
Testimony of

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## American College of Rheumatology

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## Lowering Costs for Patients:
## the Health of the Biosimilar Market

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**Introduction**

Chairman Buchanan, Ranking Member Doggett, and Members of the committee, thank you for inviting me to testify today. My name is Colin Edgerton, and I am a rheumatologist in private practice from Charleston, South Carolina where I have practiced for twelve years. Prior to private practice I served 12 years as a U.S. Army physician during which I was deployed to Iraq. In both of these roles I have seen the impact of rheumatic disease on patients and the need for effective disease interventions. Biologic medications are a biotechnology feat that has changed the outlook for our patients. Biologic drugs (biopharmaceuticals) treat complex diseases like rheumatoid arthritis or cancer that chemically synthesized drugs cannot successfully treat. However, biologics are also more complicated and expensive to make than synthetic drugs and their administration to patients is also more complex as as they must be given by injection or infusion. According to the CDC, 21.2% of Americans over 18 have doctor-diagnosed arthritis[1]. That is nearly a quarter of American adults in just one disease category where a biologic is likely to be prescribed.

**Background**

Biosimilars are medicines that could be cost-saving alternatives for these biologics. The relationship between biosimilars and biologics (at the regulatory but not biochemical level) is akin to the relationship between generic and brand-name medicines; however, biosimilars are not exact generic copies of the reference drug. Due to the complexity of biologics used in rheumatoid arthritis and other autoimmune diseases, separate regulatory approval and dispensing pathways were created to ensure effectiveness and protect patient safety. Congress authorized the FDA to provide two pathways for biosimilar approval: 1) biosimilar agents that have equivalent safety, purity, and potency as original biologics; and 2) a higher level of interchangeable biosimilars in which alternating or switching between an original biologic and biosimilar would not be predicted to cause any changes in efficacy or safety.

I also serve as a leader in the American College of Rheumatology (ACR) and ACR strongly supports the rigorous pathway for interchangeability approved by the FDA in 2019. The FDA must ensure that biosimilars and interchangeable biosimilars are safe and effective. The ACR recognizes increasing cost pressures may cause payers to push patients toward

[1] https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html

biosimilars. This is most appropriate when there is data available. In the absence of data, payers should provide transparent guardrails around "non-medical switching" which allow the patient and provider to choose the best treatment for that patient with tenuous disease control. For patients with stable disease, transition to a biosimilar product may be reasonable if cost savings are available, although the ACR remains concerned that pharmacy benefit managers' (PBMs) lack of pricing and rebate transparency leaves formulary decisions opaque.

**The Biosimilars Roadblock: Created to Cost Less but Putting Prescribers in the Red.**

The decision to change therapy from a reference product to a biosimilar should be made jointly between the patient and the physician. Federal and state/local regulations must ensure appropriate dispensing and monitoring, including regulation that prevents the rebate-based PBM system from excluding lower-cost biosimilars. Safe and effective treatments should be available to patients at the lowest possible cost. Decisions regarding the approval and use of biosimilars must be driven by sound science and consider several guiding principles, including appropriately reimbursing all biologics approved for rheumatic conditions with recognition of the complexity of administration, monitoring, coding, and reimbursement.

The ACR has been working to address a critical issue affecting rheumatologists, including my own practice, which limits our patients' access to biosimilars: the lack of adequate reimbursement for biosimilar treatments. The gap between the cost of acquiring biosimilar treatments for administration to patients, and the amount we are reimbursed upon administering those treatments is negatively impacting both physician practices and access to care for millions of patients suffering from chronic diseases.

The high cost of reference biologics has created a significant barrier to access for patients and has created the need for more affordable alternatives. Biosimilars are highly similar to the original biologics and have the potential to address this access issue. Unfortunately, despite their proven efficacy and safety, the complex cost-sharing structure of Medicare Part B, specifically the average sales price (ASP) calculation and the resulting suppressed reimbursement for biosimilars (but not suppressed purchase price) has built an obstacle that undermines their promise.

**The Underwater Biosimilars Math**

Biologic therapies sometimes exceed $50,000 per year per patient. Biosimilars are often initially 20-40% less expensive than their reference biologic. This should allow more patients to access biologic treatment without the fear of high out-of-pocket costs. However, if the biosimilar is covered under Part D, beneficiaries may face different cost-sharing rules, which may not result in savings, especially for those in the coverage gap phase, where the beneficiary is responsible for a larger portion of the cost.

For example, a 2018 JAMA[2] study looked at over 2,500 Part D plans. 96% of the plans covered original brand infliximab (the originator biologic) versus only 10% that covered infliximab-dyyb (the biosimilar). The biosimilar product had a slightly lower mean total cost per 8 weeks and annually compared with the biologic ($2185 vs $2667 and $14,202 vs $17,335, respectively). However, because all plans required coinsurance cost-sharing for the biosimilar prescriptions and set copay rates similar to the biologic (26.6% vs 28.4% of drug cost), the projected out-of-pocket costs annually were actually higher for the biosimilar than for the biologic, thus negating the financial benefit of the biosimilar. This is just one example of how the business decisions of payers and their partners can change the math.

It is often unclear how Part D plans and Medicare Advantage plans select which medications, including biosimilars, are covered or where they are placed on their formularies. These tactics mean that even if a biosimilar is less expensive, it may not be on the formulary or may be placed in a higher cost-sharing tier where beneficiaries could still pay more out-of-pocket for it compared to the reference biologic.

Another one of the major barriers preventing the widespread use of biosimilars is inadequate reimbursement of providers from insurers for office administered biologic therapies, which continues to stifle their potential and create confusion among both physicians and patients. Often PBMs negotiate rebates for biologic drug placement on formularies. These rebates are factored into the ASP, bringing down that measure but do not reduce the cost of the medication. This results in a perverse situation where the medication costs more than the rate of reimbursement, with the difference being a rebate that is siphoned off to the PBM. Patients will then not receive a treatment that costs more than is reimbursed, and the biologic (to include biosimilars) is therefore not accessable.

Rheumatologists typically receive reimbursement for biosimilars based on the ASP for the drug. When PBMs and health plans negotiate substantial rebates with manufacturers, as they often do, these rebates are not passed on to the treating physician or their practice to reduce the cost of acquiring the drug for administration. These rebates often exceed 50% of

[2] Jinoos Yazdany, MD, MPH[1]; R. Adams Dudley, MD, MBA[2]; Grace A. Lin, MD, MAS[2]; et al

the drug price. The result is a innapropriate financial incentive: the drugs with the highest rebate paid to the PBM are often the ones that are required to be used per plan policy, regardless of whether they are the most cost-effective or appropriate treatment for the patient. The rebates are then reflected in manufacturers' quarterly ASP reporting to CMS, and therefore artificially lower the ASP to the point that many providers' acquisition costs substantially exceed how much they are reimbursed.

This is especially problematic for physician practices expected to purchase biosimilars at high upfront costs when it is unlikely that reimbursement will cover the expense upon treatment. If the reimbursement does not cover the acquisition cost of the biosimilar, physicians will be operating at a financial loss. This leads to unsustainable practice economics, especially in high-volume settings such as rheumatology where biologics are a central part of patient care.. Further exacerbating the issue, these underwater biologics and biosimilars are mandated by the plans. Appealing these plan mandates is time consuming and frequently unsuccessful and not only severely limits patient access to care, but also puts extreme administrative stress on medical practices causing difficulties in managing day-to-day operations, such as paying staff or handling administrative expenses.

Smaller independent rheumatology practices may be hit hardest by this issue. Larger healthcare systems or hospital groups with greater financial resources may be able to absorb some of the financial losses associated with low reimbursement for biosimilars. This is layered with the financial strains of nearly annual Medicare Physician Fee Schedule cuts and record inflation. As a result, medical practices may face the choice of either reducing services, refusing certain patients, or even closing due to financial stress. In rheumatology this is a particular concern, as the majority of patient care occurs in independent rheumatology practices.

Financial system manipulations for prescribing biosimilars are limiting patient access to these more affordable alternatives. When physicians cannot afford to prescribe biosimilars because the reimbursement does not cover the cost of acquiring the drug, then the biosimilar will not be prescribed or administered.

Hospitals and infusion centers may still offer biosimilar treatment if the biosimilar is the best choice for the patient. In this scenario, hospital-based infusion centers are generally more expensive than office-based infusions, leading to higher costs for patients. Patients may also experience delays in accessing treatment due to the logistical complexities of hospital-based infusions, such as longer wait times and scheduling challenges.

Regardless of what choice the rheumatologist makes, patient access to high quality care is jeopardized.

**Legislative Solutions**

Much of this problem can be solved with greater transparency in drug pricing, especially with respect to biologics and biosimilars. This transparency will help both healthcare providers and patients understand the costs involved and foster a more equitable marketplace. The math problem can also be solved with legislation in one of three ways:

1) Amending Section 1847A(b) of the Social Security Act (SSA) to temporarily provide an 8% add-on to the providers' acquisition cost of all biosimilar products;
2) Amending Section 1847A(c)(4) to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% until ASP reaches sustainable levels, as determined by the Secretary; or
3) Amending Section 1847A(c)(3) to permanently remove manufacturer rebates from the ASP methodology for biosimilars.