



# NATIONAL HEMOPHILIA FOUNDATION

*for all bleeding and clotting disorders*

## **Medical Advisory #413: Baxter Voluntarily Recalls One Lot of Recombinate**

*July 28, 2011*

Baxter BioScience has announced that it is voluntarily recalling one lot of Recombinate Antihemophilic Factor (Recombinant). Baxter states that this recall is being taken as a precautionary measure after a retrospective review of its manufacturing process revealed a breach in aseptic processing. This lot did meet all in-process and final container specifications, which include sterility and pyrogenicity. There have been no adverse events reported regarding use of this lot of Recombinate to date. This action is being taken with the knowledge of the U.S. Food and Drug Administration (FDA).

### **Recalled Lot:**

**Lot Number** - TRA09834AB

**AHF IU/vial** - 1060

**Expiration Date** 1-28-2012

If you have any of this product in your possession, please contact Baxter Customer Service at: 1-800-423-2090 for instructions on how to return the product and obtain a replacement.

**PHYSICIANS:** Please distribute this information to all providers in your area who treat patients with hemophilia.

**CHAPTERS:** Please distribute this information to your membership.

Please sign up for the Patient Notification System (PNS) to be notified directly about the latest recall or withdrawal of recombinant and plasma products. The System is confidential and time sensitive. It is administered by an independent third-party organization and is free of charge.

To enroll in the PNS, please call (888) UPDATE-U or go online at

<http://www.patientnotificationsystem.org>.

This material is provided for your general information only. NHF does not give medical advice or engage in the practice of medicine. NHF under no circumstances recommends treatment for specific individuals and in all cases recommends that you consult your physician or local hemophilia treatment center before pursuing any course of treatment.



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