Public Interest Law Reporter

Volume 14
Issue 1 *Fall 2008*

Article 17

2008

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LAWSUITS OVER TAINTED HEPARIN MANUFACTURED IN CHINA: IS THE FDA BECOMING THE GLOBAL HEALTHCARE AUTHORITY?

by **Christina Laga**

Safety concerns over the integrity of drugs imported into the United States has put pressure on the Food and Drug Administration (FDA) to boost its international presence. After a spike in heparin related deaths in 2008, the FDA discovered that the U.S. had imported tainted heparin from Chinese manufacturers.[1]

Heparin is a blood thinner given to dialysis and surgery patients to prevent blood clotting in veins, arteries, or lungs.[2] Approximately 12 million Americans, or 1/3 of hospitalized patients, use the drug heparin each year.[3] According to the FDA, 161 deaths reported from November 2007 until May 2008 may possibly be linked to the tainted heparin.[4] By juxtaposing this 2007-2008 heparin death count against the 55 reported heparin related deaths in the year 2006, the magnitude of heparin deaths becomes evident.[5]

In the wake of this heparin recall, more than 40 products liability lawsuits have been filed in both federal and state courts on behalf of patients who allegedly were injured or died as a result of using the tainted heparing.[6] These complaints have primarily targeted Baxter International, Inc (Baxter), one of the largest heparin manufacturers, as well as heparin distributors and suppliers.[7] Due to the number of heparin cases filed and in an effort to facilitate discovery, on June 9, 2008, all 27 federal heparin cases were consolidated and transferred to the Honorable Chief Judge James G. Carr of the U.S. District Court of the Northern District of Ohio.[8] Further, given the complex nature of the heparin cases, the Chief Judge Carr has appointed several lawyers to a steering committee to oversee this multi-district litigation.[9] This is a common procedure in complex products liability lawsuits or other cases where many people allege injuries as a result of the same act or series of acts.[10]

The Consolidated Heparin Products Liability Litigation: What Do the Parties Allege?

David Zoll, a partner at Toledo, Ohio-based Zoll, Kranz & Borgess, has taken on the role of liaison counsel in the consolidated heparin litigation. As liaison counsel, Zoll has responsibility for facilitating communications between the respective parties and the court. According to Zoll, the plaintiffs allege that they were injured and even killed after being given heparin that contained a counterfeit active ingredient.[11] FDA officials identified the chemical as "oversulfated chondroitin sulfate."[12] The FDA believes this chemical was added to allow the substance to pass tests measuring heparin levels.[13] As for future litigation, Zoll expects that 300 to 700 claims related to the tainted heparin will eventually be brought.[14]

Baxter's defense attorney, Leslie Smith, a partner at Chicago's Kirkland & Ellis, could not comment directly.[15] However, in an e-mailed statement, Erin

Gardiner, a Baxter spokeswoman, stated that products liability suits generally involve allegation of a design defect, manufacturing defect or failure to warn.[16] In this case, Gardiner said that the tainted heparin resulted from "deliberate and sophisticated tampering" which evaded Baxter's internal drug tests.[17]

How Does the Heparin Products Liability Litigation Compare to Previous Products Liability Lawsuits?

In contrast to past pharmaceutical tort litigation, the heparin lawsuits are the first to involve pharmaceutical drug ties to China.[18] After news broke of the tainted heparin, FDA officials inspected the Chinese factory, Changzhou SPL, which supplied the raw ingredient derived from pig intestines used in Baxter's recalled heparin.[19] The FDA told Changzhou SPL that the factory had "significant deviations" from proper manufacturing processes.[20] The heparin connection to China has a potential to sway juries in favor of the plaintiffs, says Jeffrey Killino, a partner at Philadelphia's Woloshin & Killino, who filed one of the consolidated heparin lawsuits on behalf of a plaintiff.[21] Killino stated that "[j]uries are outraged about what happened in China."[22]

Another major difference in previous products liability suits stems from the fact that the heparin litigation has strategically steered away from claims for "failure to warn" of a drug's possible risks, because the theory has proven unsuccessful.[23] For example, recently in *Riegel v. Medtronic*, the U.S. Supreme Court dismissed a failure to warn argument in a products liability claim against a medical device manufacturer by upholding federal preemption.[24] In *Riegel*, the Court ruled that Congress's pre-market FDA approval process for medical devices such as Medtronic's pacemakers, expressly preempted or barred injured patients from filing lawsuits against device makers.[25]

Mark Robinson of Newport Beach, California's Robinson, Calcagnie & Robinson, and a member of the steering committee in the consolidated heparin litigation stated that preemption defenses by pharmaceutical companies have "little or no relevance in cases involving manufacturing defects [such as the heparin litigation], which allege entirely different claims."[26] Similarly, Zoll argued that Baxter has a weak federal preemption defense because (1) the heparin litigation alleges product defect claims rather than "failure to warn" claims and (2) the FDA never approved of the active pharmaceutical ingredient (API) used in Baxter's final heparin products.[27]

Measures Taken in Response to Heparin Litigation

Concerns over regulating Chinese drugs imported into the U.S. have become so intense that in October, the Health and Human Services (HHS) Secretary, Michael O. Leavitt, announced that the FDA would open its first offices overseas.[28] HHS Secretary Leavitt declared that "[w]e're making steady progress to better safeguard our supply of food and medicines."[29] To reinforce this declaration, in mid-November, FDA opened offices in Beijing, Shanghai, and Guangzhou, China with offices expected to open in India, Europe and Latin America by the end of the year.[30]

With this overseas office expansion, the question arises as to whether this is the best use of U.S. taxpayer funds allotted to the FDA. Given that over 450,000 American ingest heparin regularly as part of their dialysis regimen and tens of thousands more take heparin for other reasons, the safety of this drug rivals other issues of national security.[31] Thus, on one hand, having inspectors available 365 days a year at foreign manufacturing sites will theoretically improve safety of hundreds of thousands of Americans.[32] Yet, pharmaceutical companies now have the opportunity to buy drug ingredients at lower prices in China while U.S. taxpayers foot the bill for the additional safety inspections necessary to ensure the proper drug quality.[33]

While opening FDA offices overseas may come at a monetary cost to U.S. taxpayers, the risk of not inspecting foreign manufacturing plants may outweigh this cost. Heparin has not been the only unsafe product manufactured in China.[34] This fall, four Chinese babies died and 53,000 were sickened by melamine, a toxic chemical illegally added to watered-down baby formula, thereby artificially increasing the protein count and fooling quality tests.[35] Although no melamine tainted baby formula has been found in the U.S., other countries did import the product.[36] Yet, the list of tainted products exported from China does not end there. In recent years, China has exported poisonous toothpaste, deadly dog food, toys made with lead paint and tainted fish.[37] Therefore, with evidence mounting of China's less stringent manufacturing quality controls, it will be interesting whether the FDA continues to expand its role as a global health care authority to ensure the safety of U.S. imports.

Notes

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3 Heparin-Induced Thrombocytopenia: One of the Most Important Immunohematologic Problems in Clinical Medicine, http://www.argatroban.com/argatroban_aboutHIT.htm (last visited Dec. 1, 2008).

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5 *Id.*

6 Amanda Bronstad, *Defective Drug Manufacturing Claims, Preemption, Heparin and China Connections,* Nat'l L.J., July 21, 2008.

7 *Id.*; In re: Heparin Prods. Liab. Litig., MDL No. 1953 (N.D. Ohio July 28, 2008) (No. 1:08-hc-60000) (Pre-Trial Order No.2), *available at* http://www.toledolaw.com/hep/HeparinMDLPTO2.pdf.

8 *Heparin MDL Created, Sent to Ohio Federal Court*, Mealey's Emerging Drugs & Devices, June 9, 2008, at 1 (LexisNexis); *see* In re: Heparin Prods. Liab. Litig., MDL No. 1953 (N.D. Ohio July 28, 2008) (No. 1:08-hc-60000) (Transfer Order), *available at* http://www.toledolaw.com/pdf/1953.pdf.

9 Federal Heparin Lawsuits Consolidated in Toledo, http://www.aboutlawsuits.com/federal-heparin-lawsuits-consolidated-191/.

10 *Id.*

11 *Id.*; Telephone Interview with David Zoll, Partner, Zoll, Kranz & Borgess, in Chicago, Ill. (Oct. 31, 2008).

12 Elizabeth Weise, *FDA Sends in Federal Marshals to Seize Tainted Heparin*, U.S.A. Today, Nov. 6, 2008, *available at* http://www.usatoday.com/news/health/2008-11-06-heparin-contaminated_N.htm.

13 *Id.*

14 Telephone Interview with David Zoll, *supra* note 11.

15 Telephone Interview with Leslie Smith, Partner, Kirkland & Ellis, in Chicago, Ill. (Oct. 27, 2008).

16 Bronstad, *supra* note 6.

17 *Id.*

18 Bronstad, *supra* note 6.

19 The Associate Press, *China and U.S. Disagree Over Heparin*, N.Y. Times, Apr. 21, 2008, *available at* http://www.nytimes.com/2008/04/21/business/apee-heparin.html.

20 *Id.*

21 Bronstad, *supra* note 6.

22 *Id.*

23 *Id.*

24 Riegal v. Medtronic, Inc., 128 S. Ct. 999, 1001, 1011 (2008).

25 Brendan Borrell, *What is Preemption, and What Does it Mean for Drug Lawsuits?*, Scientific American, Nov. 4, 2008, *available at* http://www.sciam.com/article.cfm?id=what-is-preemption-drug-lawsuit&page=2.

26 Bronstad, *supra* note 6.
27 Telephone Interview with David Zoll, *supra* note 11.
28 Press Release, U.S. Dep't of Health & Human Servs., *HHS Preparing to Open FDA Offices in China, India, Europe, and Latin America This Year* (Oct. 16, 2008), http://www.hhs.gov/news/press/2008pres/10/20081016a.html.
29 *Id.*
30 Lucy Hornby, *U.S. Says Food, Drug Inspection Access in China Improving*, REUTERS, Nov. 19, 2008, http://www.reuters.com/article/worldNews/idUSTRE4AI24320081119.
31 Louis Klarevas, *Food: An Issue of National Security*, FORBES, Oct. 25, 2008, http://www.forbes.com/opinions/2008/10/24/food-national-security-oped-cx_lk_1025klarevas.html.
32 U.S. Dep't of Health & Human Servs., *supra* note 28.
33 Telephone Interview with David Zoll, *supra* note 11.
34 Harris, *supra* note 2.
35 *Id.*
36 *Id.*
37 *Id.*