

# Two New Drugs Set to Compete With Viagra

*FDA Approval Expected, but Pills Already Available on Internet; The Yellow One Works for 24 Hours*

BY VANESSA FUHRMANS

**T**HE FIRST DRUGS to challenge the blockbuster Viagra are expected to arrive on U.S. store shelves later this year.

The makers of the new drugs, called Cialis and Levitra, claim they work faster and last longer than the famous original. Both pills recently went on sale in Europe, and already eager U.S. customers are buying them on Internet sites based in Europe. It is illegal to buy drugs not yet approved by the Food and Drug Administration, but the agency has typically turned a blind eye to people doing so for personal use. Still, there is a risk that the drugs could be confiscated in the mail.

Both drugs are under review by the FDA and expected to receive approval in the second half of this year.

The new treatments have quickly proved hot sellers overseas. In its seventh week in Germany, Cialis snapped up 28% of Viagra's market share, says research firm ND-CHHealth, though the number may be inflated because of initial stocking at pharmacies.

Why all the buzz? For all of Viagra's popularity, the little blue pill has a spotty record with many patients. Doctors say about half of the men who take it don't refill their prescriptions within a year, either because they give up after a few failed attempts or because of side effects. Many more have never tried it. Urologists estimate that less than 15% of the 150 million men with impotence problems have used the drug.

Levitra and Cialis are the first drugs to challenge Pfizer Inc.'s blockbuster impotence treatment since it debuted in 1998. All three drugs work by inhibiting an enzyme called PDE-5, an action that relaxes smooth muscle cells in the penis and enables blood to flow in and create an erection. Laboratory tests suggest the two new drugs are more selective in blocking PDE-5, meaning they require smaller doses and may interact less with other molecules.

For patients, that could translate into fewer side effects. Clinical trials suggest patients taking the two new drugs are less inclined to have blue-tinted vision, which some Viagra users experience. Cialis, being developed by Eli Lilly Corp. and Icos Corp., doesn't seem to trigger as much facial flushing, another common side effect. Levitra may cause fewer headaches, studies by its makers, Bayer AG and GlaxoSmithKline PLC, suggest. In addition, both are also better absorbed on a full stomach, one reason for some of the reports of lackluster results with Viagra.

But the three drugs distinguish themselves most in how long they last and how quickly they begin to work. In clinical trials, men who took Cialis or Levitra were able to have sex within 30 minutes, often achieving an erection within 15 to 20 minutes. With Viagra, doctors say it can take an hour before men are able to have sex.

Pfizer officials say that perception is based on earlier, more conservative studies of patients' response times. In a Pfizer study presented in December, 51% of men with moderate to severe impotence

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Photo Researchers

**This yellow tablet, Cialis, is one of two drugs set to challenge the dominance of Pfizer's little blue pill.**

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were able to have sex within 20 minutes after taking Viagra.

Cialis claims to last longest, allowing men to take it as early as 12 hours before sexual activity—say, at breakfast—then not have to worry about timing it right later. Unlike a tablet of Levitra or Viagra, which has a half life of four to five hours in the body and stops being effective a few hours after that, one Cialis pill can work for as long as 24 hours.

Pfizer executives argue that they haven't proven to be much different in efficacy, nor do they have Viagra's track record of five years' clinical experience and more than 100 studies of its potency and safety. Says Mike Sweeney, a senior medical director at Pfizer, "We think doctors will stick with what they know."

Viagra has been one of the drug industry's most successful products in recent years. Last year, it had \$1.7 billion in sales. In all, doctors have written 120 million prescriptions since it was introduced.

But men like Manfred Weber, a semi-retired heating business executive from Maryland, are looking forward to the arrival of the new drugs. After more than 40 years of marriage, "things weren't working so well anymore," he says. He tried Viagra a few times, but it gave him headaches. After taking Levitra in a clinical trial, the headaches stopped. "It brought my wife and I closer to each other again," says Mr. Weber, 65. With that trial over, he is biding his time with an occasional Viagra until Levitra is approved in the U.S.

Levitra and Cialis also appear to be

### How They Compare

A look at Viagra and its first competitors:

	Cialis	Levitra	Viagra
How long it works	Up to 24 hours	Up to 5 hours	Up to 4.5-5 hours
Recommended time to take before sex	30 minutes to 12 hours	25 to 60 minutes	60 minutes
Most common side effects among participants	Headache, dyspepsia/upset stomach, back pain	Headache, facial flushing	Headache, facial flushing, altered or blueish vision

Sources: J.P. Morgan, European Agency for the Evaluation of Medicinal Products

more potent in harder-to-treat cases, such as those involving diabetes-related impotence. In studies of Levitra, 73% of diabetic men suffering from impotence had improved erections, while 76% in a Cialis trial did. By comparison, Viagra's success rate with diabetes-related impotence is 70%.

"Viagra worked fine, but it was sort of like, 'Well, here's the little blue pill we'll be using tonight,'" says Alan Purvis, a 65-year-old retired school teacher who lives in Durham, England, and took part in a Cialis study before it went on sale in the United Kingdom last month. "With Cialis, you could take a pill every few days and forget about it."

That might be especially appealing to younger men with impotence problems who would prefer to have sex more than once a week. Since most insurance coverage for impotence medication is limited,

Cialis could wind up the more cost-effective for those men.

Cialis's competitors have been attempting to play up their drug's shorter duration as an attribute. Bayer and GlaxoSmithKline point out in promotional materials that Levitra "enhances sexual response for up to five hours without staying in a man's system for longer than necessary." Says Mr. Sweeney at Pfizer: "When you need it, Viagra is there. When you don't, it's not."

Doctors say they expect patients to experiment for a while before settling on any one drug.

"It's the kind of drug where patients will want to try all three to see which works best for them," said Ian Eardley, a urologist at St. James University Hospital in Leeds, England. "I'll point out what look like the characteristics and let them make the choice."