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## **Recall -- Firm Press Release**

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### **Baxter Issues Urgent Nationwide Voluntary Recall of Heparin 1,000 Units/ml 10 and 30ml Multi-Dose Vials**

**NDC NUMBERS 0641-2440-45, 0641-2440-41, 0641-2450-45 and 0641-2450-41; LOTS: 107054, 117085, 047056, 097081, 107024, 107064, 107066, 107074, 107111**

#### **Media Contacts:**

Erin Gardiner, (847) 948-4210  
Christopher King, (847) 948-4274

**FOR IMMEDIATE RELEASE** -- DEERFIELD, Ill., January 25, 2008 – Baxter Healthcare Corporation has announced the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials. The company began recalling the lots on January 17, 2008 as a precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the product. Baxter is conducting a thorough investigation of these reports to identify the cause of the increase in allergic-type reactions.

Adverse patient reactions have included: stomach pain or discomfort, nausea, vomiting, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, feeling your heart beat strong or fast, drug ineffectiveness, burning sensation, redness or paleness of skin, abnormal sensation of the skin, mouth or lips, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, throat swelling, thirst and difficulty opening the mouth. Some of these reactions may be severe or life threatening.

Heparin is a prescription, injectable blood anticoagulant (also called a blood thinner). The 1,000 units/mL multi-dose vials are primarily used for hemodialysis and cardiac invasive procedures. To date, the company has not observed a significant increase in adverse event reports occurring with any other of its heparin presentations.

Customers have been instructed to discontinue use and segregate the recalled product from the rest of their inventory. Customers should then contact Baxter to arrange for return and replacement product. Customers with recalled product purchased indirectly should contact their wholesaler or distributor for return and replacement product. Customers with questions may contact Baxter at 1-800-667-0959. Representatives are available Monday through Friday from 7 a.m. to 6 p.m. CT.

Baxter International Inc. through its subsidiaries, assists healthcare professionals and their patients with the treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. For more information about Baxter, visit [www.baxter.com](http://www.baxter.com).

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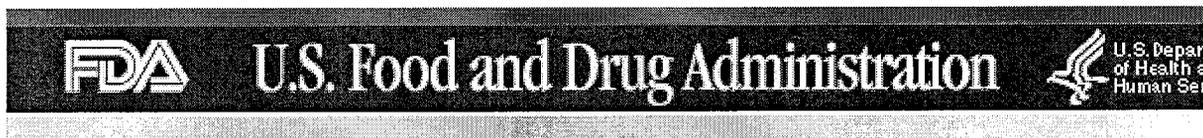
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### **Baxter to Proceed with Recall of Remaining Heparin Sodium Vial Products**

**Contact:**

Erin Gardiner, (847) 948-4210  
Deborah Spak, (847) 948-2349

**FOR IMMEDIATE RELEASE** -- DEERFIELD, Ill., February 28, 2008 – Baxter International Inc. announced today that the company is proceeding with the voluntary recall of all remaining lots and doses of its heparin sodium injection multi-dose, single-dose vials and HEP-LOCK heparin flush products.

The company initially recalled nine lots of heparin sodium injection multi-dose vials on January 17, 2008 as a precautionary measure due to a higher than usual number of reports of adverse patient reactions involving the product and suspended production earlier this month.

Given the widespread use of this blood thinner and the impact a product shortage would have on operating rooms, dialysis centers and other critical care areas, the FDA and Baxter concluded that removing additional lots and doses of Baxter's heparin from the market earlier would have created more risk to patients requiring heparin therapy than the increased potential for experiencing an adverse reaction. Accordingly, the FDA and Baxter decided not to recall all Baxter heparin vial products at that time. The FDA has now concluded that there is sufficient capacity on the part of other suppliers that Baxter's recall will not jeopardize access to this drug, and has told Baxter that the company can now proceed with recalling its remaining heparin sodium injection and heparin flush products.

Although the vast majority of the reports of adverse reactions have been associated with the multi-dose products, Baxter is taking the precautionary step of recalling all remaining heparin sodium injection and heparin flush products that are currently on the market. In addition to the previously recalled lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials, Baxter's recall will now include the remaining lots of those products and heparin sodium injection 5000 units/mL 10mL multi-dose vials, heparin sodium injection 10,000 units/mL 4mL multi-dose vials, heparin sodium injection 1000 USP units/mL, 5000 USP units/mL, and 10,000 USP units/mL single-dose vials, and all HEP-LOCK and HEP-LOCK U/P, 10 USP units/mL and 100 USP units/mL vials, both preserved and preservative-free.

This recall does not involve Baxter's heparin pre-mix IV solutions in bags: heparin sodium in 5% dextrose injection and heparin sodium in 0.9% sodium chloride injection.

"We have assurance from the U.S. Food and Drug Administration that there is an adequate supply in the market to meet the demand for these critical and lifesaving drugs," said Peter

J. Arduini, president of Baxter's Medication Delivery business. "The safety and quality of our products is always our highest priority, and we will continue to collaborate with the FDA as we work to determine the cause of the increased rate of adverse reactions and resolve this issue."

Nearly all reported adverse reactions have occurred in three specific areas of product use – renal dialysis, invasive cardiovascular procedures and apheresis procedures. Reported adverse patient reactions have included: stomach pain or discomfort, nausea, vomiting, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, the feeling of a strong or rapid heartbeat, drug ineffectiveness, burning sensation, redness or paleness of skin, abnormal sensation of the skin, mouth or lips, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, throat swelling, thirst, bleeding tendencies and difficulty opening the mouth. **Some of these reactions, particularly profound and refractory hypotension, may be severe or life-threatening.**

Customers have been instructed to **discontinue use and segregate the recalled product** from the rest of their inventory. Customers should then contact Baxter to arrange for return and replacement product. Customers with recalled product purchased indirectly should contact their wholesaler or distributor for return and replacement product. Customers with questions may contact the Center for One Baxter at 1-800-4-BAXTER (1-800-422-9837). Representatives will be available twenty-four hours a day, seven days a week.

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### **American Health Packaging Announces a Recall of Approximately 1,400 Units of Heparin Sodium Vial Products as Part of Broader Baxter Recall**

***Units for Pharmacy Automated Equipment Part of Broader Recall***

**Contact:**

Michael N. Kilpatrick  
610-727-7118

**FOR IMMEDIATE RELEASE** -- Valley Forge, PA -- March 20, 2008 --- American Health Packaging (AHP), a subsidiary of AmerisourceBergen Corporation (NYSE:ABC), today announced a voluntary recall of 1,421 units (25 vials per unit) of 10000 USP units/ml heparin sodium injection 1ml vials as part of the broader February 29, 2008 recall of Heparin products made by Baxter Healthcare Corporation. The vials were manufactured by Baxter and then placed by AHP into individually labeled bags for use in pharmacy automation equipment. The AHP packages were sold to five hospitals in Georgia and California, all of whom were notified of the recall earlier this month. Baxter Healthcare will reimburse AHP for the recalled product.

The recalled products are APS HEPARIN 10MU/ML (10000 USP units/ml) 1ml SDV 25UD (bag) **NDC # 00641-0410-25**, lot numbers 074155, 073089, 073391, 073613, 070095A, 073712, 072907, 073454, 070095D and APS HEPARIN SDV 10MU (10000 USP units/ml) 1ml 25UD (box and rod) **NDC # 00641-0410-25**, lot numbers 070095B, 070095C, 068286, 067755. AHP instructed customers to return any and all of these product lots remaining in inventory.

This recall was initiated due to the Baxter Healthcare's recall which stated, "...**voluntary recall of Heparin Sodium Injection to include all lots of single and multi-dose vial products**, due to an increase in reports of adverse patient reactions including abdominal pain, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, **including profound and refractory hypotension**, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, paresthesia (oral), pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus, and unresponsiveness to stimuli. The reports of profound and refractory hypotension usually occur with the first few minutes of bolus administration."

This recall is being made with the knowledge of the Food and Drug Administration. Health care professionals with questions about the AHP packages should contact Richard J. Augustine at 1-800-707-4621. To report adverse drug events or for information on the Baxter Healthcare recall of all Heparin Sodium Injection products, please contact Baxter Healthcare at 1-800-667-0959.

### **About AmerisourceBergen**

AmerisourceBergen is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets. Servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel, the Company provides drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to reimbursement and pharmaceutical consulting services. With more than \$66 billion in annual revenue, AmerisourceBergen is headquartered in Valley Forge, PA, and employs more than 11,500 people. AmerisourceBergen is ranked #29 on the Fortune 500 list. For more information, go to [www.amerisourcebergen.com](http://www.amerisourcebergen.com).

### **FORWARD-LOOKING STATEMENTS**

This news release may contain certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances. Actual results may vary materially from the expectations contained in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in any forward-looking statements: competitive pressures; the loss of one or more key customer or supplier relationships; customer defaults or insolvencies; changes in customer mix; supplier defaults or insolvencies; changes in pharmaceutical manufacturers' pricing and distribution policies or practices; adverse resolution of any contract or other disputes with customers (including departments and agencies of the U.S. Government) or suppliers; regulatory changes (including increased government regulation of the pharmaceutical supply channel); government enforcement initiatives (including (i) the imposition of increased obligations upon pharmaceutical distributors to detect and prevent suspicious orders of controlled substances (ii) the commencement of further administrative actions by the U. S. Drug Enforcement Administration seeking to suspend or revoke the license of any of the Company's distribution facilities to distribute controlled substances, (iii) the commencement of any enforcement actions by any U.S. Attorney alleging violation of laws and regulations regarding diversion of controlled substances and suspicious order monitoring), or (iv) the commencement of any administrative actions by the board of pharmacy of any state seeking to suspend, revoke or otherwise restrict the ability of any of the Company's distribution facilities or businesses to distribute or dispense pharmaceuticals in such state; changes in U.S. government policies (including reimbursement changes arising from federal legislation, including the Medicare Modernization Act and the Deficit Reduction Act of 2005); changes in regulatory or clinical medical guidelines and/or reimbursement practices for the pharmaceuticals we distribute, including erythropoiesis-stimulating agents (ESAs) used to treat anemia patients; price inflation in branded pharmaceuticals and price deflation in generics; fluctuations in market interest rates; operational or control issues arising from the Company's outsourcing of information technology activities; success of integration, restructuring or systems initiatives; fluctuations in the U.S. dollar - Canadian dollar exchange rate and other foreign exchange rates; economic, business, competitive and/or regulatory developments in Canada, the United Kingdom and elsewhere outside of the United States; acquisition of businesses that do not perform as we expect or that are difficult for us to integrate or control; any disruption to or other adverse effects upon the PMSI workers' compensation business caused by the Company's announcement that it is pursuing the sale of PMSI; the inability of the Company to successfully complete the sale of PMSI; the inability of the Company to successfully complete any other transaction that the Company may wish to pursue from time to time; changes in tax legislation or adverse resolution of challenges to our tax positions; and other economic, business, competitive, legal, tax, regulatory and/or operational factors affecting the business of the Company generally. Certain additional factors that management believes could cause actual outcomes and results to differ materially from those described in forward-looking statements are set forth (i) in Item 1A (Risk Factors) in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2007 and elsewhere in that report and (ii) in other reports filed by the Company pursuant to the Securities Exchange Act of 1934.

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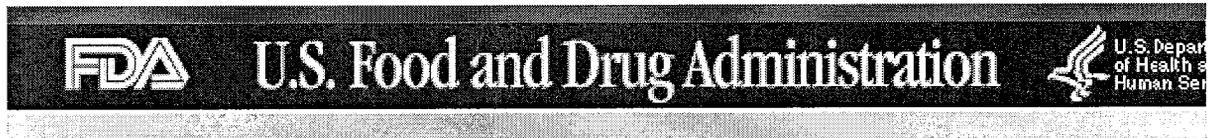
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### B. Braun's Supplier Recall of Heparin API Prompts Voluntary Recall of Heparin Solutions

*Scientific Protein Laboratories LLC (SPL) manufactures Heparin Sodium USP active pharmaceutical ingredient that is used by B. Braun Medical Inc. to produce Heparin Sodium in 5% Dextrose and 0.9% Sodium Chloride injection solution*

**Contact:**

Stephanie Euler, 908-276-4344 ext. 213  
Susan Denby, 610-997-4856

**FOR IMMEDIATE RELEASE** --Irvine, CA -- March 21, 2008 --- B. Braun Medical Inc. was recently notified by its supplier, Scientific Protein Laboratories LLC (SPL) of a nationwide recall of Heparin Sodium USP active pharmaceutical ingredient (API). The voluntary recall affects the following 23 Finished Product (FP) lots manufactured and distributed by B. Braun Medical Inc. nationwide and to Canada.

B. Braun FP Lot #	B. Braun FP Material	Description	NDC Numbers	CAN DIN
J7D490	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7C684	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7D496	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7C470	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7D580	P5671-00	Heparin Sodium 20,000 Units in 5% Dextrose Injection (500mL)	N/A	02209713
J7E420	P5872-00	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	N/A	02209721
J7C611	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933

J7C557	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7C477	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7C705	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7D485	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E415	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E416	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7E494	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7E500	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7E577	P5771-00	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	N/A	01935941
J7E489	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7N556	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7P404	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7N604	P5771	Heparin Sodium 25,000 Units in 5% Dextrose Injection (500mL)	0264-9577-10	N/A
J7P476	P5872	Heparin Sodium 25,000 Units in 5% Dextrose Injection (250mL)	0264-9587-20	N/A
J7N519	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933
J7N676	P8721	Heparin Sodium 1000 Units in 0.9% Sodium Chloride Injection (500mL)	0264-9872-10	01935933

B. Braun Medical Inc. began recalling the lots on March 21, 2008 as a precautionary measure. This product recall was initiated due to a notification received from the supplier, Scientific Protein Laboratories (SPL), disclosing that one lot of Heparin Sodium, USP Active

Pharmaceutical Ingredient acquired by B. Braun Medical Inc. has a heparin-like contaminant. To date, B. Braun Medical Inc. has not received any adverse event reports related to this issue.

The Food and Drug Administration has received reports of serious injuries and/or deaths in patients who have been administered Heparin injectable products of other companies containing this contaminant. As indicated in the notification issued by the supplier SPL, typical symptoms include anaphylactic-like reactions such as low blood pressure, shortness of breath, nausea, vomiting, diarrhea and abdominal pain.

Adverse reactions or quality problems experienced in the U.S. with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm).  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178

Adverse reactions or quality problems experienced in Canada with use of this product may be reported to Health Canada. For details on how to report these reactions please refer to the following website:

- **Online:** [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index_e.html)

Customers who have product in their possession from the recalled product lots should discontinue use immediately. Patients reporting any problems that may be related to the use of this product should be advised to contact a physician. Customers may contact B. Braun Medical Inc. Customer Support Department at (800) 227-2862 for U.S. and (800) 624-2920 for Canada, Monday through Friday, 8 AM to 7 PM EST for instructions for handling the affected product and to arrange for replacement product.

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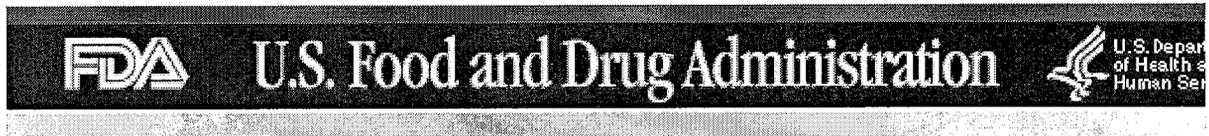
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### Covidien Initiates Voluntary Recall of Pre-Filled Syringes Containing Heparin

**Contact:**  
Eric Kraus  
508-261-8305

**FOR IMMEDIATE RELEASE -- MANSFIELD, Massachusetts -- March 28, 2008 -**  
Covidien, formerly Tyco Healthcare, was recently notified by its supplier, Scientific Protein Laboratories LLC (SPL), of a nation-wide recall of Heparin Sodium USP active pharmaceutical ingredient. The voluntary recall affects the following 32 lots manufactured and distributed by Covidien in the United States.

Product	Lot Numbers
REF # 8881580121 Monoject PreFillTM 10U/mL Heparin Lock Flush Syringe, 10mL	7082274 7113214
REF # 8881580123 Monoject PreFillTM 10U/mL Heparin Lock Flush Syringe, 3mL	7051524 7113214
REF # 8881580125 Monoject PreFillTM 10U/mL Heparin Lock Flush Syringe 5mL	7051524 7082274 7113164 7113174
REF # 8881580300 Monoject PreFillTM 10U/mL Heparin Lock Flush Syringe 2.5mL in 3mL syringe	7051444
REF # 8881581125 Monoject PreFillTM 10U/mL Heparin Lock Flush Syringe 5mL, with BLUNTIP plastic cannula	7082274
REF # 8881590121 Monoject PreFillTM 100U/mL Heparin Lock Flush Syringe 10mL	7113064
REF # 8881590123 Monoject PreFillTM 100U/mL Heparin Lock Flush Syringe 3mL	7041194 7072154 7113034 8010194
REF # 8881590125 Monoject PreFillTM 100U/mL Heparin Lock Flush Syringe 5mL	7041194 7102804 7041204 7113034

	7051534
	7113044
	7051544
	7113054
	7051554
	7113104
	7071924
	7113114
	7072034
	7113154
	7072044
	8010064
	7072054
	8010114
	7072064
	8010134
	7072154
	8010174
	7082284
REF # 8881591125 Monoject PreFill™ 100U/mL Heparin Lock Flush Syringe 5mL, with BLUNTIP plastic cannula	7082284

Covidien began recalling the lots today as a precautionary measure. This product recall was initiated due to a notification received from the supplier, SPL, disclosing that two lots of Heparin Sodium USP Active Pharmaceutical Ingredient acquired by Covidien had a heparin-like contaminant. To date, Covidien has not received any adverse event reports related to this issue. Although a very small product line for Covidien, the Company is committed to following the direction of the Food and Drug Administration (FDA) regarding this matter.

The FDA has received reports of serious injuries and/or deaths in patients who have been administered Heparin injectable products of other companies containing this contaminant. As indicated in the notification issued by the supplier SPL, typical symptoms include anaphylactic-like reactions such as low blood pressure, shortness of breath, nausea, vomiting, diarrhea and abdominal pain.

Adverse reactions or quality problems experienced in the U.S. with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Customers who have product in their possession from the recalled product lots should discontinue use immediately. Patients reporting any problems that may be related to the use of this product should be advised to contact a physician. Customers with questions about the return of recalled product should contact the Return Coordinator at 1-800-346-7197, ext. 8677, between 8:30am – 5:00pm (ET), Monday through Friday.

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## Information on Adverse Event Reports and Heparin

- The chart below shows numbers of deaths reported after heparin administration that occurred and were submitted to FDA over the last fifteen months (i.e., from January 1, 2007 through March 31, 2008).
  - The reports are sorted according to the date of the medical event in the report, indicated in the first column. This date may be different than the date of death.
  - The second column indicates the number of deaths reported after heparin administration, regardless of cause.
  - The third column indicates the number of death reports that included one or more allergic symptom(s) or symptoms of hypotension (low blood pressure). These are the events that prompted a series of heparin recalls.
  - There have been 103 reports of death since January 1, 2007; 91 were reported to FDA on or after January 1, 2008.
  - Of the 62 reports of death that included one or more allergic symptom(s) or symptoms of hypotension, 56 were reported to FDA on or after January 1, 2008.
  - The fact that allergic symptoms or hypotension was reported does not mean that these were the cause of death in all cases.
  - FDA received reports of 41 patients who died without mention of allergy or hypotension. These patients died of a variety of causes.

Number of Deaths of Patients Receiving Heparin Reported to FDA, January 1, 2007 through March 31, 2008		
Month the Medical Event(s) Occurred	Number of Reported Deaths*	Reported Deaths with One or More Allergic/Hypotensive Symptom(s)
Jan-07	3	1
Feb-07	1	1
Mar-07	4	2
Apr-07	2	2

May-07	1	0
Jun-07	3	1
Jul-07	4	2
Aug-07	1	1
Sep-07	1	1
Oct-07	6	2
Nov-07	9	8
Dec-07	20	12
Jan-08	24	16
Feb-08	20	11
Mar-08	0	0
Unknown date	4	2
Total	103	62
*The reports in this table concern heparin produced by any manufacturer.		

- For comparison purposes, FDA reviewed the reports it received for all deaths of patients in whom heparin was listed as a potentially suspect drug in 2006.
  - A total of 55 deaths were reported from January 1, 2006 to December 31, 2006 - an average of four or five per month.
  - Across these 55 reports of death, there were a variety of underlying medical conditions.
  - Three of the reports listed allergic reactions or hypotension (low blood pressure) as a medical event, similar events to the cases that prompted the heparin recall in 2008.

<b>Number of Deaths of Patients Receiving Heparin Reported to FDA, January 1, 2006 through December 31, 2006</b>		
<b>Year the Medical Event(s) Occurred</b>	<b>Number of Reported Deaths*</b>	<b>Reports with One or More Allergic/Hypotensive Symptom(s)</b>
2006	55	3
* The reports in this table concern heparin produced by any manufacturer.		

- FDA continues to receive reports of adverse events occurring after heparin administration.
  - FDA will analyze these and all other reports of adverse events after heparin administration.
  - FDA will update the data on this website on a periodic basis.

- Patients, consumers, physicians, nurses, pharmacists, and others can report adverse events either directly to the FDA via the MedWatch program (<http://www.fda.gov/medwatch/>) or to the drug product's manufacturer.
  - FDA receives approximately 400,000 reports of adverse events per year.
  - The majority of these (over 90%) come from manufacturers.
- The public can send reports of adverse events to FDA or the manufacturer any time after the event occurs.
  - In some cases, the report is sent to FDA or the manufacturer several months or more after the event has occurred.
  - After there is a lot of media attention to a particular adverse event, more reports of similar adverse events are often submitted.
- The fact that someone reports an adverse event does not necessarily mean that a specific drug caused the medical event or death.
  - Reports have to be analyzed to see if there is a plausible causal association between the drug and the medical event.
  - It is often not possible to tell in an individual case if there is a causal relationship between the drug and the medical event or death.
  - Many patients have other serious conditions that could have caused the reported problem.

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