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Biosimilars and Generic Drugs

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Key Takeaways:

1. **Generic drugs are simple, synthetic compounds** that are chemically produced and compete for market share with small molecule drugs. **Biosimilars, conversely, compete with biologic drugs,** which are grown in living sources and are made from cellular components.
2. Generics account for most prescriptions filled, but relatively little spending. In the U.S., **generics constitute 90% of all prescriptions, but only 22% of total drug expenditures.**
3. Biologics account for a disproportionately large percentage of drug spending. In the U.S., **biologics constitute two percent of all prescriptions but 43% of total drug expenditures**. All ten of the highest expenditure drugs in Medicare's Part B program are biologics.
4. After a small molecule patent expires, generics can enter the market without major regulatory hurdles. Conversely, biosimilars have a more robust approval process, similar to that of an new brand name drug.
5. Regulatory systems outside the U.S. are more favorable for biosimilar approvals. To date, **Europe has approved 67 biosimilars**, all of which have entered market. The **U.S. has approved 33 biosimilars**, and only 18 have entered market.
6. **Generics and biosimilars may save money for the U.S. healthcare system**. In the U.S., both generics and biosimilars cost on average 20-30% less than their respective brand name or biologic counterparts. They also often reduce the cost of these counterparts.
7. **Biosimilars, similarly to generics, could be a significant opportunity to reduce drug costs in the U.S. However, many questions remain around their safety, approval strategy, and market opportunity.**

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Discussion Questions

1. How closely should the regulatory process for biosimilars parallel the one used for generic small chemical drugs?
2. What lessons, if any, can the U.S. apply from its success with the penetration of generic small-molecule drugs to biologics and biosimilars?
3. What are the risks in terms of lost opportunities by the U.S.'s current model, which treats biosimilars like entirely new drugs?
4. What can the U.S. learn from the regulatory approaches other countries have taken related to biosimilars?
5. Should the U.S. adopt a model of biosimilar approvals similar to that of Europe (i.e., significantly fewer regulatory hurdles after the biologic drug's patent expires)?
6. Would the predictability of pricing regulations for biologic drugs create a better environment for innovation and/or cost savings than enabling biosimilar approvals?
7. To what degree do biosimilars drive down the cost of the original biologics through competition?
8. What role can and should biosimilars play within the broader goal of managing drug spend in the U.S.? How does the savings potential of biosimilars compare to the magnitude and likelihood of other approaches?

Additional Recommended Reading

1. **Realizing the Benefits of Biosimilars** *(full text)* – authored by Zetema Project panelist Mark McClellan, among others, this report provides an overview of the landscape of biosimilars in the U.S. It then analyzes factors that contribute to the delayed progress in biosimilar approvals in the U.S. compared to Europe. https://healthpolicy.duke.edu/sites/default/files/2021-04/Realizing%20the%20Benefits%20of%20Biosimilars.pdf

2. **Podcast: How Biosimilars Are Affecting Drug Markets** *(full podcast)* – a conversation with Zetema Project panelist Alan Weil and Ariel Stern about what biosimilars are and how the pharmaceutical market is evolving in response to their market entry. https://www.healthaffairs.org/do/10.1377/hp20210607.968777/full/
3. **Getting to Lower Prescription Drug Costs: They Key Drivers of Cost and What Policymakers Can Do to Address Them** *(full text)* – this Commonwealth Fund policy brief documents the drivers of high U.S. prescription drug spending and suggests federal policy solutions pertaining to generics and biosimilars. https://www.commonwealthfund.org/sites/default/files/2020-10/Waxman_GettingtoLowerRxPrices_report_v3.pdf
4. **"Time to Throw in the Towel on Biosimilars"** – opinion article by Peter Bach and Mark Trusheim arguing it is better to regulate prices on biologic drugs than enable competion from biosimilars in the U.S., from *The Wall Street Journal*. https://www.wsj.com/articles/time-to-throw-in-the-towel-on-biosimilars-11566428299
5. **"America Needs Generic Drugs. But Can They Trust Them?"** – narrative discussion around safety of generic drugs and potential issues with supply chain, from *The New York Times*. https://www.nytimes.com/2019/05/11/opinion/sunday/generic-drugs-safety.html