

Search:  **Web Search**

Home U.S. Business World Entertainment Sports Tech Politics Elections Science Health Most Popular  
 Health Video Weight Loss Sexual Health Medications/Drugs Parenting/Kids Seniors/Aging Diseases/Conditions

Search:  All News  Advanced

## FDA adds hearing loss risk to Viagra, others



Reuters Photo: Two boxes with the new anti-impotence drug Cialis (tadalafil) are pictured in a Munich pharmacy...

By Kim Dixon  
 Thu Oct 18, 6:48 PM ET

WASHINGTON (Reuters) - U.S. regulators on Thursday added new warnings about the potential risk of sudden hearing loss to best-selling impotence drugs Viagra, Cialis, and Levitra, used by millions of men.

The U.S. Food and Drug Administration said a published report of a man taking Pfizer Inc's Viagra, who suffered from sudden hearing loss, prompted it to explore a possible association.

A further review of the FDA's side effect data found 29 cases of sudden hearing loss with a relationship to the three drugs.

In one third of the cases the hearing loss was temporary, the agency said, the remaining cases were described as ongoing at the time of the report or the outcome was not described.

Eli Lilly sells Cialis and GlaxoSmithKline Plc sells Levitra. Pfizer's Revatio, a version of Viagra used for a lung condition, will also carry a new warning.

Erectile dysfunction drugs are a huge business, with Pfizer reporting Viagra sales of \$450 million in its most recent quarter. The drugmakers are all cooperating with the FDA and defended the safety of their drugs.

The new label warnings follow a 2005 label change noting cases of sudden vision loss in some patients.

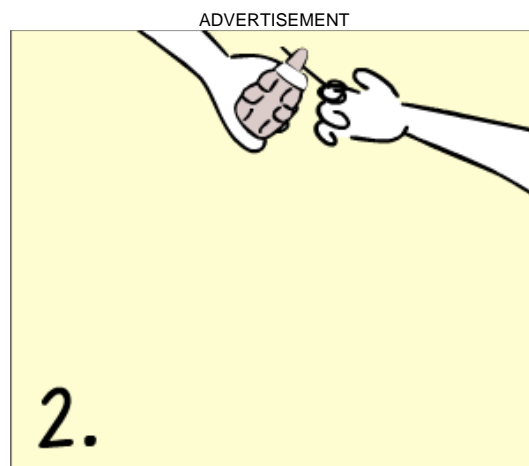
Reports of serious side effects to the FDA's safety data-base are widely viewed as representing only a fraction of actual problems with drugs and medical devices.

Drugmakers Pfizer and Lilly both said their data did not show any causal relationship between hearing loss and the drugs. The FDA said no causal link has been established.

Pfizer vice president for medical affairs, Dr. Ponni Subbiah, said hearing loss was included in Viagra's adverse events section of its label upon its 1998 FDA approval. It occurred in less than 2 percent of patients in clinical trials, which she said was statistically comparable to those in a placebo group.

About 30 million men have taken Viagra since its approval in 1998 as the first widely-used drug for erectile dysfunction, according to Pfizer.

Lilly spokeswoman Keri McGrath said a recent Lilly review found about 1.1 incidents of sudden hearing loss per million Cialis patients, which she said was lower than the incident rate in the general population. Nearly 12 million men have been prescribed the drug, the



### HEALTH VIDEO



**Vaccinations for Grown-Ups**  
 ABC News



**Anti-Aging Pilates**  
 FOX News

» All news video

### ELSEWHERE ON THE WEB

**ABC News:** [The Male Pill? Contraception of the Future](#)

**CNN.com:** [House can't override child insurance veto](#)

**Time.com:** [What You Need to Know About Staph](#)

### ADVERTISEMENT

GET A QUICK SUMMARY OF WORLD MARKETS ON THE NEW YAHOO! FINANCE HOME PAGE.

**YAHOO! FINANCE**

### FROM Y! HEALTH



**Health Questions?**  
 Find answers on Yahoo! Health:

Search

» More from Y! Health

**Add headlines to your personalized My Yahoo! page**  
(About My Yahoo! and RSS)

Sexual Health News

» More news feeds

**NEWS ALERTS**

Get an alert when there are new stories about:

- Germany
- Bayer AG
- Pfizer Inc
- Eli Lilly
- Schering-Plough Corp

Add Selected Alerts

» More alerts

company said.

Schering-Plough Corp. and GlaxoSmithKline co-market Levitra in the United States, while Germany's Bayer AG sold the drug originally.

Schering-Plough spokesman Lee Davies said the company would comply with the FDA's request and said all the hearing loss cases were temporary.

About 4,000 new cases of sudden hearing loss occur in the United States annually, according to the National Institute on Deafness and Other Communication Disorders. It typically occurs in one ear, and symptoms include ringing in the ear and dizziness.

The condition resolves itself in some cases, but in 15 percent of cases, it gets worse over time, according to the institute.

[Email Story](#)   [IM Story](#)   [Printable View](#)

**RECOMMEND THIS STORY**

Recommend It: Average (0 votes)  
☆☆☆☆☆   [» Recommended Stories](#)

**Health News**

- [Cold medicines for children scrutinized](#) AP
- [More evidence sought on PTSD treatments](#) AP
- [FDA to warn Viagra users of hearing loss](#) AP
- [Maine school to offer contraceptives](#) AP
- [Health deal sought after veto upheld](#) AP

**Most Viewed - Health**

- [Pre-Workout Stretching Won't Prevent Sore Muscles](#) HealthDay
- [Virus test found to be better than pap smear for women](#) Reuters
- [Dioxin pollution leads to more baby girls: study](#) Reuters
- [Heart patients sue Medtronic over device](#) AP
- [More evidence sought on PTSD treatments](#) AP

**Health Video**

- [Vaccinations for Grown-Ups](#) ABC News - Fri Oct 19, 1:02 AM ET
- [Anti-Aging Pilates](#) FOX News - Thu Oct 18, 5:04 PM ET
- [Freezing Eggs for Pregnancy](#) ABC News - Thu Oct 18, 2:32 PM ET
- [Fit in France](#) FOX News - Thu Oct 18, 6:04 PM ET

Sponsored Links

( [What's this?](#) )

[Refinance \\$300,000 for Only \\$965/Month](#)  
 \$300,000 Mortgage for only \$965/month. Save \$1,000's - No obligation.  
[www.HomeLoanHelpLine.com](http://www.HomeLoanHelpLine.com)

[Free Investment Guide](#)  
 How to Invest Smarter from Ameriprise Financial.  
[www.ameriprise.com](http://www.ameriprise.com)

[House Payments Fall Again](#)  
 \$180,000 Mortgage for \$999/mo. Calculate Your New Mortgage Payment.  
[www.LowerMyBills.com](http://www.LowerMyBills.com)

Search:  All News  Advanced [Yahoo! - My Yahoo! - Mail](#)

[Home](#) | [U.S](#) | [Business](#) | [World](#) | [Entertainment](#) | [Sports](#) | [Tech](#) | [Politics](#) | [Science](#) | [Health](#) | [Travel](#) | [Most Popular](#) | [Odd News](#) | [Opinion](#)

Copyright © 2007 Reuters Limited. All rights reserved. Republication or redistribution of Reuters content is expressly prohibited without the prior written consent of Reuters. Reuters shall not be liable for any errors or delays in the content, or for any actions taken in reliance thereon.

Copyright © 2007 Yahoo All rights reserved. [Copyright/IP Policy](#) | [Terms of Service](#) | [Help](#) | [Feedback](#)

NOTICE: We collect personal information on this site. To learn more about how we use your information, see our [Privacy Policy](#)