North Carolina Department of Health and Human Services
Division of Public Health

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Penelope Slade-Sawyer
Division Director

January 20, 2015

To: All North Carolina Health Care Providers
From: Megan Davies, MD, State Epidemiologist
Re: **Health Alert: Wallcur simulated IV saline solutions administered to patients**

The United States Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are currently investigating multiple instances of simulated intravenous (IV) saline products being administered to patients. These products are not sterile and should not be injected in humans or animals.

The North Carolina Division of Public Health (NC DPH) is distributing this alert in collaboration with the North Carolina Department of Agriculture and Consumer Services (NCDA&CS) Food and Drug Protection Division to provide information regarding this situation and guidance to North Carolina clinicians.

Summary

Wallcur's simulated IV saline solution, Practi-0.9% sodium chloride solution, was shipped to medical clinics, surgical centers, and urgent care facilities in numerous states, including North Carolina. In some instances, this product was administered to patients. Adverse events have been associated with these incidents, including multiple hospitalizations. Wallcur initiated a voluntary recall of Practi-0.9% sodium chloride solutions on January 7, 2015. NC DPH has contacted all facilities identified as having received these products.

Recommended Actions

All healthcare providers and clinical office staff are encouraged to take the following steps to eliminate the possibility of simulated products being administered to patients:

- Visually inspect all current IV saline solution bags. Ensure none of the bags are labeled "Wallcur," "Practi- products," "For clinical simulation," or "Not for use in human or animal patients."
- If you have products labeled with any of these words, or you suspect you may have received other products intended for training purposes, separate simulation products from existing inventory and contact your distributor for directions on how to return these products.
- If you have received Wallcur Practi-products by mistake, please contact at NCDA&CS at 919-733-7366 to report receipt of this product.
- Review your office procedures and make sure there are procedures in place to visually inspect all future shipments of normal saline products to ensure they are for clinical use.

If you suspect that any Wallcur training IV products may have been administered to a patient, whether or not the incident has resulted in an adverse event:

- Evaluate all potentially exposed patients for new or ongoing symptoms and use appropriate treatment;
- Report all potential patient exposures to the NC DPH at **919-733-3419** (24/7); and
- Report any adverse events following use of these products to FDA's MedWatch program online (http://www.fda.gov/Safety/MedWatch/) or at 1-800-332-1088.

Additional information is available at
http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.