FDA Commissioner Champions Generics in the World of Complex Drugs

On the campaign trail, one of then-candidate Trump's many promises was the promise to slash the price of prescription drugs. Since that issue doesn't appear in his Twitter feed, it's impossible to guess whether it's on his mind now. But his appointee as U.S. Food and Drug Administration (FDA) Commissioner, Dr. Scott Gottlieb, is looking at ways to lower high costs on medicines that are difficult to make. Gottlieb's answer? Generics.

Because historically developing a close replica to a complex, expensive drug on the market and then jumping through the hoops to getting that drug approved can be a long and arduous process, generic drug manufacturers might not have an incentive to even attempt it, according to Gottlieb.

Complex drugs hold complex challenges for generic drug manufacturers

Generic drugmakers must of course demonstrate that their product contains the same active ingredient as the brand-name prototype. They must also show that their drug is bioequivalent to the original. The latter measure can be tricky to prove when it comes to genericizing complex drugs and drug-device combinations (such as injectable drugs), especially when the drug can't be readily detected in the patient's blood.

In a recent FDA blog post, Gottlieb further explained that when the generic medication contains more than one active molecule, demonstrating bioequivalence can also be difficult.

"These challenges – and resulting regulatory uncertainties – may deter generic manufacturers from beginning development," Gottlieb wrote. "It can mean these ANDAs [abbreviated new drug applications] undergo more review cycles than other generic drugs. These hurdles, in turn, may result in limited competition and higher prices."

FDA will provide guidance to smooth out some approval wrinkles

Gottlieb announced the FDA's plan to shrink some of the red tape generic drugmakers face in getting these complex product substitutes to market. The agency will offer guidance to generic companies on ways to earn product approvals and incentivize drugmakers to travel this path, as well as decrease the time from application to approval. This guidance will include meetings between FDA staff and the drug companies.

The price range of complex drugs without generic equivalents that Gottlieb mentions in his post starts at $400 per month (for the Advair inhaler) to $5,200 per month (for the injectable Copaxone, used to treat multiple sclerosis). Other meds that appear in Gottlieb's post are the injectables Forteo (used to treat osteoporosis) and Victoza (used to treat high blood sugar).

(A generic form of Copaxone met FDA approval two years ago; however, it is not yet on the market because the generic manufacturer has failed to fulfill the agency's standards for production.)

Gottlieb also touched upon the agency's intention to ameliorate the problem of some products' inability to "be measured through traditional in vivo bioequivalence methods." In these cases, rigorous clinical endpoint testing is required. The FDA's generic drug regulatory science program seeks to come up with replacements to clinical endpoint testing in these instances. Gottlieb cited "a series of important scientific workshops" that the FDA has gotten underway with the goal of expanding the development of generics for complex drugs.

Commissioner looks to speed, savings and sales

Gottlieb wrote that main purposes of this work are to hasten the creation of products that can serve as generic

equivalents for complex drugs, to lower the expense of developing these products (which ideally will result in less expensive medications for the consumers), and also, to provide more ready availability to these products.

And for those critics who might accuse the FDA of cutting quality corners while widening pathways for the production of generic complex drugs, Gottlieb includes reassurance on the agency's blog:

"We're doing all of this without sacrificing the scientific rigor of the process one bit. A central aspect of our approach, and our efforts to spur innovation and generic competition, is focused on adopting more rigorous and sophisticated science, including sophisticated quantitative methods and computational modeling, in drug development, evaluation, and review."