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FDA Classifies Baxter's January HomeChoice Peritoneal Dialysis Cycler Field Corrective Action as a Class I Recall

Baxter is Deploying Revised Labeling, Training and Upcoming Software Revisions to Further Assist Clinicians and Patients

DEERFIELD, Ill., March 2, 2010 – Baxter Healthcare Corporation announced today that the U.S. Food and Drug Administration (FDA) has classified Baxter's recent Urgent Product Recall regarding Increased Intraperitoneal Volume (IIPV), or overfill of the abdominal cavity, associated with HomeChoice and HomeChoice Pro peritoneal dialysis cyclers as a Class I recall. This action has been classified as a Class I recall because of the risk of serious injury or patient death that could be associated with the use of this device. Over the last two years, Baxter has received serious injury reports and at least one patient death report associated with this issue.

About IIPV

IIPV may result in serious injury or death from conditions such as: abdominal wall and/or diaphragmatic hernias, hydrothorax, heart failure, acute hypertension, pulmonary edema, decreased pulmonary function and pericardial effusion. **Children and non-verbal patients may be at increased risk because of their smaller size and/or inability to communicate. Increased monitoring of these patients is recommended. Other vulnerable populations include critically ill patients and patients with pulmonary and hemodynamic instability.**

Patients and caregivers should watch for the potential signs of IIPV. These include: difficulty breathing; vomiting or spitting up; a child complaining of a "funny feeling" in the abdomen; a child crying during therapy without other apparent reasons; difficulties feeding; feeling full, bloated, or overfilled after treatment; abdominal pain or discomfort; expanded or tense abdomen; localized swelling around the genital area (labia, scrotum) or groin region, belly button, the tunnel tract of the peritoneal dialysis catheter or the PD catheter exit site; leakage of fluid from the PD catheter exit site; and unexpected increase in blood pressure.

If patients or caregivers notice any of these symptoms, they should stop the device, initiate manual drain, and contact their healthcare provider immediately. Additional information that will be relevant in assessing patients for IIPV includes: careful monitoring of pre- and post-treatment weight; evaluating vital signs including heart rate and blood pressure; review of the recorded ultrafiltration from the device; and development of symptoms of respiratory distress or increased effort in breathing. For patients in a clinic, hospital, or critical care setting, clinicians should consider increased monitoring. This would include evaluating oxygen saturation and evidence of abdominal tenseness.

Baxter is continuing to investigate the causes, fixes, and mitigations associated with IIPV and use of the HomeChoice device. Current mitigations under development and implementation include changes to device labeling and software, which are intended to address issues such as prescription and patient errors, including bypassing alarms. Patients will receive new Patient At-Home Guides, which contain expanded information about IIPV, the symptoms, warnings and cautions, and how to address IIPV, should it occur. Baxter has also developed and is validating a software modification to address this issue and plans to submit a 510(k) to the FDA midyear. The software update will include additional user interface messages and alarms, and change default settings and allowable ranges to reduce risk of excessive accumulation of fluid in the peritoneal cavity.

www.kcercoalition.com/alerts.htm

HomeChoice systems are intended for automatic control of dialysis solutions exchange in the treatment of adult and pediatric renal failure patients undergoing peritoneal dialysis. The recall notice does not require the physical return of HomeChoice units and patients may continue using them. **Affected model numbers include: 5C4471, 5C4471R, 5C8310, 5C8310R, 5C4474, 5C4474R, R5C8320, R5C8320R, T5C4441, T5C4441R, T5C8300, T5C8300R, 5C4474D and 5C4474DR.** It is important that clinicians rev the prescription settings for devices to help reduce prescription errors and weigh the risks and benefits of continued use of this device by their patients.

Baxter sent recall notices to clinicians and patients informing them of this action and identifying steps that are intended to reduce the harm associated with IIPV. These January 2010 letters contain more detailed information about device usage and are available at www.baxter.com. Customers or patients with questions regarding this notice may contact Baxter 24 hours a day, seven days a week at 1-800-553-6898. Any adverse reactions experienced with the use of this product, and/or quality problems, should be reported to Baxter's Renal business at 1-888-736-2543, prompt 3, and the FDA's MedWatch Program at 1-800-FDA-1088 or www.fda.gov/MedWatch/report.htm .

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