**Institute for Safe Medication Practices**
**1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006**
**www.ismp.org**

**FOR IMMEDIATE RELEASE**
**June 29, 2007**

**CONTACT: Renee Brehio, Media Relations**
**704-831-8822; rbrehio@ismp.org**

# Fatal Overdoses with Fentanyl Transdermal Patches Continue

*ISMP Issues Recommendations for Safe Use*

**Huntingdon Valley, Pa.**— Despite repeated warnings from the U.S. Food and Drug Administration (FDA), manufacturers, and patient safety agencies, fentanyl transdermal patches continue to be prescribed inappropriately to treat post-operative pain in opiate-naïve patients (those who have not been taking high doses of opiate pain killers for a week or more). The Institute for Safe Medication Practices (ISMP) is raising concerns over the steady stream of reports of adverse events associated with use of these patches--several incidents, including a fatality, have been reported in the last month alone.

Errors with fentanyl patches have occurred in multiple healthcare settings, including hospitals, physician offices, and ambulatory surgery centers. In many cases, misinformed primary care physicians unaware of proper prescribing guidelines and the potential dangers posed by this potent narcotic have prescribed the drug inappropriately, and the mistakes were not caught by pharmacists dispensing the prescriptions or nurses applying the patches to patients.

ISMP has been drawing attention to errors involving fentanyl patches since 2001. The Institute has communicated with manufacturers and the FDA to alert them to the latest reports about overdoses in opiate-naïve patients and has suggested that sales forces for fentanyl patches provide targeted education to physician groups and other healthcare practitioners.

The Institute also will continue pursuing a collaborative effort with community pharmacy chains and independent pharmacies to develop the mandatory education process for patients receiving these patches.

## ISMP Safe Practice Recommendations

ISMP recommends the following strategies to reduce the risk of inappropriate prescribing, dispensing, and administration of fentanyl patches:

- **Create specific prescribing and dispensing guidelines** congruent with the product labeling for use during order entry in inpatient and outpatient settings. Prescriptions that do not meet the guidelines should be questioned.

- **Determine the indication** for the fentanyl patch and ensure that the patient is opiate-tolerant and suffering from chronic pain that requires around-the-clock treatment before dispensing the medication.

**-more-**

- **Set dosing limits** and prescribe the patch at the lowest dose needed for pain relief. Ensure that pharmacy computer systems and prescriber order entry systems flash an alert if more than 25 mcg/hour is prescribed as a first-time dose.

- **Consider any other opiates prescribed for the patient** when determining the appropriate dose, to reduce the risk of an overdose.

- **Limit prescribing privileges** to prescribers who have been educated about the drug or require orders, particularly those that exceed the lowest available dose (12.5 mcg/hour or 25 mcg/hour), to be reviewed by a pain management specialist.

- **Require mandatory patient education** of patients using fentanyl patches and their caregivers in both inpatient and outpatient settings, including community pharmacies.

- **Know the signs of overdose**, including respiratory distress, extreme sleepiness, inability to think, talk, or walk normally, and feeling faint or dizzy. If these signs occur, medical attention should be sought immediately.

For a more detailed discussion of this issue, including recent errors involving fentanyl patches and ISMP's full practice recommendations, see the June 28, 2007, issue of the *ISMP Medication Safety Alert!* newsletter at: http://www.ismp.org/Newsletters/acutecare/articles/20070628.asp. For more information or interviews with ISMP experts and individuals affected by errors involving these patches, contact Renee Brehio at 704-831-8822.

**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 more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process.

**-end-**