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FDA Commissioner Announces Plans to Streamline Approval Process for Headline-Grabbing Products

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Last week, Dr. Scott Gottlieb, Commissioner of the FDA, touched on two issues that have frequented headlines in the past two years. First, in remarks made on November 28, 2017, Commissioner Gottlieb expanded on plans to finalize guidance related to complex generic drugs, a broader issue that received specialized focus during coverage of EpiPen's price hike that began in 2016 and has continued in 2017. Then, on November 30, 2017, Commissioner Gottlieb stated plans to leverage accelerated approval processes for promising drugs, using targeted cancer drugs as an example. Innovative cancer treatments, especially recently approved cancer treatments using gene alteration techniques, which the Commissioner specifically discussed later in the session when discussing the progress of the Oncology Center of Excellence, have also grabbed headlines of late. While these topics, and efforts to address them, are not entirely novel, each statement provided understanding into the FDA's ongoing efforts to remove regulatory barriers to drug access and gave additional insight as to concrete changes the FDA may be implementing in the foreseeable future.

On the complex generic drug issue, Commissioner Gottlieb started by noting steps the FDA has taken to address lack of competition due to branded drug makers using tactics to block generic drug makers from running bioequivalence studies, as well as opportunistic behavior by speculators who acquire off patent drugs with little competition and raise prices sharply. He then went on to expand on plans to improve the process for developing and approving complex generic drugs.

Without mentioning EpiPen by name, Commissioner Gottlieb used an example of a drug delivered through a complex device, such as an auto-injector, and went on to explain that "the branded drug maker may still hold IP on certain features of the device. In such a circumstance, the drug can be an old medicine, but the device can be hard to copy since new patents protect its key features." According to Commissioner Gottlieb, the FDA will aim to address this and similar issues in guidance it is working to finalize under which, among other things, generic products will be allowed "to have certain labeling differences from the branded product – if such labeling changes stem from permitted design

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differences." As long as differences in design will not affect the clinical effect or safety profile, the generic product can be approved. This relaxation of rigorous "sameness" standards may prove to have a significant effect on the availability of generic products in situations such as that presented by EpiPen.

Similar to the complex generics, the accelerated approval discussion was also part of a larger discussion of steps the FDA is taking to address issues in its approval process. Commissioner Gottlieb and Dr. Francis Collins, Director of NIH, addressed the House Committee on Energy and Commerce to discuss progress in implementing the 21st Century Cures Act nearly a year into its existence. The Cures Act is sweeping legislation that, among other things, aims to streamline the drug and device approval process. For earlier discussion of the Cures Act and its treatment of certain medical software, see this post from my colleague, Ross D'Emanuele. Although Commissioner Gottlieb and Dr. Collins discussed progress under the Cures Act broadly, the Commissioner used his opening statement to specifically mention his view of a potential path for accelerated approval of promising drugs such as targeted cancer treatments.

Specifically, Commissioner Gottlieb discussed the potential for using a process, similar to existing accelerated approval processes, for drugs like targeted cancer treatments that may show an "outsized benefit on overall survival" in small trials. Such drugs would ordinarily require further evidence as to how to use the drug in clinical setting, but Commissioner Gottlieb said earlier approval with post-market approval studies to collect further information could often be beneficial. As explained by the Commissioner, accelerated approval is ordinarily granted in situations where drugs show benefits on a surrogate endpoint, such as tumor shrinkage; however, he suggested in his prepared statement it may also be appropriate in these circumstances where outsized benefit is shown on a clinical endpoint, such as survival.

It remains to be seen if and how these plans will be finalized and implemented. However, it is clear that the FDA plans to continue to address issues in the drug and device approval process that have come under public scrutiny as of late.