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ISMP Calls for Greater Response to Ongoing Medication Error Risks

HUNTINGDON VALLEY, Pa.—The landmark Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System* has reached its five-year anniversary this month, leading the Institute for Safe Medication Practices (ISMP) and many other healthcare organizations to revisit progress made. Although significant strides have been achieved in patient safety, ISMP is calling for even greater attention to ongoing problems.

Five years ago, the IOM committee asked the Food and Drug Administration (FDA) to: (1) develop and enforce standards for the design of drug packaging and labeling to maximize safety; (2) require pharmaceutical testing of proposed drug names; and (3) establish an appropriate response to problems identified through postmarketing surveillance, especially those that require immediate response to protect the safety of patients. To date, there are no new labeling or packaging guidance documents, pharmaceutical companies are not required to test proposed drug names and packaging, a standard process for testing has not been established, and the response to problems is still slow or nonexistent.

ISMP applauds FDA's announcement of plans to review its medication error detection and response procedures, and urges that drug labeling, packaging, and nomenclature be targeted as a special area of focus. Labeling, packaging, and nomenclature issues play a role in about half of all medication errors reported to the Food and Drug Administration (FDA) MedWatch program, according to the FDA. Some of the medication errors that continue to be reported to the USP-ISMP Medication Errors Reporting Program, and have in many cases led to serious patient injuries and deaths, include:

- **Medications Packaged in Look-Alike Low Density Polyethylene (LDPE) Containers**. This includes respiratory medications, flush solutions, eye medications and even injectables.

- **Concentrated Liquid Morphine.** Containers are still packaged without a prominent warning that the liquid is highly concentrated.

- **Brethine (terbutaline) and Methergine (methylergonovine).** ISMP has been writing alerts for the past four years about look-alike packaging for these drugs, which are used in labor and delivery settings but have opposite effects.

- **Acetylcysteine Containers.** These containers are still available with labels that list percent concentration, not mg/mL, which is problematic because the product is most frequently dosed in mg amounts.

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- **Vaccines (Multiple Brands).** Various vaccines continue to be confused with each other due to look-alike packaging from the same manufacturer, including tuberculin skin tests and the influenza vaccine.

- **Oral Methotrexate.** ISMP recently published a study about medication errors with this drug over a four-year period, which involves more than 100 cases. Most were with patients who accidentally took their doses daily instead of weekly as indicated, mistakes that could have been avoided with specific labeling and packaging changes.

ISMP is calling for a more profound response from pharmaceutical manufacturers and regulatory and standard-setting organizations to prevent and remedy look- and sound-alike problems, among others. If the FDA does not have the authority to require action on the part of the pharmaceutical industry, its authority must be examined so that necessary legislative changes can occur and enable the agency to intervene on behalf of the patient when needed.

Open communication among all stakeholders, including FDA, pharmaceutical companies, standard setting organizations such as USP, and patient safety organizations will also play an important role in bringing about even more successful medication error prevention efforts. Although much has been done since the last IOM report, all entities involved, especially the FDA and pharmaceutical industry, need to take an even more prominent and accountable role in the future.

Please contact ISMP media relations at 704-321-3343 or rbrehio@ismp.org to arrange interviews. Click here for a recent ISMP newsletter article on this issue.

About ISMP: The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. In 2004, the Institute is celebrating the 10th anniversary of is official incorporation as a nonprofit organization. For more information on ISMP, or its medication safety alert newsletters for healthcare professionals and consumers, visit www.ismp.org

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