

## Problems with Clinical Trials of

# ADDYI

Addyi, the "female Viagra," is a daily pill for premenopausal women to boost libido. The drug affects receptors in the brain associated with mood, but beyond that researchers don't know how - or if - Addyi boosts libido.

Addyi sounds bad, but flaws in the clinical trials means that what we DON'T know about the drug could be even worse!

## 1. ADDYI IS STILL BEING TESTED FOR SAFETY CONCERNS AS DOCTORS PRESCRIBE IT

The FDA has said that the clinical trials performed so far are not enough to determine the extent of the "serious risks" associated with the drug.

The drug company is required to perform further testing, but the drug is already on the market and available to women.

ADDYI WAS REJECTED BY THE FDA TWICE BEFORE APPROVAL IN AUGUST 2015

## 2. ADDYI HAS NOT BEEN PROVEN TO INCREASE SEXUAL DESIRE

The drug company's goal with Addyi was to create a drug that promotes spontaneous desire—a sudden strong increase in libido. But studies so far show no evidence that that's how Addyi works.



The drug company only got the answers they wanted about Addyi by changing the question. They found minimal changes in sexual desire, and even the number of "sexually satisfying" events only increased by about half of one each month.

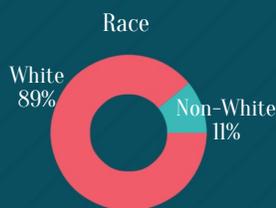
## 3. DRINKING ALCOHOL WHILE USING ADDYI COMES WITH SERIOUS DANGERS



Drinking alcohol while using Addyi can cause fainting and dangerously low blood pressure, studies have shown.

In a study of 25 people that tested the interaction between alcohol and Addyi, 4 people (16%) experienced severe low blood pressure or fainting.

## 4. WE DON'T KNOW HOW THE CLINICAL TRIALS APPLY TO THE GENERAL POPULATION



89% of the women who participated in the trials were white, 100% were heterosexual, and 85% were non-smokers. With these limitations, it's hard to tell if the results accurately apply to the general population.



The National Women's Health Network is supported by our members and by choice, we do not accept financial support from drug companies or medical device manufacturers. We bring the voices, concerns and needs of women consumers to policy and regulatory