Statement of Elizabeth Foley,
Campaign Coordinator at
Consumers Union, the independent, non-profit publisher of Consumer Reports
before the FDA Risk Communication Advisory Committee

May 16, 2008

Ladies and Gentlemen of the FDA Panel, thank you for the opportunity to comment today on including a toll-free number on prescription drug television advertisements for consumers to report side effects to the FDA. I am Elizabeth Foley with Consumers Union, the independent, non-profit publisher of *Consumer Reports*[1]

Consumers Union strongly urges the FDA to require all television advertisements for prescription drugs to include a toll-free number and a website address for the public to report serious side effects to the agency. As you are aware, the Food and Drug Administration Amendments Act, passed by Congress last year, requires this for print advertisements.[2] We believe the FDA would benefit greatly if this requirement were extended to include television advertisements. By reaching wider audiences who could report adverse events, the FDA would get a more comprehensive picture of the possible risks of medications and better monitor drug safety.

The FDA Commissioner has just announced that the agency will study this issue for two years before making a decision.[3] The FDA Amendments Act was signed into law in September of last year, yet it's only now that we're hearing from the FDA on this study. Two years is too long to study whether the FDA should expand what's already required for print ads to include TV ads, we urge the FDA to complete this study as soon as possible.

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports and ConsumerReports.org, with approximately 6.5 million combined paid circulation, regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] Pub. L. No. 110-85 (September 27, 2007).

[3] Andrew C von Eschenbach, MD., "Report to the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce. Report on Study Commitment Regarding Inclusion of Toll-Free Adverse Event Reporting Number by FDA," May 8th, 2008.

Before drugs enter the market, they have been tested on a relatively small number of people, typically a few hundred to a few thousand patients.[4] These studies may not include the elderly, children, pregnant women, or those on multiple medications.[5] A study's participants may not be truly representative of the real world when the drug is eventually used.[6]

In the last few years, Consumers Union has heard from families and individuals across the country whose lives have been impacted because of a safety problem with a prescription medicine that they were not aware of. These families learned that serious side effects may not be fully understood until a medication is on the market. Important information about a drug's safety may emerge after millions of people start taking it.

Considering the risks that may emerge after a drug is approved and comes on the market, Consumers Union believes it is critical that consumers have a simple and understandable way to report serious side effects they experience to the agency.

Adverse event reports have helped pull dangerous medications off the market such as the statin drug Baycol[7] the pain killing drug Duract and the blood pressure treatment Posicor and can be an essential tool in giving the FDA information about drug risks quickly.[8]

Because of underreporting, Medwatch catches only a small fraction of adverse events.[9] Doctors and patients – those with the most direct experience with side effects – seldom report them. The Institute of Medicine found that in 2004, only five percent of adverse event reports that year came from doctors and patients.[10]

We believe one way to improve reporting is to make sure consumers know they can report serious adverse events to the FDA.

A recent poll conducted by the Consumer Reports National Research Center asked consumers if they would know where to report a serious side effect. Among them, the vast majority (79 percent) said they would report their problems to their doctor, followed by their pharmacist at 16 percent. Only seven percent of that group said they would file a report with the FDA.

Yet, not surprisingly, Americans were very familiar with drug advertising. Eighty one percent said they had seen or heard an advertisement for prescription drugs within the past 30 days. Among them, virtually all – 98 percent – viewed an ad on television.

---

[4] Syed Rizwanuddin Ahmad, MD, MPH., "Adverse Event Drug Monitoring at the Food and Drug Administration. Your Report Can Make a Difference," J Gen Intern Med, January 2003. Vol 18, p. 57-60.
[5] Id.
[6] Id.
[7] Id.
[8] John Henkel., "Medwatch: FDA's Heads Up on Medical Product Safety," FDA Consumer Magazine, November-December 1998.
[9] Institute of Medicine," The Future of Drug Safety, 2006, p.53.
[10] Id, p.54.

Consumers Union is concerned about the amount of advertising that can accompany a drug when it first reaches the market.

Consumers are subjected to so much advertising on television that it is important to include information about reporting serious side effects – similar to what is now provided in print ads. And consumers agree this should be required in television advertising.

There is widespread support among consumers for including Medwatch's number and website in TV ads. In our poll, 87 percent of consumers said TV ads should contain this information and 90 percent said print ads should do the same.

Consumers Union recently filed a citizen's petition with the FDA, asking that the agency require this information to be in all TV drug ads. We circulated this petition and almost 56,000 consumers signed on in support.

Medwatch reporting information is already required in print ads. Yet, television drug ads run far more frequently. The average TV viewer spends about 100 minutes watching drug ads for every minute spent in a doctor's office.[11] What better way then, for consumers to find out about Medwatch than by including this information in TV ads, and give the FDA information about safety problems with prescription drugs.

We urge the FDA to require this information be included in drug television ads as soon as possible. We should not wait. The more information that is available about potentially harmful drug side effects, the better the FDA will be able to evaluate risks and inform health care professionals and consumers so they, in turn, can make better informed healthcare decisions.

[11] Id, p. 55.