

Medicine

Group is seeking stronger warnings on safety of Viagra

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Associated Press

WASHINGTON — Many men may be taking Viagra to treat impotence that was caused by other medications such as anti-depressants and blood pressure drugs, raising the question of whether some could be cured simply by adjusting their prescriptions.

The consumer group making that point yesterday also cited 174 reports of Viagra users suffering side effects, including 31 deaths, in petitioning the government to strengthen Viagra's safety warnings.

The Food and Drug Administration remains convinced that Viagra is safe, but said it will consider Public Citizen's concerns.

The drug's label already warns doctors not to prescribe Viagra to men who take nitrate-containing drugs such as the heart medicine nitroglycerin, because the mix can kill. The FDA also warns that the sudden sexual exertion may be too risky for some heart patients.

Mariann Caprino, a spokeswoman for Viagra's manufacturer, Pfizer Inc., said, "There are no new trends that have emerged that would warrant a change in the product's label."

But Public Citizen discovered that Pfizer had refused to admit into clinical trials of Viagra any men with certain heart-related conditions. Yet men with those conditions are allowed to take the drug today, and some have suffered heart attacks or strokes.

That's a dangerous double standard, the advocacy group said. It

urged the FDA to ban Viagra's use by men with those risk factors.

"They designed studies to minimize the chance this drug would have adverse events, and then they threw these people with high risks back in the pool when the drug was approved," said Public Citizen's Dr. Sidney Wolfe. "FDA needs to get a significant amount of blame for allowing" that.

In addition, the FDA should warn doctors to check whether a man's impotence is a side effect of one of more than 60 other drugs known to cause sexual dysfunction before they prescribe Viagra, Wolfe said.

"Most doctors are not even remotely aware of this long list of drugs that can cause or worsen impotence," he said. "It may be possible to lower the dose or switch to something else. . . . Those things are worth trying with these stakes."

But diagnosing drug-induced impotence can be difficult, and not every man who suffers it can switch medicines, warned FDA drug chief Dr. Robert Temple.

As for Wolfe's other complaint, the FDA does not routinely forbid people from using a new drug just because they have health risks considered troublesome when the drug was undergoing testing, Temple said.

However, some men with heart-related problems may not be good candidates for Viagra, the FDA official cautioned. The doctor must make an individual evaluation.