



**U.S. Food and Drug Administration
Behind the Counter Availability of Certain Drugs
Public Meeting**

November 14, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. 2007N-0356 in the October 4, 2007 *Federal Register* (Vol 72; No 192)

We want to thank the scientists at the FDA for convening this meeting to explore the public health benefits and limitations of expanding access to FDA approved drugs. My name is Kirsten Moore and I am President of the Reproductive Health Technologies Project (RHTP), a national nonprofit advocacy organization. Our mission is to advance the ability of every woman of any age to achieve full reproductive freedom with access to the safest, most effective and appropriate technologies for ensuring her health and controlling her fertility. RHTP does not accept any funding from drug or device manufacturers.

The need to transform the US health care system is obvious. Almost 47 million Americans are uninsured and it is estimated that another 16 million are underinsured. Among other things, this means millions of women, men and children are unable to access preventive services and treatments in an effort to avoid breaking their household budget. Creating a new class of behind the counter drugs, thus eliminating the need for a costly and time-consuming doctor's visit, may be one way to increase access and convenience to needed medication without compromising quality for many Americans.

Rather than discuss a third class in the abstract, RHTP believes it would be more useful to identify criteria for the kinds of products to which easier access would improve health outcomes. Some examples include drugs with well established safety records in the general population that are used to prevent disease, treat a long term health problem, or for which urgent and timely access is key. Once the criteria have been determined, the question becomes whether and how health outcomes can be improved by a learned intermediary such as a pharmacist or pharmacist assistant. The role of the learned intermediary must enhance the ability to, or at the very least must not deter individuals from, accessing necessary drugs.

I would like to take this opportunity to speak to the knowledge gained from our experience with the current *de facto* behind-the-counter (BTC) status of Plan B emergency contraception as a case study for both the potential benefits and drawbacks of this kind of approach.

In August 2006, the FDA approved for over the counter access to Plan B for consumers aged 18 years and over. The good news? Access to Plan B has increased for many Americans. Before the label-change, women were filling approximately 17,000 Plan B prescriptions weekly. Currently, 40,000 units of Plan B are sold weekly, of which only 6 – 7,000 are dispensed by prescription. Clearly, removing the unnecessary prescription barrier to this preventive medication has improved consumers' ability to obtain the product and potentially improve health outcomes.

The bad news? Females under the age of 18 are still required to have a prescription. This is a shame as there is ample medical evidence that the drug is safe and effective for all women of reproductive age. Also, we know that Plan B is more effective the sooner after unprotected or under-protected sex that it is used. As a result, the prescription requirement unnecessarily delays access to this time sensitive treatment, potentially increasing the risk of an unintended pregnancy.

Because of its dual label status, Plan B is kept behind the counter rather than on store shelves next to condoms. In this case, the learned intermediary's role is solely to check for proof of age. This does not enhance individuals' ability to access Plan B and, in fact, may deter them as reports persist of pharmacists or pharmacy staff using this opportunity to impose their personal view point on consumers by denying them the product. It is also worth pointing out that the proof of age requirement also impedes access for women who are 18 or older but lack official proof of age, and the requirement also serves as a waste of time for the pharmacist. In other words, there is sometimes a thin line between learned intermediary and gatekeeper.

We believe Plan B is a cautionary tale for the Agency and we urge the FDA to prioritize improved health outcomes as it considers future such arrangements. The current status of Plan B has given consumers – men and women – more timely access to a second chance to prevent an unintended pregnancy. That is a good thing since there are approximately 3 million unintended pregnancies in the United States each year. With more and more people being left behind in our health care system and with an increasingly mobile society, we think it is critical to explore creative strategies that will expand access to other proven safe and effective medications that reduce the risk of unintended pregnancy without compromising quality of care or coverage.

And this brings me to my last point. I know this is beyond the scope of FDA's regulatory authority but as we consider a potential third class RHTP believes a critical question that must be kept in the foreground of these deliberations is "who can afford BTC drugs?" If the FDA proceeds down the path of expanding access to some drugs within the confines of the current system than all we may be doing is improving convenience. Convenience may improve health outcomes for some people but, as has been shown with the Plan B experience, it leaves others behind, and therefore does not result in the kind of overall public health payoff we should strive for. There has to be a broader commitment from the Department of Health and Human Services to crafting and implementing rational, cost effective policies that will put access to medications in reach of those who have Medicaid, Medicare or otherwise cannot afford private health insurance.