

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO**

**IN RE:** ) **MDL Docket No. 1953**  
 )  
 ) **CHIEF JUDGE JAMES G. CARR**  
 ) **CASE NO. 1:08-60000**  
 )  
 )  
 ) **ALL CASES**

**HEPARIN PRODUCTS  
LIABILITY LITIGATION**

**Third Amended Pretrial Order Number 4  
PRESERVATION OF EVIDENCE**

**A. Preservation Generally**

1. The Parties shall take in good faith all reasonable steps, including due diligence, to preserve written or recorded communications, documents, electronically stored information, and other tangible objects, within their possession, custody or control that they believe may contain information that is relevant to the allegations and defenses in this matter or may lead to the discovery of admissible evidence in this action.

2. The terms “document” and “electronically stored information” shall be defined as they are in F.R.C.P. 34.

**B. Preservation as to Baxter Heparin**

3. All test results, raw data, and testing protocols from recall-related heparin testing possessed or controlled by Baxter International Inc., Baxter Healthcare Corporation, or Baxter Healthcare Corporation of Puerto Rico shall be preserved.

4. The heparin sodium injection vials possessed or controlled by Baxter International Inc., Baxter Healthcare Corporation, Baxter Healthcare Corporation of Puerto Rico, or their agents, including counsel, shall be preserved with the exception of the following: (a) Ongoing Destructive Testing by Baxter International Inc., Baxter Healthcare Corporation, Baxter Healthcare Corporation of Puerto Rico, U.S. governmental agencies and other foreign agencies; (b) vials of heparin product that never left Baxter's possession but were "returned" to Baxter's own distribution facility, Baxter Healthcare Corporation's Memphis Global Logistics Center, located 4750 Pleasant Road, Memphis, Tennessee 38118 as a result of the 2008 recalls; (c) with the exception of samples retained pursuant to paragraph 6 below, vials of heparin product that had been stored at Baxter's Cherry Hill facility but had not left Baxter's possession, custody or control; and/or (d) vials of heparin product that were returned to Baxter during the 2008 recalls (with the exception that a minimum of 200 vials per lot must be maintained; if fewer than 200 vials exist for any given lot, all vials must be maintained).

5. Pursuant to their general good faith agreement to take reasonable steps to preserve materials that may be relevant to or lead to the discovery of admissible evidence in this action (*see* ¶ 1, *supra*), Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare Corporation of Puerto Rico agree to refrain from additional Ongoing Destructive Testing of such finished lots with the exception of testing that they reasonably believe to be necessary or appropriate in order to to: (i) further the root cause investigation or analysis; and/or (ii) provide or develop information and understanding relevant to public health concerns and the safety of

heparin or other medical products; and/or (iii) respond to requests, recommendations, or requirements from U.S. governmental agencies and other foreign agencies.

6. Based upon Baxter's heparin manufacturing process, it is our understanding that each vial of Baxter's heparin product within each lot should contain the same level of OSCS (if any) because each lot of finished product is homogeneously mixed. Regardless of any Ongoing Destructive Testing, a minimum of ten vials from each finished lot of Baxter heparin sodium injection vials possessed or controlled by Baxter International Inc., Baxter Healthcare Corporation or Baxter Healthcare Corporation of Puerto Rico shall be preserved.

7. As used herein, the term “Ongoing Destructive Testing” means testing conducted to heparin samples to advance scientific or regulatory purposes, including nuclear magnetic resonance, mass spectrometry, carbohydrate analysis, capillary electrophoresis, enzymatic kinetics, enzymatic digestion, bioassay tests, and animal testing.

### **C. Preservation as to SPL and CZSPL Heparin**

8. All test results, raw data and testing protocols from recall-related heparin testing possessed or controlled by Scientific Protein Laboratories LLC (“SPL”) and Changzhou SPL Co., Ltd. (“CZSPL”) shall be preserved.

9. SPL and CZSPL have no current plans to destroy any Chinese-sourced crude heparin or 1060 or 1035 heparin sodium active pharmaceutical ingredient (“API”) currently in their possession, custody or control, by testing or otherwise. In the event SPL or CZSPL believes it necessary or appropriate to do so, it shall provide Plaintiffs’ Liaison Counsel with thirty days advance notice, and shall, in any event, preserve a minimum reserve of three grams of all Chinese-sourced crude heparin and 1060 and 1035 heparin sodium API lots currently in its possession, custody or control. In the event SPL and/or CZSPL currently have a reserve of less than three grams of any lot of Chinese-sourced crude heparin or 1060 or 1035 heparin sodium

API in their possession, custody or control, they shall preserve any and all reserves that remain from such lots.

10. In the event any government agency takes additional samples of any Chinese sourced crude heparin or 1060 or 1035 heparin sodium API currently in the possession, custody or control of SPL or CZSPL, or requests that SPL or CZSPL conduct analytical testing on such materials, which depletes or will deplete the reserves so that SPL or CZSPL has less than three grams in reserve of any lot, counsel for SPL or CZSPL shall promptly give notice to Plaintiffs' Liaison Counsel.

11. Nothing herein is intended to prevent SPL and/or CZSPL from processing any crude heparin for sale or selling any heparin sodium API in their possession, custody or control at any time.

12. As used herein, "1060 heparin sodium" refers to heparin sodium API produced by CZSPL, and "1035 heparin sodium" refers to heparin sodium API produced by SPL in Wisconsin from Chinese-sourced crude heparin.

#### **D. Notification of Third Parties**

13. Baxter agrees to immediately provide Plaintiffs' Liaison Counsel with a list of its distributors who received letters related to the recall of Baxter heparin products in 2008.

#### **E. Modification**

14. All Parties reserve the right to request a modification of this preservation order.

#### **F. Later Filed Cases**

15. This order shall also apply to related cases later filed in, removed to, or transferred to this Court.

**G. Miscellaneous**

16. Baxter Healthcare Corporation will identify to Plaintiffs' liaison counsel the approximate number of heparin sodium injection vials manufactured in each lot within thirty days of the entry of this order.

This the 13th day of December, 2013

s/James G. Carr

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Sr. United States District Judge