

Pfizer's Eagerly Anticipated Impotence Drug Viagra Wins FDA Approval

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Body

NEW YORK -(Dow Jones)- The Food and Drug Administration Friday announced **approval** of a long-awaited impotence drug, Pfizer Inc.'s **Viagra**, which is the first pill for the disorder.

With a potentially huge market, the drug is expected to become a big seller for Pfizer. Arvind Desai, an analyst who follows the company for OrbiMed Advisor, said sales could reach \$1 billion the fifth year after launch.

Some analysts are even more optimistic, saying the drug could become a household name like the antidepressant Prozac and ring up sales of \$2 billion or more annually. Last week, William C. Steere, Pfizer's chairman and chief executive, told The Wall Street Journal the drug may help Pfizer top Merck & Co. as the biggest seller of prescription medicines in the world.

The company said in the U.S. alone, 20 million to 30 million men suffer from some form of impotence.

But as with Prozac and the recent wave of diet drugs, there's a chance **Viagra** will find its way into the hands of a lot of people who don't need it medically but think it will make their sex lives better anyway. That possibility troubles medical ethicists.

Expected to hit the market around mid-April, the drug went through the **FDA**'s application process in less than six months. The drug isn't approved anywhere else in the world.

Viagra doesn't work like other treatments, which can include injections, suppository-like devices or even surgery. Generically called sildenafil, the drug was first tested to fight angina, the painful heart condition caused by constricting or clogging of heart arteries. That didn't work, but the men in the study reported having better erections than before.

As an impotence drug, **Viagra** is taken an hour or so before a sexual event. Once a man's brain kicks into gear as he becomes aroused, **Viagra** works subtly to amplify the effects of erection-promoting chemicals in the penis.

In heart patients, sildenafil was supposed to treat angina and hypertension by blocking the action of an enzyme, phosphodiesterase, that is believed to tighten muscles lining blood-vessel walls. Researchers soon discovered that

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while the drug wasn't very good at thwarting the heart enzyme it homed in on a different form of the same enzyme that is present mainly in the penis.

Pfizer, which got the blessing of the Vatican for the drug because it can enhance marital relations, tried to dissuade people into thinking that Viagra is a "love drug" that will boost one's libido.

"Viagra works in response to sexual stimulation," said Joseph Feczko, M.D., Pfizer's senior vice president for medical and regulatory operations. "It has no properties of an aphrodisiac and does not stimulate fantasy."

Also, the FDA warned that it shouldn't be taken more than once a day. Some side effects include headache, flushing, indigestion and altered color perception.

Pfizer tested Viagra on 4,000 men. The drug was 70% effective across patients with impotence caused by diabetes, spinal cord injury or psychological causes, among others.

Patients are advised not to take the medication with organic nitrates, such as nitroglycerin patches or sublingual tablets, because the combination may lower blood pressure.

Pfizer said Viagra should be available with a prescription by mid-April at a wholesale price of \$7 a tablet.

In composite New York Stock Exchange trading Friday, Pfizer shares (PFE) climbed \$1.375 to \$95.75 in active trading.

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