HOW WILL THE CVS/AETNA MERGER IMPACT BIOSIMILARS?

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BIOSIMILAR DEVELOPMENT

Mergers and acquisitions (M&As) are commonplace across the healthcare landscape. Such consolidation is intended to drive efficiencies and spur growth. Traditionally, such M&A activity has involved horizontal integration — the marriage of similar types of organizations (i.e., a pharmaceutical company and a biotech; a national insurance provider with a regional player). The desired merger of CVS and Aetna, however, introduces a dramatically different dynamic — the vertical integration of two different types of businesses, a pharmacy/drug distribution entity and an insurance company, to create a new type of healthcare system. How will such a new entity impact biosimilar use?

THE RETAIL PHARMACY PERSPECTIVE:
WILL ACCESS TO BIOSIMILARS INCREASE?

An obvious first question to ask about the CVS/Aetna merger is what does such a merger offer? In a joint statement about the merger, the companies claim that "This transaction fills an unmet need in the current healthcare system and presents a unique opportunity to redefine access to high quality care in lower cost, local settings whether in the community, at home or through digital tools." In essence, it creates a one-stop-shop for many/most primary care medical needs. CVS' 9,700 retail pharmacy locations, 1,100 walk-in clinics, home healthcare services, and infusion centers will be combined with Aetna's ≈ 44 million health plan members, creating a formidable new entity that, according to Moody's Vice President Micky Chada, *"brings together the overall management of a patient's medical bills and prescription drugs under one umbrella."*[1] There will be a better opportunity to utilize local care solutions in a more integrated fashion with the goal of improving patient outcomes.[2] Concurrent with the trend to empower patients to become more engaged in their own healthcare, can the convenience and coordination of this new system offer substantial benefit to patient access?

Clearly, the enhanced access Aetna members will have to CVS retail pharmacies could improve overall access to prescription treatments, including biosimilars. However, conditions currently treated by biosimilars (and their originator molecules), such as inflammatory diseases and cancer, are not managed the same way chronic diseases like hypertension, hypercholesterolemia, and diabetes are. The latter could benefit from a retail outlet for their medications and potentially the use of generic drugs to reduce costs. Because biosimilars are not interchangeable, pharmacists (at a CVS store, for example) could not change a prescribed brand to a biosimilar in the same way. In addition, several biosimilars are infusion agents. While the CVS organization does include Coram infusion centers, fewer than 100 exist nationally, so access would be limited. Will patients view their local drug store (a CVS retail outlet) as a healthcare facility or balk at going there for infusions? It will take some time for such patients to embrace that dynamic.

THE INSURANCE PERSPECTIVE:
COULD PATIENTS SEE LOWER DRUG PRICES?

In addition to the retail space, CVS also serves as a pharmacy benefit manager (PBM) through its CVS Caremark organization. While originally intended as a vehicle to aggregate purchasing power and negotiate better prices for drugs, PBMs have evolved into an expensive middleman that has had minimal benefit to consumers in terms of lower pharmaceutical costs. The CVS/Aetna merger could potentially remove the middleman and allow value-based contracting directly between CVS/Aetna and pharmaceutical companies. Its size and strength would be formidable. However, United Healthcare already owns a PBM (OptumRx) that has not translated into obvious consumer benefits.[3] Can the new type of strength represented by the CVS/Aetna merger translate into lower costs to consumers either as lower premiums or lower actual drug costs?

The contracting power of the new CVS/Aetna organization could offer significant value-based contracting strength to members and provide less expensive biosimilars to insurance members. However, the bulk of the expense for most pharmaceutical agents, especially among patients with insurance coverage, is paid by the insurance company. Even with tiered coverages, the bulk of the cost of pharmaceutical agents, be they brands, generics, or biosimilars, is borne by the insurance company. Certainly, a CVS/Aetna company could contract for lower overall costs for biosimilars and potentially suggest/require members use those agents, but it is uncertain how much of the negotiated savings will be seen by the patient versus the insurance company.

THE DATA ANALYTICS PERSPECTIVE:
CAN IT BE LEVERAGED EFFECTIVELY?

Perhaps the biggest long-term value of the merger involves the potential use of data analytics. The true value of a vertically integrated healthcare delivery system is the ability to capture and analyze large volumes of data and then take action based on such analytics that can improve the overall delivery of healthcare as well as reduce the cost to the consumer. In theory, this is an auspicious goal that could translate patient outcomes into treatment recommendations based on the analysis of huge amounts of data. But Big Data analytics is not a simple task. Does CVS/Aetna have the capacity and will to embrace the scope of such analytics and successfully apply learnings to bolster innovation and improve integrated healthcare delivery, including the use of biosimilars?

The data analytics power of the merged company can certainly provide substantial insight that could provide actionable recommendations for the management of chronic diseases. Data that can follow patients who use branded originator molecules versus biosimilars will provide substantial insight into the relative outcomes of biosimilars and offer insight into their clinical benefit, which can be coupled to cost reductions based on value-based contracting. But generating such data will take time, and its analysis will likely be a lower priority item.

AN EVOLVING STORY

Despite the FDA-approval of eight biosimilar molecular entities, only three are on the market in the U.S. Others remain embroiled in various forms of litigation that have slowed their emergence onto the market. Biosimilar uptake in the U.S. remains a challenge and certainly lags far behind that seen in the EU. Unlike the U.S. healthcare system, EU countries are dominated by single-payer systems that are fully integrated vertically for the delivery of all healthcare services. A clear expectation of the CVS/Aetna merger is a reduction in costs of prescribed medications through efficiencies, access, and data analytics. Can a vertically integrated CVS/Aetna healthcare system in the U.S. mimic to any degree the success biosimilars have experienced in vertically integrated, single-payer EU healthcare systems? Can the perceived benefits of the merger apply such benefits to the use of biosimilars?

It will take time to see how this proposed CVS/Aetna merger evolves (if it survives antitrust scrutiny), but biosimilars are not likely to be among their initial major concerns. The purpose of the merger is to improve access and reduce costs for primary care needs. While access, convenience, and lower costs would be benefits of the merger, loss of choice for drug delivery could be unwelcome among some patients. In addition, many patients change insurance coverage as they change employment or their employer negotiates a contract with a different insurer. The impact of such insurance changes is clearly uncertain and unknown in this newly evolving system. The merger will likely make it more convenient and less expensive for large numbers of patients to manage chronic conditions like hypertension or diabetes. The volume of such needs and the demand for operational integration will drive early priority decisions. Biosimilars offer benefit to a subset of patients with more complex diseases. While the contracting power of the organization will have a positive impact on biosimilars from a cost perspective, because the market for such agents pales by comparison to primary care chronic condition needs, focusing on this market segment is likely to be a lower priority.

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