



# Healthy Her

## *What is the BLACK BOX?*

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There are a lot of questions about the black box label being removed from all women's hormone therapy recently. So let's discuss. But first, what is a black box warning?

This is the warning that is literally encased inside of a black box on medications to alert physicians and patients to medications that may cause great harm, or possess the highest levels of danger. It doesn't mean that black boxed medications cannot be prescribed nor used. Rather it means that judicious and careful consideration should be undertaken with a careful risk/benefit analysis when considering the use of any medications within the black box. Women's hormonal therapy has been a part of the black box label for now more than 2 decades, and yet there was never great evidence for this.

And so how did we get here?

A large part of the issue were the results of the WHI (Women's Health Initiative) in the early 2000s. There has been much agreement that the results from this study were both premature and overstated.

In fact, the headlines of the day said that "Hormones Cause Cancer". However, on closer examination, that's not what the science said.

What were the problems? Well, there were many.

- 1.The study looked at women with a mean age of 63, some even as old as 73 years of age. This is at least 10 years beyond the average menopausal age.
- 2.Synthetic hormones (and not bioidentical estradiol and micronized progesterone) were used.
- 3.The estrogen was given in an oral formulation, which has an increased risk of blood clots. Currently, estrogen is given in a transdermal formulation with the exception of rare circumstances.
- 4.Later analyses actually showed that estrogen reduced heart disease, and reduced mortality when it is started within 10 years of menopause.
- 5.Further analyses also showed no significant increase in breast cancer and no increase in stroke.

<https://www.instagram.com/reel/DQ9Oj7bkckI/?igsh=eXQ5amdsems5MWpk>

For many women, estrogen is protective not only of heart and blood vessels, but bone, muscle, and quality of life. Further estradiol has been shown to positively impact the risk factors for heart disease such as lowering blood pressure and cholesterol, and improving muscle and bone strength, as well as improved insulin sensitivity and sleep..... all of which contribute to good heart health. This is an important consideration because heart disease remains the leading cause of death for women in the United States.

Best,

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*You can follow me for more medical information @drjaynemorgan on IG, Threads, TikTok, X & YouTube and @Jayne Morgan, M.D. on LinkedIn*