

Hemophilia Drug Requires Applications

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Unable to manufacture enough of a new drug for hemophiliacs, the Bayer Corporation has taken the unusual step of asking patients to apply for the drug through a corporate program rather than getting it from a pharmacy or another distributor.

Under the company's new program, patients will fill out an application, including details of their medical history and their insurance coverage, and submit it with a prescription. If the patient is accepted, the program will deliver the new drug, Kogenate FS, directly to the patients. The first ones approved will get the drug first, with others put on a waiting list.

Bayer and doctors who treat hemophiliacs expect that for the foreseeable future demand for the new drug will greatly exceed the amount of Kogenate FS the company is able to make.

The new drug is a synthetic, genetically engineered version of the naturally occurring coagulation protein that is missing or deficient in people with hemophilia A, a condition affecting about 13,000 Americans. It can cost patients as much as \$150,000 a year, according to the National Hemophilia Foundation, the nation's largest advocacy group for hemophiliacs.

Bayer executives said yesterday that they set up the unusual program because they did not want extra inventory of the drug held at pharmacies when it was in short supply.

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"We believe that we are pioneering and finding a novel alternative to a distribution system that does not work," said Terry Tenbrunsel, vice president for sales and marketing at Bayer's U.S. operations.

But Bayer's new distribution program has angered doctors and advocates for hemophiliacs at the foundation. Leaders of the foundation said yesterday that there was already a shortage of the two other synthetic versions of the drug, known as blood-clotting factors.

The foundation's leaders said they feared that Bayer would accept patients based on their insurance coverage, which could leave out poor people on Medicaid and those without insurance.

"This is going to be about who has the best insurance," said Stephen E. Bajardi, the foundation's executive director.

But Bayer denied those assertions. Mr. Tenbrunsel said the program would evaluate the patients' applications and verify the insurance coverage just as a pharmacy or a home-care company would.

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"It is a blind process," he said. "It doesn't matter what is the basis of your insurance coverage."

Stephen W. Schondelmeyer, a professor of pharmaceutical economics at the University of Minnesota, said Bayer's new program, known as Bayer Direct, is unusual for the drug industry, but not unique.

Dr. Schondelmeyer said that when some early AIDS drugs were first approved, the drug companies distributed them through a limited number of mail-order companies. He said the program did not appear unreasonable as long as it was used only in the short term. Long

term, the company should be able to find a way to meet demand, he said, and the regular distribution system should be used.

"This limits the marketplace from working," Dr. Schondelmeyer said. "Consumers can't go look for the drug at pharmacies and hospitals and get a better deal."

Kogenate FS is the new version of Bayer's Kogenate, a synthetic clotting factor that has been sold for several years, and will be priced similarly, Bayer said. Kogenate, which will be phased out, and another synthetic clotting factor, made by Baxter, have been popular with hemophiliacs because older drugs were made with human blood. In the 1980's, many hemophiliacs contracted hepatitis C, a potentially fatal liver infection, while taking the old drugs. Many also contracted H.I.V.

While Kogenate was a synthetic drug, it still contained albumin, a human protein that comes from blood. The new drug, Kogenate FS, contains one-thousandth the amount of albumin of Kogenate, and the company says that will reduce the potential risk of transmitting viruses to the patient.

Dr. Jeanne Lusher, a pediatric hematologist at the Children's Hospital of Michigan, said many patients now get their drugs through one of the companies that deliver drugs directly to homes. "That has worked very well," said Dr. Lusher, who also sits on the foundation's board. "This new program is really frightening to some patients."

Bayer has hired Express Scripts, a pharmacy benefit management company in Maryland Heights, Mo., to process the applications and deliver the drug. Bayer said that its factory, working 24 hours a day, can now produce enough of the drug for about 700 people. Bayer said it had applied to the Food and Drug Administration to double the capacity of certain equipment in the factory, which would let the company double the supply of the drug.