



Statement by Kirsten Moore on Creating a New Class of Behind-the-Counter Drugs

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WASHINGTON, Nov. 14 -- Kirsten Moore, President and CEO, Reproductive Health Technologies Project, who is presenting at today's U.S. Food and Drug Administration (FDA) public meeting regarding behind-the-counter (BTC) availability of drugs, issued the following statement:

"Creating a new class of behind-the-counter drugs may be one way to increase access and convenience to needed medication for many Americans. However, the FDA should carefully consider whether having a learned intermediary such as a pharmacist would advance quality health care or create an unnecessary barrier. It will be more useful to identify criteria for the kinds of products to which easier access with a learned intermediary would improve health outcomes.

"The current de facto behind-the-counter status of Plan B emergency contraception provides a good example of the potential benefits and drawbacks of creating a new class of drugs. Because of its dual label status, Plan B is kept behind the counter so that someone has to check for proof of age. BTC status has increased access to Plan B for many Americans but has kept it from others despite ample evidence that the drug is safe and effective for all women of reproductive age. This requirement unnecessarily delays access to this time-sensitive treatment potentially increasing the risk of unintended pregnancy.

"Plan B is a cautionary tale for the agency. We urge the FDA to prioritize improved health outcomes as it considers a new class of behind-the-counter drugs."

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