FDA 101: Medication Errors

A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient. Since 2000, the Food and Drug Administration (FDA) has received more than 95,000 reports of medication errors. FDA reviews reports that come to MedWatch, the agency's adverse event reporting program.

"These reports are voluntary, so the number of actual medication errors is believed to be higher," says Carol Holquist, R.Ph., Director of the Division of Medication Error Prevention in FDA's Center for Drug Evaluation and Research.

FDA works with many partners to track medication errors, including the U.S. Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). "Every report received through the USP/ISMP Voluntary Medication Error Reporting Program (MERP) automatically gets sent to FDA's MedWatch program," says Mike Cohen, R.Ph., Sc.D., President of ISMP. "It takes a cooperative approach to monitor errors, evaluate them, and educate the public about strategies to keep errors from happening again."

Medication errors occur for a variety of reasons. For example, miscommunication of drug orders can involve poor handwriting, confusion between drugs with similar names,

FDA Reduces the Risks by:

- ✓ **Reviewing drug names to minimize confusion**
- ✓ **Working with drug companies to improve labeling/packaging**
- ✓ **Requiring bar codes on certain products**
- ✓ **Analyzing reported errors**
- ✓ **Creating guidances for industry**
- ✓ **Educating the public**

poor packaging design, and confusion of metric or other dosing units.

"Medication errors usually occur because of multiple, complex factors," says Holquist. "All parts of the health care system—including health professionals and patients—have a role to play in preventing medication errors."

FDA'S ROLE

✓ **Drug Name Review:**
To minimize drug name confusion, FDA reviews about 400 drug names a year that companies submit as proposed brand names. The agency rejects about one-third of the names that drug companies propose.

✓ **Drug Labels:**
FDA regulations require all over-the-counter (OTC) drug products (more than 100,000) to have a standardized "drug facts label." FDA has also improved prescription drug package inserts for health care professionals.

✓ **Drug Labeling and Packaging:**
FDA works with drug companies to reduce the risk of errors that may result from similar-looking labeling and packaging, or from poor product design.

✓ **Bar Code Label Rule:**
In accordance with an FDA rule that went into effect in 2004, bar codes are required on product labels for certain drugs and biologics such as blood. When used with bar code scanner and computerized patient information systems, bar code technology can help ensure that the right dose of the right drug is given to the right patient at the right time.

✓ **Error Analyses:**
FDA reviews about 1,400 reports of medication errors per month and analyzes them to determine the cause and type of error.

✓ **Guidances for Industry:**
FDA is working on three new guidances—one on complete submission requirements for analyses of trade names, one about the pitfalls of drug labeling, and another on best test practices for naming drugs.

✓ **Public Education:**
FDA spreads the message about medication error prevention through public health advisories, medication guides, and outreach partnerships with other organizations.

EXAMPLES OF MEDICATION ERRORS

Misuse of Tussionex Prescription Cough Medicine:
On March 11, 2008, FDA informed health care professionals about adverse events and deaths in children and adults who have taken Tussionex Pennkinetic Extended-Release Suspension (Tussionex). Tussionex is a long-acting prescription cough medicine.

Hydrocodone, the narcotic ingredient in this medicine that controls cough, can cause life-threatening breathing problems when too much medicine is given at one time or when the medicine is given more frequently than recommended. Tussionex should not be used in children less than 6 years old.

Reports indicate that health care professionals have prescribed Tussionex for patients younger than the approved age group of 6 years old and older, more frequently than the labeled dosing interval of every 12 hours ("extended release"), and that patients have administered the incorrect dose due to misinterpretation of the dosing directions and the use of inappropriate measuring devices. Overdose of Tussionex in older children, adolescents, and adults has also been associated with life-threatening and fatal breathing problems.

For more information, see FDA Issues Alert on Tussionex at *www.fda.gov/bbs/topics/NEWS/2008/NEW01805.html* and the FDA Public Health Advisory at *www.fda.gov/cder/drug/advisory/hydrocodone.htm*

Overdoses of Cough and Cold Products in Children:
Roughly 7,000 children ages 11 and younger are treated in hospital emergency rooms each year because of overdoses of OTC cough and cold medication, according to a recent study by the Centers for Disease Control and Prevention. About two-thirds of those incidents occurred when children took medication without a parent's knowledge. Parents should keep medication out of children's reach and should never describe medication as "candy."

OTC cough and cold products can be harmful if more than the recommended amount is used, if they are given too often, or if more than one product containing the same active ingredient is used. In January 2008, FDA issued a public health advisory recommending that OTC cough and cold products not be used in infants and children under 2.

Serious injuries and deaths have resulted from such errors as misunderstanding directions and failing to use the measuring devices that come with the medicine.

For more information, see OTC Cough and Cold Products: Not for Infants and Children Under 2 Years of Age at *www.fda.gov/consumer/updates/coughcold011708.html*

Overdoses of Acetaminophen:
Taking too much of the pain reliever acetaminophen can lead to serious liver damage. The drug is sold under brand names such as Tylenol and Datril, and is also available in many cough and cold products, prescription pain relievers, and sleep aids.

To avoid accidental overdosing, consumers should not take more than the recommended dose on the

label. Also, acetaminophen should not be taken for more days than recommended, and should not be taken with other drug products that also contain acetaminophen without direction from a health care provider.

Parents should be cautious when giving acetaminophen to children. For example, the infant drop formula is three times more concentrated than the children's liquid. So parents need to be sure to give the appropriate dose.

Misuse of Fentanyl Patches:
FDA has issued warnings about the fentanyl transdermal system, an adhesive patch that delivers an opioid called fentanyl through the skin. An opioid is a potent pain medicine. It is also sometimes called a narcotic drug. Other examples of opioids include hydrocodone, morphine, and oxycodone.

The directions on the product label and package insert of the fentanyl transdermal system should be followed exactly in order to avoid overdose. Fentanyl patches should not be used for short-term acute pain, pain that is not constant, or for pain after an operation. The patch is only for moderate-to-severe chronic pain that is expected to last for any number of weeks or longer and that cannot be managed by acetaminophen-opioid combinations, nonsteroidal analgesics, or as-needed dosing with short-acting opioids.

Fentanyl patches are mostly prescribed for patients with cancer. Recent reports to FDA describe deaths and life-threatening side effects after doctors and other health care professionals inappropriately prescribed the patch to relieve pain after surgery, for headaches, or for occasional or mild pain in patients who were not opioid tolerant.

In other cases, patients have used the patch incorrectly. The patients replaced the patch more frequently than directed in the instructions, applied more patches than prescribed, or applied heat to the patch. All of these cases resulted in dangerously high fentanyl levels in the blood.

For more information, see FDA Issues Second Safety Warning on Fentanyl Skin Patch at
www.fda.gov/bbs/topics/NEWS/2007/NEW01762.html
and the FDA Public Health Advisory at
www.fda.gov/cder/drug/advisory/fentanyl_2007.htm

Overdoses with Methadone:
FDA has issued a public health advisory cautioning practitioners to avoid overdoses when they are prescribing methadone or managing patients taking the drug.

Since the 1970s, methadone has been primarily used in treating drug abuse, but it is increasingly being used to treat pain. FDA issued the advisory because of reports of life-threatening adverse events and death in patients receiving methadone for pain control.

Like other opioids, methadone causes slowed breathing, affects heart rate, and can also interact with other drugs. An overdose can occur because methadone stays in the body longer than the pain relief lasts.

For more information, see FDA's Public Health Advisory on methadone at
www.fda.gov/cder/drug/advisory/methadone.htm

Mix-ups Between Edetate Disodium and Edetate Calcium Disodium:
Both edetate disodium and edetate calcium disodium work by binding with heavy metals or minerals in the body, allowing them to be passed out of the body through the urine.

Edetate calcium disodium was approved to treat severe lead poisoning. Edetate disodium was approved as an emergency treatment for certain patients with very high levels of calcium in the blood or certain patients with heart rhythm problems resulting from high amounts of the medication digoxin in the blood.

But a number of uses that are not approved by FDA have emerged. These include the removal of other heavy metals from the blood and the treatment of heart disease, commonly referred to as "chelation therapies."

In January 2008, FDA issued a public health advisory, warning that some children and adults have died when they were mistakenly given edetate disodium instead of edetate calcium disodium (calcium disodium versenate), or when edetate disodium was used for chelation therapies and other uses not approved by FDA.

The drugs are easily mistaken for each other because they have very similar names and are both commonly referred to only as "EDTA." One of FDA's recommendations is that the abbreviation not be used.

For more information, see FDA's Public Health Advisory on Edetate Disodium (marketed as Endrate and generic products) at
www.fda.gov/cder/drug/advisory/edetate_disodium.htm FDA

For More Information

6 Tips to Avoid Medication Mistakes
www.fda.gov/consumer/updates/medtips062107.html

Medication Errors (FDA)
www.fda.gov/cder/drug/MedErrors/default.htm

Reporting Adverse Experiences to FDA
www.fda.gov/medwatch/how.htm

Institute for Safe Medication Practices
www.ismp.org

U.S. Pharmacopeia
www.usp.org