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Women's Health Advocates Disappointed by FDA Decision to Maintain Restrictions on Generic Emergency Contraception

(WASHINGTON, DC) --- Late Monday, FDA decided to grant market exclusivity to Teva Pharmaceuticals, Inc. – the maker of Plan B One-Step®. For the next three years, the only emergency contraception product women will be able to purchase directly from drugstore shelves without presenting identification is Plan B One-Step®. A one-pill generic version will also be available on the shelf, but only for women who can prove they are 17 or older. Those under 17 will still need a prescription to purchase the more affordable generic version.

“We are disappointed by FDA’s most recent decision to maintain age restrictions on generic brands of emergency contraception, which will leave more affordable alternatives of safe and simple emergency contraception products out of reach for many women. This decision is not supported by the evidence presented to the Administration, will only lead to more confusion on the part of consumers and pharmacies, and will continue to unnecessarily feed the false assertions by some that emergency contraception is unsafe or risky,” said Jessica Arons, President and CEO of Reproductive Health Technologies Project. “Basically, it is yet one more missed opportunity for the Administration to get it right on emergency contraception.”

“In justifying this move, FDA continues to contradict the recommendations of its own experts by arguing that insufficient data exist to approve over-the-counter status for generic brands. Yet over a decade ago, FDA scientists determined that levonorgestrel-based emergency contraception was safe and effective for over-the-counter use by women of all ages and no further information was needed to make that determination. Thus, based on FDA’s own conclusions and recommendations, all products - including the one-pill generic versions of emergency contraception - should be made available to women and couples now without unnecessary restrictions.”

While moving brand and generic products to the shelf is great news for many women, the price of emergency contraception will continue to be a barrier to timely access. This news comes a day after a report published by the American Society for Emergency Contraception showing that the average price of branded Plan B One-Step® is \$48, while the average price for a generic version is \$41.¹

¹ American Society for Emergency Contraception. The Cost of Emergency Contraception: Results from a Nationwide Survey. July 2013. Available at: <http://ec.princeton.edu/ASECPricingReport.pdf>.