Pressure Builds to Untie the FDA’s Hands on Generics: High Drug Prices Still Fuel Public—Hence Political—Pressure

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Merck’s decision to reduce the price of cholesterol-lowering simvastatin (Zocor) in the face of first-time generic competition from Teva Pharmaceuticals may be red meat for the congressional advocates of faster approval of generic versions of both chemical and biotech innovator drugs. And those forces may get a bigger boost still when Sandoz announces its pricing strategy for Omnitrope, an ostensible generic copy of Pfizer’s bioengineered growth hormone Genotropin—although the Food and Drug Administration (FDA) calls it a follow-on protein. The FDA approved Omnitrope at the end of May, the first time the agency approved a generic company’s biopharmaceutical product based on an abbreviated 505(b)(2) application that was submitted by a generic company.

Members of both political parties, on both sides of the Capitol, are anxious to increase the number of generic versions of brand-name drugs that are available. That is no secret. But the FDA has been unaccommodating in some instances—a position that charitable observers might attribute to forces beyond the agency’s control. The fact that a major brand-name company like Merck would actually price a “just-off,” patented, brand-name product like Zocor below generic versions may convince Congress, already deeply concerned about drug costs, to sweep aside some of those “forces” that have tied the FDA’s hands.

One constraint faced by the FDA is the Citizen Petitions, which brand-name drug companies file with the agency after a generic company files an application for approval of a generic drug. These petitions, in effect, force the FDA to interrupt that generic application and to conduct a detailed, time-consuming legal analysis of the issues raised in the petition.

Short-circuiting these petitions is one of the objectives sponsored by Senator Debbie Stabenow (D-Mich.). The “Lower Prices Reduced with Increased Competition and Efficient Development of Drugs Act” is one of many long-winded bills that are generally titled in such a way as to ensure a catchy acronym; this one is the “Lower PRICED Drugs Act.”

Senator Stabenow and Senator Trent Lott (R-Miss.), the other sponsor of the bill, sent a letter in June to FDA Acting Commissioner Andrew von Eschenbach complaining about the FDA’s failure to approve Impax Laboratories’ generic version of Wellbutrin XL, the antidepressant marketed by Biovail Corp. Wellbutrin’s patent expired last year, and Impax had submitted a generic application well in advance of that expiration, only to see Biovail submit a Citizen Petition, which has delayed the FDA’s consideration of Impax’s application. Senators Stabenow and Lott estimate that the delay in approving generic Wellbutrin XL is costing consumers $37 million a month.

Perhaps not coincidentally, given the frequency of their filing, a Citizen Petition filed by Pfizer slowed down FDA’s consideration of Omnitrope. The FDA does not approve generic versions of biopharmaceuticals; it does approve follow-on proteins, six of which had been previously approved under the 505(b)(2) application process. All of those products, though, were submitted by the innovator companies that sold the original drug.

The FDA’s approval of Omnitrope at the very end of May was the first time a generic company won a 505(b)(2) approval. Pfizer, Genentech, and the Biotechnology Industry Organization had filed Citizen Petitions arguing that the FDA could not approve a generic company’s follow-on protein application—which, through the 505(b)(2) process, can include limited data—because that would entail looking at the brand-name company’s clinical and manufacturing data for its product. The generic company would then be relying on this proprietary information to some extent.

The FDA obviously disagreed. In doing so, it opens the door for the approval of other follow-on proteins from other generic companies, mostly in the human growth hormone and insulin categories. Moreover, the FDA may now feel freer to publish guidance on the 505(b)(2) process that it has been delaying because of the brand-name Citizen Petitions.

Senator Orrin Hatch (R-Utah) and Representative Henry Waxman (D-Calif.), who teamed up for the pioneering 1984 Drug Price Competition and the Patent Term Restoration Act (the Hatch–Waxman Act) have been pressing the FDA to issue that guidance. According to an FDA spokeswoman, the agency has no time frame in which to issue the guidance. Pete Carr, Mr. Hatch’s spokesman, says the senator has been working on legislation for some time. This would force the agency’s hand, but Senator Hatch doesn’t appear to be in much of a rush, either.

Mr. Waxman, of course, is in the wrong party to make much happen; however, he has been active hectoring the FDA on generic drug matters, and even drug manufacturers directly, about both brand-name and generic products. He and Senator Charles Schumer (D-N.Y.) asked the generic and innovator trade groups—the Generic Pharmaceutical Association (GPhA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), respectively—to take a strong public stance against the recent dramatic rise in legal settlements in which pharmaceutical companies pay off generic drug companies to keep cheaper generic products off the market.

Senators Schumer and John McCain (R-Ariz.) are sponsors of the Greater Access to Affordable Pharmaceuticals Act, which was passed in 2003 and which closed some loopholes. Look for Congress to make more pro-generic changes in 2007 as part of the reauthorization of the Prescription Drug Users Fee Act.