Written Testimony on:

Health Subcommittee Hearing on Lowering Costs for Patients: The Health of the Biosimilar Market

Unites States House of Representatives

Committee on Ways and Means

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Chairman Buchanan, Ranking Member Doggett, and members of this subcommittee, I thank you for the opportunity to testify on the critical issue of biosimilars and their role in improving patient care and affordability in cancer treatment. What follows is my written testimony, which includes links to relevant and important references.

As background, I am Dr. Debra Patt, an oncologist specializing in breast cancer in Austin, Texas. I serve in the leadership of Texas Oncology, a large independent community oncology practice that is part of The US Oncology Network, and I am President of the Community Oncology Alliance, a nonprofit organization that represents cancer patients and their independent community oncology practices across the country.

It is important to understand that as cancer treatment continues to evolve, it is imperative that we consider the factors influencing the development and utilization of biosimilars compared to biologic products, particularly within the unique context of cancer patients in the United States. As a breast cancer specialist, I use biosimilar drugs every day in my practice and have been using them for over a decade. Our practice has over 300 sites of service and we have had a very high percentage of biosimilar utilization for many years.

In my breast cancer patients, I use biosimilars knowing that these are the highest quality products that are both effective and affordable to the patients I serve – much more affordable than their reference biologics. You may question why I would use a less expensive biosimilar rather than the more expensive originator biologic, especially given the reimbursement structure, but the answer is simple – patient affordability. Every day, as oncologists, we see patients who simply cannot afford their treatments. Our job as physicians includes being advocates for our patients and doing whatever is possible to make their treatments as affordable as possible. Biosimilars offer that affordability, but the reimbursement landscape is perilous and not necessarily viable for physicians because there are situations where the acquisition cost and related costs of using biosimilars can be greater than reimbursement.

Two pressing issues with biosimilars, and pertinent to ensuring a long-term healthy biosimilars market, are market distortions dealing with insurance companies and their pharmacy benefit managers (PBMs) and the 340B Drug Purchasing Program (340B).

PBMs and their related insurers (collectively, I refer to these as "PBMs") often force physicians *not to use the most effective and affordable drugs* for our patients, *but the most profitable drugs* for those corporations. Because they are allowed to use safe harbor rebates to force concessions from pharmaceutical manufacturers, these profit-seeking corporations can mandate the use of the more expensive originator biologic or a specific biosimilar most profitable to them when there are multiple biosimilars available to treat a specific cancer. This can create logistical nightmares for practices having to stock multiple biosimilars when different PBMs favor their most profitable biosimilar. At a macro market level, PBMs threaten the viability of a healthy biosimilar market. And I will add that these

corporate entities have now started sourcing their own "private label" biosimilars to even further increase their profitability with biosimilars.

The other market distortion impacting the increased use of biosimilars is 340B hospitals, which are significantly overpaid for drugs by the Centers for Medicare & Medicaid Services. Because these "nonprofit" facilities make substantial "profits" on drugs, they are incentivized to use the most expensive drugs, especially more expensive originator biologics, rather than biosimilars, as several studies have documented.[1] [2] This is another market distortion that threatens the long-term viability of the biosimilars market.

We need a healthy, free market environment for biosimilars that delivers on the promise of making new biologics available to oncologists and other specialists treating life-threatening diseases. Our patients who are struggling with the affordability of cancer treatment depend on us!

Understanding Biosimilars and Biologics

Biologics are complex molecules derived from living organisms, used extensively in the treatment of various diseases, including cancer. Biosimilars are nearly identical copies of these biologic originator products that have been shown to have no clinically meaningful differences in safety, potency, and purity. While the introduction of biosimilars holds significant potential for lowering costs and increasing access to life-saving biologic therapies, several barriers have emerged that impact their market entry, utilization, and viability.

"*As of October 2024, the Food and Drug Administration had approved 61 biosimilars referencing 17 different large molecules. Forty-three of the 61 have launched so far. Some of the remainder will enter the market soon, while others have been delayed by litigation*."[3] Over the next decade, some 118 biologics are expected to lose patent protection presenting an opportunity of at least $234 billion in savings from biosimilars.[4] Since 2015, biosimilars have saved our country's health care system $36 billion.[5] Despite biosimilars having substantially lower list prices than the products they reference, their adoption rates vary by molecule and therapeutic area.

[1] Bond AM, Dean EB, Desai SM. The role of financial incentives in biosimilar uptake In Medicare: evidence from the 340B program. *Health Aff (Millwood)*. 2023;42(5):632-641. doi:10.1377/hlthaff.2022.00812 Access here.
[2] Examining 340B hospital price transparency, drug profits, and incentives. Community Oncology Alliance. September 2022. Access here.
[3] Patient Access To Cheaper Biosimilar Drugs Varies Significantly Across Pharmacy Benefit Managers. Forbes. March 2025.
[4] Assessing the Biosimilar Void in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. IQVIA. February 2025. Access here.
[5] Ibid.

1. Barriers to Market Entry

The entry of biosimilars into the market is hindered by various factors, including the following:

- **Steep Development Costs:** The development of biosimilars involves high research, development, and manufacturing costs that can range from $100 million to over $300 million. The manufacturing process of biosimilars is much more complicated than traditional drugs. These costs are often a deterrent for potential pharmaceutical manufacturers, especially smaller firms.

- **Legal Hurdles:** The regulatory pathway for biosimilars is intricate, with lengthy and costly approval processes. Legal disputes related to patents can create further delays in market entry, leading to extended periods during which a biologic product enjoys market exclusivity. This causes increased costs and uncertainty for those seeking to develop biosimilar products.

2. Rebate Structures and Market Dynamics

As I have previously stated, PBMs play an important role in the biosimilar market. They often manage prescription drug benefits for health plans, negotiate drug pricing and rebates with manufacturers, and return some rebate dollars to their customers or contracted entities. Rebate structures negotiated by PBMs often favor established biologics or a particular biosimilar product that is the most profitable to them. The three largest PBMs that control 80 percent of the market may prefer the biologic product due to an advantageous rebate structure. This practice creates a financial environment where there are drivers that incentivize the utilization of more expensive biologics or "private label" biosimilars rather than lower cost biosimilars. And, as we have seen average sales price (ASP) drop precipitously for biosimilars, oncology and other specialty practices may increasingly be underwater – that is, reimbursement lower than acquisition cost – for biosimilar products, making their selection an unsustainable solution. Some biosimilars have left the market as the cost structure was so low that continued production was not sustainable.

There are also many instances when multiple biosimilar products exist within a class, but perfect selection is not possible due to the cost of the inventory burden of keeping multiple biosimilars in stock. For example, there are six biosimilar products approved for Herceptin by the FDA. Each insurance company may prefer the utilization of one biosimilar because of its financially favorable rebate structure, but it may be cost-prohibitive to keep all six biosimilar products for Herceptin in inventory to accommodate multiple preferences.

3. Impact of the 340B Drug Purchasing Program

The 340B program significantly influences the economic landscape for biosimilars. While the program aims to reduce drug costs for eligible healthcare providers serving vulnerable

populations, that intent is not mandated in policy administration. The arbitrage opportunity to "buy low" and "sell high" creates a financial incentive for preferential use of more expensive drugs, including originator biologic products, and creates complications for optimal biosimilar use. Hospitals may prefer to continue using original biologics due to the 340B discounts they receive, thus limiting the incentive to switch to lower-cost biosimilars.

4. Lower Costs and Instability in the Drug Supply Chain

The introduction of biosimilars can lead to lower drug costs; however, this transition can also destabilize the drug supply chain – similar to what we see in low cost generic injectable drugs. Pharmaceutical companies may reduce production of certain products or choose to exit the market altogether if lower-priced alternatives negatively impact their profit margins. It is crucial to ensure that introducing biosimilars does not compromise the overall stability of the oncology drug supply. As ASP has decreased substantially in the past several years for many of the biosimilar products, they are vulnerable to many of the supply chain vulnerabilities we observe with injectable generic drugs.

Conclusion and Recommendations

In conclusion, while biosimilars represent a promising opportunity to enhance patient access and reduce costs for cancer therapies and other disease treatments, the current landscape presents significant challenges. To foster a more favorable environment for biosimilars, I recommend the following actions:

- **Streamline Regulatory Pathways:** Simplify the approval process for biosimilars to encourage competition while maintaining safety and efficacy standards.

- **Disallow PBM/Insurer Rebates on Biosimilars:** Reform rebate practices to eliminate their use with biosimilars by removing safe harbor protections.

- **Disallow 340B Discounts on Originator Biologics:** Pharmaceutical manufacturers should not be required to provide 340B discounts on biologics with biosimilar competition.

- **Increase Reimbursement for Biosimilars:** Increase reimbursement for biosimilars to ASP plus 10 percent and remove the two percent sequester cut from these products (or alternatively increase reimbursement to ASP plus 12 percent with the sequester still in place).

- **Establish a Floor Price for Biosimilars**: The race to lower costs that exists today poses a threat to a sustainable biosimilar supply chain, such as see with sterile injectable generic drugs and the resultant chronic shortages of these drugs.

- **Support Development:** Provide incentives and funding for the research and development of biosimilars specifically in this country, targeting small and mid-sized companies.

- **Collaborate with Providers:** Engage with health care providers to increase awareness of the benefits and safety profiles of biosimilars, helping to promote their adoption in patient treatment.

Addressing these factors can help ensure that cancer patients have access to a broader range of effective, more affordable treatment options, ultimately leading to improved health outcomes and reduced health care costs.

Thank you for the opportunity to testify and submit this written testimony for the record.

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