



PBM Reform: Deem PBMs a “Fiduciary” Under ERISA

ERIC

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Introduction

Pharmacy Benefit Managers (“PBMs”) engage in many practices that have the potential to raise costs for employees and their family members enrolled in an employer-sponsored self-insured health plan. Unfortunately, these practices continue largely unabated because the laws governing employee benefits and health insurance currently do not hold PBMs sufficiently accountable. However, Congress can take decisive action to fix this regulatory gap by deeming PBMs “a fiduciary” under the Employee Retirement Income Security Act (“ERISA”).

In doing so, PBMs would be subject to the same fiduciary duties that have applied to employer health plan sponsors for 50 years now, and the same fiduciary duties that have protected plan participants and beneficiaries from paying unreasonably high prices for covered benefits and excessive or hidden fees. If subject to the same ERISA fiduciary duties as plan sponsors, PBMs would effectively be required to act in the best interest of plan participants and help keep plan costs low. Importantly, PBMs could not engage in self-dealing or other profiteering tactics like many do today.

The Issue Brief:



Explains current law as it applies to an ERISA fiduciary, describing who is an ERISA fiduciary and who is not, and details ERISA’s fiduciary duties and the consequences for breaching an ERISA fiduciary duty.

Pages 4-7



Illustrates what actions or inactions taken by an employer plan sponsor can result in claims of fiduciary breach filed against them, with additional illustrations of various PBM practices that could result in liability if the PBM was considered an ERISA fiduciary. These illustrations are intended to put into context how harmful PBM-related practices would be curbed if PBMs are subject to ERISA’s fiduciary duties.

Pages 8-10



Provides information regarding how plan sponsors and PBMs could satisfy their ERISA fiduciary duties if they gave due consideration to reducing the cost of covered prescription drugs by including biosimilars in drug formularies made available to employer-sponsored health plans.

Page 11



Includes a case study comparing the cost of Humira® and Humira® biosimilars. It concludes by examining what Congress needs to do to apply ERISA’s fiduciary duties to PBMs.

Pages 12-13

Overview

ERISA is a federal law governing health benefit plans sponsored by private-sector employers and other organizations like labor unions. In addition to specific notice and disclosure requirements, [1] health claims procedures, [2] and prohibitions against discrimination based on health status, [3] ERISA sets forth specific fiduciary duties that an employer-sponsor and certain third-party entities must adhere to, or face consequences for a fiduciary breach. [4]

Who Is an ERISA Fiduciary?

An ERISA fiduciary is a person or entity that has discretionary authority and control over:



The management and operation of a health plan



How the plan's assets are spent.[5]

An employer that sponsors a health benefit plan (referred to as the “plan sponsor”)[6] always has discretionary authority and control over:



The management and operation of a health plan



How the plan's assets are spent.

As such, the plan sponsor is *always* an ERISA fiduciary.

ERISA also contemplates a “plan administrator,”[7] which is typically a third-party entity that is hired by the plan sponsor to assist in administering the plan. Here, the plan sponsor will delegate to the plan administrator the requisite discretionary authority over:



The plan's operations



How the plan's assets can be spent

As a result, the plan administrator is *always* an ERISA fiduciary.

It is important to distinguish a plan administrator from other third-party entities that provide services to an ERISA-covered self-insured health plan (referred to as “TPAs”). As stated, a plan administrator has been given the requisite authority over **(1)** the plan's operations and **(2)** how the plan's assets can be spent, and thus, *is* an ERISA fiduciary. However, as discussed more fully below, in most if not all cases, TPAs are typically *not* delegated any authority to make decisions on **(1)** plan operations and **(2)** spending plan assets, and thus, these TPAs are generally *not* an ERISA fiduciary.

Overview, Cont.

Who is NOT an ERISA Fiduciary? As noted above, TPAs that are not otherwise hired as the plan administrator – but are hired to provide specified services to the plan – are not considered an ERISA fiduciary.

Why? As also noted above, these TPAs typically do not have discretionary authority over (1) the plan's operations and (2) how the plan's assets can be spent. It is true that these TPAs will perform certain functions or take on certain tasks that cost the health plan money. However, that is not the same thing as having “discretionary authority” to, for example, make decisions on how the plan's assets are spent. Those TPAs that are typically not considered an ERISA fiduciary include:

- ▶ A TPA hired to perform enrollment and other benefit administration functions for the plan, typically referred to as the “enrollment TPA” or “ben admin TPA.”
- ▶ A TPA hired to adjudicate and process health claims incurred by plan participants, typically referred to as a “claims adjudication TPA.”
- ▶ A TPA that establishes and maintains a network of medical providers that participants of the plan may access. This type of TPA (in most cases, an insurance company) is referred to as the “owner of the provider network” that “rents” its provider network to, for example, a self-insured health plan.
- ▶ A PBM is yet another service provider (like a TPA) to the health plan. Here, the PBM is hired to establish and maintain a prescription drug provider network for the plan, and the PBM will also develop and maintain the plan's prescription drug formulary. The PBM will also serve as an intermediary between the plan and drug manufacturers that make and sell prescription drugs

Note, in the event a TPA or a PBM happens to perform a task or take a certain action – like making their own decisions on how the plan's assets are spent – the TPA or PBM *will* cross-over into being considered an ERISA fiduciary. Whether a TPA or PBM crosses-over into being considered an ERISA fiduciary is a facts and circumstances-based determination made by a court of law. Employer plan sponsors and/or plan participants may file a lawsuit claiming that a TPA or PBM acted with the requisite “discretionary authority” over (1) the plan's operations or (2) how the plan's assets can be spent to make them an ERISA fiduciary. Nevertheless, the plan sponsor and participants have the burden of proving that – based on a specified set of facts and circumstances – the TPA or PBM in question did indeed cross-over into ERISA fiduciary territory, which is often difficult to prove.

Overview, Cont.

ERISA's Fiduciary Duties

For those entities that are considered an ERISA fiduciary, they must adhere to the following fiduciary duties:

- ▶ **Duty to Act In the Best Interest of Plan Participants:** An ERISA fiduciary must “*act for the exclusive purpose of providing benefits to plan participants,*” which is often characterized as requiring the fiduciary to “*act in the best interest of plan participants.*”[8] Examples of acting in the best interest of plan participants include making decisions to keep the cost of covered benefits low and covering benefits and services that will improve the health and security of participants.
- ▶ **Duty to Help Control Costs:** An ERISA fiduciary must also “defray the reasonable expense of administering the plan.”[9] Here, the fiduciary must ensure that the plan is *not* paying unreasonable or excessive fees to an entity providing services to the plan, and that the plan is not covering benefits and services that are unreasonably priced.
- ▶ **Duty to Act With Prudence:** This duty – commonly referred to as the “prudent man standard” – requires an ERISA fiduciary to “*act with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.*”[10] For example, a fiduciary must make all plan-related decisions in a way that shows that the fiduciary put effort, care, and thought into the outcome of the decision. Among other things, a prudent fiduciary must also monitor the plan’s service providers to ensure that the service provider is performing its hired functions and keeping health plan costs low.
- ▶ **Prohibition Against Self-Dealing and Conflicts of Interest:** ERISA fiduciaries are also prohibited from engaging in “*self-dealing*”[11] or acting with a “*conflict of interest.*”[12] Self-dealing occurs when the fiduciary undertakes an action where they use the plan’s assets for their own interests or make decisions which allow the fiduciary to profit from the plan. A conflict of interest occurs when the fiduciary represents or is affiliated with an entity that will profit from the plan, and the fiduciary makes a decision where this entity financially benefits from contracting or doing business with the plan.
- ▶ **Co-Fiduciary Duties:** If a fiduciary knows (or should know) that a fellow fiduciary to the plan is breaching any one of ERISA’s fiduciary duties, and if this fiduciary either assists in the breach or does not take any action to stop or remedy the breach, this fiduciary is similarly liable for its fellow fiduciary’s breach.[13] In addition, if a fiduciary undertakes actions that prevent a fellow fiduciary from satisfying their fiduciary duties, thereby causing the fellow fiduciary to breach their duties, this fiduciary will also be liable for its fellow fiduciary’s breach.[14]

Note, an ERISA fiduciary is not required to find the cheapest options for the plan and its participants. Rather, the fiduciary must choose the **best** options that a prudent person in a similar situation would agree provides the **best** value to the plan and its participants.

Overview, Cont.

Consequences for Breaching ERISA's Fiduciary Duties

If an ERISA fiduciary breaches any one of ERISA's fiduciary duties (described above), the fiduciary may be required to under law and enforced by the U.S. Department of Labor (DOL) and/or the courts to do any of the following, depending upon the circumstances:

- ▶ **Restore Plan Losses:** If a fiduciary breach causes the plan to suffer financial losses, the fiduciary could be required to fully restore any losses to the plan that resulted from the breach.[15] For example, if a fiduciary is found to have breached their duties by overpaying for covered benefits or paying excessive fees to an entity providing services to the plan, the fiduciary may be required to re-pay to the plan the difference between reasonably priced benefit costs or reasonable service fees and the amount paid out of the plan.
- ▶ **Disgorge Profits:** If the fiduciary profits from the plan in some way, the fiduciary would be required to re-pay to the plan any profits received.[16] For example, if a fiduciary enriches themselves by requiring the plan to pay unreasonably high prices and the fiduciary retains the proceeds, the fiduciary must re-pay to the plan those proceeds.
- ▶ **Civil Monetary Liability:** Depending on the nature of the fiduciary breach, the fiduciary may face a civil penalty of up to 20 percent of the amount recovered from the fiduciary.[17] In cases where the fiduciary is an individual, the fiduciary could be personally liable for monetary damages.
- ▶ **Criminal Liability:** If a fiduciary willfully engages in coercive interference of a participant's rights under ERISA, a criminal offense punishable by fines and/or imprisonment could apply.[18] Fiduciaries can also face fines and/or imprisonment if convicted of certain Federal crimes, such as theft, embezzlement, or bribery relating to an ERISA-covered plan.[19]

The above-described consequences apply to a fiduciary when **(1)** the DOL makes a judgment during a DOL enforcement proceeding and/or **(2)** a lawsuit is filed in Federal court against the fiduciary, resulting in the court rendering a binding decision on the fiduciary.





An Illustration of What Actions or Inactions Could Result in a Breach of ERISA’s Fiduciary Duties

On February 5, 2024, an employee-participant of a health plan sponsored by Johnson & Johnson (“J&J”) filed a lawsuit claiming that J&J (as plan sponsor) breached its fiduciary duties by failing to prevent the plan from overpaying for covered benefits.

In particular, the employee-participant argued that – over a period of years – J&J’s health plan paid the plan’s PBM for covered prescription drugs in excess of 200 percent – and in some cases 500 percent– times the cash-price for the covered drugs, and thus, J&J (as plan sponsor) breached the following fiduciary duties for the following reasons:

Duty to Act In the Best Interest of Plan Participants.

The lawsuit contends that J&J failed to act in the best interest of plan participants when J&J failed to recognize that the prices charged by the plan’s PBM were much higher than prices charged by other PBMs operating in the market, and in many cases, higher than the cash-price of the drug.

Duty to Help Control Costs.

The lawsuit also contends that J&J failed to take available steps to rein in the PBM’s high prices by re-negotiating the contract with the PBM. Also, J&J failed to carefully analyze different PBM payment models to determine what PBM payment model will be most beneficial and cost-effective for the plan and its participants.

Duty to Act with Prudence.

The lawsuit further asserts that **(1)** no prudent fiduciary would have allowed the plan and its participants to pay such high prices for the covered prescription drugs, **(2)** and that prudent fiduciaries must continually monitor their PBM’s actions to ensure that the PBM is minimizing costs and maximizing outcomes for plan participants, and **(3)** J&J failed to actively manage and oversee key aspects of the plan’s prescription drug program by allowing the PBM to steer participants to the PBM’s own mail-order pharmacy, forcing participants to pay higher prices for drugs when lower-priced drugs were otherwise accessible at non-PBM-owned pharmacies.

Recently, an employee-participant of a health plan sponsored by Wells Fargo filed an almost identical lawsuit as the J&J suit, asserting breach of the same ERISA fiduciary duties to act in the best interest of participants, the duty to help control costs, and the duty to act with prudence. Among other claims set forth in this lawsuit, the employee-participant asserts that the plan’s PBM charged the plan and its participants upwards to 15 times the cash-price for a covered prescription drug and the PBM steered plan participants to a mail-order pharmacy owned by the PBM, thereby forcing the plan and its participants to pay higher prices for covered prescription drugs. The plaintiff also contends that the plan’s PBM charged – and the plan paid – excessive administrative fees.

What Would Happen If PBMs Are Subject to ERISA's Fiduciary Duties?

As a Fiduciary, the PBM In the J&J and Wells Fargo Lawsuits Could Be Liable for Their Actions.

If a PBM is required to adhere to the same ERISA fiduciary duties that are applicable to a plan sponsor, many of the PBM practices highlighted in the J&J and Wells Fargo lawsuits would be mitigated if not eliminated entirely. The following illustrates this point:

Duty to Act In the Best Interest of Plan Participants.

If the PBM is an ERISA fiduciary, the PBM would be liable for failing to act in the best interest of plan participants by forcing the plan and its participants to pay higher prices for prescription drugs that the PBM knows (or should know) are currently available in the market at lower prices

Duty to Help Control Costs.

If the PBM is an ERISA fiduciary, the PBM would be subject to liability for charging unreasonably high prices for prescription drugs and demanding excessive fees, especially at a PBM-owned pharmacy.

Duty to Act with Prudence.

It would not be prudent for a fiduciary (here, the PBM) to enter into a contract with the plan that requires the plan and its participants to pay higher prices for prescription drugs that the PBM knows (or should know) are currently available in the market at lower prices. A prudent fiduciary would also pass-through any rebates or discounts the fiduciary received for covered benefits bought and paid for with the plan's assets.

Prohibition Against Self-Dealing and Conflicts of Interest.

As an ERISA fiduciary, a PBM could *not* purchase prescription drugs from a drug manufacturer for a particular price and charge the plan and its participants a *higher* price for the same drugs and then *retain* the difference between the prices paid (which is often described as PBM "spread pricing"). In addition, a PBM would be subject to liability if the PBM took steps to steer plan participants to pharmacies owned by the PBM and ultimately forced participants to pay higher prices to the PBM-owned pharmacies than pharmacies not owned by the PBM.

Co-Fiduciary Duties.

If the PBM withheld pricing and/or claims data from the plan sponsor (purposefully or inadvertently), and the plan sponsor was found liable for failing to exercise prudence in agreeing to contract terms that caused the plan to overpay for covered prescription drug benefits, the PBM would similarly be liable for the plan sponsor's breach.

What Would Happen If PBMs Are Subject to ERISA's Fiduciary Duties? Cont.

As an ERISA Fiduciary, PBMs Could Not Engage in Other Price-Inflating Behavior.

Related to the actions that we see in the J&J and Wells Fargo lawsuits, there are additional examples where the conduct of PBMs appear to be increasing costs for employers and plan participants, and such behavior would be curbed if ERISA's fiduciary duties applied to PBMs. For example, a PBM could *not*:

- ▶ Exclude certain drugs – like biosimilars [20] – from the plan's drug formulary in exchange for deep discounts and rebates that enrich the PBM and the drug manufacturer. The Federal Trade Commission (FTC) and Congress recently reported that drug manufacturers agree to deep discounts and large rebates with PBMs in exchange for the PBM excluding biosimilars from the PBM's drug formulary that a health plan utilizes. [21]
- ▶ Steer participants to expensive biologics, if cheaper biosimilars are available on the market. Studies show that biologics spending has increased significantly since 2017, even as lower-cost biosimilars have been entering the market. [22]
- ▶ Steer participants to brand name specialty drugs through the use of rebates and discounts when an equivalent biosimilar specialty drug with a lower net price is readily available in the market. [23]
- ▶ Charge exponentially higher prices for drugs purchased from PBM-owned mail-order pharmacies compared to the prices charged at retail pharmacies in the PBM's network. [24]
- ▶ Establish new offshore entities to "private label" the PBM's own biosimilar products only to sell those biosimilars – at a marked-up price – through the PBM's own established drug formularies. Reports indicate that PBMs hide behind new offshore entities designed to avoid public scrutiny and use their vertical integration to unfairly drive-up costs. [25]
- ▶ Use off-shore entities to collect manufacturer fees based on list price, keep a percentage of rebates and spread pricing, and mark-up drugs to the plan at exponential rates compared to what the PBM pays the drug manufacturer for the drug. [26]
- ▶ Inflate the costs of biosimilars through spread pricing or co-pay claw-backs. This leads to overpayments for these biosimilars when lower-cost, safe, and effective substitute biosimilars are also available. [27]



Offering Access to Biosimilars Satisfies ERISA’s Fiduciary Duties



Low-Cost Biosimilars with Identical Treatment and Efficacy.

As stated above, a fiduciary is not required to find the cheapest options for the plan and its participants. Rather, the fiduciary must choose the **best** options that provide the **best** value to the plan and its participants.

In the case of biosimilars, an ERISA fiduciary satisfies both standards. Specifically, when a fiduciary (e.g., a plan sponsor or a PBM acting as an ERISA fiduciary) affirmatively chooses to include biosimilars in a health plan’s drug formulary, the fiduciary is not only lowering costs for the plan (which is a prudent decision and in accord with acting in the best interest of plan participants), but the fiduciary is also providing value to plan participants, as biosimilars are effectively identical in the treatment and efficacy to their biologic counterparts (which is, similarly, prudent and in accord with acting in the best interests of plan participants).

When it comes to cost, biosimilars lower costs in two ways: **(1)** the average sales price for biosimilars is 50 percent lower than the relative price for the reference biologic; and **(2)** biosimilars promote competition, forcing reference biologic manufacturers to compete with biosimilars and leading to lower costs for prescription drugs for the entire health care market.

Both mechanisms to lower costs are responsible for \$56 billion in savings from 2013 to 2022, as biosimilars began to establish their presence in the market.[28] Moreover, both mechanisms have the potential to save the U.S. health care system up to \$133 billion by 2025.[29]

A win-win for both plan participants and the market as a whole.

However, if biosimilars continue to be frozen out of the market because, for example, PBMs continue to exclude biosimilars from a health plan’s drug formulary, the status quo will extend the monopolistic behavior of the reference biologic to the detriment of plan participants and the market as a whole (which is imprudent and contrary to acting in the best interest of plan participants).

Case Study: Humira® Biosimilars Are Now on the Market

Humira® – the world’s best-selling drug – has seen a price increase of 470% since the brand-name drug first entered the market. Humira® – having faced virtually no competition in the health care market – now has a price-tag of upwards to \$84,000.

Importantly, a wave of Humira® biosimilars were finally introduced in the market in 2023. The list prices of Humira® biosimilars are up to 85 percent lower-cost than the brand-name Humira®.[30] If added to drug formularies for employer-sponsored health plans, these recent launches will create a more competitive market, helping to mitigate ever-rising drug spending by employers that contribute to increases in plan premiums and expenses. Importantly, this will also help reduce out-of-pocket costs for plan participants who share the responsibility for paying premiums in addition to paying co-pays and co-insurance.

A recent report found that Humira® biosimilars competition has occurred in less than 2 percent of the U.S. market.[32] This is due in large part to PBM practices. As noted above, far too often PBMs and drug manufacturers enter into agreements to exclude biosimilars from the PBM’s drug formularies in exchange for large rebates offered to the PBM by the manufacturer for the reference biologic. Then, the PBM pockets the difference between what the plan pays for the reference biologic (which is typically the biologic’s list price) and what the PBM pays the drug manufacturer (which is the biologic’s list price, minus the large rebate offered to the PBM).[33]

If a PBM is an ERISA fiduciary – and thus subject to ERISA’s fiduciary duties – the PBM would be liable for a fiduciary breach if they engaged in the above stated practice. That is because the PBM would be held accountable to make the prudent decision to include the Humira® biosimilars in its drug formularies. Why? Because (1) plan participants save money and (2) plan participants are effectively getting the exact same health outcomes from the same type of treatment.

For example, the cost of Humira® is roughly **\$84,000...**

compared to...

the cost of a Humira® **biosimilar** is approximately **\$12,600.**

That means **a patient receiving Humira® would pay \$16,800** a year (20% copay)

compared to...

a patient receiving a Humira® biosimilar would pay \$2,520

a year (20% copay).

▶ ***The result? The Humira biosimilar equals significant savings.***

Overall, the adoption and utilization of Humira® biosimilars throughout the health care system *could save more than \$5 billion a year.* [31]

Congress Can Put an End to PBM Practices That Harm Participants and Keep Health Care Costs High

Congress can amend ERISA and specifically apply ERISA’s fiduciary duties to PBMs. It’s that simple. Here, a PBM could be added to the definition of “fiduciary” under ERISA section 3(21) by adding a new subparagraph (C).

Congress has the flexibility to be prescriptive in defining the types of actions that a PBM may undertake that would result in ERISA fiduciary status.

Or Congress may simply provide that a PBM shall become an ERISA fiduciary upon entering into an agreement to provide services to an ERISA-covered health plan. Then, all affected parties can work together within the regulatory process to further define the appropriate parameters and guardrails to ensure that PBMs cannot continue to harm plan participants and keep health care costs high.



Some may argue that requiring PBMs to adhere to ERISA’s fiduciary duties is a significant change. However, significant change is exactly what is needed. Congress should not endeavor to legislate to each cost-inflating behavior highlighted in this Issue Brief.

***PBMs will continue to innovate new arbitrage strategies to maintain their current revenue streams.
Congress has the pen. We encourage them to use it.***

Citations

- [1] Sections 101–111 of the Employee Retirement Income Security Act (ERISA).
- [2] ERISA section 503.
- [3] ERISA section 702.
- [4] See ERISA section 404(a).
- [5] ERISA section 3(21)(A).
- [6] See ERISA section 3(16)(B).
- [7] See ERISA section 3(16)(A).
- [8] ERISA section 404(a)(1)(A)(i).
- [9] ERISA section 404(a)(1)(A)(ii).
- [10] ERISA section 404(a)(1)(B).
- [11] ERISA section 406(b)(1), (3).
- [12] ERISA section 406(b)(2).
- [13] ERISA section 405(a).
- [14] Id.
- [15] ERISA section 409.
- [16] Id.
- [17] ERISA section 502(l).
- [18] ERISA section 511.
- [19] 18 U.S. Code section 664.
- [20] A Biosimilar is a biological medicine highly similar to another already approved biological medicine and can compete with the original reference biologic after the biologic's manufacturer's period of exclusivity is completed.
- [21] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, July 2024, pages 66 – 70 at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; see also, House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets*, July 2024.
- [22] See IQVIA Institute for Human Data Science, *Biosimilars in the United States 2023–2027*, Jan. 31, 2023 at <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>.
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- [25] See *The Wall Street Journal*, *Coming to a CVS Near You: A Store Brand Monoclonal Antibody*, April 29, 2024 at <https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182> (subscription required); see also, Stat, *Thanks to CVS, a biosimilar version of AbbVie's Humira is grabbing huge market share*, April 15, 2024 at <https://www.statnews.com/pharmalot/2024/04/15/cvs-abbvie-humira-biosimilar-medicines-biologic-arthritis/> (subscription required).
- [26] See Ohio Attorney General New Release, *Yost Sues Express Scripts, Prime Therapeutics and 5 Others, Blaming Exorbitant Drug Prices on Their Collusion*, March 27, 2023 at <https://www.ohioattorneygeneral.gov/Media/News-Releases/March-2023/Yost-Sues-Express-Scripts-Prime-Therapeutics-and-5>.
- [27] See Drug Channels, *Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira*, Nov. 9, 2021 at <https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html>.
- [28] See IQVIA Institute for Human Data Science, *Long-term Market Sustainability for Infused Biosimilars in the U.S.*, Jan. 24, 2024 at <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/long-term-market-sustainability-for-infused-biosimilars-in-the-us>.
- [29] See Cardinal Health, *2022 Biosimilars Report: The US Journey and Path Ahead* at <https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-2022-biosimilars-report.pdf>.
- [30] See Managed Healthcare Executive, *8 Humira Biosimilars Are on the Market*, July 4, 2023 at <https://www.managedhealthcareexecutive.com/view/8-humira-biosimilars-are-on-the-market>.
- [31] See Modern Healthcare, *Rebate Walls May Thwart Biosimilars Savings*, Sept. 13, 2022 at <https://www.modernhealthcare.com/supply-chain/humira-biosimilar-savings-may-face-delays> (subscription).
- [32] See Biospace, *AbbVie's Humira Maintains Market Dominance Amid Biosimilar Launches: Report*, Jan. 18, 2024 at <https://www.biospace.com/article/abbvie-s-humira-maintains-market-dominance-amid-biosimilar-launches-report/>.
- [33] See the FTC and House Committee on Oversight and Accountability Reports, *infra* footnote 23.

