

QUESTIONS FOR THE FDA COMMISSIONER NOMINEE

WOMEN'S HEALTH

The next FDA commissioner will play a pivotal leadership role in addressing health inequities, advancing science and increasing access to the healthcare that women are seeking.

The FDA commissioner nominee must address three questions:

1. Access

How will you ensure that access to medications and devices that have been proven to be safe for people capable of reproduction are not stymied due to undue political influence? For example, will the upcoming FDA approval process for over-the-counter access to the contraceptive pill be evidence-based and conducted in a timely manner?

Background

Women's medications have been stymied in the FDA process by social bias and political interference, such as the major delay in over-the-counter approval of emergency contraception. Soon the FDA may rule on applications for oral contraception over-the-counter. Major medical groups have endorsed the prospect of over-the-counter access to the contraceptive pill and studies show it is safe and effective. 70% of women of reproductive age favor being able to access the pill on the store shelf.

2. Equity

What is your definition of health equity and, if confirmed, what role will the FDA—and you, as commissioner— play in achieving health equity?

Background

Women often encounter disparate treatment regarding reproductive health care. For example, the FDA has subjected mifepristone to outdated medically unnecessary restrictions for over 20 years that obstruct timely access to essential, sensitive health care for pregnant women.

3. Inclusion

How will the FDA improve and modernize drug and medical device trials—including equitable inclusion of people of color and women?

Background

Historically women of reproductive age were often excluded or underrepresented in clinical trials (e.g., diabetes, heart disease). This impedes the ability of women and health care providers to make safe, informed decisions--resulting in lower quality and less access to healthcare. The problem persists.