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## REPORT

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"EIGHT OF 10 DRUGS TAKEN OFF THE MARKET HAD GREATER ADVERSE EFFECTS IN WOMEN THAN IN MEN. OUR BODIES REACT DIFFERENTLY."

## $\rightarrow$ Afundamentalflaw in medical research isfinally being addressed. Why it mattersfor you BY CAITLIN MOSCATELLO

Historically, women have been underserved by preclinical research (when drugs and medical devices, among other things, are tested on cells and animals). That may partially explain why one government report found that 8 of the 10 drugs taken off the market had greater adverse effects in women than in men. This fall, the National Institutes of Health-the government agency that funds medical research across the countrywill begin to roll out new policies requiring that scientists take sex into account when planning preclinical studies. We spoke to Janine Austin Clayton, M.D., NIH associate director for research on women's health, to find out what's changing under her watch.

What are the new policies?
DR. CLAYTON We are calling on scientists to take sex into account in their plans for preclinical research, and for them to display balance in addressing male and female differences in cells and animals. Right now, we're treating a unisex person.

Why have researchers favored male animals and cells?
DR. CLAYTON Scientists are concerned about hormonal cycling and that it might affect the outcome of their experiments, but the preponderance of evidence in terms of this cycling issue shows that females are not inherently more variable than males for many biological traits.


How will these policies help women? DR. CLAYTON One example: Anxiety and depression are twice as common in women as men. But fewer than 50 percent of the animal studies for these conditions include females. Women also react to medication differently for many reasons. We have more fat in our bodies than men do, and certain medications might bind to those fat cells. Now these differences will be accounted for.

Why is this your personal mission? DR. CLAYTON Before I came to NIH, I was an ophthalmologist, and I noticed many sex differences in eye disease. If a female patient is seeing a clinician, I want that clinician to be basing the treatment decisions on female data. Right now, there just isn't that sex-specific evidence. And in 2014, that's something that needs to happen.

