

# ADDYI - HOW A DRUG COMPANY MADE A BILLION DOLLARS BRINGING A BAD DRUG TO MARKET

2006

A German pharmaceutical company develops flibanserin as an antidepressant, but trials show that it is ineffective.

When some trials suggest that it may have the power to increase libido for women, it is re-purposed as an aphrodisiac.

2009

After additional trials, the company submits flibanserin to the FDA for approval as a first-of-its kind treatment for hypoactive sexual desire disorder (HSDD).

2010

The FDA rejects the application, citing evidence from the clinical trials of limited effectiveness and strong side-effects. The drug company abandons flibanserin.

2011

U.S.-based Sprout Pharmaceuticals purchases flibanserin and raises funding to support a new clinical trial.

2013

Sprout resubmits flibanserin for FDA approval as a treatment for HSDD. The FDA rejects the application, but gives Sprout the chance to resubmit with additional safety information.

2014

Sprout Pharmaceuticals funds Even the Score, a coalition of nonprofit and for profit organizations that includes women's groups. The group launches a campaign accusing the FDA of sexism in rejecting flibanserin and releases a Viagra ad parody that urges the public to support the approval of the drug.

2015

**February 17:** Sprout re-applies to the FDA for approval of flibanserin.

**March 26:** In honor of the 17th anniversary of the FDA's approval of Viagra, 11 Members of Congress pressure the FDA to approve flibanserin.

**August 18:** The FDA approves flibanserin, but requires a Risk Evaluation and Mitigation Strategies (REMS) program and a black box safety warning on the drug's packaging. Sprout agrees to refrain from broadcast marketing the drug for 18 months and complete further alcohol trials to address FDA safety concerns.

**August 20:** Sprout Pharmaceuticals is sold for \$1 billion to Valeant Pharmaceuticals, just two days after the FDA approves flibanserin.

**October 17:** Flibanserin becomes available for prescription in the US under the name Addyi.

