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Baxter Rival APP Steps In Quickly To Supply Heparin

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As Baxter International Inc. struggles to understand the cause of hundreds of allergic reactions in patients who took its heparin blood thinner, a leading competitor, APP Pharmaceuticals Inc., is making fast inroads to steer the market in its direction.

Some major hospitals and a chain of 1,600 U.S. kidney-dialysis centers run by Fresenius Medical Care North America, a unit of Germany's Fresenius Medical Care AG , already have switched over to buying exclusively from APP, which is rapidly ramping up its production. The Food and Drug Administration, which has said it never inspected a Chinese plant that was the source for much of the active ingredient in Baxter's drug, confirmed yesterday that it had inspected the Chinese operation that produces some active ingredient for APP and plans to inspect the Baxter supplier's Chinese operation this week.

The agency said that, to its knowledge, only two Chinese plants are making the active ingredient in heparin for the U.S. market.

Baxter, which supplies about half the U.S. heparin market, said last week it had temporarily stopped production because of about 350 bad reactions, including four fatalities, potentially tied to the drug. About 40% of the reactions were classified as serious, ranging from stomach pain to vomiting and diarrhea, low blood pressure, speeding heartbeats and fainting.

Yesterday the FDA said it is inspecting a Cherry Hill, N.J., Baxter facility and the Waunakee, Wis., plant of Baxter's supplier, Scientific Protein Laboratories LLC. Scientific Protein's Chinese joint venture, Changzhou SPL in Changzhou, China, will be examined closely by a team that will include manufacturing experts and a Chinese-speaking chemist.

But the agency said it doesn't know the cause of the heparin reactions potentially tied to Baxter's drug. Baxter said earlier it was focused on differences among batches of the heparin. It offered few details, but yesterday Baxter disclosed that the variations from standard product occurred in the Chinese-made batches.

FDA officials also yesterday offered new details of how the agency failed to inspect the Changzhou SPL plant. Joseph Famulare, deputy director of the FDA drug center's office of compliance, said the name of the operation "that was sent to the office of compliance for evaluation was not the correct firm.

It was another firm with a similar name," which had been inspected and found to be in compliance. So the Changzhou SPL plant wasn't put in the proper database and "was not put forward for evaluation," Mr. Famulare said, adding that the discrepancy had been found "within the last month" and the agency believes it is an "isolated situation."

However, the slipup is likely to become the focus of congressional scrutiny, because various investigations on Capitol Hill already are considering the FDA's broader problems with information technology and difficulty in tracking foreign makers of drugs, devices and food.

The FDA acted quickly to approve the new APP production lines because of the threat of a national shortage of the blood-thinning medication, used in millions of heart operations and kidney dialysis center procedures each year, APP said. APP has now arranged new production lines at its Grand Island, N.Y., plant. With production at its Melrose Park, Ill., plant as well, APP has said it now is ready to supply the entire U.S. market's needs for heparin.

For APP, Baxter's troubles present a marketing opportunity. APP, of Schaumburg, Ill., recently spun off its biotech business but said in a November filing that it expects pro forma revenue for the remaining company to be approximately $630 million for 2007. A spokeswoman, Maili Bergman, said, "We expect to have a fair increase in our heparin business."

A Baxter spokeswoman, Erin Gardiner, said she can't comment on any recent changes in market share, but noted that heparin makes up less than 1% of Baxter's corporate sales.

Marc Moreau, senior director of materials management at Fresenius, said, "We're no longer ordering Baxter heparin at this point. We are using just the APP product." Fresenius has 120,000 dialysis patients who get treatments three times a week, and is among the largest purchasers of heparin. Its chief medical officer, Mike Lazarus, said the Baxter recall and subsequent announcements "created a small crisis in our clinics."

While hospitals theoretically can switch to other blood thinners, heparin is strongly preferred, both because it costs relatively little and its effects can be quickly reversed. The University of Alabama at Birmingham, for instance, already has switched over to APP heparin. Its move began with Baxter's Jan. 17 announcement of its heparin recall, which at that time covered nine specific batches of heparin and certain limited large dosages.

UAB Medical Center is among 100 academic hospitals and about 2,000 community hospitals of the Voluntary Hospital Association chain that are

members of the Novation LLC purchasing group. After taking bids from Baxter and APP, Novation had signed a sole-source purchasing agreement with Baxter last Sept. 30.

Patrick Condon, a senior pharmacist at UAB, said Novation has left it up to individual hospitals how to respond. He said UAB, for now at least, has decided to switch over entirely to APP heparin. He contacted a big drug distributor and obtained a three-month supply of APP product, largely to fill the hole left when UAB decided not to use its Baxter inventory. Mr. Condon said he has begun arranging 12-day supplies directly from APP and plans to do so each week until the hospital builds up inventory to its normal level. Elizabeth Ashby, a product manager for Novation, said the group is negotiating with APP for a two-year supply agreement.

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