



Public Comment by Kirsten Moore
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To the Food and Drug Administration Reproductive Health Drugs Advisory Committee
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My name is Kirsten Moore and I am the President and CEO of the Reproductive Health Technologies Project (RHTP). RHTP is 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 for-profit companies or from drug or device manufacturers.

We want to thank the Food and Drug Administration for allowing public comment during the advisory committee meeting for ulipristal acetate 30 mg, or ella – a new safe and effective emergency contraceptive product.

We also want to thank you, the Advisory Committee members, for making the time to participate in this review process; your clinical, scientific, and real world experience can help shape the FDA's approach to this application. We know from experience that the FDA has not always followed the expert advice of its advisory committees – and even, on occasion – its own staff. However, your review and discussion today will go a long way to informing public perception of this product, so thank you in advance for your efforts.

As women's health advocates, we are encouraged to see the continued development of new, effective contraceptive options that help women prevent unintended pregnancy. In reviewing the published data on ella as well as the FDA's own scientific review, we are reassured to see that clinical trials conducted with significant sample sizes have shown

- that treatment with a 30 mg tablet of ulipristal acetate statistically lowered the observed pregnancy rate compared to the expected pregnancy rate,
- that the efficacy of ella remained consistent regardless of the time interval between unprotected sex or contraceptive failure and treatment with the product, and
- that no unexpected adverse events were recorded.

Based on this data, [we join with other health care providers and consumer advocates to call on the FDA](#) to quickly review and approve ella for use as a prescription method of emergency contraception.

The FDA has posed a series of questions related to labeling and distribution which we would like to comment upon. We want a woman to have the best information available to help inform her decision-making around pregnancy prevention options. This information – whether presented in labeling or in patient provider counseling – should be based on scientific evidence, and not on conjecture or speculation.

We would like to commend HRA Pharma for conducting clinical trials that include a representative population of women of reproductive age. As we know, however, clinical trial data can sometimes mask or miss important distinctions within a population. Therefore, we appreciate HRA's willingness to explore the impact of BMI on ella's efficacy. If the available data supports a conclusion that higher BMI may make the product less effective than a woman expects, we think this information should be included on the label. However, if the data is not sufficient to draw a conclusion on this question, this lack should not preclude FDA from approving the product.

The FDA consistently relies on product labeling and provider education to ensure against inappropriate off-label use of prescription drugs. Based on the available data, we see no reason for any additional measures in the case of ella. Reading between the lines of the FDA review question, the agency seems to be concerned that ella could end an established pregnancy. Data on the 30mg dose does not support that speculation. The truth is that we don't know what effect a higher dosage would have on a woman or a potential pregnancy, and the prescription status of the product will help ensure appropriate use. More importantly, if a woman wants to end a pregnancy, a health care provider can counsel about other safe, FDA approved options.

We are also concerned by discussion about whether labeling should recommend pregnancy testing prior to dosing. This stipulation is unnecessary as it does not apply to other EC products. It could also create confusion among health care providers and patients. For example, we can envision a scenario in which a woman who uses a prescription obtained through advanced provision or who acquires ella directly from a pharmacist could be denied access if she is unable or unwilling to verify the date of her last menstrual period at a crowded pharmacy counter. Further, given the rate of false positives of very early pregnancy tests, this would simply add cost to a patient and delay intervention with no clinical benefit.

In closing, ella meets the FDA standards for drug approval. We ask the FDA not to fall victim once again to political pressure and subject this safe, effective product to unnecessary restrictions that may limit a woman's access to a time sensitive method of backup birth control.

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