

My name is Dr. Mary Carol Jennings and I speak today on behalf of the National Research Center for Women & Families.

Our nonprofit research center's medical and public health experts analyze and review research to provide objective information to patients, providers, and policy makers. We do not accept funding from pharmaceutical companies so I have no conflicts of interest.

I trained in obstetrics and gynecology at Boston University Medical Center.

We can all agree we need safer, effective alternatives to hormones. Paxil is widely used and available for depression and several other indications. The key questions today are whether there is clear scientific evidence that this version of paroxetine works for hot flashes, and if so, do the benefits outweigh the risks.

As the FDA has clearly stated in their memo to you, the company reported a significant reduction of the frequency of hot flashes at week 4 but only in one study at week 12. And, one of the studies did NOT show a significant reduction in severity of hot flashes through week 12.

What are the risks? FDA notes that the greatest risk is depression and suicide. Although patients were screened, and depression and a long list of psychiatric disorders were exclusion criteria for most patients, p15), the data clearly show that the women taking paroxetine were more likely to have suicidal thoughts and behaviors than the women taking placebo (p36, 37). This was true even on the small dose of 7.5 mg .

The CDC tells us that women between the ages of 45-54 have the highest rates of suicide in the country. That is the same age group most likely to take a drug for hot flashes.

Again, the FDA must decide if the benefits of this drug for hot flashes outweigh the risks.

The approval decision for hot flashes is different from depression or OCD, because hot flashes are not fatal.

I also want to speak on behalf of breast cancer patients who might consider this drug for the hot flashes caused by tamoxifen. FDA scientists expressed concern that paroxetine's (*inhibitory*) effect on the liver enzyme (*CYP2D6*) that processes tamoxifen may reduce the effectiveness of this cancer drug (p42).

The benefits of paroxetine for severe depression may outweigh the risks – even for breast cancer patients taking tamoxifen. BUT, the data today DO NOT prove that the benefits for hot flashes outweigh the risks for breast cancer patients or for any other patients.

The drug is already available off label for women who want it, and in generic form, at a similar low dose, making it an easier and less expensive option than the same drug, with a newer name, specifically approved for hot flushes.

Given the risks, if the benefits are questionable, there is no reason to approve paroxetine for this new indication.

Thank you.