July 08, 2010

Dear working group member,

As you may have seen, an article was posted yesterday on Newsweek.com that highlights some of the activities of the OCs OTC Working Group ("Should the Birth-Control Pill Be Sold Without a Prescription?"). The article does a nice job of highlighting some of the important issues and concerns related to an OTC switch for OCs. However, it also has several inaccuracies, which I've highlighted below:

- Regarding the timeline for an OTC switch, the article says, "They hope to have a proposal before the FDA within the year and an over-the-counter pill available in five years." When I spoke with the author, I said that we hoped to have a meeting within a year (and hopefully this year) with the FDA to get feedback on the draft study protocols and labeling the working group has developed. The actual use and label comprehension studies would need to be completed before an application could be submitted, and those studies will take time—and additional funding. The working group is still in the process of exploring partnerships with pharmaceutical companies, since such a company would likely be the sponsor of a switch application to the FDA. I also said that the five-year goal of having an OTC pill on the market depended on a lot of factors, including an assurance that low-income women would be able to access such a product.

- The article confuses the FDA advisory panel's recommendation on the EC product ella with an actual approval, and incorrectly describes ella as containing progestin when it is composed of
ulipristal acetate.

- The article misquotes the Pharmacy Access Partnership's national survey, which asked women about pharmacy access to hormonal contraception, rather than OTC access.

- The article references our paper on contraindications among Mexican OC users, but that paper did not find "that women who buy pills directly from pharmacies often have greater understanding of the contraindications than women who visit clinics."

- The working group is currently supported by a grant from the Hewlett Foundation, which is misspelled in the article.

Please let me know if you have any comments or reactions to the article or the points I've highlighted above.

Thanks,
Dan

Daniel Grossman
Senior Associate, Ibis Reproductive Health