'Female Viagra' to treat low libido gets go-ahead from FDA panel

05/06/2015

Flibanserin, sometimes called the female Viagra, was approved by 18 votes to 6 by a US Food and Drug Administration advisory panel yesterday, although some of the committee members had doubts about the drug's risks and benefits.

They required that certain "risk-management options" be put in place, on top of the usual list of side effects listed in the medicine's patient information leaflet. We have yet to hear what this means, but options include doctors having to verbally warn women not to drink alcohol or use various other medicines when taking the drug.

The FDA's final say is due by August, but it usually follows the decision of its advisory panel. Assuming it gets the go-ahead, manufacturer Sprout Pharmaceuticals of Raleigh, North Carolina, plans to give the drug the brand-name Addyi, and has promised not to advertise the product directly to patients – which is normally allowed in the US – for the first 18 months it goes on sale.

Addyi is no Viagra though – women would have to take it every day, whether or not they want sex. And, while the famous little blue pill works by increasing blood flow to the genitals, this new drug instead alters brain chemistry, affecting receptors for various signalling chemicals including serotonin and dopamine.

Limited effects

Yesterday, the panel members expressed concerns about the drug's side effects: it can cause sleepiness, sudden drops in blood pressure and fainting, especially in combination with alcohol. Yet its effects on sexual desire are limited. In tests it led to couples having sex – or other "sexually satisfying encounters" – an average of once a month extra, from a baseline of two to three times a month.

The medicine has been controversial because it has been rejected by the FDA twice before, with the agency requesting further trials and safety data. Sprout has claimed it is sexist that there are several medicines available for treating male impotence, yet none for women with low desire.

That premise is rejected by those such as Cindy Pearson of the National Women's Health Network who urged the FDA panel to reject the drug yesterday. "The problem is not gender inequity, the problem is the drug," she says.