IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Nina Y. Wang

Civil Action No. 24-cv-00810-NYW-SBP

AMGEN INC.;
IMMUNEX CORPORATION; and
AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board;
SAMI DIAB, MD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
AMARYLIS GUTIERREZ, PharmD, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
CATHERINE HARSHBARGER, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
JAMES JUSTIN VANDENBERG, PharmD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; and
PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,

Defendants.

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Plaintiffs' Motion for Summary Judgment and Memorandum in Support [Doc. 24 ("Plaintiffs' Motion for Summary Judgment")] and Defendants' Combined Cross-Motion for Summary Judgment and Response in Opposition to Plaintiffs' Motion for Summary Judgment [Doc. 29 ("Defendants' Motion for Summary Judgment")] (collectively, the "Motions").

The Court has reviewed the Motions and the related briefing, *see* [Doc. 35; Doc. 42], the applicable case law, and the entire docket. For the reasons set forth herein,

Defendants' Motion for Summary Judgment is respectfully **GRANTED** as to standing, and Plaintiffs' Complaint is **DISMISSED without prejudice** for lack of subject matter jurisdiction. Plaintiffs' Motion for Summary Judgment is therefore **DENIED as moot**.

BACKGROUND

I. Factual Background

Plaintiffs Amgen, Inc.; Immunex Corporation; and Amgen Manufacturing, Limited (collectively referred to as "Plaintiffs" or "Amgen") are the manufacturer and exclusive patent licensees of a prescription medication designed to treat various autoimmune conditions called ENBREL® (hereinafter, "Enbrel"). [Doc. 24 at 10].[1] Enbrel is covered by several United States patents, including two patents that limit competing biosimilar products from entering the market until 2029 (at the earliest). [*Id.* at 20; Doc. 1 at ¶¶ 52–53].

The prescription drug supply chain. As a manufacturer, Amgen sits at the top of the pharmaceutical supply chain, which "starts with the manufacturer who sells to a wholesaler for the wholesale acquisition cost ('list price')," and "[w]holesalers then sell to the pharmacy, who dispense the product to the patient with a doctor's prescription." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practs. & Antitrust Litig.*, 44 F.4th 959, 965 (10th Cir. 2022). Nearly all of Amgen's domestic sales are to wholesale distributors for the list price (or "WAC"), and the wholesalers then sell Amgen's products to providers, hospitals, and pharmacies. [Doc. 29 at 13–14 & nn.1–3]; *see also* Amgen, Letter to Shareholders (2023) at 2, 42, 76, https://investors.amgen.com/static-files/eeb1013b-

[1] When citing to the Parties' briefing, the Court uses the page numbers assigned by the Court's Case Management/Electronic Case File system.

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Health plans or "payers" and pharmacy benefit managers ("PBMs") also play a key role in the pharmaceutical market. As to health plans, insured patients access prescription drugs through the prescription drug benefits of their health plans. *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023). The cost of a prescription drug is shared between an insured and their health plan; an insured's share of the cost is determined by the scope of the prescription drug benefit under their health plan. *In re EpiPen*, 44 F.4th at 965. The health plan controls the scope of the prescription drug benefit, including "what drugs the plan covers (the formulary), how much the plan will pay for those drugs (the cost-sharing terms), and at which pharmacies beneficiaries can have prescriptions filled (the pharmacy network)." *Mulready*, 78 F.4th at 1188.

Health plans often outsource the formulation and oversight of prescription drug benefits to PBMs. *Id.* Before a pharmacy fills a patient's prescription, the pharmacy checks with the PBM to confirm whether the prescription drug is covered under the patient's health plan and to ascertain the patient's payment. *See Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 84 (2024). The PBM reimburses the pharmacy on the health plan's behalf in exchange for reimbursements and fees from the health plan. *Id.* PBMs also negotiate directly with manufacturers for rebates on prescription drugs. *See Mulready*, 78 F.4th at 1188.

Amgen is a member of PhRMA, a "voluntary nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies," and Amgen's CEO serves on PhRMA's Board of Directors. [Doc. 27 at 1; Doc. 29 at 16 n.6]. According to PhRMA, "prices paid by wholesalers, pharmacies, PBMs, and health plan

sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power." [Doc. 29 at 16 (quoting PhRMA, *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines* 1 (2017), https://cdn.aglty.io/phrma/global/resources/import/pdfs/Follow-the-Dollar-Report.pdf ("Follow the Dollar"))]. As a result of this structure, even though an insured patient's "cost-sharing amount may exceed the price the health plan actually pays for a medicine or . . . what the patient would pay at the pharmacy counter without using insurance," pharmacies may be contractually prohibited from informing patients about the lower cost alternative (i.e., paying cash for a prescription at the pharmacy counter). [Doc. 29 at 17 (citing Follow the Dollar at 6)].

In a hearing before Congress, Amgen's CEO, Robert Bradway, testified that while "[c]ompanies in virtually every other industry compete by offering the lowest price," the pharmaceutical industry players are "often . . . require[d] [to] match[] a competitor's *higher* price." [*Id.* at 16 & n.7 (quoting *Unsustainable Drug Prices: Testimony from the CEOs (Part II): Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. 5 (2020) (statement of Robert Bradway, CEO, Amgen), https://tinyurl.com/mtj35txr)]. "Prescription drug list prices increase so that manufacturers can absorb more and more payer demands for rebates and other discounts." [*Id.* at 16–17 & n.8 (quoting Smart Brevity Studio x Amgen, *Inside the Drug Pricing Loop*, Axios, https://www.axios.com/sponsored/amgen/inside-the-drug-pricing-loop (last visited Mar. 26, 2025)]. Amgen's CEO also testified that "the primary reason the list price of Enbrel® has increased as much as it has" is due to a pharmaceutical market "structured in a way

to benefit intermediaries"—e.g., wholesalers, PBMs, health plans, and pharmacies—and "not in a way to get lower prices to patients." [*Id.* at 24 & n.21 (quoting *Testimony of Robert A. Bradway, Chairman and Chief Executive Officer Amgen Inc., Before the U.S. House Committee on Oversight and Reform* 7 (Oct. 1, 2020), https://tinyurl.com/mufwzev3 ("Bradway Written Statement"))]. Indeed, the pharmaceutical industry is rife with "counterintuitive pricing behavior." *See* Bradway Written Statement 8. For example, Amgen often "pay[s] higher and higher rebates to remain on [PBMs'] formulary," and "increases in list prices . . . significantly increase total rebates paid to the PBMs" but "generally have limited impact on net prices." *Id.* at 7. As a result, "Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies." *Id.*

Colorado's Prescription Drug Affordability Review Program. In 2021, the Colorado General Assembly enacted legislation to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1); *see also* Colo. Rev. Stat. §§ 10-16-1401 to -1416 (the "Act"); 2021 Colo. Sess. Laws 1256. The Act also established a five-member "Prescription Drug Affordability Review Board" (or "the Board"), Colo. Rev. Stat. § 10-16-1402, tasked with (1) "[p]erform[ing] affordability reviews of prescription drugs," and (2) potentially "establish[ing] upper payment limits for" prescription drugs (like Enbrel) that the Board deems unaffordable for Colorado consumers, *id.* § 10-16-1403(1). The Board implemented procedures for these two statutory directives through both rules and policies. *See* 3 Colo. Code. Regs. §§ 702-9:1.1 to -9:5.1; Prescription Drug Affordability Board ("PDAB") Policies 01 to 05, https://tinyurl.com/djct93ch; *see also* [Doc. 29 at 18]. The Court refers to the Act and the

Board's procedure-implementing rules and policies collectively as the "Affordability Program."

According to the Board, the focus of the affordability review is not to determine "the appropriateness of a manufacturer's price," but "whether *use* of a drug, consistent with standard medical practice or the FDA label, is unaffordable for Colorado consumers." [Doc. 29 at 19 (emphasis added) (citing Colo. Rev. Stat. § 10-16-1406(3))]. The Board further contends that an unaffordability determination "does not impact any rights or obligations of anyone selling or purchasing the [subject] prescription drug," because it is "not a final agency action" and "serve[s] standalone purposes of transparency and accountability." [*Id.* at 20 (citing Colo. Rev. Stat. §§ 10-16-1407(1), -1407(9), -1408(1)(c))].

The Board approved a list of 604 prescription drugs eligible for affordability reviews in June 2023. [Doc. 24 at 20–21; Doc. 29 at 25]. Approximately six weeks later, the Board selected five of those prescription drugs for affordability reviews, one of which was Enbrel. [Doc. 24 at 21; Doc. 29 at 25; Doc. 1-2 at 5]. In February 2024, members of the Board—acting pursuant to the Affordability Program—voted to declare Enbrel unaffordable for Colorado consumers and voted to "select Enbrel for establishment of an upper payment limit" (or "UPL"). [Doc. 24 at 11]; *see also* Colo. Rev. Stat. § 10-16-1407(1)(a) (providing that the Board may establish a UPL if it determines that a drug is "unaffordable for Colorado consumers"). The Act defines UPLs as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug." Colo. Rev. Stat. § 10-16-1401(23). In other words, a UPL sets a

price ceiling applicable to various purchase points along the pharmaceutical supply chain, provided that the drug purchased is dispensed or distributed in Colorado. *See id.*

Amgen's participation in the affordability review of Enbrel. The Board's affordability review of Enbrel occurred over a span of six months and included three public Board meetings on December 8, 2023; February 16, 2024; and February 23, 2024. [Doc. 29 at 25 & n.22 (citing publicly available recordings of 2023 and 2024 Board meetings, respectively)]. Amgen participated at each of the foregoing Board meetings; participated in a September 2023 stakeholder meeting facilitated by the Board; voluntarily submitted information to the Board in October 2023; and provided written comments to the Board ahead of both February 2023 Board meetings. [Doc. 29 at 25].

The Board's affordability review of Enbrel culminated in a 500-plus-page affordability review report, which the Board approved by vote on February 23, 2024. [*Id.* at 26]; PDAB 2023 Affordability Review Summary Report: Enbrel (Feb. 23, 2024). The Board subsequently voted to initiate rulemaking to establish a UPL for Enbrel and set a preliminary timeline for rulemaking hearings in September, October, and December 2024. [Doc. 29 at 26 & n.23]. The timeline was later modified by the Board and based on the record before the Court, the first rulemaking hearing for establishing a UPL for Enbrel is set for April 11, 2025. *See* [Doc. 46; Doc. 47; Doc. 48; Doc. 48-1].

II. Procedural History

On March 22, 2024, Amgen filed this action seeking declaratory and injunctive relief with respect to the constitutionality of the Act. [Doc. 1]. Amgen asserts four claims challenging the validity of the Act: (1) preemption under federal patent law ("Count I"); (2) violation of due process ("Count II"); (3) interference with federal healthcare programs

("Count III"); and (4) violation of the Commerce Clause ("Count IV"). [*Id.* at 26–36].

In May 2024, the Parties sought and received leave to file consolidated cross-motions for summary judgment without separate statements of undisputed material facts as contemplated by Local Rule 56.1. [Doc. 18; Doc. 20]. The Court held oral argument on the Motions for Summary Judgment on October 22, 2024. *See* [Doc. 42]. The Motions are ripe for review and the Court addresses the Parties' arguments below.

LEGAL STANDARD

I. Standing

Federal courts are courts of limited jurisdiction. Under Article III of the United States Constitution, federal courts only have jurisdiction to hear certain "cases" and "controversies." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014). As such, courts "are duty bound to examine facts and law in every lawsuit before them to ensure that they possess subject matter jurisdiction." *Wilderness Soc'y v. Kane Cnty.*, 632 F.3d 1162, 1179 n.3 (10th Cir. 2011) (Gorsuch, J., concurring). Indeed, courts have an independent obligation to determine whether subject matter jurisdiction exists, even in the absence of a challenge from any party. *1mage Software, Inc. v. Reynolds & Reynolds, Co.,* 459 F.3d 1044, 1048 (10th Cir. 2006) (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514 (2006)). A court may not simply presume jurisdiction to reach the substantive issues before it. *See Colo. Outfitters Ass'n v. Hickenlooper*, 823 F.3d 537, 543 (10th Cir. 2016). Rather, a federal court must resolve jurisdictional issues before reaching the merits. *United States v. Springer*, 875 F.3d 968, 973 (10th Cir. 2017).

The doctrine of standing serves as "[o]ne of those landmarks" in identifying "the 'Cases' and 'Controversies' that are of the justiciable sort referred to in Article III." *Lujan*

v. Defs. of Wildlife, 504 U.S. 555, 560 (1992); *see also Citizen Ctr. v. Gessler*, 770 F.3d 900, 906 (10th Cir. 2014) (standing is jurisdictional). Under Article III, standing requires three elements: injury in fact, causation, and redressability. *Colo. Outfitters*, 823 F.3d at 544. These three elements of standing are "an indispensable part of the plaintiff's case," and thus the plaintiff must support each element "with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561 (quotation omitted). At the summary judgment stage, a plaintiff's standing must be supported by specific evidentiary facts and not by mere allegations. *Id.*

"[T]he proof required to establish standing increases as the suit proceeds." *Rio Grande Found. v. Oliver*, 57 F.4th 1147, 1162 (10th Cir. 2023) (quotation omitted). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, while on summary judgment, the plaintiff must set forth by affidavit or other evidence specific facts which for purposes of the summary judgment motion will be taken to be true." *Id.* (cleaned up).

II. Rule 56 of the Federal Rules of Civil Procedure

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A dispute is genuine if there is sufficient evidence so that a rational trier of fact could resolve the issue either way. A fact is material if under the substantive law it is essential to the proper disposition of the claim." *Crowe v. ADT Sec. Servs., Inc.*, 649 F.3d 1189, 1194 (10th Cir. 2011) (citation and quotations omitted).

"Cross-motions for summary judgment are treated as two individual motions for

summary judgment and held to the same standard." *Banner Bank v. First Am. Title Ins. Co.*, 916 F.3d 1323, 1326 (10th Cir. 2019); *see also Buell Cabinet Co. v. Sudduth*, 608 F.2d 431, 433 (10th Cir. 1979) ("Cross-motions for summary judgment are to be treated separately; the denial of one does not require the grant of another."). However, the summary-judgment burden slightly differs depending on which party bears the ultimate burden at trial. A movant that does not bear the ultimate burden of persuasion at trial does not need to disprove the other party's claim; rather, the movant must only point the Court to a lack of evidence for the other party on an essential element of that party's claim. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 671 (10th Cir. 1998). Once this movant has met its initial burden, the burden then shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). But "if the moving party has the burden of proof [at trial], a more stringent summary judgment standard applies." *Pelt v. Utah*, 539 F.3d 1271, 1280 (10th Cir. 2008). A moving party who bears the burden at trial "must establish, as a matter of law, all essential elements of the issue before the nonmoving party can be obligated to bring forward any specific facts alleged to rebut the movant's case." *Id.*

When considering the evidence in the record, the Court cannot and does not weigh the evidence or determine the credibility of witnesses. *See Fogarty v. Gallegos*, 523 F.3d 1147, 1165 (10th Cir. 2008). At all times, the Court views each motion in the light most favorable to the nonmoving party. *Banner Bank*, 916 F.3d at 1326.

ANALYSIS

In Defendants' Motion for Summary Judgment, Defendants argue, *inter alia*, that this Court lacks subject matter jurisdiction because Amgen does not have standing and

the case is not ripe. [Doc. 29 at 28]. The Court begins with Defendants' standing argument, because it may not reach the merits of the action without first assuring itself that it has subject matter jurisdiction over each of the claims. *See Colo. Outfitters*, 823 F.3d at 543.

I. Subject Matter Jurisdiction

A. Applicable Law

A plaintiff's "burden to demonstrate standing for each form of relief sought . . . exists at all times throughout the litigation." *Collins v. Daniels*, 916 F.3d 1302, 1314 (10th Cir. 2019) (quotations omitted). To establish standing, a plaintiff must show it (1) suffered an injury in fact that (2) is fairly traceable to the defendant's conduct and (3) can be redressed by a favorable judicial decision. *See Baker v. USD 229 Blue Valley*, 979 F.3d 866, 871 (10th Cir. 2020). However, because causation and redressability are often "flip sides of the same coin," *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 288 (2008), "the two key questions in most standing disputes are injury in fact and causation," *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380–81 (2024).

An injury in fact must be "concrete, meaning that it must be real and not abstract," and the injury must be "actual or imminent, not speculative," meaning that it "must have already occurred or be likely to occur soon." *All. for Hippocratic Med.*, 602 U.S. at 381 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). Where, as here,[2] "a

[2] Amgen seeks, *inter alia*, (1) a declaratory judgment that the Affordability Program is facially unconstitutional; and (2) an injunction against the establishment and enforcement of a UPL for Enbrel. [Doc. 1 at 36–37]. A declaratory judgment and an injunction are both forms of prospective relief. *See, e.g.*, *Collins*, 916 F.3d at 1314 (declaratory relief); *Colo. Cross Disability Coal. v. Abercrombie & Fitch Co.*, 765 F.3d 1205, 1211 (10th Cir. 2014) (injunctive relief).

plaintiff seeks prospective relief," the plaintiff must establish "a sufficient likelihood of future injury." *Id.*; *see also Colo. Cross Disability Coal. v. Abercrombie & Fitch Co.*, 765 F.3d 1205, 1211 (10th Cir. 2014) ("When prospective relief . . . is sought, the plaintiff must be suffering a continuing injury or be under a real and immediate threat of being injured in the future." (quotation omitted)). With respect to causation, a plaintiff must also establish that its injury "likely was caused or likely will be caused by the defendant's conduct." *All. for Hippocratic Med.*, 602 U.S. at 382.

Standing is "usually easy to establish" in cases challenging regulations that "require or forbid some action by the plaintiff"—i.e., where the government is directly regulating the plaintiff. *Id.* Conversely, standing is "ordinarily substantially more difficult to establish" where an unregulated plaintiff challenges the government's "unlawful regulation . . . of someone else." *Id.* at 382–83 (collecting cases). The Court's inquiry thus begins with whether Amgen is subject to direct regulation under the Act.

B. Amgen is Not Subject to Direct Regulation.

Defendants contend that Amgen is not subject to direct regulation under the Act because UPLs do not apply at the pharmaceutical manufacturer's point of sale; instead, UPLs apply only to downstream actors. [Doc. 29 at 28–30]. Amgen argues that the statute contains no such express limitation. [Doc. 35 at 12–13]. The Court finds that both the statutory language and legislative history of the Act support the conclusion that a UPL does not directly apply to a wholesaler's purchase from a manufacturer at the top of the supply chain. Instead, a UPL applies directly only to downstream transactions for the actual sales and reimbursements of the prescription drug dispensed to Colorado consumers.

The Act defines a UPL as "the maximum amount that may be paid or billed for a prescription drug that is *dispensed or distributed in Colorado* in any financial transaction concerning the purchase of or reimbursement for *the* prescription drug." Colo. Rev. Stat. § 10-16-1401(23) (emphasis added). A UPL applies to "all purchases of and payer reimbursements for a prescription drug that is *dispensed or administered in the state*," *id.* § 10-16-1407(5), including a consumer's purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies and providers' purchases of the prescription drug, *see* 3 C.C.R. § 702-9:4.2.C.[3] Amgen reads this language to include "'*any financial transaction'*" along the supply chain. [Doc. 35 at 12 (quoting Colo. Rev. Stat. § 10-16-1401(23))]. But the Court respectfully agrees with Defendants insofar as the statute's use of the definite article "the" in the phrase "*the* prescription drug" demonstrates the General Assembly's intent to cabin application of UPLs to financial transactions in which "*the*" prescription drug is "*dispensed or distributed in Colorado*." Colo. Rev. Stat. § 10-16-1401(23); *see also Nielsen v. Preap*, 586 U.S. 392, 408 (2019) ("[G]rammar and usage establish that 'the' is 'a function word . . . indicat[ing] that a following noun or noun equivalent is definite or has been previously specified by context.").

Moreover, the statute instructs the Board, in establishing a UPL, to consider the costs of "administering," "dispensing," and "distributing" the prescription drug, *see* Colo.

[3] The Court is respectfully unpersuaded by Amgen's argument that the Board's regulation, C.C.R. § 702-9:4.2.C, is inconsistent with the statutory language, Colo. Rev. Stat. § 10-16-1401(23). *See* [Doc. 35 at 12–13 (citing *Canyon Fuel Co. v. Sec'y of Labor*, 894 F.3d 1279, 1291 (10th Cir. 2018); *McCool v. Sears*, 186 P.3d 147, 151 (Colo. App. 2008))]. That the regulation provides further clarity to the statutory text does not render the two inconsistent and, for the reasons discussed above, the statute also supports Defendants' interpretation of the Act.

Rev. Stat. § 10-16-1407(2), i.e., the costs associated with providers, pharmacies, and wholesalers, respectively. In passing the Act, the General Assembly expressly stated its intent for UPLs to apply specifically to the state and municipalities, contractors and vendors, commercial health plans, providers, and pharmacies. *See* 2021 Colo. Sess. Laws 1256, 1257. The UPLs contemplated by the Act do not apply to a prescription drug manufacturer's point of sale; instead, UPLs apply to downstream transactions in the pharmaceutical supply chain.

Thus, the Court concludes based on the unambiguous statutory text that Amgen is not subject to direct regulation under the Act.[4] Accordingly, Amgen cannot challenge the constitutionality of the Act under this theory of standing.

C. Amgen Fails to Establish Standing as an Unregulated Party.

According to Amgen, even if UPLs apply only downstream, "common sense and basic economics" support standing here because a price cap downstream will reduce prices upstream. [Doc. 35 at 13–17]. Thus, the Court next considers whether Amgen, as an unregulated party asserting various challenges to the Affordability Program, has satisfied the standard set forth in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). For the following reasons, the Court finds that Amgen's asserted future injury is simply too speculative to be "concrete" and "imminent." *See id.* at 386–93 (claims of future injury are insufficient where plaintiffs cannot show that the harm is likely to occur).

To establish standing as an unregulated party, "the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in

[4] The Court notes that, even if it did find ambiguity in the statutory text, the canon of constitutional avoidance supports the Court's interpretation of the Act. *See F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

other words, that the government action has caused or likely will cause injury in fact to the plaintiff." *Id.* at 385. The Supreme Court has repeatedly emphasized that an Article III injury must be "actual or imminent, not speculative." *Id.* at 381; *see also Clapper*, 568 U.S. at 409; *Lujan*, 504 U.S. at 560.

"In cases of alleged future injuries to unregulated parties from government regulation, the causation requirement and the imminence element of the injury in fact requirement can overlap" because both causation and imminence "target the same issue: Is it likely that the government's regulation . . . of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?" *All. for Hippocratic Med.*, 602 U.S. at 385 n.2. "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2).

Here, relying on "basic economics and common sense" and the Declaration of Patrick Costello, an Associate Vice President of United States Value and Access, Amgen argues that it has standing to challenge the Act because "a price cap on Amgen's drug will result in less revenue for Amgen's wholesalers and distributors, who will in turn demand lower prices or other compensation from Amgen, reducing Amgen's profits." [Doc. 35 at 9, 15–16 (citing [Doc. 35-1 (the "Costello Declaration")])]. The Court respectfully disagrees with Amgen's argument for at least two reasons.

First, the Court finds Amgen's appeal to "basic economics and common sense" unpersuasive. Nothing in the record defines what the amorphous concepts of "basic economics and common sense" entail, or if such "basic economics and common sense"

even apply to the pharmaceutical industry. Amgen's position assumes, without establishing as an undisputed fact, that any UPL established will necessarily fall below the WAC, or what Amgen's customers currently pay. Furthermore, it does not consider the undisputed complexity of the supply chain and the various rebates, reimbursements, chargebacks, and discounts that are exchanged at various levels of the supply chain. To the extent that Amgen suggests that it will necessarily be injured regardless of whether, when, or what UPL may be set due to "basic economics and common sense," this Court respectfully declines to conclude that Amgen has carried its summary judgment burden of establishing injury-in-fact on such speculation. Indeed, Amgen's CEO testified before Congress that the pharmaceutical market is driven by "counterintuitive pricing behavior." [Doc. 29 at 24 & n.21 (quoting Bradway Written Statement at 7–8)].

Second, and more fundamentally, Mr. Costello has not articulated a specific and concrete injury to Amgen under the Affordability Program—particularly in light of the fact that no UPL for Enbrel has been set and it is unclear when and if such a UPL will be set. Instead, Mr. Costello's Declaration is based on two unfulfilled conditions precedent: (1) "*if* an upper payment limit is imposed on wholesalers' sales of Enbrel," *then* "there is no realistic chance that wholesalers will absorb the discount required to comply with the upper payment limit without passing cost on to Amgen," [Doc. 35-1 at ¶ 12 (emphasis added)]; and (2) "*if* Colorado dictates that wholesalers must sell the products for less than WAC," *then* "Amgen cannot reasonably expect wholesalers to purchase products at WAC, without any discount or reimbursement from Amgen," [*id.* at ¶ 13 (emphasis added)]. But, at this juncture, Colorado has not fulfilled either of these prerequisites. Moreover, Mr. Costello's statement that "[t]here is no scenario in which an upper payment

limit for Enbrel would not negatively impact Amgen," necessarily relies on both foregoing conditions and is conclusory in nature. [*Id.* at ¶ 14].

The Costello Declaration reinforces the speculative nature of Amgen's theory of standing. Amgen *might* be able to demonstrate harm *if* the Board sets a UPL for Enbrel; *if* that UPL is set lower than the WAC for Enbrel; and *if* wholesalers react by demanding that Amgen absorb any costs associated with the same. Unless and until a UPL is set for Enbrel and at a price lower than WAC, however, Amgen's alleged future injuries are hypothetical at best. In other words, Amgen's theory of standing is premised on "the predictable effect" of a *hypothetical* UPL on the decisions of wholesalers.

Notably, Amgen fails to cite any authority for the proposition that an unregulated plaintiff can establish standing based on hypothetical government action. *Compare* [Doc. 35 at 13–17 (collecting cases)], *with Kane Cnty. v. United States*, 928 F.3d 877, 888–89 (10th Cir. 2019) (finding environmental group had standing to challenge government plans to "double the width of [two] roads" in scenic areas because widening the roads in a scenic area "would almost inevitably increase traffic"); *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017) (finding standing based on future economic injury where lumber companies challenged an existing "critical habitat designation" that would reduce their timber supply); *Wedges/Ledges of Calif., Inc. v. City of Phoenix*, 24 F.3d 56, 60–61 (9th Cir. 1994) (manufacturer and operator of crane arcade game had standing to challenge city policies where manufacturer demonstrated that city had "succeeded in destroying the market for crane games"); *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (ethanol producers had standing to challenge EPA's test fuel regulation prohibiting the producers' product from being used as a test fuel); *Maine Lobstermen's*

Ass'n v. Nat'l Marine Fisheries Serv., 70 F.4th 582, 592 (D.C. Cir. 2023) (finding lobstermen had standing to challenge already-promulgated rule that would "cost lobstermen $50 to $90 million"); *Dep't of Com. v. New York*, 588 U.S. 752, 764–68 (2019) (holding that "respondents have met their burden of showing that third parties will likely react in predictable ways to the citizenship question" that agency sought to reinstate in census where "evidence at trial established that noncitizen households have historically responded to the census at lower rates than other groups, and the . . . discrepancy is likely attributable at least in part to noncitizens' reluctance to answer a citizenship question").[5] Even if the Board may one day establish a below-list-price UPL for Enbrel, the Court is not at liberty to assume or predict one of several possible outcomes to find Article III standing at this time. *Cf. Clapper*, 568 U.S. at 413–14 (declining to "abandon" the Supreme Court's "usual reluctance to . . . endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment"); *Garcia v. Texas*, 564 U.S. 940, 941 (2011) ("Our task is to rule on what the law is, not what it might eventually be.").

The economic injuries alleged by Amgen are too speculative and too attenuated to support standing in this case. Because Amgen's "allegations of possible future injury are not sufficient," the Court concludes that Amgen has failed to satisfy the requirement that "threatened injury must be certainly impending to constitute injury in fact." *See Clapper*, 568 U.S. at 409 (cleaned up). And it is clear that the Court cannot presume subject matter jurisdiction in order to reach the merits of this case. *Cf. DaimlerChrysler*

[5] Two cases cited by Amgen do not address standing whatsoever. *See Caldwell Wholesale Co. v. R J Reynolds Tobacco Co.*, 781 F. App'x 289, 291 (5th Cir. 2019) (per curiam); *Money Mailer, LLC v. Brewer*, 449 P.3d 258, 264 (Wash. 2019).

Corp. v. Cuno, 547 U.S. 332, 348 (2006) (holding that a taxpayer litigant cannot assume a particular disposition of government funds in order to establish standing); *Colo. Outfitters*, 823 F.3d at 543 ("[A] federal court can't 'assume' a plaintiff has demonstrated Article III standing in order to proceed to the merits of the underlying claim, regardless of the claim's significance." (citing *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 94 (1998) (explaining that "such an approach . . . carries the courts beyond the bounds of authorized judicial action and thus offends fundamental principles of separation of powers"))). Accordingly, Amgen has failed to meet its burden at summary judgment to establish standing, and this Court must dismiss Amgen's Complaint without prejudice for lack of subject matter jurisdiction.

CONCLUSION

For the reasons set forth above, **IT IS ORDERED** that:

(1) Defendants' Motion for Summary Judgment [Doc. 29] is **GRANTED**;

(2) Plaintiffs' Complaint [Doc. 1] is **DISMISSED without prejudice** for lack of subject matter jurisdiction;

(3) Plaintiffs' Motion for Summary Judgment [Doc. 24] is **DENIED as moot**; and

(4) The Clerk of Court is directed to **TERMINATE** this matter accordingly.

DATED: March 28, 2025

BY THE COURT:

Nina Y. Wang
United States District Judge