

FOR IMMEDIATE RELEASE December 6, 2012

CONTACT: Elizabeth Dawes Gay, Reproductive Health Technologies Project

202-530-4401

HHS: Remove Emergency Contraception Restrictions Now Advocates Urge Sebelius to Prioritize Women's Health Over Politics One-Year After She Overruled FDA

(WASHINGTON, DC) --- One year ago, December 7, 2011, Health and Human Services (HHS) Secretary Kathleen Sebelius overruled the Food Drug Administration (FDA) and insisted on keeping Plan B One Step® emergency contraception restricted behind the pharmacy counter. To mark the anniversary, more than 40 organizations representing millions of Americans have signed a letter urging Secretary Sebelius to revisit the evidence and remove the restrictions. The coalition letter is part of an extended public awareness campaign that has galvanized support from citizens, scientists, medical professionals and women's health advocates.

"Emergency contraception needs to be on the pharmacy shelf between condoms and pregnancy test kits, available to women and couples without hassle or delay," said Kirsten Moore, President and CEO of Reproductive Health Technologies Project, the organizer of the coalition effort. "Doctors are leading the way saying that all contraception should move over-the-counter and be available to women of all ages. Politicians need to follow the doctors' lead and get politics out of women's health once and for all," Moore added, referring to recent announcements by the American College of Obstetricians and Gynecologists, and the American Academy of Pediatricians encouraging easier access to oral contraception and emergency contraception for teens.

Many believe Sebelius' unprecedented action last year was more about politics than health care. "Government's role is to determine the safety and effectiveness of products, to protect consumers from harm, not to make it difficult for consumers to take care of their health," Moore said. "Emergency contraception has been studied and debated for a decade, and it has been determined to be safe and effective for all ages, so the government should get out of the way and let consumers decide what is best for them," she added.

In addition to the coalition letter, the campaign urging HHS to act featured a video explaining how EC works from <u>ASAPScience</u>, and another featuring a couple discussing how they were <u>refused EC by a pharmacist</u>. A recording of an <u>audio news conference</u> held on the issue can be found at RH Reality Check, and <u>social media tools</u> have helped citizens engage. <u>Petitions</u> from various organizations are urging HHS to act and so far have gathered nearly 40,000 signatures collectively. The full context of the coalition letter follows:

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. 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

WV FREE

Amy S. Gottlieb, M.D. - The Warren Alpert Medical School of Brown University Beth Lewis, MD

Clace Cleaver-Felice, BA, BS, RD, CDE, AFAA, ACE – Meridian Medical Associates

Cynthia H. Chuang, M.D., M.Sc. - Penn State College of Medicine

Diane S. Morse, MD - University of Rochester School of Medicine

Eleanor Bimla Schwarz, MD, MS – University of Pittsburgh

Ellen Chesler, Ph.D. Senior Fellow, the Roosevelt Institute

Frances C. Brokaw MD - Dartmouth-Hitchcock Medical Center

Jamie Stern, MD

Lawrence I Kaplan, MD FACP - Temple University School of Medicine

Michael P. Carson, MD - UMDNJ-Robert Wood Johnson Medical School

Nancy A. Rigotti, MD - Harvard Medical School

Nancy L. Keating, MD, MPH - Harvard Medical School

Rachel Hess, MD, MS - Center for Research on Health Care

Richard M. Abramowitz, MD, FACP, FACOEM - Jersey Shore University Medical Center Sally Rafie, PharmD – University of California San Diego Skaggs School of Pharmacy and

Pharmaceutical Sciences

Tsonwin Hai, Ph.D. - Ohio State University

Vic Strasburger, M.D. – University of New Mexico