FDA Proposes Reforms to Approval Process for Biosimilars

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The U.S. Food and Drug Administration (FDA) recently announced new guidance aimed at bringing lower-cost biosimilar drugs to American patients. Biosimilar drugs are "generic versions" of biologic drugs, offering the same safety and efficacy at lower costs. Notwithstanding their efficacy and lower cost, the market share for biosimilar drugs remains below 20%, and only about 10% of biologic drugs that are expected to lose patent protection in the next decade currently have a biosimilar drug in development.

The FDA has recognized that one barrier to market entry of biosimilars is the high cost of development, which is often inflated by unnecessary comparative efficacy studies. In response, the FDA has proposed to eliminate unnecessary comparative efficacy studies and allow pharmaceutical companies to rely more heavily on improved analytical testing methods. The FDA has also recognized that the current biosimilar approval process is burdensome and has kept patients from accessing treatment and has therefore proposed to streamline the biosimilar drug development process to speed up approvals and encourage market entry. By optimizing biosimilar drug development and lowering research and development costs, the FDA hopes to encourage market competition and for patients to have expanded and less costly options.

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