NATIONAL PBM COMMUNICATION · August 20, 2009

Watson Pharmaceuticals Announces a Nationwide Voluntary Recall of a Specific Lot of Fentanyl Transdermal System Due to Leaking Contents

- Watson Pharmaceuticals is voluntarily recalling Fentanyl Transdermal System, lot numbers 145287A and 145287.
- The affected lots are being recalled because two patches were confirmed to be leaking.
- Gel containing active fentanyl drug may be released from the gel reservoir into the pouch in which the patch is packaged, making it possible for patients and caregivers to be directly exposed to the controlled substance.
- Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal.
- This is a RETAIL level recall.
- The following products are being recalled:

Product Description	ID Number (NDC/ UPC/ Catalog)	Package Size	Lot # / Expiration date	Manufacturer Initial Ship Date
Fentanyl, 100mcg, pat, 5 **ABC# 617148**	0591-3214-72 (carton unopened) 0591-3214-54 (patch)	5	145287A 02/28/2011 145287	April 2009

- Return all remaining product at the facility level with the affected lot numbers to McKesson, NOT as instructed in the product recall documents. Affected lots of in-house stock are to be sequestered within 24 hours of this notice. Please inform your Facility Recall Coordinator when the sequestering actions have been completed.
- Determine whether the affected medication (information provided above) was dispensed to any patient(s). The time frame for the distribution of the affected lots is noted above. A file containing the last 6 months of VAMC pharmaceutical prime vendor purchases is attached. This should only be used as a guide because it does not include direct purchases and drop shipments.
- If an affected product was dispensed to patients, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product by any appropriate method.
    - A sample letter can be found at: http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc.
    - This template can be altered according to site-specific needs.
  - Provide patient(s) with instructions on the following:
    - How to obtain a new supply of medication.
    - How to return the medication being recalled to the pharmacy.
    - To continue taking the medication with the affected lot number until they receive a new supply. When correct medication is received, patient should begin taking the new medication and return the recalled supply as instructed.
    - Never use a damaged patch or a patch with a hole in it. Do not touch a damaged patch with your fingers and wash hands immediately if a damaged patch is handled. Discard used or damaged patches by folding the patch in half and flushing down the toilet.
- Report any adverse reactions experienced with the use of this medication to the VA ADERS program.

ACTIONS:

- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, pain specialists, palliative care providers, and oncology providers,*** *including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*