Institute for Safe Medication Practices

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ISMP Alerts Lead to Important Safety Changes

HUNTINGDON VALLEY, Pa.— Advocacy by the Institute for Safe Medication Practices (ISMP) has contributed to two major medication safety advances that will help safeguard patients--a recall of several Tylenol products and more requirements for labeling containers used in the sterile operative field.

In late March, the USP-ISMP Medication Errors Reporting Program received a practitioner report regarding confusion over the labeling and packaging of children's Tylenol Meltaways (acetaminophen). The product comes in blister packs that contain either one or two 80mg tablets, but the front of the carton indicates "medicine per dose 80 mg," and all of the packs are labeled "Children's Tylenol 80mg." With the two tablet packs, parents or healthcare practitioners may assume that BOTH tablets should be given to provide the 80mg, resulting in a dangerous double dose that could cause liver damage.

ISMP followed up with both the Food and Drug Administration (FDA) and Johnson & Johnson's McNeil Consumer & Specialty Pharmaceuticals division to stress that the blister package design and labeling could lead to improper dosing. On Friday, June 3, McNeil announced the recall of several Tylenol products for children as a direct result of ISMP's alert.

The Institute has also promoted labeling of containers being used in the sterile field during operations, following a well-publicized fatal error last December in Seattle. Due in part to ISMP's advocacy, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced last week that a new 2006 Patient Safety Goal will focus on labeling of all medications, medication containers (e.g., syringes, medicine cups, basins), or other solutions on and off the sterile field in operative and other medical procedure settings.

Actions like these can only occur with cooperation between consumers and practitioners who report their concerns to safety agencies like ISMP, USP, and FDA, and ultimately the medical products industry. We thank Johnson & Johnson and McNeil Consumer & Specialty Pharmaceuticals for their prompt action in the Tylenol case and JCAHO for helping to make medication container labeling a safety priority.

For more information on these two safety issues, see the attached copies of ISMP's *Medication Safety Alert!* newsletter or go to www.ismp.org. For details on the Tylenol recall, visit http://www.jnj.com/news/jnj_news/20050603_104923.htm.
For details on the 2006 JCAHO National Patient Safety Goals, visit
http://www.jcaho.com/accredited+organizations/patient+safety/06_npsg/06_npsg_amb_obs.htm
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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 celebrated 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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