

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.

Like all of you, I understand the need for safer alternatives to hormone drugs for hot flushes and symptoms of menopause. The question is: is gabapentin a safe and effective alternative, or will its use harm more patients than it helps?

The key to your decision today lies in the efficacy analyses agreed upon before these studies began. FDA states that **all three of the phase 3 studies failed to meet required statistical significance in reducing hot flash frequency from baseline to Week 12, and one study failed to show required significant reduction in severity from baseline to Week 12.**

In other words, based on the company's own acknowledged criteria for approval, the drug failed.

That doesn't mean you have to agree with the company, so let's look at this carefully.

The data indicated a decrease in the frequency of hot flushes at week four, but that effect disappeared by week 12. Hot flushes may continue for months, so 4 weeks is completely inadequate.

The company conducted the most recent study using a longer, 2-week baseline, hoping to "minimize the placebo response." If one week was insufficient, why would you accept it in the first studies?

Since the benefits of this product are extremely questionable, let's discuss its safety profile.

If it were absolutely safe for everyone, then perhaps the fact that it doesn't really work would be less important to some of you.

Dizziness and related symptoms are the most common side effect, seen in one in four women. Women in the gabapentin group were six times as likely to fall.

Women up to the age of 70 were included in these studies, and falling is dangerous in aging women: it can lead to broken bones and in turn to reduced life expectancy.

A warning would be helpful, but would it really be enough?

What about cancer? **The company's clinical trials recorded 5 cancer diagnoses for patients taking gabapentin, and none for placebo.** *We agree the evidence is inconclusive.* **But the possible cancer risk can't be ignored, especially given the limited benefits of the drug.**

Gabapentin is an antiepileptic drug, and FDA warns that all drugs in this class have a higher risk of depression and suicide.

In 2009, the FDA asked the company to study suicidality in a third trial (p10). During the trial and followup, 2% of the patients on gabapentin were almost 3 times as likely to show a risk of suicide compared to the placebo group.

The studies are too small to show a significant effect, but the difference is substantial and deserves further study. Including women with a history of depression raises ethical and study design concerns.

In conclusion, hormone therapy can reduce hot flushes, but has rare but serious risks. It's not accurate to say that this drug significantly reduces hot flushes, but it has potential serious risks.