CAPITOL STREET

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FDA Expedites Biosimilar Approvals In Quest to Lower Rx Prices

Non-Animal Testing & More MFN Announcements Likely Next Week

Relevant Companies

Our Take & Next Up

The FDA intends to accelerate biosimilar review by eliminating comparative validity and switch study requirements; however, formulary and coverage challenges remain unaddressed. The agency claims these moves could cut development timelines from the current 5-8 years down to 2.5-5 years. Yesterday, HHS and the FDA announced two major regulatory changes that are intended to lower approval hurdles for biosimilars, including assessment of the 'interchangeable' designation, with the FDA now more systematically not recommending 'switching studies', as well as proposing an assessment of the need for Comparative Efficacy Studies (CES). See HHS release here.

FDA Commissioner Makary noted the agency will make an announcement on reducing animal testing next week. We could see additional guidance documents that articulate non-animal testing usage in various development programs or explicitly allow them, or it could be an announcement of a new incentive for companies that utilize non-animal testing. See our analysis on the non-animal testing initiatives here.

Key Points

FDA released a draft guidance (here) to reduce the burden of comparative validity for biosimilars. The draft guidance updates the 2015 biosimilarity guidance and provides a framework for comparative efficacy studies. In the announcement, Commissioner Makary noted that the reform could reduce the 5-8 year development timeframe to about 2.5-5 years, saving an estimated $100 M in development costs for pharma companies.

If a biosimilar is highly similar, FDA recommends a streamlined approach for comparative efficacy. The agency defines the criteria for streamlined approval as:

- (1) the biosimilar and reference biologic are made from clonal cell lines, highly purified and well-characterized analytically,
- (2) the relationship between quality attributes and clinical efficiency is understood,
- (3) a relevant human pharmacokinetic similarity study can be conducted.

FDA will issue final guidance to remove switching study requirements, with guidance expected within 3-6 months. The FDA now will not recommend 'switching studies' for the designation of 'interchangeable'. The new framework reflects the agency's view that all biosimilars, as effectively interchangeable and advanced testing like analytical and pharmacokinetic testing, can prove the same effectiveness as human trials. The change intends to streamline biosimilar development and align biosimilar and generic reviews. As a reminder, President Trump referenced improving the approval of generics and biosimilars earlier this year in his EO on drug pricing priorities. See our analysis of the April drug pricing EO here. The administration is quietly moving forward on other priorities to lower drug prices.

An FDA announcement on non-animal testing initiative is likely coming next week. As a reminder, in April the FDA announced a roadmap to phase out animal testing in preclinical studies and increase usage of New Approach Methodologies (NAMs) - a broad category that includes artificial intelligence (CERT), organ-on-a-chip systems, and in silico computer models (Insilico Medicine, SDGR). The announcement could include additional guidance that provides clarity on NAMs or an announcement of a new incentive for companies that utilize non-animal testing. The FDA has already proposed phasing out animal testing in the development of monoclonal antibody therapies here. The FDA and NIH are working together in advancing NAMs with NIH proposing to no longer fund research proposals that rely solely on animal models. See our analysis of the announcement here.

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