



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

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**ATTENTION: Hospitals, Pharmacies, Emergency Medical Services, Diagnostic and Treatment Centers, Local Health Departments, Regional Office Directors**

**FROM: New York State Department of Health**

**IMPORTANT HEALTH ADVISORY: SAFETY WARNINGS REGARDING  
USE OF FENTANYL TRANSDERMAL PATCH**

Please distribute immediately to the Chief of Medicine, Emergency Medicine, Pain Management/Anesthesiology, Pharmacy, Pathology, Laboratory Director

**Fentanyl Transdermal Patch:** This Health Advisory is being issued in response to a December 21, 2007 Food and Drug Administration (FDA) Safety Warning to alert health care providers regarding the proper use of and safety concerns regarding the fentanyl transdermal patch to treat pain. Fentanyl is a schedule II prescription narcotic 50 to 80 times more potent than morphine. The FDA has approved the fentanyl patch to manage persistent, moderate to severe chronic pain in opioid-tolerant patients only. The fentanyl patch is contraindicated in the management of mild, intermittent or post-operative pain or in patients who are not opioid-tolerant. In 2006, over 68,000 patients in NYS received prescriptions for fentanyl.

**Warnings/Advisories Regarding Fentanyl (See Below):** In July 2005, the FDA issued an Alert emphasizing safe use of the fentanyl patch. Since then, the FDA has continued to receive reports of deaths and life-threatening side effects in patients who use the fentanyl patch. In some cases, doctors have inappropriately prescribed the fentanyl patch. The FDA is asking the manufacturers of all fentanyl patches to update their product information and to develop a medication guide for patients. On December 21, 2007, the FDA issued a second safety warning, emphasizing the importance of following the directions on the product label and on the patient package exactly. According to the FDA:

The fentanyl patch is only indicated for use in patients with persistent, moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid-tolerant. Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin which can result in fatal overdose. The directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose.

Fentanyl has a high potential for risk of fatal overdose and for abuse and diversion from legitimate medical use. Any theft, loss, or diversion of fentanyl is required to be reported to the Department's Bureau of Narcotic Enforcement at (518) 402-0707.

Illicit fentanyl is also produced in clandestine laboratories and mixed with or substituted for heroin. In August 2006, the Department issued a Health Advisory regarding an outbreak of fentanyl-related overdose deaths that was subsequently traced to heroin laced with illicit fentanyl. The outbreak was responsible for over 1,000 deaths nationwide.

**Fentanyl Reference Material:** We encourage you to review the following FDA materials to familiarize yourself with the safety precautions for use of the fentanyl transdermal patch:

- FDA News: FDA Issues Second Safety Warning on Fentanyl Skin Patch  
At: <http://fda.gov/consumer/updates/fentanylpatch122107.html>
- FDA Public Health Advisory: Important Information for the Safe Use of Fentanyl Transdermal System (Patch) at: [http://www.fda.gov/cder/drug/advisory/fentanyl\\_2007.htm](http://www.fda.gov/cder/drug/advisory/fentanyl_2007.htm)
- FDA Public Health Advisory: Safety Warnings Regarding Use of Fentanyl Transdermal (Skin) Patches at: <http://www.fda.gov/cder/drug/advisory/fentanyl.htm>
- FDA Alert 7/15/05: Update 12/21/07: Information for Healthcare Professionals: Fentanyl Transdermal System at: [http://fda.gov/cder/drug/infosheets/hcp/fentanyl\\_2007hcp.htm](http://fda.gov/cder/drug/infosheets/hcp/fentanyl_2007hcp.htm)

**Information for Patients and Their Families:** The FDA's Patient Information Sheet Fentanyl Transdermal System is also available for use. It can be obtained at:  
<http://fda.gov/cder/drug/infosheets/patient/fentanylpis.pdf>

**Opioid Overdose Prevention:** In New York State, Opioid Overdose Prevention Programs train individuals to reverse potentially fatal overdoses. Trained overdose responders may legally obtain and administer naloxone, an FDA-approved opioid antagonist. Information about opioid overdose prevention, including a registration form for interested providers and practitioners to become opioid overdose prevention programs, is available at:  
[http://nyhealth.gov/diseases/aids/harm\\_reduction/opioidprevention/index.htm](http://nyhealth.gov/diseases/aids/harm_reduction/opioidprevention/index.htm)

### Questions:

Questions about Opioid Overdose Prevention Programs may be directed to the AIDS Institute at (212) 417-4770 or by sending an e-mail to [hivprev@health.state.ny.us](mailto:hivprev@health.state.ny.us)

Questions about completion and submission of death certificates may be directed to the Bureau of Production Systems Management, Vital Records Section, at (518) 474-5245 or send an email to [vr@health.state.ny.us](mailto:vr@health.state.ny.us) with the subject line "Fentanyl-Related Overdose Deaths".

Questions about controlled substances or prescribing controlled substances may be directed to the Bureau of Narcotic Enforcement at 1-866-811-7957, option 2, or by sending an email to [narcotic@health.state.ny.us](mailto:narcotic@health.state.ny.us)