## BIOLOGICS AND BIOSIMILARS & BIOPHARMA & BIOTHERAPEUTICS

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## Understanding the market access landscape for biosimilars

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**B**iosimilars were touted as a payer's tool to gain savings in specialty markets, but a recent survey by Avalere of the top 25 payers in the U.S. (about 189 million covered lives) using publicly available coverage policies found that biosimilars are commonly subject to step through policies, including those that require the patient to "fail" first on a branded product and only then will the payer cover a biosimilar of that same branded product (i.e., the biosimilar's reference product). Policies like this may be why although the Congressional Budget Office (CBO) originally estimated a 10-year decrease in federal spending of \$5.9 billion attributable to "follow-on biologics"/biosimilars in 2009, it is estimated the actual savings have only been 8 percent of that amount (approximately \$241 million). Some of the biggest challenges to biosimilar uptake are patent and *intellectual property* (IP) issues since we have 12 approved agents but only three which have been launched commercially. While the USA is currently the largest single market in the world overall by dollar value, the healthcare system comprises of thousands of payers and a lot of the incentives on how their choices are made are less than transparent. Contracting incentives from originator companies may play a part in the lackluster performance of those biosimilars which are available on the market but the bigger issue for a multisource market is that the promise of increased access for patients is not currently being realized. This presentation will review the barriers and possible future opportunities for biosimilar uptake in the USA.

## **Biography**

Anita Burrell is Vice President, Global Market Access at Health Strategies Group where she is responsible for leading and growing the global market access practice including syndicated and custom market research services. Prior to joining Health Strategies Group, she spent over 18 years with legacy Sanofi companies (23 years in the pharmaceutical industry) where she led worldwide strategy for launch pricing and reimbursement including evidence generation strategies. She was also the product champion for Aubagio (oral MS therapy) and coordinated commercial effectiveness for diabetes franchise. Her work is regularly published and presented at conferences. She is frequently invited to speak on real-world evidence, managed entry agreements, value proposition development and value frameworks.

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