
New York Metro Religious Coalition for Reproductive Choice
New York State Association of Licensed Midwives
New York State Coalition Against Sexual Assault
New York State Coalition Against Domestic Violence
New York State Nurses Association
New York Professional Nurses Union
Northern Manhattan Perinatal Partnership, Inc.
Northern Adirondack Planned Parenthood
Oswego County Opportunities, Inc.
Pharmacists Society of the State of New York
Physicians for Reproductive Choice and Health
Planned Parenthood of Buffalo & Erie County
Planned Parenthood Hudson Peconic, Inc.
Planned Parenthood of Nassau County
Planned Parenthood of New York City
Planned Parenthood of the Rochester/Syracuse Region
Planned Parenthood of South Central New York
Planned Parenthood of the Southern Tier
Pro-Choice Network of Western New York
Public Health Association of New York City
Rape & Abuse Crisis Service of the Finger Lakes
Rape Crisis of the Southern Tier
Republican Pro-Choice Coalition of New York
Sexual Assault Support Services of Planned Parenthood Mohawk Hudson
Statewide Youth Advocacy
Threshold Center for Alternative Youth Services, Inc.
Tioga Opportunities, Inc. – Family Health Services
Upper Hudson Planned Parenthood
Victims Assistance Services
Westchester Coalition for Legal Abortion
Women of Reform Judaism/District 3
Women's Rights at Work
Women's Center – Brooklyn College
Women's City Club of New York
Youth Empowerment Activists (YEA!)
YWCA of Binghamton/Broome County