

Feds Eye Viagra-Blindness Reports

WASHINGTON, May 26, 2005

Federal health investigators are looking into reports that some men who used Viagra may have suffered a new and very serious side effect -- blindness.

Twenty-three million men worldwide have used Viagra. A very small number of them are going blind after taking normal doses. And **CBS News** has learned from the FDA that it is urgently meeting about it with experts and Pfizer.

Jimmy Grant started using Viagra in 1998, when he was 57. At first, he felt pressure in his temples and saw color changes in his vision.

"I noticed the symptoms probably within 45 minutes to an hour," he told **CBS News correspondent Sharyl Attkisson**.

Soon, he went blind in his right eye. Doctors didn't make a connection to Viagra.

"After your loss of vision, did you continue taking doses?" Attkisson asked.

"On occasions, I did," he said. "And then in March 2000 after taking Viagra I experienced loss of sight -- partial loss of sight in my left eye."

With both eyes damaged, a friend found an article on the Internet about Viagra and blindness, and Grant put two-and-two together.

"What convinced me that Viagra did it was what Dr. Pomeranz had in his report."

That's Dr. Howard Pomeranz, an eye specialist who appears to be the first doctor to make a connection in one of his patients back in '98. To him, it made sense that Viagra -- which alters blood flow in key parts of the body -- could also affect circulation to the optic nerve.

"And so I thought, well, in both of these situations, blood flow is being altered, so maybe there is a connection between the two," said the University of Minnesota neuro-ophthalmologist.

He published his patient's case looking for feedback. By 2001, he had five cases to report to the FDA and Pfizer, the makers of Viagra. Slowly, more reports trickled in.

"So they certainly are aware of this possible side effect of their medication," Pomeranz said.

The FDA tells **CBS News** it's looking at about 50 reported cases of vision loss and, while no direct link has been proven, an FDA medical supervisor says "We're very concerned. This issue is front and center, it's a priority. We know people need to know as promptly as possible."

Pfizer told us its Viagra studies show no report of vision loss and say there is no more evidence of vision loss in men taking Viagra than those who don't. However Pfizer confirmed it in discussions with the FDA to update the labels to reflect the rare occurrences.

Jimmy Grant is now spending retirement in a way he never imagined: living with his 83-year-old mother, suing Pfizer, and sorry he ever tried Viagra.

"I've pretty much accepted that my eyesight is not going to come back. But I've also pretty much accepted that Viagra done it," he said.

The FDA says it's monitoring adverse event reports for the similar drugs in the same class as well.

Pfizer Statement Regarding Viagra:

A review of 103 Viagra clinical trials involving 13,000 patients found no reports of non-arteritic anterior ischemic optic neuropathy (NAION). Outside of clinical trials, Viagra has been used by more than 23 million men worldwide over the past seven years and reports of visual field loss due to NAION are extremely rare.

There is no evidence showing that NAION occurred more frequently in men taking Viagra than men of similar age and health who did not take Viagra.

NAION is the most common acute optic nerve disease in adults over age 50 and it shares a number of common risk factors with erectile dysfunction: age over 50, high blood pressure, high cholesterol, diabetes. Most of the reported cases in which NAION has occurred in men taking Viagra have involved patients with underlying anatomic or vascular risk factors associated with the development of NAION. This makes it impossible to determine whether these events are caused by the patient's underlying vascular risk factors, anatomical defects, Viagra or a combination of these factors -- or to other factors.

Pfizer is in discussions with the Food and Drug Administration to update the Viagra label to reflect these rare ocular occurrences. Viagra has a strong safety profile and remains an effective medication that benefits millions of patients.

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