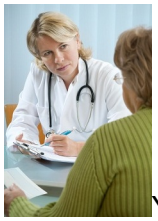
Fentanyl Patch Can Be Deadly to Children



Young children have died or become seriously ill from accidental exposure to a skin patch containing a powerful pain reliever.

As a result of this, the Food and Drug Administration (FDA) is issuing a safety alert to warn patients, caregivers and health care professionals about the dangers of accidental exposure to and improper storage and disposal of the fentanyl patch.

"These types of events are tragic; you never want this to happen. We are looking for ways that we can help prevent this from happening in the future," says Douglas Throckmorton, M.D., deputy director of FDA's Center for Drug Evaluation and Research. "This reinforces the need to talk to patients and their families to make sure that these patches are stored, used and disposed of carefully."

The fentanyl transdermal system—the patch marketed under the brand name Duragesic and available as a generic product—contains fentanyl, a potent opioid pain reliever, and treats patients in constant pain by releasing the medicine over the course of three days. (Opioids are synthetic versions of opium that are used to treat moderate and severe pain.) An overdose of fentanyl—caused when the child either swallows the patch or applies it to his or her own skin—can cause death by slowing breathing and increasing the levels of carbon dioxide in the blood.

According to Zachary A. Oleszczuk, PharmD, in FDA's Division of Medication Error Prevention and Analysis, there have been 26 cases of accidental exposure to fentanyl since 1997, most of them involving children younger than 2 years old. There have been 10 deaths and an additional 12 cases requiring hospitalization.

Reducing the Risk

"The best thing a patient can do is to follow the instructions on the medicine label and talk to a health care professional about how to prevent anyone else from coming in contact with the fentanyl patch," says Throckmorton.

Children are particularly vulnerable to a fentanyl overdose because, unlike adults, they have not been exposed to this type of potent medicine before and are more vulnerable to its effects. And a greater amount of the medicine is released if the patch is chewed and swallowed. Even after the patch is worn for three days, it may still retain more than 50 percent of the fentanyl.

Focusing on the prevention of medical errors, Oleszczuk and his colleagues at FDA report that infants and toddlers have unique risks of accidental exposure to fentanyl. Infants are often held by adults, increasing the chances that a partially detached patch could be transferred from adult to child. Toddlers are more likely to find lost, discarded or improperly stored patches and ingest them or stick them on themselves.

Early signs of fentanyl exposure could be hard to identify in young children. Lethargy has been among the reported symptoms, but that could be misinterpreted as fatigue. If there is reason to suspect that a child has been exposed to a fentanyl patch, Throckmorton says that emergency medical help should be sought immediately.

To reduce the possibility that children will be exposed to fentanyl, FDA recommends that fentanyl patch users take these precautions:

- Keep fentanyl patches and other drugs in a secure location that is out of children's sight and reach. Toddlers may think the patch is a sticker, tattoo or bandage.
- Consider covering the fentanyl patch with an adhesive film to make sure the patch doesn't come off your body.
- Throughout the day, make sure—either by touching it or looking at it—that the patch is still in place.

Proper Disposal

FDA recommends disposing of used patches by folding them in half so that the sticky sides meet, and then flushing them down a toilet. They should not be placed in the household trash where children or pets can find them.

FDA recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic

medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home.

FDA has included fentanyl patches on a list of medicines that should be flushed down a toilet because they could be especially harmful, and possibly fatal, in a single dose if used by someone other than the person for whom the medicine was prescribed.

FDA has issued two public health advisories—in 2005 and 2007—about the safe use of fentanyl patches and is continuing its outreach to patients, caregivers and health care professionals about the dangers of accidental exposure.

Health care professionals and patients are asked to report any cases of accidental exposure to the FDA's MedWatch Safety Information and Adverse Event Reporting program.