

For Immediate Release

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Washington, DC - The National Health Law Program expressed disappointment with the decision today by the Secretary of Health and Human Services (HHS) to deny full over-the-counter (OTC) status for Plan B One-Step.

"Today's decision puts politics over the health needs of young women," said Emily Spitzer, NHeLP executive director. "We are incredibly disappointed HHS succumbed to political pressure at the expense of women's health."

The Food and Drug Administration (FDA) had been reviewing a supplemental application by the makers of emergency contraception Plan B One-Step, Teva Women's Health Inc., to market the drug, nonprescription without an age restriction. The FDA, through the Center for Drug Evaluation and Research (CDER), reviewed Teva's application and supporting evidence and concluded that Plan B One-Step was safe and effective for adolescent women, and that young women understood the use and limitations of the drug. FDA Commissioner Margaret Hamburg agreed with the analysis and data, finding that the evidence supported making Plan B One-Step available without a prescription for all females of child-bearing ability.

Today, however, the Secretary of HHS issued a letter to Commissioner Hamburg overruling her decision, and directing the FDA to deny the supplemental application. When the FDA initially approved Plan B One-Step in 2009 without a prescription for females age 17 and older, it did so in the face of considerable pressure from anti-women opponents. The delay in initial approval of emergency contraception without a prescription has been highly politicized and the subject of a lawsuit by the Center for Reproductive Rights.

“The Secretary’s decision today disregards the breadth of scientific evidence and analysis the FDA considered when agreeing that Plan B One-Step should be OTC for all women,” said Susan Berke Fogel, NHeLP director of reproductive health and justice programs. “Put simply, restricting access to the drug for women 16 and under is at odds with the scientific evidence.”

Emergency contraception, including Plan B One-Step, is currently available without a prescription for persons 17 and older. The drug is located behind the pharmacy counter, and persons must present proof of age for purchase. Persons aged 16 and younger can only obtain emergency contraception with a prescription.

NHeLP supports the ability of women of all ages to have access to the full range of FDA-approved contraceptive services and supplies. Restricting access to emergency contraception on the basis of age undermines sexually active teenager’s ability to make individual health care decisions to prevent pregnancy.

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Founded in 1969, the National Health Law Program works with and on behalf of limited-income people, people with disabilities, and children to improve their access to quality health care and to enforce their legal rights to health. NHeLP works with courts, government agencies, and Congress to ensure quality health care for the most vulnerable members of our society.

