

ASN Member Alert

February 12, 2008

TO: ASN Members

FROM: ASN Policy Board
ASN Dialysis Advisory Group

RE: **FDA Advisory – Temporary Suspension of Multiple-dose Vial Heparin**

The U. S. Food and Drug Administration (FDA) announced yesterday that Baxter Healthcare Corporation (Baxter) has temporarily stopped manufacturing multiple-dose vials of the injectable blood-thinning drug Heparin due to reports of serious allergic reactions and hypotension in adult and pediatric patients who receive high doses of the drug. The first reports of severe reactions took place in pediatric dialysis patients.

The FDA is investigating these adverse events and is working closely with Baxter to inspect manufacturing sites. They are also working with other manufacturers to prevent any inventory shortfall.

For your information, we have provided a link to the official FDA Advisory which clearly summarizes the issue and outlines recommended actions for physicians, dialysis center staff and health care providers.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01797.html>

The ASN Policy Board and Dialysis Advisory Group will continue to monitor this issue and will forward any information to our members as warranted.