UNFINISHED BUSINESS ON EMERGENCY CONTRACEPTION

AN ACTION AGENDA FOR COMPREHENSIVE ACCESS

In the summer of 2013, reproductive health advocates celebrated the U.S. Food and Drug Administration’s (FDA) approval of Plan B One-Step® emergency contraception (EC) for use without a prescription for all women of child-bearing potential. This major victory came after more than a decade of research, advocacy, and legal action. However, as we near the anniversary of Plan B One-Step® arriving on store shelves, the Supreme Court decision in the Burwell v. Hobby Lobby and Conestoga Wood v. Burwell cases is a fresh reminder that the fight for unfettered access to safe and effective reproductive health products, like EC, is far from over. The Reproductive Health Technologies Project has identified the following areas in need of ongoing attention and advocacy.

AFFORDABILITY

Several recent developments serve to improve the availability of EC. FDA’s approval of Plan B One-Step® for people of all ages was followed by a letter in February 2014 indicating that generic EC could be sold on store shelves and would no longer require proof of age for purchase. Since then, FDA has approved three generics for sale without proof of age, including After Pill – a product chemically identical to Plan B One-Step® that is only available online at a price point of $20 per dose (compared to $48 on average for Plan B One-Step®). This option is a significant step toward creating downward price pressures in the market and improving the affordability of over-the-counter EC. Unfortunately, current Health and Human Services regulations do not require insurers to cover OTC preventive products, such as EC, at no cost unless the consumer has a prescription and the Hobby Lobby decision puts no-cost coverage for prescription EC at risk for millions of women.

ACTION:

- Support legislative and administrative fixes to the Hobby Lobby decision in order to ensure women get the coverage they need for all forms of contraception, including EC
- Advocate for an interpretation of the women’s preventive services section of the Affordable Care Act that would require no-cost coverage of any over-the-counter EC product without a prescription
- Encourage market developments that will help to lower the price of EC so that cost does not remain a barrier to access

APPROPRIATE STOCKING AND RETAILER ACCOUNTABILITY

Since Plan B One-Step® became available for sale without age or point-of-sale restrictions in July 2013, retail and pharmacist response has been confusing at best and non-compliant at worst. A survey completed in early 2014 found that only half of stores actually stocked Plan B One-Step® on store shelves. In some stores there are signs directing shoppers to the pharmacy or even photo counters. Even when stocked in appropriate areas, some stores lock the product in a large plastic case or behind a glass case that must be opened by store staff, with some retailers citing a fear of theft as the reason. All of these measures deter access.

Moreover, the original FDA approval only allowed Plan B One-Step® to be stocked on store shelves and sold without age restrictions but left generics such as Next Choice One Dose® and My Way® age-restricted and behind the pharmacy counter. A February 2014 letter from FDA indicated generics could be sold without requiring proof of age, but the labels for existing generics must be updated before the products can be moved to store shelves. This has caused additional confusion about what products are available without proof of age and where they can be stocked.

ACTION:

- Educate the public and retailers on the status of the various EC products and where they should be stocked
- Create accountability among retailers to ensure they stock EC in a manner that does not deter access and that removes unnecessary barriers
PROACTIVE POLICY TO PROTECT AND EXPAND ACCESS

On May 29, 2013, Oklahoma Governor Mary Fallin signed HB 2226 into law. The bill attempted to continue the 17 and older age restriction on EC that was removed by the FDA. In August 2013, an Oklahoma judge ruled that the law could not take effect because it violated the state’s “single subject” rule. Despite this victory, the political landscape is such that other states may follow Oklahoma’s example and enact legislation that impedes access to EC. Indeed, policymakers in Mississippi and New York introduced legislation to restrict access to EC via prescription and parental notification requirements for those under 18, but those bills did not progress. And the Oklahoma legislature has revitalized its efforts to restrict access to EC.

In a memorandum dated August 14, 2013, the Department of Defense (DoD) instructed all military treatment facilities to stock Plan B One-Step® and provide it at no cost, with no apparent age limits. This is important progress in ensuring affordable access to EC for women in the military and military dependents. Unfortunately, Native American women who rely on the Indian Health Service for their health care are not so lucky. A 2012 four-city survey of IHS pharmacies indicates that nearly half of pharmacies included in the survey did not stock any EC. Apparently an oral directive regarding EC was issued in 2013, but it has not been followed with a written directive. Regardless, internal agency sources indicate that EC availability continues to vary as there seems to be little regional accountability to IHS headquarters.

Finally, ideological objection to EC is often based on the incorrect belief that it prevents implantation of a fertilized egg, which some people mischaracterize as an abortion. While the labels for EC products include this as a possible mechanism of action, the latest scientific evidence indicates the product is ineffective after ovulation. Updating the label could quell some objections to EC that are based on its mechanism of action.

ACTION:
- Develop strategies to protect EC from attacks at the state level
- Push Indian Health Service to provide EC to women of all ages at no cost
- Encourage an update to EC labels to reflect the latest scientific evidence

ELLA®, PARAGARD®, BODY MASS, AND EFFICACY OF EC

Emerging data indicate that levonorgestrel EC, such as Plan B One-Step® and its generic equivalents, may be ineffective in women over 176 pounds, with efficacy beginning to decline at 165 pounds. The label of a European version of Plan B One-Step has been updated to reflect this data, which has raised the question of whether U.S. labels for levonorgestrel-based EC pills should also change. ella® appears to maintain efficacy at higher weights than levonorgestrel EC, though data suggest it may also lose efficacy past a certain weight. However, in July 2014, the European Medicines Agency released a statement finding that the data are too limited to conclude that efficacy of EC pills are reduced with increasing bodyweight. The FDA and the World Health Organization are currently reviewing available information.

The efficacy of the ParaGard® IUD is not impacted by weight, is the most effective form of EC overall, and can continue to be used as routine contraception. Both ParaGard® and ella® are effective up to 120 hours after intercourse, whereas levonorgestrel products may be effective only up to 72 hours. Unfortunately, few people are aware of ella® and ParaGard® as EC options compared to levonorgestrel products. Moreover, ella® requires a prescription and ParaGard® may require more than one doctor’s visit.

ACTION:
- Improve provider and public awareness of ella® and ParaGard®
- Increase stocking of ella® in pharmacies, federal facilities - such as those run by the Department of Defense and Indian Health Service – public health clinics, and health centers
- Streamline IUD insertion protocols to ensure use within the window of efficacy
- Encourage additional research on the efficacy of various types of EC products in relation to weight

While a great deal of progress has been made to improve and expand access to EC, financial and physical barriers and political threats to comprehensive access remain. Advocates and policymakers alike have a role in taking action to ensure access to basic preventive health care like EC.

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