

December 7, 2012

Secretary Kathleen Sebelius
Department of Health and Human Services
Hubert H. Humphrey Building
Washington, D.C., 20201

Dear Secretary Sebelius,

We write to respectfully ask HHS to revisit the evidence regarding non-prescription access for Plan B One-Step emergency contraception (EC) and to remove the restrictions that prevent this safe and effective product from being accessible to women and couples who need it. In the year since overruling the conclusions of FDA experts, barriers such as age, valid identification, and less than universal availability have continued to undermine timely access by those who need this product to prevent unintended pregnancy. Scientific research and expert opinions support removal of any age restriction and moving this safe and effective medication from behind the pharmacy counter to store shelves.

The unique dual-labeling of Plan B One Step has led to confusion among consumers and health care professionals alike, particularly regarding age restrictions and whether men and women can purchase non-prescription EC. A recent Boston University study of 943 pharmacies in five major cities revealed that, when callers posed as 17 year olds seeking EC, one in five were told they could not purchase EC under any circumstances.¹ Pharmacies gave more than half of all young people and physicians in the study inaccurate information about how old a patient has to be to purchase emergency contraception. The investigators conclude that, “such misinformation poses a potentially substantial barrier to access.”

These obstacles can easily be avoided by making emergency contraception - which has continuously been determined by the FDA to be safe and effective - available on store shelves without unnecessary and harmful age restrictions. Medical societies, journals, and experts - including the American Congress of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Society of Adolescent Health and Medicine, the American College of Clinical Pharmacy Women’s Health Practice and Research Network, and a former U.S. Surgeon General - disagreed with HHS’s decision to maintain unnecessary and harmful age restrictions on access to emergency contraception. Current data suggests that access to emergency contraception does not increase sexual activity; rather, the evidence shows that access to emergency contraception gives teens who are already sexually-active another option to prevent an unintended pregnancy.²

Plan B One-Step was extensively studied during its ten-year journey through the FDA science-based approval process, and its safety and efficacy are not in question. It is essential that HHS remove harmful and unnecessary restrictions on Plan B One-Step, both to improve access to contraception and to reinforce that politics has no place in FDA approval processes, now or in the future.

¹ Wilkinson T et al. Pharmacy Communication to Adolescents and Their Physicians Regarding Access to Emergency Contraception. *Pediatrics*. 2012;129(4):624-629.

² Weiss DC, Harper CC, Speidel JJ, Raine TR. Does Emergency Contraception Promote Sexual Risk-Taking? Bixby Center for Global Reproductive Health, University of California, San Francisco. April 2008.

Signed,

Advocates for Youth
American Association of University Women
American Civil Liberties Union
American Society for Emergency Contraception
American Society for Reproductive Medicine
Association of Reproductive Health Professionals
Black Women's Health Imperative
California Family Health Council
Catholics for Choice
Center for Reproductive Rights
Choice USA
Colorado Organization for Latina Opportunity and Reproductive Rights
Family Planning Association of Northeast Ohio, Inc.
Gynuity Health Projects
Ibis Reproductive Health
Jacob's Institute of Women's Health
Law Students for Reproductive Justice
Metropolitan Community Churches
NARAL Pro-Choice America
National Asian Pacific American Women's Forum
National Association of Nurse Practitioners in Women's Health
National Center for Lesbian Rights
National Council of Jewish Women
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Organization for Women
National Partnership for Women and Families
National Women's Health Network
National Women's Law Center
National Women's Liberation
Partnership for Civil Justice Fund
Physicians for Reproductive Choice and Health
Planned Parenthood Federation of America and all Planned Parenthood Affiliates Nationwide
Population Connection
Population Council
Religious Coalition for Reproductive Choice
Religious Institute
Reproductive Health Technologies Project
Sexuality Information and Education Council of the U.S.
The United Methodist Church, General Board of Church & Society
Union for Reform Judaism
Union of Concerned Scientists
Wisconsin Alliance for Women's Health
Women of Reform Judaism
Women's Reproductive Rights Assistance Project
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