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What to Do If You Experience an ADR

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Only 1 to 10 percent of all serious adverse drug reactions, or ADRs, are ever reported to Food and Drug Administration's MedWatch program, according to estimates from the FDA.

Although drugs undergo extensive testing before they go to market, a clinical trial can't reveal every potential side effect—particularly because most trials exclude older patients, children, pregnant women, patients with multiple diseases, and people on medications that may interact with the drug under investigation. Health care providers are not required to report ADRs to the FDA, so that's where patients come in.

If you experience a serious ADR—one that is life-threatening, causes disability, or other significant medical events—let your doctor know right away. Doctors can use the FDA's Adverse Event Reporting System to fill out voluntary FDA Form 3500. Your physician will use your medical information as much as it applies to the ADR, but will keep your name and other contact information confidential.

However, doctors don't always have time to complete paperwork, and may not immediately submit the form. If you are concerned that your report isn't being turned in, you can fill out the form yourself using MedWatch. Be prepared to fill in detailed information about anything that might have impacted or caused the ADR. The clearer the information submitted to MedWatch, the more helpful it is to the FDA's Office of Drug Safety.

If you are participating in a clinical study, notify the physicians leading the study of all side effects. The role of clinical testing is to determine safety issues with an investigational agent; properly reporting an ADR is a study requirement and can help the researchers determine the drug's safety.

For more information about MedWatch or to submit a report, go to [www.fda.gov/medwatch](http://www.fda.gov/www.fda.gov/medwatch). Or call 800-332-1088 to report by telephone. The public can also subscribe to the MedWatch e-list to receive safety alerts by e-mail.