

Blindness noted in men using impotence drugs

WASHINGTON - Federal health officials are probing reports of blindness among dozens of men who used Viagra and other impotence drugs — but at the same time cautioning that the vision loss can be linked to the same illnesses that lead to impotence.

The Food and Drug Administration disclosed Friday that it was in discussions with the makers of Viagra, Cialis and Levitra about what the labels of those drugs should say about the rare cases of varying degrees of vision loss, including blindness. The maker of Cialis already has voluntarily added a one-line mention to its label.

At issue is sudden vision loss when blood flow to the optic nerve is blocked, a condition called NAION or non-arteritic anterior ischemic optic neuropathy.

The FDA has 43 reports of NAION among the impotence drug users: 38 for Viagra, four for Cialis and one for Levitra, said spokeswoman Susan Cruzan.

Those are rare numbers, given that Viagra alone has been used by 23 million men worldwide since its approval in 1998, according to maker Pfizer Inc.

Also complicating the question: NAION is considered one of the most common causes of sudden vision loss in older Americans, and estimates suggest there are anywhere from 1,000 to 6,000 cases a year. Risk factors include diabetes and heart disease, two of the leading causes of impotence.

Still, “we take this seriously,” Cruzan said.

Side effects include vision problems

The questions come at a time when federal regulators and the drug industry are facing criticism about what they do to ensure the safety of drugs already on the market. Pressure on the FDA to investigate reports of side effects has increased since Merck & Co. yanked its pain

reliever Vioxx from the market last year because of potentially deadly heart trouble.

Big money is at stake. Pfizer Inc. said in its most recent quarterly filing with the Securities and Exchange Commission that sales of Viagra rose 5 percent — to \$438 million — in the first quarter of the year.

Pfizer shares declined Friday on the New York Stock Exchange after news of the blindness cases.

Warning Labels:

- **Viagra:** "Less common side effects that may occur are temporary changes in color vision (such as trouble telling the difference between blue and green objects or having a blue color tinge to them), eyes being more sensitive to light or blurred vision."
- **Cialis:** "may uncommonly cause ... vision changes, such as seeing a blue tinge to objects or having difficulty telling the difference between the colors blue and green."
- **Levitra:** "may uncommonly cause ... vision changes, such as seeing a blue tinge to objects or having difficulty telling the difference between the colors blue and green."

Source: Associated Press

Viagra and its competitors are blockbuster drugs that revolutionized treatment of erectile dysfunction, and they already come with serious warnings: They're not to be used by men who take nitrate-containing drugs, because the interaction could cause deadly drops in blood pressure, or by men with heart conditions whose doctors have warned that sex itself could be too

much exertion.

All three also warn about temporary vision changes — seeing bluish tinges or having difficulty distinguishing between green and blue. The drugs apparently have a temporary effect on the retina, a different issue from NAION.

Viagra also is at the center of controversy over Medicaid's payment for prescriptions of the drug for convicted sex offenders in New York and other states.

Some evidence of connection

The possibility of a link with blindness was raised publicly earlier this year, when Dr. Howard Pomeranz of the University of Minnesota reported in an ophthalmology journal seven patients who reported NAION vision loss occurring within 36 hours of a Viagra dose.

"A definite causal relationship cannot be established at this time," Pomeranz wrote.

Viagra and its competitors work by slightly dilating arteries so that blood flow in the penis increases. Whether it affects blood flow to the eye isn't known, but Pomeranz argued that some effect on the optic nerve is plausible.

So he urged that ophthalmologists ask NAION patients whether they use impotence drugs, and report any additional cases. Also, Viagra users who suffer NAION in one eye should be cautioned that continued use might raise the risk of vision loss in the other eye, Pomeranz wrote.

The loss of vision is permanent.

Pomeranz told MSNBC Friday that "the drug is doing something to alter the circulation of blood to the optic nerve and in turn causing an injury to the nerve resulting in a loss of vision."

The patients in the study had a history of high blood pressure and an anatomical risk factor involving the optic nerve.

"If a patient takes the medication and 45 minutes later suddenly notices the onset of vision loss, to me that's certainly some evidence there is a connection between the two," Pomeranz told MSNBC.

Because the drugs affect blood flow a connection "makes sense," NBC's chief science correspondent Robert Bazell told MSNBC Friday. He added that the condition is rare and there isn't yet cause for widespread concern.

But publicity over the FDA investigation could result in more cases coming forward, said Bazell, noting that a bigger study examining the link is needed.

'Confident about safety'

Levitra is sold in the United States by GlaxoSmithKline PLC and Schering-Plough Corp. and overseas by Bayer AG.

Viagra was approved by the government in 1998. It may aid in the treatment of enlarged hearts that can result from high blood pressure, tests on animals indicate.

Levitra was approved in August 2003, and Cialis in November of that year.

There have been no reports connecting Levitra to blindness, said Michael Fleming, a spokesman for GlaxoSmithKline PLC. "We are confident about the safety of our product," said Fleming.

Viagra, approved to treat erectile dysfunction, should not be used by men with heart conditions whose doctors have warned them not to have sex. Also, patients taking drugs that contain nitrates have been warned not to take Viagra because of sudden, unsafe drops in blood pressure.

The drug's label also warns of erections lasting longer than four hours, painful erections lasting longer than six hours, headache, flushed skin and vision problems.

Pfizer Inc. said in its most recent quarterly filing with the Securities and Exchange Commission that sales of the drug rose 5 percent — to \$438 million in the first quarter of the year. Pfizer also said at the time that Viagra had a 68 percent worldwide market share.

Viagra sales have been under pressure from new competitors Cialis and Levitra, with revenue sinking 11 percent last year to \$1.68 billion from \$1.88 billion.

Doctors and patients have become increasingly wary of the downsides of prescription drugs after Merck & Co. yanked its pain reliever Vioxx from the market last year because of its potentially lethal side effects.

Merck potentially faces thousands of lawsuits over Vioxx and analysts have estimated its liability may reach \$18 billion.

Pfizer was asked to remove its pain reliever Bextra from the market because of its side effects and sales of its other arthritis drug Celebrex are falling. Vioxx, Celebrex and Bextra all fall into a category of drugs known as Cox-2 inhibitors.

Industry critics have been demanding that drug companies conduct more post-marketing studies in order to do a better job of discovering side effects once drugs hit the market.

For more than two decades, Americans have mostly pressed for quicker approval of what they hope can be lifesaving drugs for such

diseases as AIDS and cancer. But many now are wondering if medicines — a \$200 billion industry annually — are coming out too fast and doing too much harm.

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