Can Policies at the FDA Help Curb Rising Drug Prices?

In a recent blog post, Scott Gottlieb, the Commissioner of the Food and Drug Administration (FDA), signaled that the FDA would take a more proactive approach to approving drugs to attempt to increase competition in the pharmaceutical market. In the post, Gottlieb acknowledged that the "FDA doesn't control drug pricing, [but] our policies do affect competition in the market. This is the nexus of our current efforts on drug pricing."

Details of the Announcement

In his blog post, Gottlieb describes two draft guidances to aid in the approval of generic equivalents for complex drug and drug-device combination products. Gottlieb defines complex drugs as those that "have at least one feature that makes them harder to 'genericize' under our traditional approaches," including injectable drugs and metered dose inhalers for asthma.

The first draft guidance details, clarifies, and encourages earlier and more frequent meetings between the FDA and a generic manufacturer to help streamline the approval process. The second draft guidance specifically encourages generic development of five peptide drugs.[1] Peptide drugs are comprised of fewer than 40 amino acids and can be either synthesized directly or made by recombinant DNA technology.

The second draft guidance details how generic manufacturers can demonstrate equivalency between the two methods of manufacturing and allow the drugs to be approved by the Abbreviated New Drug Application (ANDA) pathway even if it is manufactured differently from the branded drug. Gottlieb explains that "this guidance represents how advances in

regulatory science – when coupled with careful policy considerations – can enable generic drug development that was previously infeasible." Specifically, advances in peptide synthesis and characterization allow the FDA additional methods for assessing whether a generic equivalent is the same as, i.e. therapeutically equivalent to, a branded drug.

According to Gottlieb, the draft guidances issued earlier this month are just the start of a broader effort by the FDA to enable more generic competition to reduce prices and increase access to needed medications. A third draft guidance, issued last week, helps industry determine when to file an ANDA and a 505(b)(2) application. A 505(b)(2) application is similar to an ANDA and is used when a new drug product differs slightly from a reference or brand drug (e.g., in dosage form or conditions of use). The FDA issued this guidance to "familiarize potential drug product developers with these abbreviated pathways" and streamline the approval process for products that can use these applications.

FDA's Action Plan: Increasing Drug Competition

These draft guidances come at the same time the FDA approved a record number of ANDAs (763 approvals in 2017). The number of ANDA approvals has been increasing by nearly 20% every year since 2014, when the Generic Drug User Fee Amendments (GDUFA) allowed the FDA to hire nearly 1,000 new employees to decrease a backlog of generic drug applications.

When a generic equivalent is approved, the branded drug faces direct competition. Further, state substitution laws ensure that, when appropriate, pharmacists substitute the less expensive generic medication for the branded drug. As a result, once a generic competitor enters the market, the branded drug typically loses a substantial share of the market. For example, Grabowski and colleagues analyzed drugs for which a generic equivalent was released between 2003 and 2012 and found that the average market share of the brand drug

dropped to approximately 20% of its original value.[2] A study by the IMS Institute for Healthcare Informatics found that, on average, prices for branded drugs fall 51% in the first year that a generic equivalent is released and 74% by the second year. As a result, if the FDA can streamline the approvals of generics, the costs for drugs should decrease substantially as the patents and FDA-granted exclusivities expire.

Conclusion

The recent blog post by FDA Commissioner, Scott Gottlieb, and new draft guidances demonstrate the FDA's willingness to use additional scientific and clinical evidence in making its determinations. It further demonstrates the FDA's recognition that its polices have an effect on drug prices, even if they do not consider costs as part of their determinations. FDA's increased approval of generic equivalents and a willingness to consider alternative methods of synthesizing generic drugs should increase competition and bring down prices for drugs near the end of their patent cycle.

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[1] The five peptide pharmaceuticals are: glucagon, liraglutide, nesiritide, teriparatide, and teduglutide.

[2] Grabowski, H., G. Long, and R. Mortimer. "Recent Trends in Brand-Name and Generic Drug Competition." *J Med Econ* 17, no. 3 (Mar 2014): 207-14. Available at: http://fds.duke.edu/db/attachment/2575.