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The Impact of Biosimilars on Pharmaceutical Marketing and Commercial Strategy in Global Biologics Markets

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Abstract

Biosimilars were introduced into regulated markets as a cost containment mechanism modelled loosely on small molecule generics. This paper argues that their more consequential effect has been structural rather than fiscal: Biosimilars have dismantled the marketing logic on which the branded biologics industry was built. Drawing on market data, regulatory documents and corporate disclosures published during 2023 and 2024, and situating these against a conceptual literature on regulated market positioning, health system financing, supply chain governance and commercial data infrastructure, the study examines how biosimilar competition reallocated commercial power from prescribers to intermediaries, forced originators into portfolio substitution rather than brand defence, and produced a new channel form, the payer affiliated private label biosimilar, that has no clear precedent in pharmaceutical distribution.

Four findings are advanced. First, the decisive commercial variable in 2024 was not clinical differentiation or regulatory status but formulary architecture: The removal of Humira from a major national commercial formulary in April 2024 moved more market share in weeks than the preceding period of biosimilar promotion had moved.

Second, interchangeability, long treated by manufacturers as a commercial asset worth substantial clinical investment, was empirically decoupled from market share and then regulatorily devalued by the FDA's June 2024 draft guidance. Third, originators increasingly responded to loss of exclusivity not by defending the eroding asset but by migrating demand to adjacent, patent protected molecules, a strategy visible in AbbVie's transfer of immunology revenue from Humira to Skyrizi and Rinvoq. Fourth, the pharmacy benefit and medical benefit now behave as two distinct markets requiring incompatible commercial models.

The paper further argues that the capabilities determining biosimilar commercial outcomes are increasingly infrastructural rather than promotional, residing in contracting systems, customer data architecture, analytics governance, distribution visibility and manufacturing quality assurance. It concludes that biosimilar marketing has become an exercise in channel economics and gross to net engineering rather than in demand generation, and that this shift carries consequences for market sustainability, patient access and the durability of biosimilar development pipelines.

Keywords: Biosimilars, Pharmaceutical Marketing, Commercial Strategy, Loss of Exclusivity, Pharmacy Benefit Managers, Private Label, Market Access, Interchangeability, Gross to Net, Supply Chain Governance

1. Introduction

1.1 Background

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure pathway for biological products demonstrated to be highly similar to an approved reference product. Policymakers anticipated that this pathway would reproduce, in the biologics sector, the price competition that the Hatch Waxman Act of 1984 had produced for small molecule drugs. The analogy was imperfect from the outset. Generic small molecules are chemically identical to their reference products, are approved on bioequivalence data, and in most jurisdictions are automatically substitutable at the pharmacy counter under state law. Biosimilars are highly similar but not identical, are approved on a comparative analytical and clinical package, and historically required a separate regulatory designation before automatic substitution was permitted.

These differences matter commercially. The generic model works because substitution occurs downstream of the prescription and is largely invisible to the prescriber, which means generic manufacturers do not need a marketing function in any conventional sense. Biosimilar manufacturers, by contrast, entered a market in which prescribers retained meaningful control, patients had years of exposure to originator brand equity and patient support infrastructure, and payers and intermediaries had contractual reasons to prefer the incumbent. The result was a hybrid: A low margin product that nonetheless required brand style commercial investment.

The gap between what a biosimilar can theoretically deliver and what it delivers in practice is an instance of a more general phenomenon in health systems, in which scientific innovation fails to translate into improved patient outcomes where the surrounding delivery and financing infrastructure is not aligned to carry it (Ilodigwe & Adesemoye, 2019b). Biosimilars are a particularly clean example, because the science is settled and the failure, where it occurs, is entirely commercial. Comparable translation gaps have been documented between healthcare infrastructure investment and measurable population health outcomes, where the determining variable is the operating model rather than the asset itself (Ogbete & Aminu-Ibrahim, 2024).

By September 2024 the FDA had approved 61 biosimilars across 17 reference molecules, of which 41 had reached the market (Samsung Bioepis, 2024). Savings attributed to biosimilars rose by more than 30 percent to \$12.4 billion in 2023, bringing cumulative savings since first entry to approximately \$36 billion, across almost 2.7 billion days of patient therapy and more than 495 million incremental days of treatment that would not otherwise have been delivered (Association for Accessible Medicines, 2024). On these measures the policy is working. On other measures, particularly the sustainability of biosimilar development and the distribution of savings between patients and intermediaries, the picture is considerably less settled.

1.2 Problem statement

Most existing analysis treats biosimilars as a pricing and access question. The commercial and marketing dimension has received comparatively little systematic attention, despite the fact that biosimilar market outcomes in 2023 and 2024 were determined overwhelmingly by commercial rather than clinical or regulatory factors. The adalimumab market provides the clearest illustration. Ten biosimilar versions of Humira were available in the United States from 2023, several with list prices substantially below the reference product and one holding the first interchangeability designation, yet Humira retained roughly 97 percent of adalimumab prescriptions through March 2024 (GaBI Online, n.d.). A single formulary decision by one intermediary in April 2024 changed that position more quickly than the entire preceding period of commercial effort.

This outcome is not explicable within the traditional pharmaceutical marketing paradigm, in which share follows clinical evidence, prescriber preference and brand investment. It requires a different analytical frame, closer to the literature on differentiation and market entry in heavily regulated sectors, where permissible claims are constrained and competitive position is established through structural

rather than promotional means (Sanni *et al.*, 2020b; Sanni & Attah, 2023c).

1.3 Research questions

1. How has biosimilar entry altered the identity and behaviour of the decision maker in biologics markets?
2. What commercial strategies have originator companies adopted in response to biologic loss of exclusivity, and how do these differ from small molecule patent cliff strategies?
3. What marketing and go to market models have biosimilar entrants adopted, and which have proved effective?
4. How do the medical benefit and pharmacy benefit channels differ in their commercial logic, and what does this imply for strategy?
5. What commercial infrastructure, in data, systems, distribution and quality assurance, is required to compete under biosimilar economics?
6. How do United States dynamics compare with European markets operating under statutory pricing and tendering?
7. What are the implications for long term market sustainability and patient access?

1.4 Significance

The paper contributes to four literatures. For marketing scholarship, it documents a market in which classical differentiation has been regulatorily suppressed, offering a natural experiment in what remains of marketing when product attributes are held constant by law. For health policy, it identifies mechanisms by which savings are absorbed within the supply chain rather than transmitted to patients, extending work on the relationship between supply chain structure and medication affordability (Asiedu & Asiedu, 2023b). For operations and supply chain scholarship, it treats commercial performance as a function of distribution visibility, quality assurance and resilience rather than of promotion (Nnabueze *et al.*, 2021; Asiedu & Asiedu, 2024b). For practitioners, it offers a typology of viable commercial archetypes in a category where conventional launch playbooks have repeatedly failed.

1.5 Scope and structure

The analysis centres on the United States market during 2024, with comparative treatment of the EU4 markets and the United Kingdom. Adalimumab is used as the principal case, with supporting evidence from infliximab and the oncology monoclonal antibodies. Section 2 reviews the relevant literature across six streams. Section 3 sets out the method. Section 4 presents findings. Section 5 discusses implications, Section 6 draws out managerial and policy recommendations, Section 7 addresses limitations and Section 8 concludes.

2. Literature Review and Conceptual Framework

2.1 The economics of biologic loss of exclusivity

The classical patent cliff literature describes a predictable sequence: Generic entry, rapid price collapse, near total volume transfer, and originator revenue decline of 80 to 90 percent within twelve to eighteen months. Biologics have not followed this curve. Erosion has been slower, price reductions have been shallower, and originators have

retained share long after exclusivity lapsed. Several explanations have been proposed, including manufacturing complexity, physician conservatism regarding immunogenicity, patient attachment to devices and support programmes, and the cost of biosimilar development, which limits the number of entrants and therefore the intensity of price competition.

The evidence assembled here suggests these explanations are secondary. The primary constraint is contractual. Where an intermediary earns revenue proportional to a product's list price, that intermediary has a direct financial interest in maintaining the highest list price product on formulary, irrespective of net cost to the plan sponsor. This mechanism, described in the literature as the rebate wall, converts an apparently competitive market into a de facto exclusive one. It is a specific instance of the incentive misalignment that arises wherever payer and provider payment mechanisms reward gross rather than net economic outcomes (Ilodigwe & Adesemoye, 2019a).

2.2 The rebate wall and misaligned intermediary incentives

Analysis of the adalimumab market found that an additional \$5.7 billion in savings might have been realised over the first eleven months of 2023 had all Humira volume converted to biosimilars, but that such conversion would have reduced pharmacy benefit manager profits in the category by close to 90 percent through lower rebates, lower specialty pharmacy fees and lower reimbursement spreads (Biosimilars Review and Report, 2024). Separately, rebate arrangements were estimated to protect roughly \$2 billion in profit associated with the originator, and biosimilars listed more than 80 percent below the reference product had nonetheless secured only about 2 percent share (American Journal of Managed Care, n.d.). The commercial implication is stark: For a period, the entity best positioned to drive biosimilar adoption was the entity with the strongest financial reason to prevent it.

Structurally, this is a compliance and incentive design problem rather than a failure of competition. Where contracting arrangements generate incentives that diverge from the stated policy objective, the observable outcome is systematic and predictable, and assessing that divergence is properly a compliance risk exercise (Akomolafe *et al.*, 2023b).

2.3 Marketing theory under enforced parity

Pharmaceutical brands are conventionally analysed as credence goods, where the buyer cannot readily verify quality and therefore relies on brand signals, professional endorsement and accumulated trust. Biosimilar regulation deliberately suppresses the attributes on which such differentiation would normally rest. A biosimilar must demonstrate no clinically meaningful difference from its reference product, and asserting superiority is generally not permissible.

Marketing theory offers limited guidance for this condition. The nearest analogue is the literature on brand positioning in regulated professional markets, where claim latitude is externally constrained and positioning must be constructed from evidence, service and structural access rather than from asserted product advantage (Sanni *et al.*, 2020b). Related work on entry barriers in regulated industrial service sectors

indicates that in such environments the decisive competitive constraint is frequently institutional rather than promotional (Sanni & Attah, 2023c), and analyses of go to market design under compliance constraint reach a similar conclusion (Sanni & Atima, 2021a). The pattern parallels the adoption gap identified in other technology diffusion contexts, where objectively superior or lower cost solutions fail to displace incumbents because adoption is treated as a technical rather than a commercial problem (Ogundairo & Ayivi-Donkor, 2024a). Emerging work on autonomous purchasing agents suggests this dynamic will intensify as more purchasing decisions are mediated by systems rather than by persuadable individuals (Ogundairo & Ayivi-Donkor, 2024b).

Portfolio level framing is also relevant. Where a firm holds multiple assets addressing overlapping demand, value maximisation operates across the portfolio rather than within any single brand, which reframes the defence of an individual product as a capital allocation question (Lawal & Oduleye, 2021a, 2023a).

2.4 Channel theory and vertical integration

The emergence of payer affiliated private label biosimilars, in which a pharmacy benefit manager's subsidiary co-commercialises a manufacturer's product under its own label and then preferences that label on its own formularies, represents vertical integration into the marketing function itself. Channel theory would predict that such integration reduces transaction costs and aligns incentives, but also that it concentrates bargaining power and raises barriers to entry for non-partnered suppliers. Both predictions find support in the 2024 evidence.

Analogous dynamics appear in the procurement literature, where supplier relationship structures, qualification requirements and negotiation design determine which suppliers can participate at all, irrespective of their price competitiveness (Akin-Oluyomi *et al.*, 2023b, 2024; Akinleye & Adeyoyin, 2022b; Ike *et al.*, 2021). Negotiation optimisation models indicate that outcomes in concentrated buyer markets are driven by structural position rather than by incremental concession (Akinleye & Adeyoyin, 2022a), and multinational procurement risk frameworks identify supplier dependency of exactly the kind private label arrangements create (Bello *et al.*, 2023).

2.5 Supply chain governance, resilience and access

A parallel literature treats medicine availability as a supply chain governance outcome rather than a pricing outcome. Work on pharmaceutical supply chain governance links environmental and operational risk management directly to sustained access to essential medicines (Eze *et al.*, 2023). Supply chain inefficiency has been shown to translate directly into affordability loss at the patient level (Asiedu & Asiedu, 2023b), and last mile distribution research demonstrates that formulary availability and actual patient access are distinct conditions (Asiedu & Asiedu, 2022).

Resilience frameworks developed after pandemic era disruption are directly applicable to a market where price compression may thin the supplier base (Efobi *et al.*, 2023; Anene & Clement, 2022; Tonoyan *et al.*, 2024a). End to end visibility and traceability frameworks provide the operational instrumentation such resilience requires (Nnabueze *et al.*, 2021; Okoruwa *et al.*, 2024), and lean

supply chain practice offers the cost structure that low margin biosimilar operations demand (Ike *et al.*, 2022; Efobi *et al.*, 2022b).

2.6 Commercial data infrastructure and analytics

A biosimilar commercial organisation competing on contracts rather than promotion depends on systems more than on messages. Three infrastructural streams are relevant. The first concerns customer data and relationship management architecture. Governance frameworks for platform management in regulated healthcare environments address precisely the conditions biosimilar commercial teams operate under, in which customer records contain sensitive information and access must be controlled by role (Badmus *et al.*, 2019b, 2024). Integration and data engineering design determine whether account, contract and dispensing data can be reconciled at all (Badmus *et al.*, 2019a), while deployment governance determines whether commercial systems can change at the speed contracting cycles require (Badmus *et al.*, 2018, 2022a).

The second concerns analytics and measurement. Marketing return on investment measurement is unusually difficult in regulated categories, where the buyer, the prescriber and the patient are distinct parties and the causal chain between activity and revenue is long (Sanni *et al.*, 2020a). Attribution modelling addresses the resulting bias in multi touch journeys (Sanni *et al.*, 2022b; Basnet *et al.*, 2024), and funnel level instrumentation addresses revenue leakage between stages (Sanni & Wedraogo, 2024; Eyetsemitan *et al.*, 2024b). Forecasting under volatility, dashboard design for executive visibility and real time performance tracking complete the measurement stack (Sanni & Atima, 2021b; Tonoyan *et al.*, 2024b; Medon & Oduleye, 2024).

The third concerns the governance of analytics itself. As commercial decisions are increasingly automated, auditability and explainability become preconditions rather than refinements, particularly in healthcare applications (Sanni *et al.*, 2022c). Data protection constraints shape what customer and patient data may be used and how (Aliliele *et al.*, 2024b; Atakpa & Abolaji, 2022), and federated approaches offer a route to cross organisational analysis without pooling sensitive data (Sanni *et al.*, 2023).

2.7 Compliance, audit and the governance of commercial practice

Because biosimilar competition is conducted through contracts, rebates and channel arrangements rather than through promotion, the governance risks migrate accordingly. Risk based auditing and compliance risk assessment frameworks provide the control environment for contracting practice (Akomolafe *et al.*, 2023a; Akomolafe & Agu, 2018), and integrated governance approaches link compliance capability to financial resilience (Akomolafe & Agu, 2019c). Audit analytics applied to healthcare financial oversight offers the detection layer (Abetoh & Atakpa, 2024; Atakpa & Fobellah, 2023; Adelanwa *et al.*, 2023b).

A distinct legal literature addresses the governance of algorithmic decision making, data privacy across jurisdictions and the treatment of proprietary models, all of which bear on commercial systems that allocate access or price (Annan, 2022, 2024). Intellectual property questions arising from automated generation of commercial content are also unresolved (Annan, 2023).

2.8 Research gap

The literature documents biosimilar pricing, uptake rates and policy barriers extensively. It documents the commercial and marketing response only sporadically and largely through practitioner commentary, and it rarely connects that response to the infrastructural and governance literatures on which execution depends. This paper addresses that gap by treating the 2024 market as a case in strategic adaptation.

3. Methodology

3.1 Design

The study uses a qualitative, theory building multiple case design supported by descriptive secondary quantitative data. This design suits a phenomenon that is recent, structurally complex and characterised by a small number of consequential events rather than a large population of comparable observations. The approach is consistent with conceptual model building methods used elsewhere in health system and commercial strategy research, where the object of study is a mechanism rather than an effect size (Ilodigwe & Adesemoye, 2024b; Lawal & Oduleye, 2018a).

3.2 Data sources

Category	Sources
Market share and pricing	Samsung Bioepis US Biosimilar Market Report, Q4 2024; IQVIA analyses; published average sales price series
Savings and volume	Association for Accessible Medicines and IQVIA Institute savings report, 2024 edition
Regulatory	FDA draft guidance on interchangeability, June 2024; FDA approval and interchangeability records
Corporate strategy	AbbVie and other manufacturer disclosures and launch announcements through Q4 2024
Channel behaviour	Trade and analyst reporting on formulary exclusions and private label arrangements during 2024
European comparison	ISPOR Europe 2024 pricing policy analysis; European tendering literature
Conceptual and framework literature	Peer reviewed work on regulated market positioning, payer and provider incentive alignment, pharmaceutical regulatory science, supply chain governance, commercial data infrastructure and compliance analytics

3.3 Case selection

Three molecule markets were selected on a most different basis to permit contrast:

- **Adalimumab** (pharmacy benefit, self administered, high rebate intensity, ten entrants) as the principal case.
- **Infliximab** (medical benefit, provider administered, longer competitive history) as a maturity comparison.
- **Trastuzumab, bevacizumab and rituximab** (medical benefit, average sales price reimbursement) as a contrasting case isolating the effect of channel economics.

3.4 Analytical approach

Documents were coded thematically against the research questions, with particular attention to sequencing: Which commercial action preceded which market movement. Where quantitative series were available, inflection points were identified and matched against contemporaneous commercial or regulatory events. Triangulation across

manufacturer, payer, provider and analyst sources was used to mitigate the promotional bias present in individual sources, following practice in evidence synthesis under conflicting source incentives (Adelanwa *et al.*, 2024).

3.5 Framework construction

The archetype typology presented in Section 5.3 was constructed inductively by grouping observed firm behaviours against three dimensions: Customer interface ownership, cost structure and portfolio breadth. Comparable capability maturity and readiness framing informed the construction (Eze *et al.*, 2022b).

3.6 Limitations of method

Net prices in the United States are confidential. All price analysis therefore relies on list prices, average sales prices and inference, and understates the true competitive position of rebated products. Private label contract terms are not disclosed. Attribution of share movement to specific commercial actions is inferential rather than causal. These limitations are revisited in Section 7.

4. Findings

4.1 The 2024 market baseline

By late 2024 the United States biosimilar market had reached meaningful scale but highly uneven penetration. Approximately 61 biosimilars had been approved across 17 molecules, with 41 marketed, and four approvals were added in the final quarter covered, spanning eculizumab, aflibercept and ustekinumab. Average sales prices for biosimilar molecules declined by roughly 53 percent across the first five years following initial biosimilar entry, and biosimilars captured on average about 53 percent share within five years of launch (Samsung Bioepis, 2024). Penetration varied sharply by channel and molecule:

Molecule group	Channel	Approximate 2024 position
Trastuzumab, bevacizumab, rituximab	Medical benefit	Deep price erosion; Q4 2024 average sales price discounts of roughly 56, 48 and 65 percent respectively against reference
Infliximab	Medical benefit	Biosimilar share approaching 47 percent
Pegfilgrastim, ophthalmology agents	Medical benefit	High biosimilar share
Adalimumab	Pharmacy benefit	Approximately 2 percent in early 2024, rising to roughly 22 percent by late 2024
Insulin glargine	Pharmacy benefit	Persistently low

The pattern is unambiguous. Biosimilars perform well where the purchaser is a provider reimbursed on a percentage of average sales price and therefore neutral or favourable to lower cost products, and poorly where the purchaser is an intermediary earning rebates calculated against list price.

Slower uptake categories, including immunology, filgrastim, epoetin alfa and insulin glargine, reached only about 26 percent share by year five, roughly half the all category average (American Journal of Managed Care, n.d.).

4.2 The decision maker has moved

The central commercial finding of the period is that the

effective buyer in the pharmacy benefit channel is no longer the prescriber. Through the first quarter of 2024, the largest pharmacy benefit managers maintained the reference product on formulary, and adalimumab biosimilar uptake remained close to 2 percent despite aggressive discounting and available interchangeable options (American Journal of Managed Care, n.d.; GaBI Online, n.d.).

In April 2024 a major pharmacy benefit manager removed Humira from its main national commercial formularies in favour of biosimilar options. Prescriptions for the preferred biosimilar, Hyrimoz, grew 36 percent in the first week following the change (Venable LLP, 2024), and the product reached roughly 14 percent of adalimumab claims over the following period (GaBI Online, n.d.). Adalimumab biosimilar share overall rose from about 2 percent in early 2024 to roughly 22 percent by late 2024, driven principally by private label brands rather than by conventionally marketed biosimilars (Samsung Bioepis, 2024).

Three implications follow.

First, the marketing target has shifted decisively upstream. Share was determined by a contracting decision, not by prescriber persuasion or patient preference. Conventional segmentation and targeting models built around prescriber deciles have limited value where the effective decision unit is a small number of institutional accounts, a condition already documented in other regulated professional service markets (Atima *et al.*, 2022; Basnet *et al.*, 2021).

Second, the mechanism operated without interchangeability. The products that gained share were not automatically substituted at the pharmacy; they were positioned by formulary. Conversely, Cyltezo, the first interchangeable adalimumab biosimilar, held under 1 percent share (Venable LLP, 2024). Interchangeability, in which manufacturers had invested significant clinical development expenditure on the assumption of commercial value, was empirically shown not to drive share in this market.

Third, the gain was structurally conditional. Patient level transition remained limited: In 2023 only about 2 percent of treatment naive patients began adalimumab therapy on a biosimilar, rising to roughly 14 percent in 2024, with the originator still capturing approximately 86 percent of new patients, and most biosimilar starts arising from switches rather than from new initiation (GaBI Online, n.d.). Access therefore improved on the terms of the formulary and private label arrangements rather than through independent clinical adoption. Because these arrangements govern which product a chronically treated patient receives and for how long, they raise continuity of care questions of the kind examined in the hospital pharmacy access literature, where therapy interruption risk rises when supply arrangements rather than clinical judgement determine product availability (Asiedu & Asiedu, 2024a).

4.3 Private label as channel innovation

The private label or white label biosimilar is the most significant commercial innovation of the period. Under this model, an intermediary establishes a subsidiary that partners with a biosimilar manufacturer to co commercialise the product under the subsidiary's own label. The subsidiary then holds a favourable position on the affiliated formulary. The leading example during 2024 was Cordavis, established by a major pharmacy benefit manager's parent, which co promoted and commercialised Hyrimoz with Sandoz alongside the originator product (GaBI Online, n.d.).

Aggregate uptake gains in the adalimumab market during 2024 were attributed principally to private label brands of this type (Samsung Bioepis, 2024).

Strategically, the model resolves the rebate wall by internalising it. The intermediary's margin no longer depends on the originator's rebate because it now earns on the sale of the product it labels. For the manufacturer, a private label agreement converts an uncertain commercial launch into a contracted volume commitment, and substantially reduces the need for a field force, brand campaign and patient support infrastructure. The specialty pharmacy is not a neutral conduit in this arrangement but an active commercial participant whose dispensing capability and cooperation determine whether formulary access converts into patient level supply, consistent with evidence on pharmacy led delivery models as determinants of medicine availability (Ilodigwe & Adesemoye, 2020).

The costs are equally clear. The manufacturer surrenders brand identity, direct customer relationships and pricing autonomy, and becomes a contract supplier whose position depends on periodic renegotiation. This is the classic dependency exposure identified in supplier relationship research, where concentrated buyer power converts a commercial relationship into a structural vulnerability (Akinleye & Adeyoyin, 2022b; Ike *et al.*, 2021; Tonoyan *et al.*, 2024a). Non partnered manufacturers face effective exclusion regardless of price, which raises unresolved questions about the long term vibrancy of a market in which vertically integrated intermediaries both supply and prefer their own products.

4.4 The dual list price problem

A distinctive artefact of the rebate system is the dual pricing strategy, in which the same molecule is offered at two list prices: A high list price version generating large rebates for intermediaries operating on rebate retention models, and a low list price version for plan sponsors seeking lower net cost and lower patient coinsurance.

Several adalimumab manufacturers launched both versions. The tactic did not by itself displace the originator, because a high list price biosimilar competes on the incumbent's terms without the incumbent's rebate scale, while a low list price biosimilar is unattractive to rebate driven purchasers. That biosimilars listed more than 80 percent below the reference product nonetheless held only about 2 percent share before the formulary change demonstrates the point directly (American Journal of Managed Care, n.d.).

Dual pricing is best understood as a symptom rather than a strategy. It exists because manufacturers cannot identify a single price that satisfies both purchasing logics, and it imposes real costs in complexity, channel conflict and patient confusion. Pricing architecture research indicates that where a single asset must be valued differently across segments, the resulting structure is stable only when the segments are genuinely separable, a condition the rebate system does not satisfy (Tonoyan *et al.*, 2023).

4.5 Originator response: Substitution rather than defence

The most consequential originator strategy of the period was not defence of the eroding brand but migration of demand to adjacent, patent protected molecules.

AbbVie's execution is the reference case. Anticipating adalimumab erosion, the company invested heavily in

Skyrizi and Rinvoq, pursued label expansion across the indications Humira had held, and generated head to head evidence, including a psoriasis trial in which risankizumab achieved 90 percent skin clearance in 72 percent of patients at week 16 against 47 percent for adalimumab, with 66 percent of adalimumab responders who switched maintaining high clearance against 21 percent of those who continued (Center for Biosimilars, 2024b). By the third quarter of 2024 the substitution was visible in reported results: Global Humira revenue fell 37.2 percent to \$2.227 billion with United States sales down 41.6 percent, while Skyrizi rose 50.8 percent to \$3.205 billion and Rinvoq rose 45.3 percent to \$1.614 billion (Center for Biosimilars, 2024b).

The commercial significance is that total adalimumab molecule volume declined during 2024 even as biosimilar fill volume grew sharply, rising roughly 400 percent between March and April 2024, with the contraction in total volume attributed to the growth of the successor products (Center for Biosimilars, 2024b). Biosimilar manufacturers were competing for a shrinking pool. Critics describe this as product hopping; the firms describe it as portfolio lifecycle management. Either characterisation identifies the same strategic reality: In biologics, the originator's most effective response to loss of exclusivity may be to make the contested market smaller. The underlying logic is one of portfolio architecture and capital allocation, in which value is maximised across a set of assets rather than defended within any single one (Lawal & Oduleye, 2021a, 2023a).

Secondary originator tactics observed include:

- **Unbranded biologics:** Launching an unbranded version of the reference product at a lower list price, allowing the originator to compete in the low list price tier without repricing the brand.
- **Formulation lifecycle management:** Migrating patients to high concentration, citrate free presentations before entry, so that biosimilars referencing the older formulation face a partially converted base (Center for Biosimilars, 2024a).
- **Patent estate management:** Sequencing a large patent estate to defer entry, which in the adalimumab case delayed United States biosimilar competition for years after initial approvals (Center for Biosimilars, 2024a).
- **Contracting depth:** Rebate structures conditioned on formulary position across a portfolio rather than a single product.

Forecasting the timing and depth of erosion is itself a demanding analytical exercise, since revenue projection under structural discontinuity behaves differently from projection under continuous conditions (Tonoyan *et al.*, 2021a; Lawal & Oduleye, 2019b).

4.6 Biosimilar entrant strategy: from promotion to access

Biosimilar entrants in 2024 substantially reallocated commercial resources away from demand generation and toward access, contracting and service. The shift mirrors the broader migration from promotional to analytics driven go to market design observed in sectors where compliance constraints limit conventional promotion (Sanni & Atima, 2021a).

Access first resourcing: The unit of commercial planning became the payer contract rather than the prescriber territory. Field force models moved from share of voice

towards account based coverage of integrated delivery networks, group purchasing organisations and specialty pharmacies. Where target populations are concentrated, segmentation and forecasting models must operate at account rather than individual level (Basnet *et al.*, 2021; Atima *et al.*, 2022).

Reimbursement and conversion support: For products in the medical benefit, field reimbursement managers, coding and billing support and prior authorisation assistance materially affect adoption. For the pharmacy benefit, the operative metric became conversion: Analysis found that only about one in three patients prescribed an adalimumab biosimilar successfully filled within thirty days of the first attempt (Biosimilars Council & IQVIA, 2024). A prescription that does not convert to a fill is commercially worthless, so support programme design, copay deployment speed and specialty pharmacy coordination became primary rather than supporting functions. Diagnosing where volume is lost between prescription and dispense is structurally a funnel leakage problem, and benefits from the same stage level instrumentation used to resolve revenue leakage in other high value service categories (Sanni & Wedraogo, 2024; Eyetsemitan *et al.*, 2024b; Ogundairo & Ayivi-Donkor, 2023a). Workflow automation in the support function itself determines whether that instrumentation can be acted upon at operating speed (Eyetsemitan *et al.*, 2024a; Akinleye & Adeyoyin, 2021).

Peripheral differentiation: With molecule level differentiation prohibited, entrants competed on device design, injection comfort, citrate free formulation, presentation breadth, cold chain and supply reliability, and digital adherence support. Supply reliability in particular is a function of manufacturing quality systems rather than of commercial effort, and is increasingly treated as a determinant of competitive standing rather than a compliance baseline (Asiedu & Asiedu, 2024b). Delivery system innovation offers a further, if narrow, avenue (Ike *et al.*, 2024b).

Evidence and value demonstration: Where price parity is approached, competition shifts to demonstrated total cost of care. Real world evidence and outcomes analytics have accordingly become part of the commercial rather than the medical function, supporting budget impact arguments made directly to plan sponsors (Ilodigwe & Adesemoye, 2024a). Decision support tooling that translates such evidence into operational and resource planning terms strengthens these arguments materially (Adelanwa *et al.*, n.d.; Adelanwa *et al.*, 2023a).

Education as market development: Because prescriber and patient hesitancy suppresses category volume for all entrants, education about biosimilarity functions partly as a public good. Firms have addressed this through trade associations and coalitions rather than through proprietary campaigns, an unusual configuration in pharmaceutical marketing. Professional education design and digital delivery research is directly relevant to how such programmes reach clinicians at scale (Orise & Niniola, 2024).

Portfolio scale: Firms with multiple biosimilars across molecules can amortise regulatory, quality, distribution and account management infrastructure, negotiate across a basket, and absorb single product losses. Firms dependent on one or two assets have limited resilience against a lost formulary cycle (Lawal & Oduleye, 2021a).

4.7 Two markets, two models

The evidence supports treating the medical benefit and pharmacy benefit as separate markets requiring separate commercial models.

Dimension	Medical benefit (buy and bill)	Pharmacy benefit
Effective buyer	Provider practice or hospital	Pharmacy benefit manager and plan sponsor
Reimbursement basis	Percentage of average sales price	Rebate and net price negotiation
Incentive direction	Broadly compatible with lower cost adoption, though percentage based margin can favour higher priced units	Historically opposed to biosimilar adoption absent private label
Decisive commercial capability	Account economics, reimbursement support, contracting with group purchasing organisations	Rebate and net price engineering, private label partnership
Observed uptake	Moderate to high	Low to moderate, and concentrated in partnered products
Marketing intensity required	Moderate	Low if partnered, futile if not

An important nuance is that percentage based reimbursement in the medical benefit is not straightforwardly pro biosimilar: Because provider margin is a percentage of an average sales price, a lower priced product yields a smaller absolute margin. Proposals for prospective shared savings arrangements between payers and providers have been advanced to neutralise this residual bias (Journal of Managed Care and Specialty Pharmacy, 2021). This is a specific application of the wider problem of aligning payer and provider incentives so that the party controlling utilisation shares in the savings it generates (Ilodigwe & Adesemoye, 2019a).

Institutional purchasing in the medical benefit channel also depends on the acquiring organisation's own procurement analytics, since hospital and network buyers assess biosimilars against internal cost, risk and continuity criteria rather than against manufacturer claims (Filani *et al.*, 2022; Akinleye *et al.*, 2023; Babatope *et al.*, 2023). On the payer side, the increasing use of algorithmic risk assessment in coverage and underwriting decisions further removes the determination from individual clinical judgement (Oluwo *et al.*, 2024).

4.8 Regulation as a commercial variable

On 20 June 2024, the FDA issued draft guidance proposing that switching studies would generally no longer be required to support interchangeability, reasoning that accumulated experience showed negligible risk of safety or diminished efficacy from switching (U.S. Food and Drug Administration, 2024). The agency noted that nine of the thirteen interchangeable biosimilars approved to that point had been approved without switching studies, and the comment period closed on 20 August 2024 (Venable LLP, 2024).

The commercial consequences are significant and largely negative for incumbents' differentiation strategies.

- Development cost falls, lowering entry barriers and increasing the expected number of competitors per molecule.

- Interchangeability ceases to function as a differentiator once most or all competitors can obtain it.
- Investments already made in switching studies for competitive positioning are devalued.
- Firms that had built commercial narratives around interchangeability require repositioning.

The evidence for the second point was already visible before the guidance: Oncology molecules with deep biosimilar penetration had no approved interchangeable products at all, while adalimumab had several, indicating that payer preference rather than regulatory designation drove uptake in both directions (Venable LLP, 2024).

The wider lesson is that in a category defined by regulation, regulatory change is a first order commercial risk rather than a compliance matter, and should be modelled as such in launch planning. Frameworks that treat regulatory readiness as a staged organisational capability rather than a submission event are directly applicable here (Eze *et al.*, 2022b). Equally, the trade off the FDA navigated between approval speed, evidence quality and safety assurance is the same trade off formalised in risk based accelerated approval models, and its resolution has direct commercial consequences for the number and timing of competitors a firm will face (Eze *et al.*, 2024b). Comparative regulatory governance research indicates that the pace and predictability of such shifts varies substantially across jurisdictions, which complicates global launch sequencing (Afrihyia *et al.*, 2024a; Eze *et al.*, 2024a).

4.9 Commercial operations infrastructure

A finding that emerges across cases is that biosimilar commercial performance depends disproportionately on operational systems rather than on customer facing activity. Three capabilities recur.

Contract and account data architecture: A biosimilar competing across dozens of plan and institutional accounts must reconcile contract terms, formulary status, dispensing data and rebate obligations. This is a data integration problem before it is a commercial one (Badmus *et al.*, 2019a), and the governance and interoperability requirements resemble those identified for health system data architecture at national scale (Ilodigwe & Adesemoye, 2021). Platform governance in regulated healthcare settings additionally constrains how such records are structured and accessed (Badmus *et al.*, 2019b, 2024), and role based security design is a functional requirement rather than an IT preference (Aliliele *et al.*, 2024a).

Deployment velocity: Formulary cycles are annual, and contract terms change within them. Commercial systems that cannot be modified quickly impose a strategic cost, which is why development and release governance has commercial rather than purely technical significance (Badmus *et al.*, 2018, 2022a; Ladapo *et al.*, 2022; Sanni & Attah, 2023a). Service management maturity determines whether field and account teams can rely on these systems operationally (Ladapo *et al.*, 2023a, 2023b), and CRM based forecasting design determines whether the resulting data supports commercial planning rather than merely recording it (Dada *et al.*, 2021b).

Analytics governance: Where pricing, targeting or access decisions are automated or model assisted, the organisation must be able to explain them to payers, auditors and regulators. This requirement is heightened in healthcare

contexts, where automated decisions may bear on patient access (Annan, 2024; Afrihyia *et al.*, 2024a).

These capabilities are not glamorous and are frequently under resourced in organisations whose leadership formed in branded pharmaceutical environments, where commercial advantage was understood to reside in messaging and relationships. The 2024 evidence suggests the advantage now resides substantially in systems.

4.10 Distribution, traceability and contracting infrastructure

Biosimilar competition also increases the operational load on distribution and settlement. Volume shifts between products with short notice following formulary changes, as the roughly 400 percent month on month increase in adalimumab biosimilar fills after the April 2024 change illustrates (Center for Biosimilars, 2024b), and rebate and chargeback obligations must be reconciled across wholesalers, specialty pharmacies and plans.

End to end visibility frameworks provide the traceability necessary to manage such shifts without stockouts or overstock (Nnabueze *et al.*, 2021; Okoruwa *et al.*, 2024), and demand forecasting under discontinuity becomes materially harder when a single contracting decision can reallocate a large share of category volume within weeks (Aifuwa *et al.*, 2020; Akin-Oluyomi *et al.*, 2023c).

On the settlement side, the administrative burden of rebate and chargeback reconciliation is substantial and largely invisible in strategic discussion. Work on automated contract execution and dispute resolution in supplier payment systems addresses precisely this class of problem (Akomolafe *et al.*, 2022, 2024b), as does research on payment architecture, interoperability and regulatory adaptation across jurisdictions (Adesuyi *et al.*, 2023; Akomolafe *et al.*, 2024a; Olaogun *et al.*, 2023). Distributed ledger approaches to verifiable commercial workflows have been proposed for related transparency problems (Sanni *et al.*, 2024).

4.11 Manufacturing quality, supply reliability and shortage risk

Where products are clinically equivalent and price converges, the ability to supply becomes a primary competitive attribute. Quality assurance in manufacturing has accordingly been reconceptualised as a determinant of supply reliability rather than as a regulatory floor (Asiedu & Asiedu, 2024b), and inventory and distribution process design carries direct commercial consequence (Ike *et al.*, 2022).

This matters more in biosimilars than in small molecules because manufacturing is more complex, capacity is less fungible, and a supply interruption in a contracted private label arrangement may terminate the commercial relationship as well as the supply. Resilience indices and vendor risk models offer a means of assessing this exposure prospectively (Efobi *et al.*, 2023; Tonoyan *et al.*, 2024a; Bello *et al.*, 2023), while shortage early warning frameworks address the system level consequence when it materialises (Eze *et al.*, 2022a). Infrastructure resilience planning under stress conditions provides a parallel from the diagnostic sector, where continuity of a service depends on capacity decisions taken years earlier (Aminu-Ibrahim *et al.*, 2018).

4.12 European contrast

European markets operate under materially different commercial logic. Pricing is frequently statutory, procurement is often conducted through tendering at national, regional or hospital level, and prescriber level demand generation is correspondingly less influential.

Illustrative arrangements include France, where biosimilar prices are set at approximately 40 percent below the originator with tenders conducted at national, regional and hospital levels, and Germany, where regional quotas and physician discretion combine with reference pricing to produce steadier, competition led reductions. Between January 2019 and May 2024, 17 biosimilars launched across the EU4 markets and the United Kingdom, and markets with regulated pricing and hospital level tendering pursue affordability and market stability as joint objectives (Yadav, 2024).

The European model produces faster, more predictable uptake and lower prices, but carries its own risk. Sustained tender driven price compression has raised concerns about supplier exit, thinning emergency stock, reduced competition over time and shortage vulnerability of the kind already familiar in off patent small molecules (Off-patent biologicals and biosimilars tendering in Europe, 2021). Commentators have suggested that a sustainable market may require roughly three to four viable suppliers per molecule, and that award criteria should extend beyond price alone to include supply security. Because tender qualification and supplier risk assessment determine which manufacturers can compete at all, procurement design functions as a de facto market structure instrument (Akin-Oluyomi *et al.*, 2023b; Akinleye & Adeyoyin, 2022b). Award criteria incorporating sustainability and non price dimensions have been developed in other procurement contexts and are directly transferable (Akin-Oluyomi *et al.*, 2023a, 2023d).

For manufacturers, the two regions demand different capabilities: Tender pricing discipline, cost of goods leadership and supply reliability in Europe; rebate architecture, channel partnership and account management in the United States. Firms operating across both must also manage divergent regulatory requirements and cross border supplier relationships, a coordination burden that harmonisation frameworks are intended to reduce but which remains material outside the most integrated markets (Eze *et al.*, 2024a; Akin-Oluyomi *et al.*, 2024; Annan, 2022).

5. Discussion

5.1 What marketing becomes when the product cannot differ

The biosimilar category constitutes an unusual natural experiment. Regulators have fixed the product attribute set; differentiation claims on efficacy or safety are largely foreclosed. The evidence indicates that marketing does not disappear under these conditions but relocates, consistent with findings that positioning in regulated markets is constructed from structural and evidentiary assets rather than asserted product advantage (Sanni *et al.*, 2020b).

Reconsidered against the classical marketing mix:

- **Product** collapses towards parity at molecule level and reasserts itself at the periphery: Device, formulation, presentation and packaging.
- **Price** becomes the dominant variable, but bifurcates into list price and net price, which move in opposite directions and serve different buyers.

- **Place**, historically a low salience element in pharmaceutical marketing, becomes the decisive one. Formulary position, specialty pharmacy cooperation and private label partnership determine outcomes.
- **Promotion** shifts from persuasion to enablement: Reimbursement support, conversion assistance and category level education rather than share of voice.

The implication for practice is that biosimilar commercial leadership requires competencies closer to those of a business to business industrial supplier or a contract manufacturer than to those of a branded pharmaceutical marketing organisation. Several early biosimilar failures are attributable to organisations staffing and structuring biosimilar units as though they were brand units. Where content and communication retain a role, their function is conversion support rather than preference formation (Sanni & Attah, 2023b).

5.2 Gross to net and the economics of promotion

Biosimilar net prices in competitive molecules can sit far below reference list prices, with observed list discounts exceeding 80 percent in the adalimumab market (American Journal of Managed Care, n.d.). This compresses the absolute margin available to fund commercial activity, which in turn constrains field force size, support programme scope and marketing expenditure. A commercial model designed for branded gross margins will be unprofitable at biosimilar net prices even at respectable share.

Margin compression also raises the evidentiary bar for commercial spend. Where contribution per unit is thin, investment must be justified against measured incremental effect rather than against activity metrics, which is difficult in regulated categories where attribution across payer, provider and patient touchpoints is confounded (Sanni *et al.*, 2020a, 2022b; Basnet *et al.*, 2024). Forecasting commercial performance across channels under these conditions carries irreducible uncertainty that should be represented explicitly rather than suppressed (Wedraogo & Sanni, 2024). Embedding economic evaluation directly into operational data flows, rather than conducting it retrospectively, has been proposed as a response (Ogundairo & Ayivi-Donkor, 2023b), alongside cost optimisation modelling at the portfolio level (Tonoyan *et al.*, 2022b; Lawal & Oduleye, 2023a). Executive visibility into these economics, in near real time, is itself a capability rather than a reporting formality (Sanni & Atima, 2021b; Tonoyan *et al.*, 2024b).

This creates a reinforcing dynamic. Firms that cannot fund conventional commercial infrastructure are pushed towards private label arrangements, which further reduce their need for that infrastructure, which further erodes their capacity to compete independently should the partnership lapse. Over time this concentrates commercial capability in the intermediaries rather than the manufacturers.

5.3 A typology of viable archetypes

The evidence supports four broadly viable commercial archetypes, with a fifth that appears structurally unviable.

The channel partner: Competes primarily to win private label or exclusive contracts. Minimal customer facing infrastructure, competitive cost of goods, high volume, thin margin, high dependency risk.

The portfolio scale player: Operates numerous biosimilars across molecules and channels, amortising fixed infrastructure and negotiating across a basket. Resilient but

capital intensive (Lawal & Oduleye, 2021a).

The integrated originator entrant: An established biologics company using existing manufacturing, quality, medical affairs and account relationships to enter selectively, often in its own therapeutic areas. Strong synergies and the ability to sustain losses.

The medical benefit specialist: Concentrates on buy and bill categories where provider economics are more favourable, competing on reimbursement support, supply reliability and account management.

The independent branded biosimilar: which appears structurally challenged. This model attempts to build a differentiated biosimilar brand with a conventional field force and promotional programme in the pharmacy benefit channel without an intermediary partnership. The 2023 to 2024 adalimumab experience suggests it does not clear the rebate wall regardless of discount depth.

Transitions between archetypes are organisationally demanding, since they require simultaneous change in capability, cost structure and customer interface. The change management literature on digital and operating model transformation is directly relevant to firms attempting them (Eyetezmitan *et al.*, 2023a), as is work on lean scaling of operations under resource constraint (Ambali *et al.*, 2021).

5.4 Implications for originator pre loss of exclusivity planning

Three lessons emerge for originators approaching biologic loss of exclusivity.

First, the successor asset must be commercially mature before entry, not after. The AbbVie transition worked because Skyrizi and Rinvoq had indication breadth, evidence and payer position established in advance.

Second, evidence generation should be comparative and prospective. Head to head superiority data against the firm's own soon to be genericised molecule is commercially valuable in a way that is unusual in pharmaceutical development.

Third, contracting and formulation lifecycle decisions taken three to five years before entry constrain the whole subsequent defence. Presentation migration, patent sequencing and portfolio rebate architecture are pre loss of exclusivity decisions with post loss of exclusivity consequences. Capital allocation and treasury planning across such a transition is non trivial, since revenue declines in one geography while investment rises in another (Dada *et al.*, 2021a; Tonoyan *et al.*, 2021b).

It is important to note that the third of these attracts substantial policy criticism, and firms should anticipate that tactics which are currently lawful may face legislative or regulatory constraint.

5.5 Sustainability tension

A tension runs through the findings. Mechanisms that accelerate biosimilar uptake in the short run, notably private label exclusivity and aggressive tendering, simultaneously reduce the number of manufacturers able to sustain participation. If commercial returns do not support development, the pipeline thins irrespective of regulatory facilitation, and the savings already demonstrated will not extend to the far larger wave of biologic expiries still ahead (Association for Accessible Medicines, 2024).

This is ultimately a question of supply chain governance rather than of pricing policy alone, since the conditions that

sustain multiple qualified suppliers also determine access continuity and resilience to disruption (Eze *et al.*, 2023; Efobi *et al.*, 2023). The policy objective, then, is not merely lower prices but a market structure in which several suppliers can remain viable. This is a market design problem rather than a pricing problem, and it is not obviously solved by either the United States rebate model or the European tender model in their current forms.

5.6 Access, equity and the distribution of savings

A recurring question is who ultimately receives the savings biosimilars generate. Where patient cost sharing is calculated against list price while plan economics are settled on net price, competition can reduce system cost without reducing patient cost. This is the mechanism by which supply chain inefficiency translates into affordability loss at the point of care (Asiedu & Asiedu, 2023b).

Access is also unevenly distributed geographically and socioeconomically. Formulary availability does not guarantee dispensing availability, particularly in underserved areas where distribution and pharmacy infrastructure is thinner (Asiedu & Asiedu, 2022; Aminu-Ibrahim *et al.*, 2020; Akinse *et al.*, 2023a). Geospatial methods developed to assess catchment and siting decisions in other sectors offer a means of quantifying this unevenness (Tonoyan *et al.*, 2022a). Infrastructure investment translates into access outcomes only where the operating model supports it (Aminu-Ibrahim & Ogbete, 2023; Ogbete & Aminu-Ibrahim, 2024; Aminu-Ibrahim *et al.*, 2024).

Digital access mechanisms extend reach but introduce their own equity and trust considerations (Orise & Niniola, 2022), and earlier detection of chronic disease expands the treated population against which biosimilar demand is measured (Afrihyia *et al.*, 2023).

5.7 Governance, compliance and reputational risk

As competition moves into contracting, the associated governance risks move with it. Rebate arrangements, private label agreements and channel exclusivity attract regulatory and litigation attention, and the control environment around them requires the same rigour applied to financial reporting (Akomolafe *et al.*, 2023a; Akomolafe & Agu, 2018; Akomolafe *et al.*, 2023b).

Two specific exposures merit attention. The first is data protection. Commercial and patient support operations handle patient level information, and the applicable obligations are jurisdictionally variable and enforcement sensitive (Aliliele *et al.*, 2024b; Mbonu *et al.*, 2018, 2022a; Afrihyia *et al.*, 2024b; Orise & Niniola, 2023). The second is systems integrity: Healthcare and payer connected infrastructure is an established target, and disruption carries commercial as well as clinical consequence (Adebayo *et al.*, 2023). Control automation and continuous monitoring reduce the cost of maintaining assurance across these exposures (Mbonu *et al.*, 2022; Aliliele *et al.*, 2023a).

6. Managerial and Policy Implications

6.1 For biosimilar manufacturers

1. Resource access and contracting ahead of promotion. In the pharmacy benefit channel, promotional investment without formulary position produces negligible return.
2. Decide the partnership question explicitly. Pursuing private label and independent branding simultaneously dilutes both, and dependency exposure should be

assessed formally rather than assumed (Bello *et al.*, 2023).

3. Measure conversion, not prescriptions. Fill rate within thirty days is the operative commercial metric, and should be instrumented at each stage between prescription and dispense (Sanni & Wedraogo, 2024; Eyetsemitan *et al.*, 2024b).
4. Build cost of goods advantage early. It is the only durable defence in a market that converges on price (Tonoyan *et al.*, 2022b).
5. Treat regulatory posture as a commercial capability rather than a submission activity, and stress test interchangeability investment against the possibility that the designation becomes widely available (Eze *et al.*, 2022b).
6. Differentiate where differentiation is permitted: Device, presentation, supply reliability and service, while recognising the limits of these levers when payers decide on net cost (Asiedu & Asiedu, 2024b).
7. Invest in contract, account and dispensing data architecture as a commercial asset, not as IT overhead (Badmus *et al.*, 2019a, 2019b).
8. Where analytics and automation are deployed against payer and prescriber targeting, prioritise auditability and explainability, since decision logic in regulated health markets must withstand scrutiny (Sanni *et al.*, 2022c).

6.2 For originators

1. Begin succession planning at least five years before anticipated entry and judge the transition on portfolio revenue rather than brand retention (Lawal & Oduleye, 2021a).
2. Generate comparative evidence supporting migration to successor assets.
3. Expect defence tactics to attract policy scrutiny and plan for a narrowing legal envelope (Annan, 2024).
4. Consider participating in the biosimilar market directly where manufacturing and account assets can be reused.
5. Model the erosion curve explicitly rather than extrapolating from small molecule precedent, since the shape differs materially by channel (Tonoyan *et al.*, 2021a; Medon & Oduleye, 2024).

6.3 For payers and policymakers

1. Address the divergence between list and net price, which currently prevents price competition from reaching patients whose cost sharing is calculated on list price (Asiedu & Asiedu, 2023b).
2. Scrutinise vertical integration in the private label model, which delivers uptake but concentrates market power and may foreclose non-partnered suppliers.
3. Extend procurement award criteria beyond lowest price to include supply security and multi-supplier sustainability, particularly in tender-based systems (Akin-Oluoyomi *et al.*, 2023a, 2024).
4. Align provider economics in the medical benefit through prospective shared savings rather than percentage-based margins (Ilodigwe & Adesemoye, 2019a).
5. Monitor pipeline thinning as a leading indicator of market failure, since development decisions precede shortages by several years, and pair this monitoring with the early warning mechanisms already developed

for essential medicine supply (Eze *et al.*, 2022a).

6. Treat access as a distribution and infrastructure question as well as a coverage question, since coverage without dispensing capacity does not produce access (Asiedu & Asiedu, 2022; Aminu-Ibrahim *et al.*, 2020).

6.4 For organisational capability building

Biosimilar commercial organisations require a capability mix that few pharmaceutical firms possess natively: Contracting depth, cost discipline, data engineering and operational service management alongside conventional commercial skills. Building it is a change programme rather than a hiring exercise (Ilodigwe & Adesemoye, 2024b; Eyetsemitan *et al.*, 2023a). Clinical and commercial education pathways may need redesign to support it (Orise & Niniola, 2024), and where automated tooling is introduced into commercial workflows, governance should precede deployment rather than follow it (Annan, 2023).

7. Limitations

Five limitations bound the conclusions.

Price opacity: Net prices are confidential. Analysis based on list prices and average sales prices systematically misstates real competitive position, and private label contract economics are entirely undisclosed.

Causal attribution: The association between the April 2024 formulary change and subsequent share movement is strong and temporally clear, but this is a single natural experiment without a control, and concurrent factors including portfolio substitution were reducing total molecule volume simultaneously.

Period truncation: The analysis closes at the end of 2024. Several developments visible at that point, including the ustekinumab biosimilar cohort approved during 2024 but not yet launched, will materially affect the conclusions and cannot yet be assessed. The private label model in particular was approximately eight months old at the close of the study period, so its durability is untested.

Geographic and channel scope: The analysis centres on the United States with selective European comparison. Emerging markets, Japan and Canada operate under different conditions and are not examined; markets pursuing regulatory harmonisation face an additional set of commercial constraints not modelled here (Eze *et al.*, 2024a).

Source composition: Several sources are produced by manufacturers, trade associations or consultancies with commercial positions. Triangulation mitigates but does not eliminate this bias. In addition, several conceptual frameworks drawn on in Sections 2, 4.9, 4.10 and 5.7 were developed in adjacent sectors and are applied here analogically; their transferability to pharmaceutical commercial operations is argued rather than empirically demonstrated.

7.1 Future research

Priority directions include: Quantitative analysis of net price transmission to patient cost sharing under private label arrangements; longitudinal study of biosimilar developer entry and exit decisions as a function of realised commercial returns; assessment of whether the private label model sustains or suppresses share gains beyond its first year; comparative assessment of tender design features against supplier survival; empirical testing of whether the

infrastructural capabilities identified in Section 4.9 predict biosimilar commercial outcomes; and prescriber and patient level research on how private labelling affects trust in biosimilars, given that the label under which a product reaches the patient is increasingly determined by their insurer rather than its manufacturer.

8. Conclusion

Biosimilars have changed pharmaceutical commercial strategy more profoundly than their aggregate savings figures suggest. The 2024 evidence indicates that the locus of commercial decision making in biologics has moved from the prescriber to the intermediary, that classical brand differentiation has limited purchase in a category where regulators enforce product parity, and that the marketing function has been substantially displaced by contracting, channel partnership and gross to net engineering.

Four conclusions stand out. First, formulary architecture determined outcomes in 2024 more decisively than clinical evidence, price or regulatory designation, as the adalimumab market demonstrated when a single contracting decision achieved in weeks what years of competitive discounting had not. Second, originators have largely stopped defending assets at loss of exclusivity and started replacing them, which means biosimilar entrants increasingly compete for a market their originator competitor is actively shrinking. Third, the private label model resolved the rebate wall by absorbing it, delivering genuine uptake while concentrating commercial power in vertically integrated intermediaries and raising unresolved questions about access on non-partnered terms. Fourth, the capabilities that now determine competitive outcome are infrastructural, residing in contracting systems, data architecture, distribution visibility and manufacturing reliability rather than in promotional capability.

The underlying policy question is no longer whether biosimilars can lower prices. They demonstrably can, having generated approximately \$36 billion in cumulative savings and nearly 500 million incremental days of therapy since first entry (Association for Accessible Medicines, 2024). The question is whether the commercial conditions surrounding them can sustain enough suppliers to keep delivering those savings across the far larger wave of biologic patent expiries still to come. That outcome will be determined by market design rather than by science, which returns the argument to where it began: A therapeutic advance delivers value only when the system carrying it is configured to let it (Ilodigwe & Adesemoye, 2019b).

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