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FDA Adverse Events MedWatch Program

http://www.fda.gov/medwatch/

The American Food and Drug Administration (FDA) has "the responsibility for assuring the safety and efficacy of all (American) regulated marketed medical products including drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas)." MedWatch, the FDA Medical Products Reporting Program, "is an initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events and problems to FDA and/or the manufacturer and; to ensure that new safety information is rapidly communicated to the medical community thereby improving patient care." As such, one purpose of the MedWatch program is "to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products."

The MedWatch program is an excellent sources of adverse event data. For instance, according to the FDA, "between June 1993 and July 1994, FDA received 14,357 MedWatch reports. Of those, 9,879 were for adverse drug events; 2,648 for medical device events or problems; 1,406 for drug quality problems; 337 for biologic adverse events; 88 for medical food problems; and eight for veterinary medicine problems." Of course, health professionals who monitor for and report adverse events and product problems to the FDA are an especially important aspect of this process. Indeed, an Internet tool is available for the voluntary reporting of adverse events and product problems - with the mere click of a button, one can complete, print, and submit the Voluntary MedWatch Form (3500) online through the World Wide Web.

The MedWatch site also has a number of valuable safety resources, such as their 164 page report in PDF format "Managing the Risks from Medical Product Use: Creating a Risk Management Framework." Also included are "Dear Health Professional" Letters and Other Safety Notifications, as well as reports on Labeling Changes Related to Drug Safety and a comprehensive FDA Enforcement Report Index, containing "information on actions taken in connection with agency regulatory activities." I was also pleased with the short online report entitled "Taxonomy of Medication Errors", available in PDF format from National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).

Other notable resources include:

[1] Adverse Event Reporting System (AERS) *http://www.fda.gov/cder/aers/*

This program "is intended to build a world class safety surveillance system, based upon a revitalized pharmacovigilance program, new regulations, and international harmonization agreements."

[2] Medical Device Reporting Data Files *http://www.fda.gov/cdrh/mdrfile.html*

These files contain information on medical devices which may have malfunctioned or caused a death or serious injury. It includes reports received under both the mandatory Medical Device Reporting Program (MDR) from 1984 - 1996, and the voluntary reports up to June 1993. The database contains over 600,000 reports.

[3] Continuing Education Articles.
http://www.fda.gov/medwatch/articles.htm
Sample CME Article: Improving Patient Care by Reporting Problems with Medical Devices Article.

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