No. 25-1641

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC., IMMUNEX CORPORATION,
AMGEN MANUFACTURING, LIMITED,
Plaintiffs-Appellants,

v.

GAIL MIZNER, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, SAMI DIAB, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board, AMARYLIS GUTIERREZ, 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, 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, PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,
Defendants-Appellees.

On Appeal from the United States District Court for the District of Colorado, No. 1:24-cv-00810-NYW-SBP, Hon. Nina Y. Wang

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CORRECTED JOINT APPENDIX

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TABLE OF CONTENTS

Page

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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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

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.

FINAL JUDGMENT

In accordance with the orders filed during the pendency of this case, and pursuant to Fed. R. Civ. P. 58(a), the following Final Judgment is hereby entered.

Pursuant to the Order entered by United States District Judge Nina Y. Wang on March 28, 2025 (ECF No. 49), it is

ORDERED that summary judgment is hereby entered in favor of Defendants against Plaintiffs. It is

FURTHER ORDERED that Defendants shall have costs by the filing of a Bill of Costs with the Clerk of this Court within fourteen days of the entry of judgment, pursuant to Fed. R. Civ. P. 54(d)(1) and D.C.COLO.LCivR 54.1. It is

FURTHER ORDERED that this case is terminated.

Dated at Denver, Colorado this 28th day of March, 2025.

FOR THE COURT:
JEFFREY P. COLWELL, CLERK

By: s/C. Pearson, Deputy Clerk

FEDAPP,JD1,NDISPO,TERMED

U.S. District Court - District of Colorado
District of Colorado (Denver)
CIVIL DOCKET FOR CASE #: 1:24-cv-00810-NYW-SBP

Amgen Inc. v. Colorado Prescription Drug Affordability Review Board et al
Assigned to: Judge Nina Y. Wang
Referred to: Magistrate Judge Susan Prose
Case in other court: United States Federal Circuit Court of Appeals, 25-01641
Cause: 28:2403 - Constitutionality of State Statute(s)

Date Filed: 03/22/2024
Date Terminated: 03/28/2025
Jury Demand: None
Nature of Suit: 950 Constitutionality of State Statutes
Jurisdiction: Federal Question

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Date Filed	#	Docket Text
03/22/2024	1	COMPLAINT *against Colorado Prescription Drug Affordability Review Board, et al.* against Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Filing fee $ 405,Receipt Number ACODC-9602293)Attorney Ashley Charles Parrish added to party Amgen Inc.(pty:pla), Attorney Ashley Charles Parrish added to party Immunex Corporation(pty:pla), Attorney Ashley Charles Parrish added to party Amgen Manufacturing, Limited(pty:pla), filed by Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Summons, # 6 Civil Cover Sheet)(Parrish, Ashley) (Entered: 03/22/2024)
03/22/2024	2	Case assigned to Judge Nina Y. Wang and drawn to Magistrate Judge Susan Prose. Text Only Entry. (blaws) (Entered: 03/22/2024)
03/22/2024	3	Magistrate Judge consent form issued pursuant to 28 U.S.C. 636(c). No Summons Issued: Summons submitted has an incorrect caption and has not been issued. Please file completed summons for issuance using the event Summons Request. (blaws) (Entered: 03/22/2024)
03/22/2024	4	CORPORATE DISCLOSURE STATEMENT identifying Corporate Parent Amgen Inc. for Amgen Manufacturing, Limited, Immunex Corporation. (Parrish, Ashley) (Entered: 03/22/2024)
03/22/2024	5	SUMMONS REQUEST as to COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD; GAIL MIZNER, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board; SAMI DIAB, AMARYLIS GUTIERREZ, CATHERINE HARSHBARGER, and JAMES JUSTIN VANDENBERG, in their official capacities as members 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 re 1 Complaint,, by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation. (Parrish, Ashley) (Entered: 03/22/2024)
03/23/2024	6	ORDER REFERRING CASE: This case is referred to Magistrate Judge Susan Prose for **non-dispositive matters**. Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B) and Fed. R. Civ. P. 72(a) and (b), this case is referred to the assigned United States Magistrate Judge to (1) convene a scheduling conference under Fed. R. Civ. P. 16(b) and enter a scheduling order meeting the requirements of D.C.COLO.LCivR 16.2, (2) conduct such status conferences and issue such orders necessary for compliance with the scheduling order, including

		amendments or modifications of the scheduling order upon a showing of good cause, and (3) hear and determine pretrial matters, including discovery and other non-dispositive motions. Court-sponsored alternative dispute resolution is governed by D.C.COLO.LCivR 16.6. On the request of the parties by motion, this Court may direct the parties to engage in an early neutral evaluation, a settlement conference, or another alternative dispute resolution proceeding. Alternatively, the Magistrate Judge, at her discretion, may convene such early neutral evaluation and/or settlement conferences and direct related procedures as may facilitate resolution of this case without the necessity of a motion or prior authorization of the undersigned. **Counsel for the Parties and all counsel who may later enter an appearance shall review and familiarize themselves with the undersigned's Practice Standards, as well as the Practice Standards of the assigned Magistrate Judge.** By Judge Nina Y. Wang on 3/23/2024. Text Only Entry (nywlc6,) (Entered: 03/23/2024)
03/25/2024	7	WAIVER OF SERVICE Returned Executed by Immunex Corporation, Amgen Manufacturing, Limited, Amgen Inc.. Colorado Prescription Drug Affordability Review Board waiver sent on 3/25/2024, answer due 5/24/2024; Michael Conway waiver sent on 3/25/2024, answer due 5/24/2024; Sami Diab waiver sent on 3/25/2024, answer due 5/24/2024; Amarylis Gutierrez waiver sent on 3/25/2024, answer due 5/24/2024; Catherine Harshbarger waiver sent on 3/25/2024, answer due 5/24/2024; Gail Mizner waiver sent on 3/25/2024, answer due 5/24/2024; James Justin VandenBerg waiver sent on 3/25/2024, answer due 5/24/2024; Philip Weiser waiver sent on 3/25/2024, answer due 5/24/2024. (Parrish, Ashley) (Entered: 03/25/2024)
03/26/2024	8	NOTICE of Entry of Appearance by Paul Alessio Mezzina on behalf of Amgen Inc., Amgen Manufacturing, Limited, Immunex CorporationAttorney Paul Alessio Mezzina added to party Amgen Inc.(pty:pla), Attorney Paul Alessio Mezzina added to party Amgen Manufacturing, Limited(pty:pla), Attorney Paul Alessio Mezzina added to party Immunex Corporation(pty:pla) (Mezzina, Paul) (Entered: 03/26/2024)
03/26/2024	9	NOTICE of Entry of Appearance by Alexander Kazam on behalf of Amgen Inc., Amgen Manufacturing, Limited, Immunex CorporationAttorney Alexander Kazam added to party Amgen Inc.(pty:pla), Attorney Alexander Kazam added to party Amgen Manufacturing, Limited(pty:pla), Attorney Alexander Kazam added to party Immunex Corporation(pty:pla) (Kazam, Alexander) (Entered: 03/26/2024)
03/26/2024	10	NOTICE of Entry of Appearance by Kelly Nicole Reeves on behalf of Amgen Inc., Amgen Manufacturing, Limited, Immunex CorporationAttorney Kelly Nicole Reeves added to party Amgen Inc.(pty:pla), Attorney Kelly Nicole Reeves added to party Amgen Manufacturing, Limited(pty:pla), Attorney Kelly Nicole Reeves added to party Immunex Corporation(pty:pla) (Reeves, Kelly) (Entered: 03/26/2024)
03/26/2024	11	NOTICE of Entry of Appearance by Brian Alan Bohnenkamp on behalf of Amgen Inc., Amgen Manufacturing, Limited, Immunex CorporationAttorney Brian Alan Bohnenkamp added to party Amgen Inc.(pty:pla), Attorney Brian Alan Bohnenkamp added to party Amgen Manufacturing, Limited(pty:pla), Attorney Brian Alan Bohnenkamp added to party Immunex Corporation(pty:pla) (Bohnenkamp, Brian) (Entered: 03/26/2024)
03/26/2024	12	NOTICE of Entry of Appearance by Cliff Stricklin on behalf of Amgen Inc., Amgen Manufacturing, Limited, Immunex CorporationAttorney Cliff Stricklin added to party Amgen Inc.(pty:pla), Attorney Cliff Stricklin added to party Amgen Manufacturing, Limited(pty:pla), Attorney Cliff Stricklin added to party Immunex Corporation(pty:pla) (Stricklin, Cliff) (Entered: 03/26/2024)
04/02/2024	13	NOTICE of Entry of Appearance by Abby L. Chestnut on behalf of Colorado Prescription Drug Affordability Review Board, Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip WeiserAttorney

		Abby L. Chestnut added to party Colorado Prescription Drug Affordability Review Board(pty:dft), Attorney Abby L. Chestnut added to party Michael Conway(pty:dft), Attorney Abby L. Chestnut added to party Sami Diab(pty:dft), Attorney Abby L. Chestnut added to party Amarylis Gutierrez(pty:dft), Attorney Abby L. Chestnut added to party Catherine Harshbarger(pty:dft), Attorney Abby L. Chestnut added to party Gail Mizner(pty:dft), Attorney Abby L. Chestnut added to party James Justin VandenBerg(pty:dft), Attorney Abby L. Chestnut added to party Philip Weiser(pty:dft) (Chestnut, Abby) (Entered: 04/02/2024)
04/02/2024	14	NOTICE of Entry of Appearance by Pawan Nelson on behalf of Colorado Prescription Drug Affordability Review Board, Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip WeiserAttorney Pawan Nelson added to party Colorado Prescription Drug Affordability Review Board(pty:dft), Attorney Pawan Nelson added to party Michael Conway(pty:dft), Attorney Pawan Nelson added to party Sami Diab(pty:dft), Attorney Pawan Nelson added to party Amarylis Gutierrez(pty:dft), Attorney Pawan Nelson added to party Catherine Harshbarger(pty:dft), Attorney Pawan Nelson added to party Gail Mizner(pty:dft), Attorney Pawan Nelson added to party James Justin VandenBerg(pty:dft), Attorney Pawan Nelson added to party Philip Weiser(pty:dft) (Nelson, Pawan) (Entered: 04/02/2024)
04/02/2024	15	NOTICE of Entry of Appearance by Heather Suzanne Flannery on behalf of Colorado Prescription Drug Affordability Review Board, Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip WeiserAttorney Heather Suzanne Flannery added to party Colorado Prescription Drug Affordability Review Board(pty:dft), Attorney Heather Suzanne Flannery added to party Michael Conway(pty:dft), Attorney Heather Suzanne Flannery added to party Sami Diab(pty:dft), Attorney Heather Suzanne Flannery added to party Amarylis Gutierrez(pty:dft), Attorney Heather Suzanne Flannery added to party Catherine Harshbarger(pty:dft), Attorney Heather Suzanne Flannery added to party Gail Mizner(pty:dft), Attorney Heather Suzanne Flannery added to party James Justin VandenBerg(pty:dft), Attorney Heather Suzanne Flannery added to party Philip Weiser(pty:dft) (Flannery, Heather) (Entered: 04/02/2024)
04/08/2024	16	ORDER SETTING CONSENT DEADLINE AND SCHEDULING CONFERENCE by Magistrate Judge Susan Prose on 4/8/2024. Consent Form due by 6/25/2024. Proposed Scheduling Order due 7/1/2024. Telephonic Scheduling Conference set for 7/9/2024, at 11:00 AM MDT in Courtroom C205 before Magistrate Judge Susan Prose. The parties shall attend by calling 571-353-2301, Guest meeting ID- 868150043. All attendees shall please mute their phone when not speaking and not use speaker phone. (trvo,) (Entered: 04/08/2024)
04/08/2024	17	NOTICE of Entry of Appearance by Russell Dorian Johnson on behalf of Colorado Prescription Drug Affordability Review Board, Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip WeiserAttorney Russell Dorian Johnson added to party Colorado Prescription Drug Affordability Review Board(pty:dft), Attorney Russell Dorian Johnson added to party Michael Conway(pty:dft), Attorney Russell Dorian Johnson added to party Sami Diab(pty:dft), Attorney Russell Dorian Johnson added to party Amarylis Gutierrez(pty:dft), Attorney Russell Dorian Johnson added to party Catherine Harshbarger(pty:dft), Attorney Russell Dorian Johnson added to party Gail Mizner(pty:dft), Attorney Russell Dorian Johnson added to party James Justin VandenBerg(pty:dft), Attorney Russell Dorian Johnson added to party Philip Weiser(pty:dft) (Johnson, Russell) (Entered: 04/08/2024)
05/16/2024	18	Joint MOTION for Leave to *Establish Briefing Schedule and for Related Relief* by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation. (Parrish, Ashley) (Entered: 05/16/2024)

05/16/2024	19	NOTICE of Voluntary Dismissal of Party *Colorado Prescription Drug Affordability Review Board* by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation (Parrish, Ashley) (Entered: 05/16/2024)
05/21/2024	20	ORDER: The Parties' 18 Joint Motion to Establish Briefing Schedule and for Related Relief is hereby **GRANTED**. The briefing schedule on the Parties' cross-motions for summary judgment is hereby **SET** as follows: Defendants' deadline to answer and raise affirmative defenses is **May 24, 2024**; Plaintiffs' deadline to file a motion for summary judgment (not to exceed 40 pages) is **June 24, 2024**; Defendants' deadline to file a combined cross-motion for summary judgment and response to Plaintiffs' motion for summary judgment (not to exceed 50 pages total) is **August 9, 2024**; Plaintiffs' deadline to file a combined reply in support of Plaintiffs' motion for summary judgment and response to Defendants' motion for summary judgment (not to exceed 30 pages total) is **September 6, 2024**; and Defendants' deadline to file a reply in support of Defendants' motion for summary judgment (not to exceed 20 pages) is **October 4, 2024**. The Parties' request for leave to file motions for summary judgment without statements of undisputed material facts as contemplated by Local Rule 56.1 is hereby GRANTED. The Parties' request for oral argument is hereby **GRANTED**, and Oral Argument is hereby **SET** for **October 22, 2024 at 10:00 AM** in Courtroom A 502 before Judge Nina Y. Wang. By Judge Nina Y. Wang on 05/21/2024. Text Only Entry (nywlc7). Modified on 5/22/2024 to correct formatting(norlin,). (Entered: 05/21/2024)
05/21/2024	21	ORDER by Magistrate Judge Susan Prose on 5/21/2024. In light of the parties' agreement that discovery is unnecessary (ECF No. 18 at 2) and this case now having a briefing schedule, the deadline to file a proposed scheduling order and the scheduling conference set for 7/9/2024 are VACATED. Text Only Entry (sbplc1) (Entered: 05/21/2024)
05/23/2024	22	MINUTE ORDER: This matter is before the Court on the 19 Notice of Dismissal of Party filed by Plaintiffs, which is a self-effectuating notice of dismissal pursuant to Rule 41(a)(1)(A)(i) of the Federal Rules of Civil Procedure. Plaintiffs' claims against Defendant Colorado Prescription Drug Affordability Review Board were dismissed as of the filing of the Notice. The Clerk of Court is DIRECTED to terminate Colorado Prescription Drug Affordability Review Board as a defendant in this matter accordingly. By Judge Nina Y. Wang on 05/23/2024. Text Only Entry (nywlc7). (Entered: 05/23/2024)
05/24/2024	23	*Defendants'* ANSWER to 1 Complaint,, by Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Chestnut, Abby) (Entered: 05/24/2024)
06/24/2024	24	MOTION for Summary Judgment *and Memorandum in Support* by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation. (Parrish, Ashley) (Entered: 06/24/2024)
06/30/2024	25	NOTICE re 24 MOTION for Summary Judgment *and Memorandum in Support* by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Parrish, Ashley) (Entered: 06/30/2024)
07/01/2024	26	NOTICE of Entry of Appearance by Jeffrey L. Handwerker on behalf of Pharmaceutical Research and Manufacturers of America, The Chamber of Commerce of the United States of America Attorney Jeffrey L. Handwerker added to party Pharmaceutical Research and Manufacturers of America(pty:am), Attorney Jeffrey L. Handwerker added to party The Chamber of Commerce of the United States of America (pty:am) (Handwerker, Jeffrey) (Entered: 07/01/2024)
07/01/2024	27	MOTION to File Amicus Brief by Amicus Parties Pharmaceutical Research and Manufacturers of America, The Chamber of Commerce of the United States of America.

		(Attachments: # 1 Brief of Amici Curiae, # 2 Proposed Order (PDF Only))(Handwerker, Jeffrey) (Entered: 07/01/2024)
07/02/2024	28	ORDER: The 27 Motion to File Amicus Brief is **GRANTED**. The [27-1] Proposed Amicus Brief is **ACCEPTED** and the Clerk of Court is **DIRECTED** to separately docket [27-1] as the *Brief of Amici Curiae Pharmaceutical Research and Manufacturers of America and the Chamber of Commerce of the United States of America in Support of Plaintiffs' Motion for Summary Judgment*. By Judge Nina Y. Wang on 07/02/2024. Text Only Entry (nywlc7). (Entered: 07/02/2024)
07/02/2024	33	Brief of Amici Curiae Pharmaceutical Research and Manufacturers of America and the Chamber of Commerce of the United States of America in Support of Plaintiffs' Motion for Summary Judgment (norlin,) [docketed by Clerk of Court pursuant to 28 ORDER] Modified on 8/20/2024 to correct file date (norlin,). (Entered: 08/20/2024)
08/09/2024	29	RESPONSE to 24 MOTION for Summary Judgment *and Memorandum in Support anc Cross Motion for Summary Judgment* filed by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Attachments: # 1 Exhibit Ex 1, # 2 Exhibit Ex 2)(Chestnut, Abby) Modified on 10/22/2024 to correct event type (norlin,). (Entered: 08/09/2024)
08/16/2024	30	Unopposed MOTION for Leave to *File Briefy as Amicus Curiae* by Amicus Colorado Center on Law and Policy, Inc.. (Attachments: # 1 Proposed Document Proposed order re Motion for Leave to File, # 2 Exhibit Amici Curiae brief in support of Defendants) (Martinez, Annamarie) (Entered: 08/16/2024)
08/20/2024	31	NOTICE of Entry of Appearance by Annamarie Martinez on behalf of Colorado Center on Law and Policy, Inc. (Martinez, Annamarie) (Entered: 08/20/2024)
08/20/2024	32	ORDER: The 30 Motion to File Amicus Brief is **GRANTED**. The [30-2] Proposed Amicus Brief is **ACCEPTED** and the Clerk of Court is **DIRECTED** to separately docket [30-2] as the *Brief of Amici Curiae Colorado Center on Law and Policy in Support of Defendants' Combined Cross-Motion for Summary Judgment and Memorandum in Support and Response in Opposition to Plaintiff's Motion for Summary Judgment*. By Judge Nina Y. Wang on 08/20/2024. Text Only Entry (nywlc7,). (Entered: 08/20/2024)
08/20/2024	34	Brief of Amici Curiae Colorado Center on Law and Policy in Support of Defendants' Combined Cross-Motion for Summary Judgment and Memorandum in Support and Response in Opposition to Plaintiff's Motion for Summary Judgment filed by Amicus Colorado Center on Law and Policy, Inc.. (norlin,)[docketed by Clerk of Court pursuant to 32 ORDER] (Entered: 08/20/2024)
09/06/2024	35	REPLY to Response to 24 MOTION for Summary Judgment *and Memorandum in Support of Plaintiffs' Motion for Summary Judgment and Opposition to Defendants' Cross-Motion for Summary Judgment* filed by Plaintiffs Amgen Inc., Amgen Manufacturing, Limited, Immunex Corporation. (Attachments: # 1 Exhibit A - Declaration of Patrick Costello, # 2 Exhibit B - Declaration of Kathy Sherman, # 3 Exhibit 1 to Sherman Declaration (Dec. 5, 2023 Letter), # 4 Exhibit 2 to Sherman Declaration (Feb. 1, 2024 Letter), # 5 Exhibit 3 to Sherman Declaration (Feb. 22, 2024))(Parrish, Ashley) (Entered: 09/06/2024)
09/13/2024	36	NOTICE of Entry of Appearance by Douglas H. Hallward-Driemeier on behalf of Biotechnology Innovation OrganizationAttorney Douglas H. Hallward-Driemeier added to party Biotechnology Innovation Organization(pty:am) (Hallward-Driemeier, Douglas) (Entered: 09/13/2024)
09/13/2024	37	NOTICE of Entry of Appearance by Andrew J. O'Connor on behalf of Biotechnology Innovation OrganizationAttorney Andrew J. O'Connor added to party Biotechnology Innovation Organization(pty:am) (O'Connor, Andrew) (Entered: 09/13/2024)

09/13/2024	38	NOTICE of Entry of Appearance by Phillip Z. Yao on behalf of Biotechnology Innovation OrganizationAttorney Phillip Z. Yao added to party Biotechnology Innovation Organization(pty:am) (Yao, Phillip) (Entered: 09/13/2024)
09/13/2024	39	MOTION for Leave to *File Brief as Amicus Curiae* by Amicus Biotechnology Innovation Organization. (Attachments: # 1 Brief of Amicus Curiae, # 2 Proposed Order)(Hallward-Driemeier, Douglas) (Entered: 09/13/2024)
09/17/2024	40	ORDER: The 39 Motion of Biotechnology Innovation Organization for Leave to File Brief as Amicus Curiae is **GRANTED**. The [39-1] Proposed Amicus Brief is **ACCEPTED** and the Clerk of Court is **DIRECTED** to separately docket [39-1] as the *Brief of Amicus Curiae Biotechnology Innovation Organization in Support of Plaintiffs' Opposition to Defendants' Cross-Motion for Summary Judgment*. By Judge Nina Y. Wang on 09/17/2024. Text Only Entry(nywlc7,) (Entered: 09/17/2024)
09/17/2024	41	BRIEF of Amicus Curiae Biotechnology Innovation Organization in Support of Plaintiffs' Opposition to Defendants' Cross-Motion for Summary Judgment. by Amicus Biotechnology Innovation Organization. (Brief filed pursuant to #40 Order). (sphil,) (Entered: 09/23/2024)
10/04/2024	42	REPLY to Response to 24 MOTION for Summary Judgment *and Memorandum in Support Reply in Support of Defendants Cross Motion for Summary Judgment* filed by Defendants Colorado Prescription Drug Affordability Review Board, Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Chestnut, Abby) (Entered: 10/04/2024)
10/15/2024	43	ERRATA re 42 Reply to Response to Motion, by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Chestnut, Abby) (Entered: 10/15/2024)
10/22/2024	44	MINUTE ENTRY for Oral Argument Hearing held on 10/22/2024 before Judge Nina Y. Wang. Taking under advisement Plaintiffs' 24 Motion for Summary Judgment and Defendants' 29 Combined Cross-Motion for Summary Judgment. Court Reporter: Darlene Martinez. (hguer) (Entered: 10/22/2024)
10/28/2024	45	TRANSCRIPT of Motions Hearing held on 10/22/24 before Judge Wang. Pages: 1-64. **NOTICE - REDACTION OF TRANSCRIPTS: Within seven calendar days of this filing, each party shall inform the Court, by filing a Notice of Intent to Redact, of the party's intent to redact personal identifiers from the electronic transcript of the court proceeding. If a Notice of Intent to Redact is not filed within the allotted time, this transcript will be made electronically available after 90 days. Please see the Notice of Electronic Availability of Transcripts document at www.cod.uscourts.gov.** Transcript may only be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber prior to the 90 day deadline for electronic posting on PACER. (dmart,) (Entered: 10/28/2024)
12/18/2024	46	NOTICE *of Scheduling of UPL Rulemaking Hearing* by Plaintiffs Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Attachments: # 1 Exhibit A, # 2 Exhibit B) (Mezzina, Paul) (Entered: 12/18/2024)
01/09/2025	47	NOTICE re 46 Notice (Other) *of Rescheduling of UPL Rulemaking Hearing* by Plaintiffs Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Attachments: # 1 Exhibit A)(Mezzina, Paul) (Entered: 01/09/2025)
02/28/2025	48	NOTICE re 47 Notice (Other) *of Rescheduling of UPL Rulemaking Hearing* by Plaintiffs Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Attachments: # 1 Exhibit A)(Mezzina, Paul) (Entered: 02/28/2025)

03/28/2025	49	ORDER denying as moot 24 Motion for Summary Judgment, granting 29 Motion for Order, dismissing 1 Plaintiff's Complaint. Judgment shall enter accordingly. Entered by Judge Nina Y. Wang on 3/28/2025. (cpear) (Entered: 03/28/2025)
03/28/2025	50	FINAL JUDGMENT pursuant to 49 Memorandum Opinion and Order. Entered by the Clerk of the Court on 3/28/2025. (cpear) (Entered: 03/28/2025)
04/08/2025	51	NOTICE OF APPEAL to FEDERAL CIRCUIT as to 49 Order on Motion for Summary Judgment, Order on Motion for Order, 50 Judgment by Plaintiffs Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Filing fee $ 605, Receipt Number ACODC-10264608) (Mezzina, Paul) (Entered: 04/08/2025)
04/09/2025	52	LETTER Transmitting Notice of Appeal to all counsel advising of the transmittal of the 51 Notice of Appeal, filed by Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited to the Federal Circuit Court of Appeals. (Retained Counsel, Fee paid,) (Attachments: # 1 Preliminary Record)(norlin,) (Entered: 04/09/2025)
04/14/2025	53	Federal Circuit Case Number 2025-1641 for 51 Notice of Appeal, filed by Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited. (norlin,) (Entered: 04/14/2025)
04/25/2025	54	TRANSCRIPT ORDER FORM re 51 Notice of Appeal, by Plaintiffs Amgen Inc., Immunex Corporation, Amgen Manufacturing, Limited (Mezzina, Paul) (Entered: 04/25/2025)

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UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

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

Plaintiffs,

v.

COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD;
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.

Civil Action
No. 1:24-cv-00810

COMPLAINT

PRELIMINARY STATEMENT

1. Innovative drugs have enriched the lives of countless Coloradans. One of those drugs, Enbrel®, provides disease-transforming and life-changing relief to more than 3,000 Coloradans every year who suffer from arthritis and other autoimmune diseases. As one example, Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis, allowing many patients who previously would have endured progressive and painful deformities and immobility to live for years or even decades with lower pain, less progression, and greater function.

2. Often, innovative drugs like Enbrel® are available at very little out-of-pocket cost to the patient. But in February 2024, Colorado's newly-created "Prescription Drug Affordability Review Board," ignoring the concerns of patient-advocacy groups, unlawfully found Enbrel® to be "unaffordable"—a term not defined in any statute or regulation—and voted to subject Enbrel® to an "upper payment limit." The Board's decision, and the statutory scheme on which it is based, are unconstitutional because they conflict with federal law, violate basic requirements of due process, and impermissibly seek to regulate outside of Colorado. In violating both the federal Constitution and federal laws, the Board's decision puts in jeopardy access to Enbrel® and other innovative drugs, endangering the lives and well-being of thousands of

Coloradans with serious medical conditions.

3. Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited bring this action for declaratory and injunctive relief against the Colorado Prescription Drug Affordability Review Board, the Board Chair and other members of the Board in their official capacities, the Commissioner of the Colorado Division of Insurance in his official capacity, and the Attorney General of the State of Colorado in his official capacity (collectively, "Defendants"), alleging as follows:

NATURE OF THE ACTION

4. This lawsuit seeks to have the Court declare invalid, and enjoin the enforcement of, a facially unconstitutional Colorado law that delegates sweeping authority to a new "Prescription Drug Affordability Review Board" to impose arbitrary price controls on the sale of prescription drugs, including drugs protected by the federal patent laws. *See* Colo. Rev. Stat. § 10-16-1401 *et seq*.

5. Enacted as Senate Bill 21-175, and amended by House Bill 23-1225, the stated purpose of the price-control statute ("the Act") is to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1). The Act seeks to accomplish that goal in ways that violate the Constitution, conflict with federal law, and threaten patient access to

lifesaving medical innovations.

6. The Act provides that the Prescription Drug Affordability Review Board "shall … [c]ollect and evaluate information concerning the cost of prescription drugs sold to Colorado consumers," "[p]erform affordability reviews of prescription drugs," and "[e]stablish upper payment limits for prescription drugs." *Id.*

7. The Act confers vast unguided discretion on the Board to declare certain prescription drugs "unaffordable for Colorado consumers." *Id.* § 10-16-1406. If the Board deems a prescription drug to be "unaffordable for Colorado consumers," the Board is empowered to impose an "upper payment limit" on the drug. *Id.* § 10-16-1407. The Act does not provide any standards, definitions, or guidance to constrain the Board's decisions about what it means for a drug to be "unaffordable" and what the "upper payment limit" for a drug should be.

8. That "upper payment limit" applies to "all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by other means." *Id.* The upper payment limit thus applies even to "upstream" transactions—transactions that occur entirely outside of Colorado, but where the drug involved in the transaction is later dispensed or administered in Colorado.

9. The Act does not contain any exemption for prescription drugs that are patented under federal law. In fact, in conducting affordability reviews, the Board stated that it is targeting drugs that are protected by the federal patent laws, like Enbrel®, because patents limit competition. This limiting of competition is, of course, a deliberate element of federal law. Patents reward inventors with the ability to charge prices that can be used to help fund further important investment—for example, in reliable manufacturing of the drug itself—and facilitate additional innovation during and beyond the term of the patent.

10. The Board's novel regulatory scheme violates the U.S. Constitution in at least four ways.

11. *First*, the Act violates the Supremacy Clause because it conflicts with the federal patent laws, including the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the "Hatch-Waxman Act"). To incentivize the immense risk-taking and investment necessary to discover and develop new medical treatments, Congress has established a carefully calibrated intellectual property regime that rewards pharmaceutical innovation with a period of market exclusivity and the ability to charge prices that allow for further investment and innovation during that period. The Act upsets that federal legislative balance by allowing five members of a state-

created board to strip away the very rights and economic incentives that Congress sought to create in enacting the patent laws.

12. *Second*, the Act violates the Due Process Clause of the Fourteenth Amendment because it lacks the procedural protections necessary to guide the Board's decision-making and avoid the imposition of arbitrary, confiscatory, or otherwise constitutionally inappropriate prices. Neither the Act nor the Board's implementing regulations provide any standard for the Board to apply either when determining whether a drug is "unaffordable" or when setting an "upper payment limit" (nor has the Board even adopted such standards through individualized adjudication with respect to specific drugs). As a result, the Act fails to provide drug manufacturers with a meaningful opportunity to be heard and fails to protect them against erroneous deprivations of their property.

13. *Third*, the Act violates the Supremacy Clause for the additional reason that Colorado's statute applies the "upper payment limit" so broadly as to encompass even federal payors such as Medicare. Federal law preempts state laws that impermissibly interfere with the federal government's ability to control its own payment and coverage decisions under federal healthcare

programs.[1]

14. *Fourth*, the Act violates the Commerce Clause because it regulates commercial transactions that occur entirely outside of the state of Colorado.

15. For these reasons, and as further explained below, this Court should declare the Act unconstitutional and enjoin its enforcement against Plaintiffs.

PARTIES

16. Plaintiff Amgen Inc. ("Amgen") is a biopharmaceutical company that discovers, develops, manufactures, and delivers innovative medicines to fight some of the world's toughest diseases. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that dramatically improve people's lives, while also reducing the social and economic burden of disease. Amgen is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

[1] A policy document the Board issued in January 2023 states without elaboration that "[a]n upper payment limit does not apply to [a] purchase or reimbursement made by Medicare." Ex. A at 2 (Prescription Drug Affordability Rev. Bd., PDAB Pol'y No. 05, Upper Payment Limit Policy & Procedure (Jan. 13, 2023), *available at* https://drive.google.com/drive/folders/1SVcgHEv4CNgyspCnm79VnqFkJjG2PaDH). This document is not legally binding, does not purport to supersede or limit the statute, and thus does not provide legally adequate assurance against preempted applications of Colorado's price-control law.

17. Plaintiff Immunex Corporation ("Immunex") is a wholly owned subsidiary of Amgen and the manufacturer of the patent-protected drug Enbrel®, an injectable medicine that is approved for the treatment of a variety of autoimmune diseases such as moderate to severe rheumatoid arthritis, psoriatic arthritis, and moderate to severe plaque psoriasis. Immunex is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

18. Plaintiff Amgen Manufacturing, Limited ("AML") is an indirect wholly owned subsidiary of Amgen. Since its inception, AML has invested billions of dollars to provide a reliable and safe source of drug supply for patients. To this end, AML has been involved in the complex manufacturing of Enbrel® drug substance from living cells and then transforming the active medicine into drug product that can be administered to patients, all the while ensuring top-quality operations and innovative enhancements to the manufacturing process. AML is a corporation organized and existing under the laws of the territory of Bermuda, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777.

19. Defendant Prescription Drug Affordability Review Board is a five-member body within the Colorado Division of Insurance charged with

determining whether certain prescription drugs are "unaffordable for Colorado consumers" and establishing "upper payment limits" for drugs it declares unaffordable. Colo. Rev. Stat. §§ 10-16-1402, 10-16-1403(1), 10-16-1406(3), 10-16-1407(1)(a). The Board is also required to "promulgate rules as necessary … for the implementation" of the Act. *Id.* § 10-16-1403(5). The Board has its principal office in Denver, Colorado.

20. Defendant Gail Mizner, MD, FACP, AAHIVS, of Snowmass Village, Colorado, is sued in her official capacity as the Chair of the Prescription Drug Affordability Review Board.

21. Defendant Sami Diab, MD, of Greenwood Village, Colorado, is sued in his official capacity as a member of the Prescription Drug Affordability Review Board.

22. Defendant Amarylis Gutierrez, PharmD, of Aurora, Colorado, is sued in her official capacity as a member of the Prescription Drug Affordability Review Board.

23. Defendant Catherine Harshbarger, of Holyoke, Colorado, is sued in her official capacity as a member of the Prescription Drug Affordability Review Board.

24. Defendant James Justin VandenBerg, PharmD, BCPS, of Denver, Colorado, is sued in his official capacity as a member of the Prescription Drug

Affordability Review Board.

25. Defendant Michael Conway is sued in his official capacity as the Commissioner of the Colorado Division of Insurance, which oversees the Prescription Drug Affordability Review Board. *See* Colo. Rev. Stat. §§ 10-16-1402(1), 24-1-105(1)(b). If a manufacturer of a prescription drug subject to an upper payment limit seeks to withdraw its drug from sale or distribution in Colorado, the manufacturer must provide written notice to the Commissioner at least 180 days prior to the withdrawal. *Id.* § 10-16-1412(1)(a). The Commissioner may impose a penalty of up to $500,000 if the manufacturer fails to provide the requisite notice. *Id.* § 10-16-1412(3). Commissioner Conway maintains an office in Denver, Colorado.

26. Defendant Philip Weiser is sued in his official capacity as the Attorney General of the State of Colorado. The Attorney General is "authorized to enforce [the Act] on behalf of any state entity or any consumer of prescription drugs." Colo. Rev. Stat. § 10-16-1411(3). Attorney General Weiser maintains an office in Denver, Colorado.

JURISDICTION AND VENUE

27. This Court has original subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331 because it arises under the Constitution and laws of the United States.

28. This Court has personal jurisdiction over Defendants because they are domiciled in Colorado, and because the enactment and enforcement of the state laws at issue in this lawsuit occurred and continues to occur within Colorado.

29. An actual controversy exists between the parties with respect to the validity and enforceability of the Colorado laws at issue, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202, 42 U.S.C. § 1983, Federal Rules of Civil Procedure 57 and 65, and this Court's inherent equitable powers.

30. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1) because at least one Defendant resides in this District and all Defendants are residents of the State in which this District is located. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in this District.

STATUTORY AND REGULATORY BACKGROUND

The Federal Patent System

31. The Constitution vests in Congress the power to grant authors and inventors exclusive rights to their creations for limited times "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. As the Supreme Court has explained, "[t]he economic philosophy behind the clause

empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors." *Mazer v. Stein*, 347 U.S. 201, 219 (1954). American intellectual property law thus "*celebrates* the profit motive" because it "recogniz[es] that the incentive to profit … will redound to the public benefit by resulting in the proliferation of knowledge." *Eldred v. Ashcroft*, 537 U.S. 186, 212 n.18 (2003) (quotation marks omitted).

32. Pursuant to its constitutional power to protect intellectual property and promote technological innovation, Congress has established an extensive, nationally uniform system for the granting and maintenance of patents. *See* 35 U.S.C. § 1 *et seq*. Under the Patent Act, a patent grant confers "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C. § 154. The "economic rewards during the period of exclusivity" provide a critical "incentive for innovation." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). Once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the costs of the product.

33. The federal patent system thus embodies "a careful balance" between "the need to promote innovation" by allowing innovators to charge appropriate prices during the term of the patent, and the benefits of greater

affordability that flow from "imitation" and increased competition after the patent term expires. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Congress has fine-tuned that balance by specifying the duration of patent terms and establishing procedures for the adjustment of those exclusivity periods under certain circumstances. *See* 35 U.S.C. § 154. As explained below, that is especially true in the context of pharmaceutical patents.

34. The patent laws protect not only innovative products, but also innovative methods that may enhance the usefulness or effectiveness of existing products or processes. *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor ….").

35. Patent protection is especially important for promoting pharmaceutical research and development because of the extraordinary costs and high level of uncertainty involved in seeking to discover and develop new drugs, guide them through the lengthy FDA approval process, and bring them to the patients who need them. The average cost of bringing a single new drug

to market is commonly estimated to be more than $2 billion,[2] the process takes an average of 10 to 15 years,[3] and only about 1 in 5,000 potential new drugs actually obtain approval and reach patients.[4]

36. In 1984, recognizing the unique challenges posed by the costly drug-development process, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act"). The Hatch-Waxman Act extended the patent term for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18 (1984); *see* 35 U.S.C. § 156. The statute was designed to "promote medical breakthroughs and drug innovation by granting drug companies up to 5 more years of patent protection for new drugs" to "help compensate for the years of patent life lost due to the time-consuming, but essential, testing required by the Food and Drug

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[2] Stephen Ezell, Info. Tech. & Innovation Found., *Ensuring U.S. Biopharmaceutical Competitiveness*, at 30 (July 2020), *available at* https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[3] GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 20, 2019), *available at* https://www.gao.gov/assets/gao-20-215sp.pdf.

[4] Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021), https://doi.org/10.1016/j.csbj.2021.08.011.

Administration." Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

37. At the same time, once an innovator drug is no longer patent-protected, Congress has sought to promote the benefits of competition by creating an abbreviated pathway for competing products to obtain FDA approval. For chemically synthesized, small-molecule drugs, that abbreviated pathway was created by the Hatch-Waxman Act, which allowed generic versions of those drugs to receive FDA approval without the same level of clinical testing required for approval of a new brand-name drug. *See* 21 U.S.C. § 355(j). For more complex "biologic drugs" (large molecules made from living cells), a similar abbreviated pathway for FDA approval of "biosimilars" was created by the Biosimilar Price Competition and Innovation Act of 2009, commonly known as the "BPCIA." *See* 42 U.S.C. § 262(k).

38. In this way, Congress struck a deliberate balance in the pharmaceutical arena—allowing those who develop innovative new drugs, and who can be expected to invest in new innovations, to benefit from market exclusivity for a specific and defined period while encouraging price competition thereafter.

Colorado's Price-Control Scheme

39. Colorado's Prescription Drug Affordability Review Board consists

of five members appointed by the Governor of Colorado and confirmed by the state senate. Colo. Rev. Stat. § 10-16-1402(2). The Board is an entity within the Colorado Division of Insurance. *Id.* § 10-16-1402(1).

40. The Act provides that, "[t]o protect Colorado consumers from excessive prescription drug costs," the Board "shall … [c]ollect and evaluate information concerning the cost of prescription drugs sold to Colorado consumers," "[p]erform affordability reviews of prescription drugs," and "[e]stablish upper payment limits for prescription drugs." *Id.* § 10-16-1403. An "upper payment limit" is defined 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." *Id.* § 10-16-1401(23).

41. The Board must first identify a list of prescription drugs eligible for an affordability review based on certain cost-related criteria. *Id.* § 10-16-1406(1); 3 Colo. Code Regs. § 702-9:3.1(C). Eligible drugs include "brand-name drug[s] or biological product[s]" as well as biosimilar and generic drugs that meet the applicable criteria. Colo. Rev. Stat. § 10-16-1406(1).

42. Next, the Board decides which eligible drugs to select for an affordability review. In making that determination, the Board considers (a) "the class of the prescription drug and whether any therapeutically

equivalent prescription drugs are available for sale"; (b) "aggregated data" regarding costs, pricing, expenditures, utilization, and "health equity impact"; (c) input from the Board-appointed Prescription Drug Affordability Advisory Council; and (d) "the average patient's out-of-pocket cost for the prescription drug." *Id.* § 10-16-1406(2); 3 Colo. Code Regs. § 702-9:3.1(D).

43. When the Board conducts an affordability review for a drug, its task is to "determine whether use of the prescription drug … is unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). In performing the affordability review, the Board is instructed to "consider" "to the extent practicable" various factors, including: cost-related considerations; "[t]he effect of the price on Colorado consumers' access to the prescription drug"; whether the drug has orphan-drug status under federal law; input from patients, caregivers, and experts; information voluntarily submitted by manufacturers or other entities; and "[a]ny other factors as determined by rules promulgated by the [B]oard." *Id.* § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E). The Board has promulgated rules specifying that it will consider additional factors, including "Rebates, Discounts, and Price Concessions"; "Health Equity Factors"; relevant analyses conducted by the Department of Health Care Policy and Financing; information regarding safety-net providers participating in the federal 340B discount program; and "information regarding non-adherence to

the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug." 3 Colo. Code Regs. § 702-9:3.1(E).

44. In conducting the affordability review, the Board "may" also "consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug." Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E).

45. Despite the provisions directing and authorizing the Board to consider certain information, the statute does not include any definition or standards to guide the Board's decision-making or to help the Board determine when a drug should be classified as "unaffordable" under the statute.

46. If the Board determines that a prescription drug is "unaffordable for Colorado consumers," the Board is authorized to establish an "upper payment limit" for that prescription drug. Colo. Rev. Stat. § 10-16-1407(1)(a).

47. The Act directs the Board to "determine by rule the methodology for establishing an upper payment limit for a prescription drug to protect

consumers from the excessive cost of prescription drugs and ensure they can access prescription drugs necessary for their health." *Id.* § 10-16-1407(2). The methodology "must include consideration" of: "(a) The cost of administering or dispensing the prescription drug; (b) The cost of distributing the prescription drug to consumers in the state; (c) The status of the prescription drug on the drug shortage list published by the drug shortage program within the FDA; and (d) Other relevant costs related to the prescription drug." *Id.* The methodology must also consider the impact on "older adults and persons with disabilities," without placing a lower value on their lives because of disability or age, and must allow pharmacies to charge "reasonable fees" for dispensing or delivering drugs that are subject to an upper payment limit. *Id.* §§ 10-16-1407(3), 10-16-1407(4).

48. The Board's rules regarding the methodology for establishing upper payment limits state that the Board "shall review" the factors specified in § 10-16-1407(2). 3 Colo. Code Regs. § 702-9:4.1(C)(2). The rules elaborate on how the Board might, in its discretion, consider those statutory factors. For example, "[t]o approximate prescription drug costs," the Board "may consider" "one or more price and cost metrics" that "include but are not limited to" a list of 10 different measures. *Id.* § 702-9:4.1(C)(2)(a). Similarly, the Board's consideration "may include" whether the prescription drug is on the FDA's

drug shortage list and, if so, the Board "may consider" factors such as the estimated shortage duration, the shortage reason, therapeutic classification, and "[o]ther related information." *Id.* § 702-9:4.1(C)(2)(b).

49. Regarding the "Process for Establishing Upper Payment Limits," the Board's rules provide that the Board will set upper payment limits "through rulemaking." *Id.* § 702-9:4.1(D). The Board "shall receive stakeholder information" submitted through the rulemaking, "containing information relevant to any of [the] considerations that the Board may take into account in establishing an upper payment limit." *Id.* § 702-9:4.1(C)(2)(f).

GENERAL ALLEGATIONS

Plaintiffs' Patent-Protected Drug Enbrel®

50. Enbrel®, first approved by the Food and Drug Administration in 1998, is an innovative medicine used to treat certain autoimmune diseases, including rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile psoriatic arthritis, and polyarticular juvenile idiopathic arthritis. Enbrel® can help patients with moderate to severe rheumatoid arthritis or psoriatic arthritis reduce joint pain, avoid permanent joint damage, and dramatically improve their physical function and overall quality of life.

51. Enbrel® is a biologic drug, meaning that it is made from living

cells. The active ingredient in Enbrel® is a fusion protein called etanercept. Etanercept works by attaching to a protein in the body called "tumor necrosis factor" (TNF) and thereby inhibiting TNF's inflammatory activity. When a patient's immune system produces too much TNF, it may lead to inflammation that causes pain, swelling, and joint damage.

52. Enbrel® is covered by a number of United States patents, including U.S. Patent No. 8,063,182 ("the '182 patent"), which is directed to etanercept and issued on November 22, 2011, and U.S. Patent No. 8,163,522 ("the '522 patent"), which is directed to methods of making etanercept and issued on April 24, 2012.

53. Those two patents grant Enbrel® market exclusivity and limit competing biosimilar products from entering the market until 2029 at the earliest.

54. Immunex is the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell Enbrel®. Immunex has also granted AML an exclusive sublicense to the '182 and '522 patents.

55. Federal courts have upheld the validity of Enbrel®'s patents, including the patents that limit biosimilar competition until 2029. *See, e.g.*, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020).

The Board's Proceedings Regarding Enbrel®

56. On June 9, 2023, the Board approved the final list of prescription drugs eligible for affordability reviews. The list included 604 drugs that the Board claimed met one or more of the statutory eligibility criteria to be subject to an affordability review.[5]

57. On August 4, 2023, the Board selected five drugs for affordability reviews. All of the selected drugs were brand-name drugs covered by unexpired patents. Enbrel® was one of those drugs.

58. On February 9, 2024, the Board published its draft affordability review summary report for Enbrel®. The report expressly discussed Enbrel®'s patents as a reason for deeming Enbrel® "unaffordable" and subjecting it to an upper payment limit.

59. The report observed that "[c]urrently, Enbrel has patent protection and is protected from biosimilar competition" due to "patents that prevent the introduction of biosimilar products" that are set to expire in 2029.[6] The report contrasted this with "[t]wo of Enbrel's therapeutic alternatives, Humira and

[5] Colo. Div. of Ins., *CO PDAB 2023 Eligible Drug Dashboard* (Oct. 19, 2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/0_Navigation?publish=yes.

[6] Ex. B at 26 (Colo. Prescription Drug Affordability Bd., DRAFT 2023 Affordability Review Summary Report: Enbrel (Feb. 9, 2024), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

Remicade, [which] have recent FDA-approved biosimilar products," and noted that "there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets."[7]

60. Further emphasizing Enbrel®'s patent protection, the report included an appendix section specifically devoted to the topic of "Patents and Exclusivity."[8] The report catalogued Enbrel®'s various patents, highlighted two patents that it stated currently "prevent the introduction of biosimilar products," and explained that "[e]valuating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices, delayed availability, and increased costs to consumers and governments."[9] The report went on to state that Enbrel®'s '182 and '522 patents are "'core'" patents that are "considered to be quite strong" and "make the creation of a non-infringing biosimilar drug nearly impossible."[10] Finally, the report noted that "Amgen has protected Enbrel through litigation of its patents in U.S. courts" and that multiple courts had upheld Enbrel®'s '182 and

[7] *Id.* at C-9 to C-11.

[8] *Id.*

[9] *Id.* at C-9.

[10] *Id.* at C-11.

'522 patents against challenges from potential competitors seeking to market biosimilar drugs prior to the expiration of those patents in 2029.[11]

61. On February 16, 2024, the Board held a meeting at which four of its members (Dr. Diab was recused) voted to declare Enbrel® "unaffordable for Colorado consumers." At the meeting, one of the members remarked that even though an Enbrel® competitor had historically been more expensive than Enbrel®—in fact, it had topped the Board's list of the "top 10 highest spend eligible drugs"[12]—the Board did not conduct an affordability review for the competitor because it had recently become subject to biosimilar competition (*i.e.*, its patent exclusivity period had ended).

62. On February 23, 2024, the Board held a meeting at which three of its members (Dr. Diab was again recused and Ms. Harshbarger was absent) voted to approve the final affordability review summary report for Enbrel.® The Board then voted—without further deliberation and without responding to public comments—to select Enbrel® for establishment of an upper payment limit and directed its staff to initiate a rulemaking to determine the precise

[11] *Id.*

[12] *See* Ex. C (Colo. Div. of Ins., *CO PDAB 2023 Eligible Drug Dashboard: Eligible List Summary* (Oct. 19, 2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/1_EligibleListSummary).

amount of that upper payment limit. The rulemaking is to take a maximum of 180 days, *see* Colo. Rev. Stat. § 24-4-103(4)(d), and the upper payment limit is expected to become effective six months after the Board promulgates a rule establishing the limit, *see id.* § 10-16-1407(5).

63. The Board's final affordability review summary report for Enbrel® was made publicly available on March 21, 2024. In a new section titled "Board Deliberation and Vote Summary," the report noted the Board's finding that Enbrel® is "unaffordable for Colorado consumers" and listed factors the Board had considered in reaching that determination, including "availability of biosimilars."[13] The final report was otherwise identical to the draft report in all relevant respects, including the discussion of Enbrel®'s patents.[14]

64. While the specific amount of the upper payment limit for Enbrel® is still being determined, the Board's decisions to date mean that Enbrel® will be subject to an upper payment limit that will prevent Plaintiffs from realizing the full benefit of their federal patent exclusivity.

65. Moreover, the Board's determination that Enbrel® is

[13] *See* Ex. D at 2–3 (Colo. Prescription Drug Affordability Bd., 2023 Affordability Review Summary Report: Enbrel (Feb. 23, 2024), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

[14] *See id.* at 25 and C-11 to C-13.

"unaffordable" and its decision to select Enbrel® for establishment of an upper payment limit are already harming Plaintiffs by, for example, causing them to incur substantial costs to participate and defend their interests in a preempted state price-setting process that violates the U.S. Constitution and federal law and casting a shadow of uncertainty over Plaintiffs' longstanding contractual relationships involving Enbrel®.

CLAIMS FOR RELIEF

Count 1
Preemption Under the Federal Patent Laws

66. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

67. Under the Supremacy Clause of the United States Constitution, federal statutes are "the supreme Law of the Land." U.S. Const. art. VI, cl. 2.

68. Under well-established federal "conflict preemption" principles, no state law may "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This inquiry "ranges beyond the literal text" of the federal statute and requires an examination of its "'purpose and intended effects.'" *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373,

(2000)).

69. "The federal patent system … embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats*, 489 U.S. at 150–51. The "pecuniary rewards stemming from the patent right" incentivize the costly research and development that drives technological innovation. *BIO*, 496 F.3d at 1372.

70. As reflected in the enactment of the Hatch-Waxman Act and the BPCIA, Congress has taken special care to safeguard those incentives for innovation in the pharmaceutical field and has struck a careful and deliberate balance, ensuring that those who develop innovative medicines are rewarded with a period of federal patent exclusivity and pricing discretion, while encouraging generic and biosimilar competition after the end of the relevant patent terms.

71. Because it contains no exemption for patented drugs like Enbrel®, Colorado's price-control scheme frustrates the purposes and objectives of the federal patent laws by "re-balanc[ing] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. A state price-setting process for patented drugs is preempted by federal law,

regardless of its outcome, because it is fundamentally inconsistent with the congressional design and imposes hardships of expense, delay, and uncertainty on the very parties the patent laws are designed to protect.

72. As the Federal Circuit recognized in striking down another state law that sought to cap the prices of patented drugs, "Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *Id.* at 1373. A state cannot take it upon itself to alter that balance by preventing a patent owner or licensee from charging prices that reflect its federally guaranteed patent exclusivity. "The underlying determination about the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress." *Id.* at 1374.

73. The Board's conduct in selecting Enbrel® for an affordability review and performing that review further confirms that the Board is attempting to alter the balance Congress struck when calibrating the federal patent laws. For example, the Board's affordability report emphasized Enbrel®'s patent protection and observed that "such intellectual property rights can be associated with increased drug prices."[15] In addition, a Board

[15] Ex. B at C-9; Ex. D at C-11.

member expressly acknowledged that the Board selected Enbrel®, rather than a competitor, for an affordability review because unlike Enbrel®, the competitor is subject to biosimilar competition and no longer patent-protected. The Board has thus targeted Enbrel® specifically because it is still on patent.

74. Accordingly, the Act stands as an obstacle to Congress's clear purposes and objectives and is preempted by the federal patent laws.

Count 2
Violation of Due Process

75. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

76. The Due Process Clause of the Fourteenth Amendment prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. Plaintiffs have a protected property interest in their patent-protected medication, Enbrel®.

77. At its core, the Due Process Clause requires notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)); *see C1.G ex rel. C.G. v. Siegfried*, 38 F.4th 1270, 1280 (10th Cir. 2022).

78. The Act, as implemented by the Board, violates the Due Process

Clause because it provides no standards for the Board to apply either when determining whether a drug is "unaffordable for Colorado consumers" or when setting an upper payment limit. Although the statute provides an assortment of factors for the Board to consider in making those determinations, the statute does not explain how the Board should assess and weigh those factors, and the Board's regulations largely echo the statute.

79. As a result, the Act fails to provide drug manufacturers with a meaningful opportunity to be heard, encourages arbitrary and discriminatory enforcement, and creates an unacceptable risk of erroneous deprivations of manufacturers' property interests.

80. The Act also violates the more specific due-process principles that courts have applied in the context of administrative price-control schemes.

81. Due process requires that the procedures employed by agencies be designed to ensure that prices set by the government are, at minimum, "just and reasonable" and not unduly discriminatory or "confiscatory." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 592–93 (6th Cir. 2001); *see Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989); *Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990), *as amended* (Nov. 8, 1990). Due process also requires a mechanism through which a regulated entity can "challenge the imposition of rates which may be confiscatory" as well as adequate safeguards to "ensur[e]

a constitutional rate of return." *Mich. Bell*, 257 F.3d at 592–93.

82. Here, as discussed above, the Act does not provide any standards to ensure a constitutional rate of return for drug manufacturers. Indeed, the law does not even include the manufacturer's return on investment as one of the many factors the Board is required to consider when determining affordability and setting an upper payment limit. The Act therefore fails to provide Plaintiffs with due process.

Count 3
Interference with Federal Healthcare Programs

83. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

84. The Act is also preempted insofar as it purports to dictate the prices that federal healthcare programs—such as Medicare, TRICARE, the Veterans Health Administration, and the Federal Employees Health Benefits Program—are required to pay for Enbrel and other prescription drugs on behalf of beneficiaries of those programs. In doing so, the Act directly regulates federal activities and interferes with the operation of federal healthcare programs. It is well-settled that "the activities of the Federal Government are free from regulation by any state." *Mayo v. United States*, 319 U.S. 441, 445 (1943); *see United States v. Sup. Ct.*, 839 F.3d 888, 927 (10th Cir. 2016) (noting

"the fundamental importance of the principles shielding federal installations and *activities* from regulation by the States" (quotation marks omitted)).

85. Moreover, the Act is expressly preempted under the "sweeping" preemption provisions applicable to the federal Medicare Part C and D programs. *Pharm. Care Mgmt. Ass'n v. Mulready* ("*PCMA*"), 78 F.4th 1183, 1206 (10th Cir. 2023).

86. Medicare Parts C and D are public-private partnerships between the federal Centers for Medicare & Medicaid Services and private insurers (called plan sponsors). Plan sponsors may offer prescription-drug coverage to Medicare recipients and must abide by federal statutes and regulations in doing so. Against that "backdrop of extensive federal regulation," Medicare Parts C and D have "broad preemption clause[s]." *Id.* at 1205. Those clauses provide, in relevant part, that "[t]he standards established under [Part C or D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part C or D plans] which are offered by [plan sponsors] under [Part C or D]." 42 U.S.C. § 1395w-26(b)(3) (Part C); *see id.* § 1395w-112(g) (incorporating same preemption clause into Part D). The Tenth Circuit has held that this "sweeping" preemption language "is 'akin to field preemption' and precludes States from regulating Part [C or] D plans except for licensing and plan solvency." *PCMA*, 78 F.4th at 1206.

87. These principles make clear that Colorado's price-control law is preempted insofar as it purports to dictate the prices that Medicare and other federal healthcare programs must pay for prescription drugs on behalf of beneficiaries of those programs. Under Colorado's law, an upper payment limit "applies to *all* purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state." Colo. Rev. Stat. § 10-16-1407(5) (emphasis added). The law does not exempt federal payors; nor does it make their participation optional.

88. Accordingly, the Act impermissibly regulates "with respect to" Medicare plans. *PCMA*, 78 F.4th at 1208 (quotation marks omitted). And it impermissibly subjects all federal healthcare programs "to the discretionary authority of a state agency for the terms on which [they] can make arrangements for" the purchase of prescription drugs. *Pub. Utils. Comm'n v. United States*, 355 U.S. 534, 539 (1958).

Count 4
Violation of the Commerce Clause

89. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

90. The Commerce Clause of the Constitution grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. As the

Supreme Court has long recognized, this affirmative grant of power to Congress implies "'a further, negative command,' one effectively forbidding the enforcement of 'certain state economic regulations even when Congress has failed to legislate on the subject.'" *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (brackets omitted) (quoting *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995)).

91. Under this "dormant Commerce Clause" doctrine, a state law "that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid" per se. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989); *see Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 668 (4th Cir. 2018) ("A state law violates the extraterritoriality principle if it … expressly applies to out-of-state commerce."); *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615 (9th Cir. 2018) ("The mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions.").

92. The Act violates that extraterritoriality principle because it purports to regulate transactions that occur entirely outside of the State of Colorado. Under the Act, an upper payment limit set by the Board "applies to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by

other means." Colo. Rev. Stat. § 10-16-1407(5). By its terms, this language applies the upper payment limit even to wholly out-of-state, upstream transactions, so long as the drug is eventually dispensed or administered in Colorado. Colorado may not directly regulate a sale that occurs in another state simply because the product may eventually make its way into Colorado.

93. As the Fourth Circuit recognized in striking down a similar drug-pricing law, a state law is invalid under the Commerce Clause if it attempts to "control[ ] the price of transactions that occur wholly outside the state." *Ass'n for Accessible Meds.*, 887 F.3d at 671; *see id.* at 672 ("[T]he Act is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland."); *see also Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586, at *3 (D. Minn. Dec. 4, 2023) (holding that Minnesota could not "directly regulate[ ] extraterritorial sales of drugs … simply because the product eventually makes its way into Minnesota"), *appeal docketed*, No. 24-1019 (8th Cir. Jan. 20, 2024).

94. Accordingly, insofar as Colorado's price-control law directly regulates the prices charged in wholly out-of-state transactions, it is per se invalid under the Commerce Clause. Moreover, even if Colorado's attempt to directly regulate out-of-state transactions were not per se invalid, it would still

violate the Commerce Clause because the burden imposed on interstate commerce by such extraterritorial regulation "is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see Ass'n for Accessible Meds.*, 2023 WL 8374586, at *9.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

1. A declaration that the Act is unconstitutional and void because it conflicts with the federal patent laws, and an injunction preventing Defendants from enforcing the Act as to patented drugs.

2. A declaration that the Act is unconstitutional and void because it denies Plaintiffs due process of law, and an injunction preventing Defendants from enforcing the Act against Plaintiffs.

3. A declaration that the Act is unconstitutional and void insofar as it regulates transactions involving federal healthcare programs, and an injunction preventing Defendants from enforcing the Act with respect to such transactions.

4. A declaration that the Act is unconstitutional and void insofar as it regulates wholly out-of-state transactions, and an injunction

preventing Defendants from enforcing the Act with respect to such transactions.

5. An award of costs and attorneys' fees.

6. Such other and further relief as may be just and proper.

Dated: March 22, 2024

Respectfully submitted,

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2023 Affordability Review Summary Report: Enbrel

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Draft Submitted to: the Colorado Prescription Drug Affordability Board

COLORADO
Prescription Drug Affordability Board
Division of Insurance

2023 Affordability Review Summary Report: Enbrel

February 23, 2024

Executive Summary

Affordability Review Summary Report Findings

Enbrel (etanercept), first approved by the United States Food and Drug Administration in 1998, is a tumor necrosis factor (TNF) inhibitor and is used to treat rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile psoriatic arthritis, and polyarticular juvenile idiopathic arthritis. The FDA granted orphan drug designation in 1998 for polyarticular-course juvenile rheumatoid arthritis, now referred to as polyarticular juvenile idiopathic arthritis. The relevant professional medical guidelines identify the following in-class therapeutic alternatives for Enbrel: Humira, Cimzia, Simponi/Simponi Aria, and Remicade. Patients and caregivers, as well as individuals with scientific and medical training, provided input that patients need many treatment options to identify the medications that work for them.

When compared to a placebo, Enbrel has shown improvements in symptoms for each indication. For some indications, there is evidence that Enbrel and its in-class therapeutic alternatives are associated with beneficial treatment effects when compared to other prescription drug treatments not in class. Of the few studies evaluating Enbrel compared to in-class therapeutic alternatives for rheumatoid arthritis, most found no difference in treatment, though one study found Enbrel to be inferior to Humira for remission, while another study found Enbrel to be superior to Remicade for different measure of remission.

In passing Senate Bill 21-175, the legislature recognized the importance of evaluating both the effectiveness of a drug, as well as its cost to consumers and the larger health care system. Enbrel's wholesale acquisition cost has increased 1,582.24%, from [redacted] per unit at its launch in November 1998 to [redacted] per unit in January 2024, which is significantly greater than the increase in inflation for the same time period. Over half of insurance carriers who submitted information to the Colorado All Payer Claims Database (APCD) reported that Enbrel was one of the top 15 prescription drugs that raised premiums for all covered lives. Enbrel has also appeared in other states' assessments of the costliest drugs, including contributing to increases in insurance plan spending.

In Colorado in 2022, Enbrel was the second most utilized drug (3,406 patients) compared to its in-class therapeutic alternatives, Humira (7,526), Remicade (698), Simponi (579), and Cimzia (475), and saw relatively steady utilization from 2018 to 2022. According to 2022 APCD data, Enbrel cost $46,772 per patient and over $159,305,653 in total. In that year, the average annual out-of-pocket cost for patients with commercial insurance was $3,980 annually. Though there was evidence in both APCD data and patient and caregiver survey responses that monthly out-of-pocket costs were quite varied, 27 of 38 (71.1%) of Colorado patients and caregivers reported the cost of Enbrel has made it difficult to access the drug. The majority of patients and caregivers surveyed (33 of 38) stated they used some form of assistance program to access Enbrel, with over a quarter of patients (10 of 38) reporting they still had trouble affording Enbrel.

In 2023, it is estimated that [redacted] of Amgen Inc.'s national gross sales for Enbrel was spent on rebates, 340B discounts, manufacturer financial assistance programs, and other price concessions. International net revenue for Enbrel decreased from $4.465 billion in 2021 to $4.177 billion in 2022, which may be partly explained by [redacted].

The following report and its appendices provide detailed evidence necessary for the Board's consideration of whether Enbrel is unaffordable to Coloradans.

Board Deliberation and Vote Summary

After receiving and reviewing evidence in support of the affordability review components set forth in statute and rule, on February 16, 2024, the Colorado Prescription Drug Affordability Board (the Board)

acknowledged there was sufficient evidence to proceed with deliberations for the Enbrel affordability review. The Board then deliberated whether the use of Enbrel was unaffordable for Colorado consumers.

During deliberations, Board members noted that the data concerning out-of-pocket costs and patient and caregiver experience purchasing the drug provided evidence that the drug is unaffordable to patients in Colorado. Deliberation also included discussion of:

- Enbrel is clearly an effective drug that is comparable to therapeutic alternatives;
- Utilization of therapeutic alternatives and availability of biosimilars;
- Average out-of-pocket cost is relatively higher than some therapeutic alternatives;
- Concerns that Colorado patients may be paying higher out-of-pocket costs or have more affordability concerns than survey results from patients outside of Colorado;
- Health equity and patients in rural counties may be going undiagnosed or be unable to access medications; and
- High changes in wholesale acquisition cost (WAC).

After deliberations and hearing public comment from six individuals, the Board voted 4-0 that the use of Enbrel consistent with the labeling approved by the FDA or with standard medical practice is unaffordable for Colorado consumers. Dr. Sami Diab recused himself from the deliberation and vote due to a conflict of interest.

To view the meeting recording in full, see:
https://us06web.zoom.us/rec/share/Qok1gyXB8g_7SJI2Bt4UJSXdHre7F3jgFAdCJnaaxNplnTyuLgc3Vzt4RbyC5xpb.7RBSR3AvYJkCKjjw

Introduction

The Colorado Prescription Drug Affordability Board (the Board) was established in 2021 through the passage of Senate Bill 21-175. Governor Polis appointed five members to the Board in September 2021. Since then, the Board has appointed members to the 15-person Prescription Drug Affordability Advisory Council (the Advisory Council) and hosted a five-part learning series in spring 2022 to provide Board members, Advisory Council members, and interested stakeholders foundational knowledge necessary to implement a successful new prescription drug affordability program. The Board has also promulgated five rules to implement statutory requirements and developed five policies to guide the program.

One of the Board's duties is to perform affordability reviews of prescription drugs as described in section 10-16-1406, C.R.S. This section outlines the Board's four steps in conducting affordability reviews:(1) identification of eligible drugs, (2) selection of drugs for affordability reviews, (3) conducting affordability reviews on selected drugs, and (4) determining if use of the selected drugs are unaffordable for Colorado consumers.

The first step - identification of prescription drugs eligible for affordability reviews - was completed when the Board approved the final list of prescription drugs eligible for affordability reviews on June 9, 2023. The second step - selection of prescription drugs for affordability reviews - was completed when the Board selected five drugs for affordability reviews on August 4, 2023. This report has been prepared by Board staff to assist the Board in completing the third and fourth steps of the affordability review process for the prescription drug, Enbrel.

This report of the affordability review for Enbrel was conducted in accordance with 3 CCR 702-9, Part 3.1.E.6. Additionally, this report contains appendices with detailed information for each of the fifteen criteria the Board shall and may consider as a part of its affordability review, to the extent practicable.

Report Structure

About This Report

The main body of the Affordability Review Summary Report is divided into three profiles: a therapeutic and utilization profile; a cost and price profile; and an access to care profile. The profiles contain information from the fifteen statutory and regulatory components the Board considers as a part of an affordability review. The profiles were identified by Board members and Board staff as a way to present affordability review evidence in a commonsense manner. While these profiles incorporate all fifteen components the Board considers during affordability reviews, additional information is provided for each of the fifteen components in the appendices, with each component having an individual appendix. More information on the structure of each profile and the appendices is provided in the sections below.

While several components lend themselves to inclusion in only one profile, three components inform all profiles contained in the Summary Report. Those components, and information regarding the type and volume of feedback Board staff received, are summarized below:

- Input from patients and caregivers - Board staff gathered input from three patients and caregivers at one public meeting on September 19, 2023. Additionally, 287 patients and caregivers completed surveys regarding the health and financial effects of Enbrel, and many of these patients and caregivers also attended the public meetings.
- Input from individuals with scientific and medical training - Board staff gathered input from two individuals with scientific or medical training at one public meeting on September 19, 2023 as well as five individuals at small-group meetings. Additionally, three individuals with scientific & medical training completed surveys regarding the health and financial effects of Enbrel.
- Voluntarily submitted information - two patients, caregivers, and other entities submitted voluntary information. Amgen Inc., the manufacturer of Enbrel, also voluntarily submitted public and confidential information. Note: no assessment was conducted of accuracy of voluntarily submitted information or the extent to which the information applies to Coloradans.

The Summary Report and Appendices may contain proprietary, confidential, and trade-secret information. Such information is redacted in public reports.

Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives. Affordability review components present in this profile include information from Appendices B, G, H, I, J, and L.

Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs. Affordability review components present in this profile include information from Appendices A, B, D, E, H, I, J, K, and O.

Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile

includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design. Affordability review components present in this profile include information from Appendices A, B, C, E, F, H, I, J, K, M, and N.

Appendices

This report contains an appendix for each of the fifteen components the Board is to consider as a part of affordability reviews, as well as a last appendix, Appendix P - Data Sources and Limitations. Descriptions of the appendices related to the fifteen affordability review components are outlined below. Some appendices contain data and information specific to one or more of Enbrel's six FDA-approved indications. Those appendices are noted below with an asterisk (*). All other appendices contain data for Enbrel irrespective of indication.

Table 1
Appendices and Relevant Statutory, Rule, and Policy Guidance for Affordability Review Components

Component Name	Component Details
***Appendix A:** Current WAC & Change in WAC	The Board shall consider the wholesale acquisition cost of the drug. C.R.S. § 10-16-1406(4)(a).
***Appendix B:** Therapeutic Alternatives	The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. C.R.S. § 10-16-1406(4)(b).
Appendix C: Price Effect on Access	The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. C.R.S. § 10-16-1406(4)(c).
***Appendix D:** Relative Financial Effects	The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. C.R.S. § 10-16-1406(4)(d).
Appendix E: Patient Copayment & Other Cost Sharing	The Board shall consider the patient copayment or other cost sharing of the drug. C.R.S. § 10-16-1406(4)(e).
Appendix F: Safety Net Providers	The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. C.R.S. § 10-16-1406(4)(f).
***Appendix G:** Orphan Drug Status	The Board shall consider orphan drug status. C.R.S. § 10-16-1406(4)(g).
***Appendix H:** Patients & Caregivers	The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(I).
***Appendix I:** Individuals with Scientific & Medical Training	The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(II).
Appendix J: Voluntarily Submitted Information	The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. C.R.S. § 10-16-1406(4)(i).

Component Name	Component Details
Appendix K: Rebates, Discounts, and Price Concessions	The Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.i.
***Appendix L:** Health Equity	The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.ii.
***Appendix M:** Information from HCPF	The Board shall consider information from the Department of Health Care Policy and Financing, including additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub. L. 78-410. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.iii.
Appendix N: Non-Adherence & Utilization Management	The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, 3.1.E.2.j.iv.
Appendix O: Pricing Information	The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. C.R.S. § 10-16-1406(6). The Board may access pricing information for prescription drugs by: (I) accessing publicly available pricing information from a state to which manufacturers report pricing information; (II) accessing available pricing information from the all-payer health claims database and from state entities; and (III) accessing information that is available from other countries. C.R.S. § 10-16-1406(7)(a).

*Appendix contains information specific to one or more of the six indications Enbrel treats.

Enbrel Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives.

Indications

Enbrel has six FDA-approved indications:

- Rheumatoid arthritis (RA) - reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA (FDA approval in 1998).
- Ankylosing spondylitis (AS) - reducing signs and symptoms in patients with active AS (FDA approval in 2003).
- Plaque psoriasis (PsO) - treatment of patients 4 years or older with chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy (FDA approval in 2004).

Figure 4

Insurance information for Therapeutic Alternatives

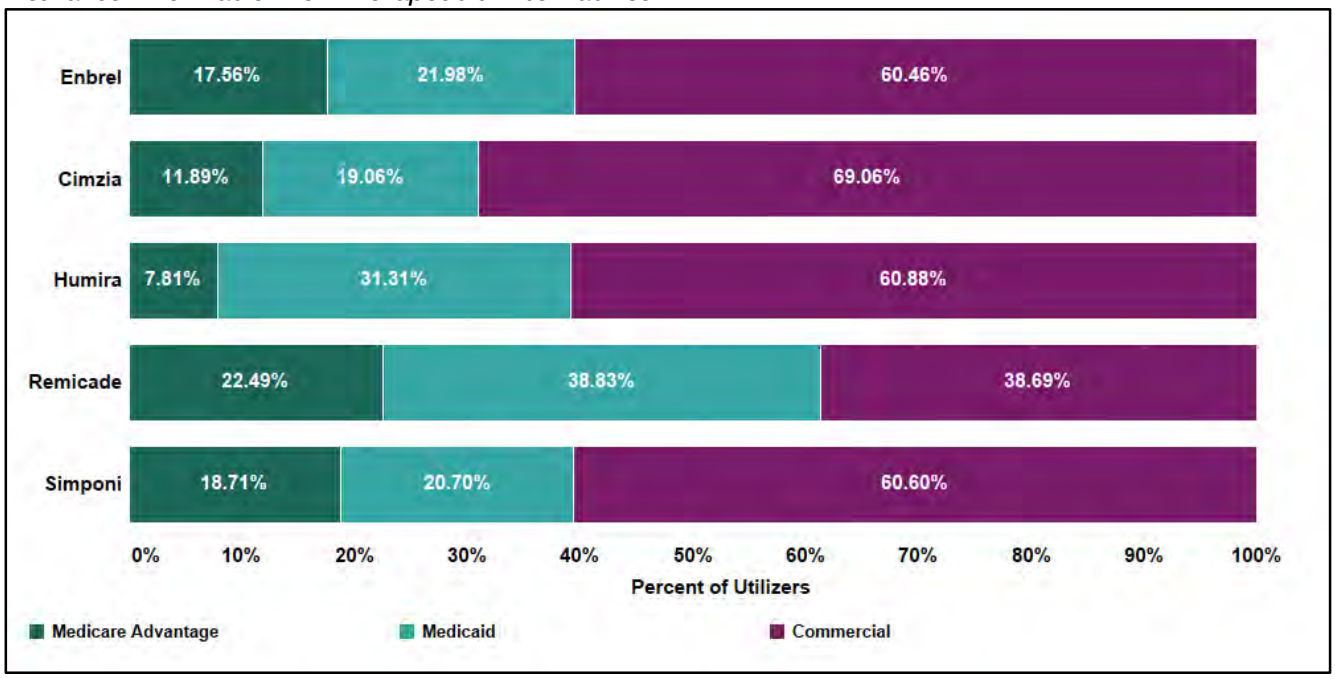


Figure 4 shows the 2022 payer mix for Enbrel and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, Teal represents patients with Medicaid, and purple represents patients with commercial insurance. Enbrel, Humira, and Simponi had around 60% of patients with commercial insurance while Cimzia had higher commercial coverage (69.06%) and Remicade had lower commercial coverage (38.69%).

Enbrel Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs.

Table 6

Enbrel's 2022 Price & Cost per Person Statistics

Price & Cost Per Person Statistics	Amount
Average WAC per Course of Treatment per Person[57]	[redacted]
Average Paid per Person	$46,772
APPY - Plan Paid	$41,769

[57] Course of treatment is calculated based on utilization not FDA labeling recommended doses. For course of treatment methodology please see June 9th, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiuImYzhKhxeGjvbFoh88cTs/view?usp=sharing

APPY - Out-of-Pocket[58]	$2,295

Table 7
Enbrel's 2022 Statewide Price & Cost Statistics

Statewide Price and Cost Statistics	Amount
Total Paid Amount	$159,305,653
Total Plan Paid[59]	$142,264,673
Total Medicaid Paid	$24,456,550
Total Patient Paid	$9,860,820
Gross-to-net Estimates	[redacted]

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[60] See Appendix A for more information.

Pursuant to section 10-16-1405, C.R.S., carriers and pharmacy benefit managers submit data about the highest cost prescription drugs to the APCD, including the fifteen prescription drugs that caused the greatest increase to the carrier's premiums. Ten of the nineteen carriers who submitted data reported Enbrel in the top fifteen drugs that caused the greatest increase to premiums, seven of these submitters reported Enbrel in the top five drugs that caused the greatest increase to premiums. Additionally, prescription drug transparency data from other states indicates Enbrel is among the costliest drugs in the state (Maine, Oregon) and has price increases above certain thresholds (Minnesota). See Appendix O for more information. The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[61] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). See Appendix O for more information.

Out-of-Pocket Estimates

Patient copayment and other cost sharing depends on many factors, including: a patient's insurance coverage, how much has already been contributed to out-of-pocket maximum amounts in a benefit year, and whether the patient receives other assistance to pay for their portion of prescription drug. The APCD

[58] Medicaid copayments are $0-$3 for each prescription fill, as a result, Medicaid out of pocket paid amounts are removed from all averages in the data presented below, however, it is included in the statewide totals when reviewing the total amount patients paid. Medicaid copay information: https://www.healthfirstcolorado.com/copay/
[59] Total Plan Paid represents the amount paid by a patient's primary insurance coverage, even though secondary coverage may have paid an amount. Secondary insurance coverage paid amounts are generally captured in Total Paid Amounts.
[60] Course of Treatment methodology outlined in Board Staff Memo from June 6, 2023: https://drive.google.com/file/d/16BFOEB-LMiuImYzhKhxeGjvbFoh88cTs/view?usp=sharing.
[61] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

Figure 6

Changes in Copay amounts by Year and Drug 2018-2022

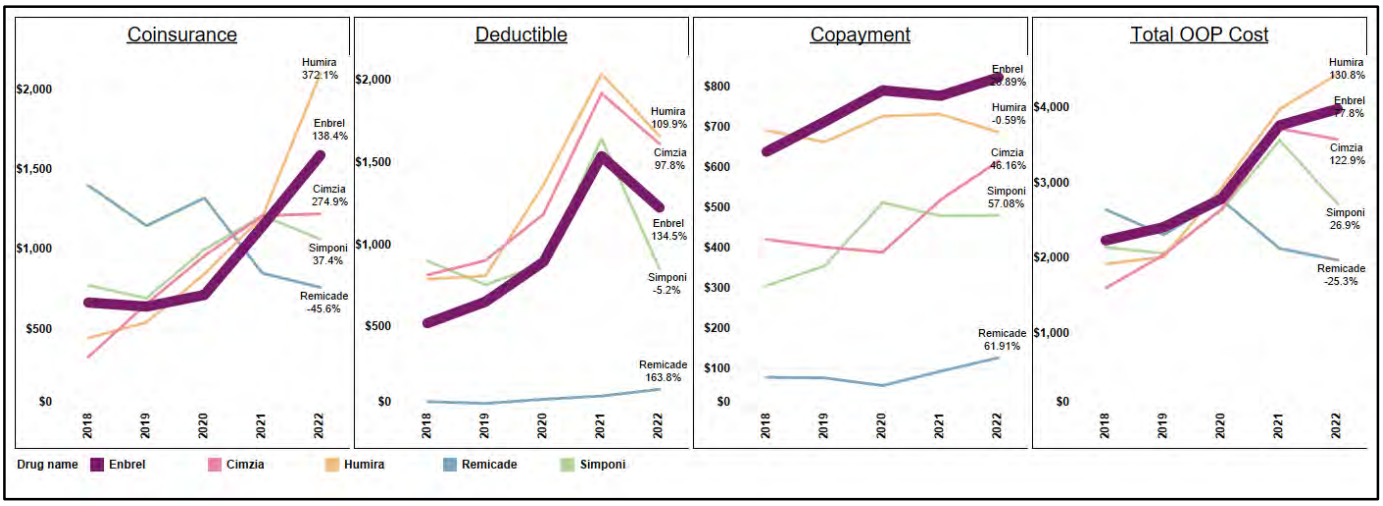


Figure 6 shows the annual change in the annual average oop amounts comparing Enbrel (dark purple) to its therapeutic alternatives. Each line is labeled with the name of the therapeutic alternative and the percent change from January 2018 - December 2022. Enbrel had the third highest increase in total out-of-pocket costs with a 77.8% increase. See Appendix E for more information.

Amgen Inc. provided information on the Enbrel Co-Pay Card program and Amgen Safety Net Foundation, which is available to eligible patients who need additional help and provides free or reduced medicine to patients who do not have insurance and meet certain eligibility criteria. See Appendices J and K for more information. Board staff received information in surveys that as many as 87% (33 of 38) of patients utilize some form of patient assistance program (could be manufacturer or another entity), though 30% (10 of 33) still had trouble affording Enbrel. See Appendices H, I, J, and K for more information.

Rebates, Discounts, and Price Concessions Estimates

The gross-to-net sales estimate is a proprietary estimate where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, assistance programs, and other price concessions provided by manufacturers compared to gross sales to get a percentage estimate of all discounts.[63] The gross-to-net sales estimate was [redacted] in the third quarter of 2008 (the earliest SSR Health estimates available), which increased to [redacted] in the third quarter of 2023. Additionally, In 2021, 14 of 25 carriers reported to the APCD that Enbrel was in the top 15 drugs for which the carrier received the largest rebate. See Appendix K for more information.

[63] All gross-to-net estimates are provided on a four quarter moving average.

Figure 7
Estimated Total Gross-to-Net Sales

Figure 7 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Enbrel's Health and Financial Effects

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social service costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. Information regarding Enbrel's relative financial effects on health, medical, or social service costs is summarized here from literature reviews (Appendix D), input from patients and caregivers (Appendix H), input from individuals with scientific and medical training (Appendix I), and voluntarily submitted information (Appendix J). These summaries are structured to focus first on Enbrel's health effects, followed by financial effects.

Enbrel's Health Effects

The FDA label provides information on Enbrel's impact on the health effects on the indications it is approved to treat. See Appendix D for more information. Patients, caregivers, and individuals with scientific and

medical training reported in meetings and surveys regarding health effects. Examples of feedback, including two quotes that summarize common themes, are provided below; see Appendix H and Appendix I for more information.

- *"This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises"* Survey respondent with rheumatoid arthritis.
- *"We cycle through these drugs because sometimes they lose effectiveness or we just build up an immunity to them. That happened with Enbrel, but it was a glorious remission when I had it."* Public input session attendee.
- Enbrel has reduced pain and symptoms in the majority of patients of all indications, though some rheumatoid arthritis and psoriatic arthritis patients reported no improvements. Other patients stated that Enbrel worked well until it lost its effectiveness and they had to cycle to a new medication. One patient at a public input session liked that Enbrel is self-injectable, which cut down on trips to the doctor to get infusions.
- The most common side effect reported for all indications was pain and bruising at the injection site. Less common symptoms were chills, nausea, lowered immune system, depression, and dry mouth leading to dental issues. One patient reported not caring for the delivery method of self-injection.

Additionally, patients and caregivers provided input regarding therapeutic alternatives. Select answers are summarized below; see Appendix H for more information.

- **Humira:** Many patients reported it to be ineffective, and others reported that it worked well for a time to reduce inflammation and pain before it lost efficacy. One patient stated that it works better than Enbrel for them. Patients reported similar side effects as Enbrel.
- **Remicade**: Patients reported that this worked well but then plateaued and stopped working. One patient stated it gave them no relief.
- **Cimzia**: Effective and pregnancy safe option. One said getting sick too often.
- **Methotrexate:** Some patients said it did not work, others said it reduced inflammation but caused extreme severe side effects leading them to stop taking it. Reported side effects include nausea, blurry vision, severe fatigue and nausea, brain fog, hair loss, sores in mouth, and liver damage.

In addition to gathering information from patients, caregivers, and individuals with scientific and medical training, Board staff conducted literature reviews to compile evidence of the clinical effectiveness of Enbrel. To do this, Board staff examined studies conducted by Health Technology Assessment (HTAs) organizations. HTA organizations, often found within or supporting governmental agencies in other countries, can provide consistent and thorough assessments of a prescription drug's clinical and cost effectiveness. See Appendix D for information compiled from six HTA organizations for Enbrel's FDA-approved indications.

Enbrel's Financial Effects

Understanding a prescription drug's financial effects on health, medical, and social service costs as compared to therapeutic alternatives can be a complex task. HTA organizations conduct evaluations of the effects and impacts of a prescription drug, which may address the direct, intended consequences as well as their indirect, unintended consequences. Though nearly all HTA organizations take into account patient, caregiver, and provider perspectives when determining a prescription drug's cost effectiveness, Board staff were able to gather direct input from those groups on Enbrel's financial effects on health, medical, and social service costs.

Patients, caregivers, and individuals with scientific and medical training were asked in public meetings and in surveys to share any additional information about how Enbrel affects them financially. Participants and

respondents shared experiences related to out-of-pocket costs, assistance programs, and utilization management requirements. Select answers are highlighted below; see Appendix H for more information.

Table 9

National and Colorado Patient Responses: How does Enbrel impact each patient or their family?[64]

Survey Prompt	National Responses	Colorado Responses
This medication reduces the amount of time and money going to the doctor.	110 of 267	14 of 38
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	63 of 267	9 of 38
This medication allows me to work and support my family.	110 of 267	15 of 38
Due to the cost of this medication, I have had to cut costs in other areas of my life.	74 of 267	20 of 38
Out-of-pocket costs have caused me to accrue medical debt.	36 of 267	8 of 38

Additionally, of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance. See Appendix H (input from patients and caregivers), Appendix I (input from individuals with scientific and medical training), and Appendix J (voluntarily submitted information) for more detail.

Board staff conducted literature reviews to compile evidence of the cost effectiveness of Enbrel. A summary of these organizations, the country where they are found, and their conclusions regarding the clinical effectiveness of Enbrel are outlined in Appendix D.

Enbrel Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design.

Price Effect on Access

Enbrel's WAC has increased 36 times since it was approved by the FDA in 1998, increasing a total of 1,582.24% since introduction, an increase that is significantly more than inflation (Figure 8 below). See Appendix A for more information. From 2018 to 2022, APCD data shows fluctuations in Enbrel's average annual patient out-of-pocket costs and total patient paid amounts, but with general increases across the five years and a 35.9% increase in average annual out-of-pocket costs (Table 10 below). See Appendix E for more information. Meanwhile, APCD data shows monthly fluctuations in average utilization of Enbrel, which

[64] 45 out of 267 national survey participants did not answer regarding the impact Enbrel has on the patient or their family. 3 out of 38 Colorado survey participants did not answer regarding the impact Enbrel has on the patient or their family.

appear relatively steady, though there was a decrease in utilization from 2018 to 2022 (See Figure 9 and Table 10 below).

Two of Enbrel's therapeutic alternatives, Humira and Remicade, have recent FDA-approved biosimilar products. While this affordability review does not contain information or analyses related to biosimilar products, there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets.[65] Currently, Enbrel has patent protection and is protected from biosimilar competition and patents that prevent the introduction of biosimilar products are set to expire in 2029.[66] See Appendix C for more information.

Patient and caregiver survey results provide further insight that patients report the cost of Enbrel has impacted their ability to access the prescription drug (see Table 11 below). While this impact varies by the self-reported out-of–pocket cost per month, over half (10 of 19) of Colorado patients paying between $0-50 per month for Enbrel still reported that cost has at some point impacted their ability to access Enbrel. See Appendices E and H for more information.

Table 10
Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	3,890	3,653	3,440	3,692	3,406
Total Paid	$129,421,272	$127,959,896	$134,815,241	$161,483,771	$159,305,653
Average Paid Per Person	$33,270	$35,029	$39,190	$43,739	$46,772
Total Patient Paid	$6,720,180	$7,399,691	$7,700,602	$10,524,066	$9,860,820
Average OOP	$1,688	$1,866	$2,189	$2,526	$2,295
WAC Per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 10 shows the year-over-year increases in the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

[65] https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1151764/full
[66] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

Figure 10
Monthly Total Paid and Average Total Paid

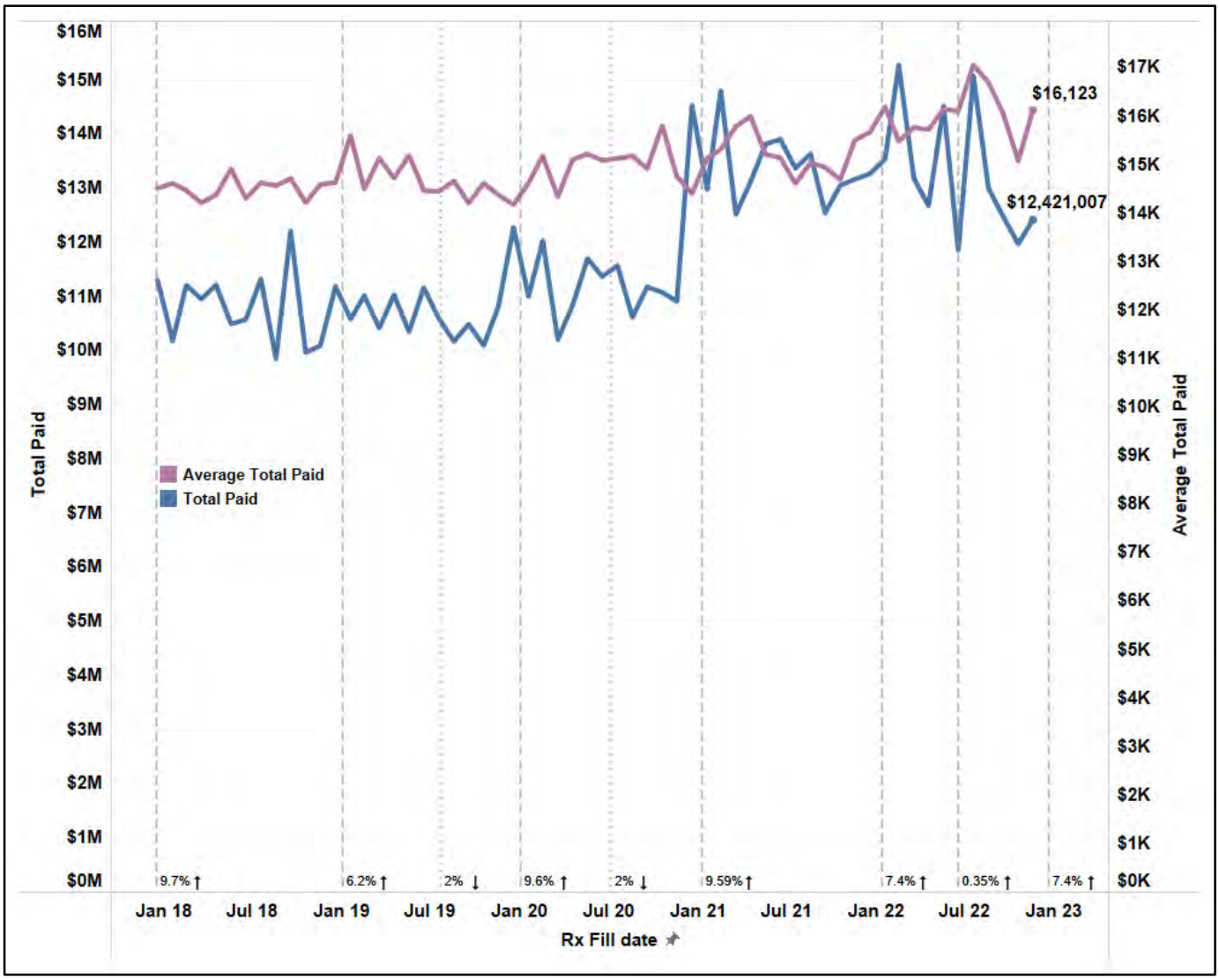


Figure 10 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel increased from 3,890 in 2018 to 3,406 in 2022.

Table 11
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19 said cost does affect access.

$50 - 100	4 of 38	2 of 4 said cost does affect access.
$100 - $150	1 of 38	1 of 1 said cost does affect access.
$150 - $250	2 of 38	2 of 2 said cost does affect access.
$250 - $500	1 of 38	1 of 1 said cost does affect access.
$500 - $1000	6 of 38	6 of 6 said cost does affect access.
More than $1000 per month	5 of 38	5 of 5 said cost does affect access.

Safety Net Providers, Utilization Management Requirements, and Health Benefit Plan Design

Individuals with scientific and medical training provided input that safety net providers participate as covered entities in the federal 340B Drug Pricing Program administered by the U.S. Health Resources & Services Administration (HRSA) and dispense Enbrel. See Appendix H for more information. No safety net providers volunteered information regarding Enbrel's utilization in a safety net setting, nor the nature of the 340B discount for Enbrel. See Appendices F, I, and M for more information.

It is difficult to precisely know how many uninsured patients in Colorado have an indication treated by Enbrel. Patients and caregivers who responded to the survey provided some insight. See Appendix H for more information.

Patients and caregivers who completed surveys provided the following information regarding utilization management:

Table 12
Survey response: Utilization management.

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	23 of 267 (9%)	6 of 38 (16%)
My insurance plan has dropped or switched my drug coverage after the plan year started.	25 of 267 (9%)	2 of 38 (5%)
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	73 of 267 (27%)	14 of 38 (37%)
My insurance plan requires prior approval to fill the prescription.	183 of 267 (69%)	24 of 38 (63%)
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	97 of 267 (36%)	18 of 38 (47%)

I worry that the cost of my prescription will raise my insurance premium.	56 of 267 (21%)	8 of 38 (21%)

Table 12 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices. See Appendix H for more information.

Utilization management requirements, along with prescription drug formularies, are meant to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient populations.[68] To better understand health benefit plan design coverage and formulary structure, data was accessed by Colorado Division of Insurance (DOI) staff for the affordability review. Data pulled was for carriers in the individual and small group markets for which DOI receives annual rate filings. As such, this data does not describe the entire insurance market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Of the ten carriers that submitted filings, eight carriers cover four or more dosage forms of Enbrel. All carriers that cover Enbrel require prior authorization. In total, 576 plans provide coverage for Enbrel and the majority of carriers place Enbrel on the highest two formulary tears, meaning a higher portion of the drug is paid by patients than prescription drugs on lower tiers (until the maximum out-of-pocket amount under the plan is paid by the patient). See Appendix E for more information.

68 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/#:~:text=The%20intent%20of%20a%20formulary,the%20needs%20of%20patient%20populations.

Appendix A

Enbrel: Wholesale Acquisition Cost

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the wholesale acquisition cost of the drug. (C.R.S. § 10-16-1406(4)(a)).

Rule: The Board will consider both the current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time. (3 CCR 702-9, Part 3.1.E.2.a).

Policy: Information regarding the initial WAC, the current WAC, and changes to WAC over time. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff compiled wholesale acquisition cost (WAC) data for Enbrel for the Board's consideration in the following manner:

1. Using AnalySource, staff pulled all effective WAC per unit amounts and dates associated with the drug.
2. Staff calculated the percent change in WAC since launch and in past five years by using the following calculation: (Current WAC - Initial WAC) / Initial WAC
3. Staff calculated annual inflation amounts by identifying the Bureau of Labor Statistics' (BLS) Annual Inflation Numbers using the Denver-Aurora-Lakewood area to compare WAC changes over time to inflation.[1]

Data Source(s):

- AnalySource's WAC amount, representing the manufacturer's published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer.
- U.S. Bureau of Labor Statistics for Denver-Aurora-Lakewood for annual inflation numbers.

Considerations and Data Limitations:

- Precise WAC amounts are confidential and may only be shared with the Board, Board staff, and Board contractors.
- The WAC does not consider rebates, discounts, or actual paid amounts.

Appx0614

[1] https://www.bls.gov/regions/mountain-plains/news-release/ConsumerPriceIndex_Denver.htm. Annual inflation numbers were for all items, not seasonally adjusted, with the current base (1982-40 = 100), and inflation change was calculated on an annual basis.

Enbrel: Wholesale Acquisition Cost Evidence

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[2]

Table A-1

WAC per unit: Date, Price, and Percent Increase (Enbrel)

Enbrel WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	2.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	104.08%
[redacted]	[redacted]	4.31%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	-3.92%

[2] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiuImYzhKhxeGjvbFoh88cTs/view?usp=sharing

[redacted]	[redacted]	9.18%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	8.40%

[redacted]	[redacted]	9.68%
[redacted]	[redacted]	6.20%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	0.35%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	4.99%

Table A-1 shows all historical WAC per unit amounts and the percent difference of each change.

Figure A-1
Change in WAC per Unit Price (Enbrel)

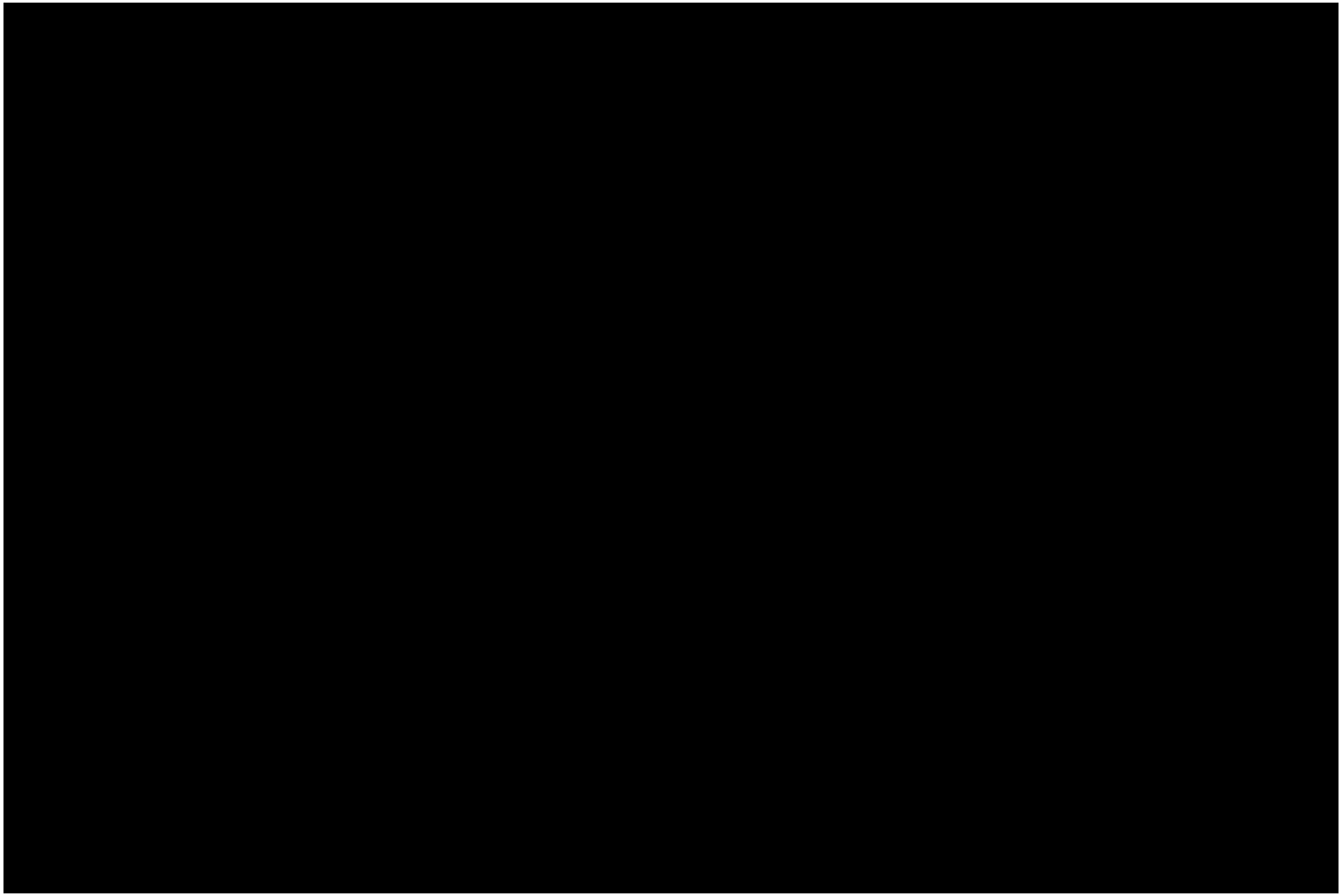
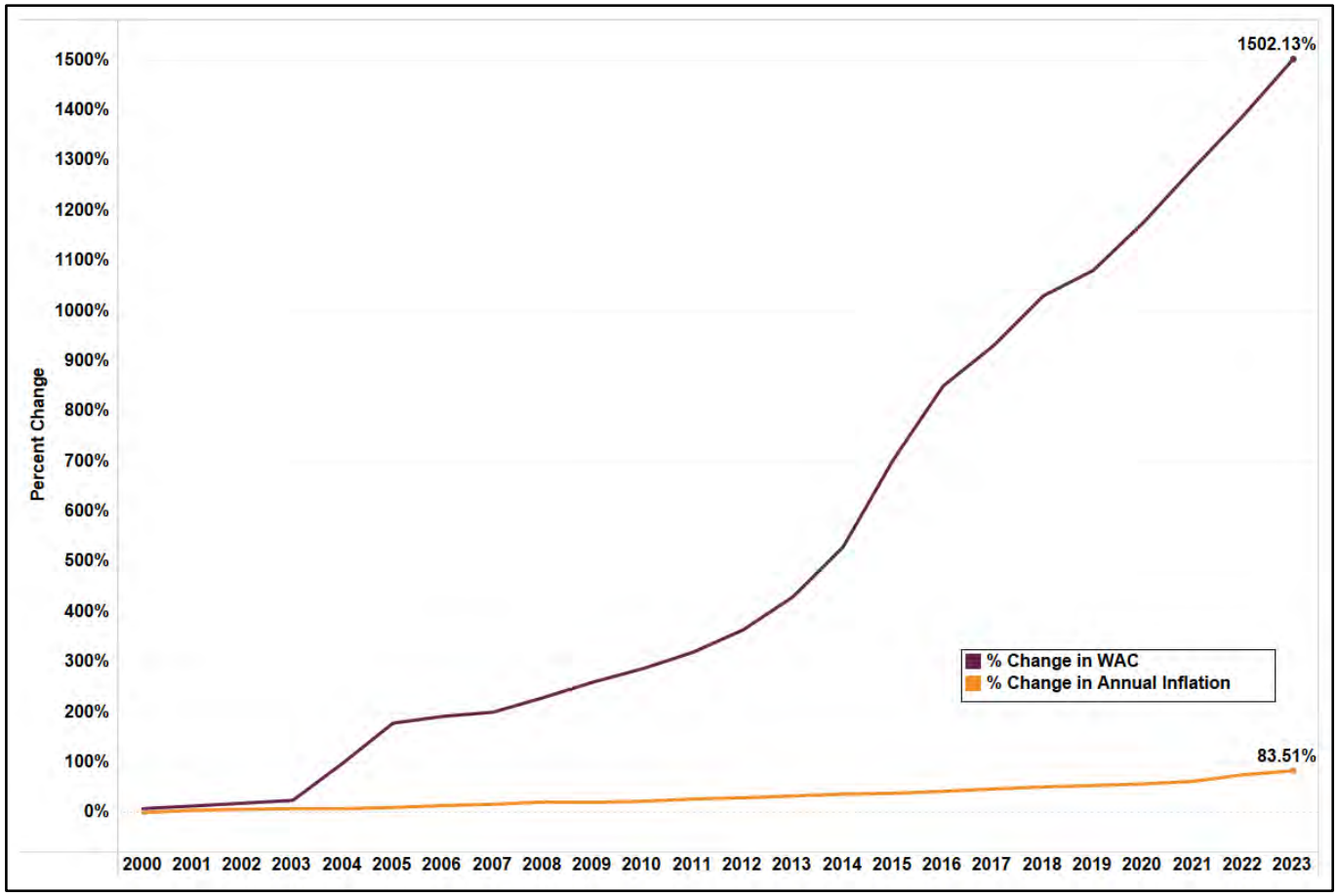


Figure A-1 shows the change in WAC per unit price since its initial WAC price in November 1998.

Figure A-2
Percentage Change in WAC (Enbrel)



For additional context, Figure A-2 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[3]

[3] Figure A-2 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure A-3

WAC per Course of Treatment for Enbrel and Therapeutic Alternatives

Figure A-3 shows the changes in WAC per course of treatment for Enbrel and identified therapeutic alternatives.[4] This graphic highlights the changes in WAC for each drug, as listed in table A-2 below, as well as the WAC per course of treatment of each drug as determined by average

[4] The course of treatment calculation used in selecting drugs, calculated from 2021 APCD claims experience was used across all time frames to highlight the changes in WAC relative to each drug. For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiuImYzhKhxeGjvbFoh88cTs/view?usp=sharing

utilization in Colorado. If a line does not continue to the end of the figure, it is because the WAC has not changed from the last year displayed. Enbrel has the third highest current WAC per course of treatment after Humira and Simponi.

Table A-2

WAC Changes from Initial and within the Last 5 Years for Therapeutic Alternatives to Enbrel

Cimzia WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	228.90%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	4.00%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%

Humira WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	395.00%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%

[redacted]	[redacted]	8.00%

Remicade WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	136.74%
[redacted]	[redacted]	4.90%

Simponi WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	205.33%
[redacted]	[redacted]	4.50%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.80%
[redacted]	[redacted]	5.30%
[redacted]	[redacted]	4.00%

Table A-2 shows the initial WAC and any changes in WAC in the last five years for identified therapeutic alternatives.[5]

[5] The first percent increase may cover up to 16 years, which is why some of the initial increases appear to be larger. Where there are multiple WACs per unit for a drug, only one strength and dosage form is included to display the increases in identified therapeutic alternatives.

Analysis of differences in WAC for Enbrel and identified therapeutic alternatives is complex due to the different indications a prescription drug may be used to treat. More information regarding Enbrel and identified therapeutic alternatives' indications and FDA-recommended dosages is provided below for context.

Table A-3

FDA Recommended Dosage by Drug & Indication

Drug Name	Indication	FDA Recommended Dosage
Enbrel[6]	Rheumatoid Arthritis (RA)	50 mg once weekly
	Polyarticular Juvenile Idiopathic Arthritis (JIA)	0.8 mg/kg weekly with a max of 50 mg per week
	Psoriatic Arthritis (PsA)	50 mg once weekly
	Ankylosing Spondylitis (AS)	50 mg once weekly
	Plaque Psoriasis (PsO)	50 mg twice weekly for 3 months, followed by 50 mg once weekly
Therapeutic Alternative	**Indication**	**FDA Recommended Dosage**
Cimzia[7]	Rheumatoid Arthritis (RA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Psoriatic Arthritis (PsA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Ankylosing Spondylitis (AS)	400 mg is given as 2 subcutaneous injections of 200 mg each (initially) and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks
	Rheumatoid Arthritis (RA)	40 mg every other week.

[6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103795s5591lbl.pdf

[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125160s270lbl.pdf

Humira[8]	Juvenile Idiopathic Arthritis (JIA)	• 10 kg (22 lbs) to <15 kg (33 lbs):10 mg every other week • 15 kg (33 lbs) to < 30 kg (66 lbs):20 mg every other week • ≥ 30 kg (66 lbs):40 mg every other week
	Psoriatic Arthritis (PsA)	40 mg every other week.
	Ankylosing Spondylitis (AS)	40 mg every other week.
	Plaque Psoriasis (Ps)	80 mg initial dose, followed by 40 mg every other week starting one week after the initial dose.
Remicade[9]	Rheumatoid Arthritis (RA)	In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
	Psoriatic Arthritis (PsA)	5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
	Ankylosing Spondylitis (AS)	5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
	Plaque Psoriasis (Ps)	5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
Simponi[10]	Rheumatoid Arthritis (RA)	50 mg administered by subcutaneous injection once a month.
	Psoriatic Arthritis (PsA)	50 mg administered by subcutaneous injection once a month.
	Ankylosing Spondylitis (AS)	50 mg administered by subcutaneous injection once a month.

Table A-3 shows the FDA label's suggested dosing for each indication of Enbrel and identified therapeutic alternatives.

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[8] https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf
[9] https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf
[10] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf

Patents and Exclusivity

There are several ways for prescription drugs to gain exclusivity, which is a period of time when a brand-name drug is protected from generic competition. As of January 29, 2024, there were 75 approved patents for Enbrel with the latest expiration date of 12/31/2039.[4] Thirty-five of these patents expired between 2009 and 2021, while 40 will expire between 2024 and 2039. The Enbrel-related patents that prevent the introduction of biosimilar products are set to expire in 2029.[5] Evaluating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices, delayed availability, and increased costs to consumers and governments.[6]

[4] I-MAK's 'The Drug Patent Book' https://drugpatentbook.i-mak.org/.

[5] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

[6] https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4

Figure C-2

Enbrel Patents and Expiration dates

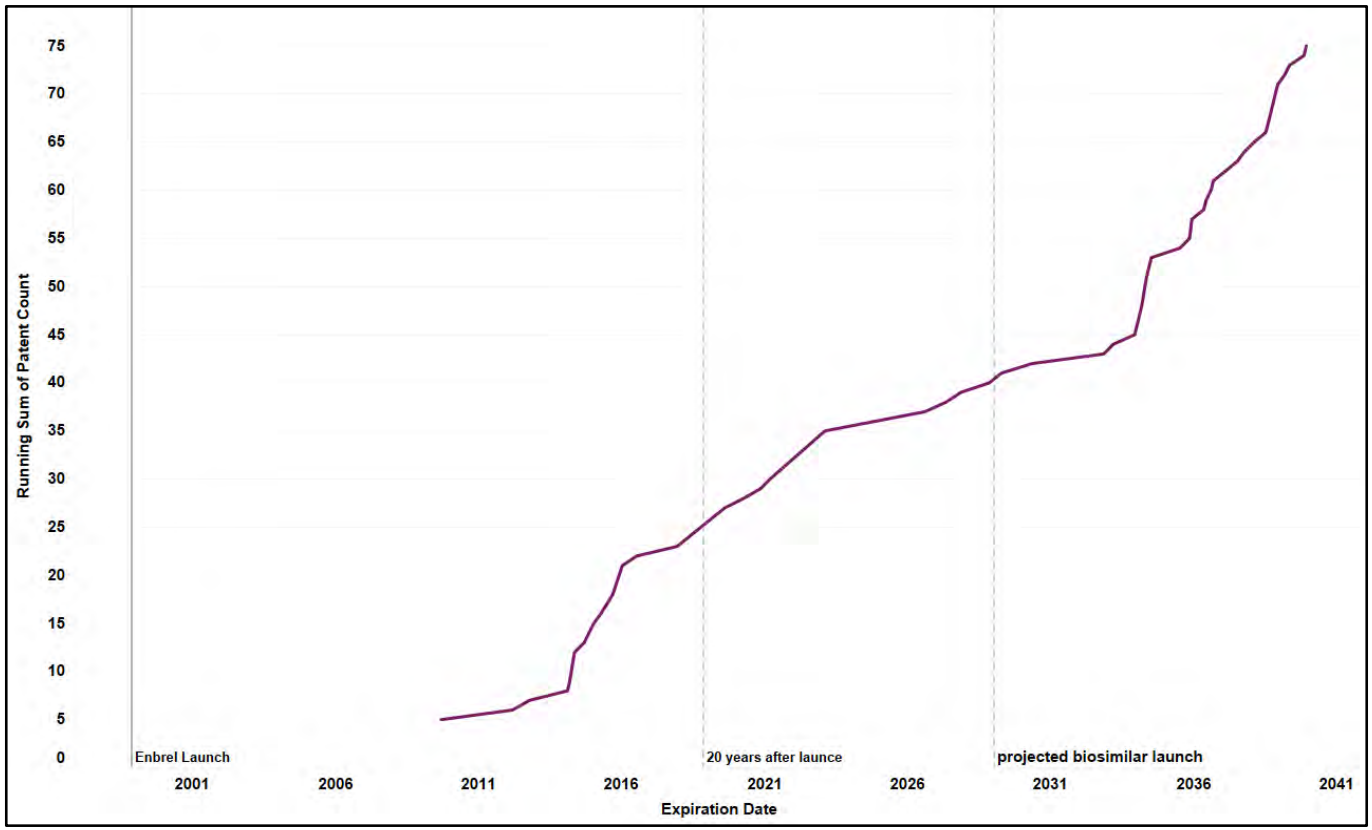

Figure C-2 shows the total number of approved patents for Enbrel based on their expiration date with reference lines highlighting 20 years after launch, the typical patent protection window, and the projected launch of approved biosimilars.

Information about patents for Enbrel contain important public information related to exclusivity of the drug due to litigation around these patents.

A patent for a recombinant protein encoding a receptor for tumor necrosis factor (TNF) was initially issued in 1997 with an expiration date in 2014 under US Patent #5610279.[7] This so-called '279 patent is one of several "core" patents that Amgen has used to ensure its U.S. market exclusivity of Enbrel.[8]

In 2011 and 2012, Amgen applied for two additional patents. The granting of these patents (US Patents #8063182 and 8163522) was somewhat unusual in that the '182 is a "composition of matter" patents for a larger version of the protein claimed in the '279 patent, and the '522 patent describes the method to isolate that larger protein version. These "core" patents—which are considered to be quite strong—are usually granted very early in drug development and make the creation of a non-infringing biosimilar drug nearly impossible. The '182 and '522 patents are due to expire in 2028 and 2029, respectively.[9]

Amgen has protected Enbrel through litigation of its patents in U.S. courts. In 2016, Novartis subsidiary Sandoz gained FDA approval for the first etanercept biosimilar, Erelzi. Amgen sued Sandoz later that year, claiming that Erelzi infringed on the '182 and '522 patents. In defense, Sandoz claimed that the 2 patents were invalid. The US District Court of New Jersey decided against Sandoz and found that both patents were valid. In 2019, drug manufacturer Samsung Bioepis gained approval for a second etanercept biosimilar, Eticovo. Amgen again sued claiming that Eticovo would infringe the same two patents and won in 2021. As a result, despite there being two approved biosimilars for Enbrel, both biosimilars are not allowed to enter the market until at least 2029.[10]

[7] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[8] Estimates of the number of patents protecting Enbrel range from around 40 to 68, with at least 57 patent applications included in one analysis. ~40 patents, pg. 126 https://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=1263&context=ckjip, ~68 patents, https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/, at least 57 patent applications https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf).

[9] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[10] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

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October 2, 2023

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, CO 80202

Enbrel® Submission Pursuant to 3 Colo. Code Regs. § 702-9-3.1(E)(2)(i)

Amgen is a company that is committed to improving the lives of patients by discovering and developing treatments and cures for serious diseases. **Amgen understands that the cost of prescription drugs is a concern for many Coloradans and has programs in place to ensure affordability, while avoiding access hurdles from pharmacy benefit managers (PBM) and others to the extent possible**. Amgen is committed to the responsible pricing of our medicines, and we price products based on the value they deliver, while aiming to employ flexible pricing approaches to ensure patient access. The list price of a medicine is only one potential factor in determining the ultimate cost to the patient, and all parts of the supply chain have a role in ensuring the affordability of medicines like Enbrel® to Colorado consumers.

The introduction of Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis (RA). Many patients who previously would have endured progressive and painful deformities and immobility now live for years or decades with lower pain, less progression, and greater function. Since introduction, Enbrel® has been approved in four more disease areas, owing to the broad utility of tumor necrosis factor (TNF) inhibition in transforming the clinical course of many inflammatory diseases.

Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related symptoms. Enbrel® is effective for long-term control of disease and has demonstrated these benefits in head-to-head as well as standalone studies. For example, Enbrel® monotherapy in moderate to severe RA has shown greater efficacy than methotrexate monotherapy, the previous standard treatment, in achieving American College of Rheumatology (ACR) criteria, low disease activity (LDA) response, and reduced radiographic progression. Looking at head-to-head performance in PsA, combining methotrexate with Enbrel® did not improve Enbrel® efficacy, distinguishing the TNF pathway as uniquely important and Enbrel® as an effective monotherapy.

In PsO, where safety of systemic treatments is particularly important in the risk-benefit calculation, Enbrel® improves multiple measures of skin signs and symptoms, as well as a number of patient reported outcome (PRO) measures. Improvements in disease activity and PROs with Enbrel® were maintained long-term (up to 96 weeks). Finally, looking at Enbrel® compared with other TNF agents and non-TNF systemic therapies, numerous claims analyses using a validated algorithm have consistently shown Enbrel® to have the highest proportion of "effectively" treated patients compared to adalimumab and infliximab. This has been confirmed in three network meta-analyses (NMA) in RA, helping to differentiate Enbrel® from other biologics.

Enbrel® achieves disease transforming efficacy while also offering an established safety profile. There is not a single therapeutic alternative for Enbrel. Although there are number of biologicals that are indicated for the treatment of moderate to severe RA and other autoimmune disorders treated by Enbrel, **Enbrel and its competitor products do not provide the same response in all patients and they are not simply interchangeable**. More than 600 distinct therapy sequences have been observed for the course of care for moderate to severe RA. This underscores the vital importance of having a wide range of therapeutic choices for patients in this population. The therapeutics most similar to Enbrel are TNF inhibitors – adalimumab, certolizumab pegol, golimumab and infliximab. In RA, Enbrel® patients experience fewer adverse reactions, including infections, compared to those on methotrexate (MTX). Enbrel® may also require less MTX supplementation than other biologics, which could reduce the additional side effects. Real-world evidence (RWE) has shown Enbrel® to have fewer adverse reactions than infliximab and adalimumab as well, with Enbrel® patients having higher adherence as a result. Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers.

Looking beyond Enbrel®, in reviewing the information reflected in the "CO PDAB 2023 Eligible Drug Dashboard" and the criteria to be considered by the Board in assessing the affordability of medicines to Colorado consumers, three elements are critical to developing a more complete picture of innovators' impact on consumer affordability.

- **First,** list prices have become increasingly misleading as the gap between list prices and net prices, known as the "gross-to-net bubble," has become significantly wider in recent years.
- **Second,** in fueling this gross-to-net bubble, the complex system around paying for medicines has not led to corresponding improvements in patient affordability. The extent to which each player in this system may influence a particular medicine's affordability to the patient can vary significantly.
- **Finally,** Amgen has a deep interest in supporting access to life-changing therapies for patients. To this end, Amgen provides financial support information and resources, regardless of a patient's current financial situation or type of insurance they have, to help eligible patients access their prescribed Amgen medication.

Net Prices Declined as List Prices Increased

Much of the public debate about the cost of medicines has been largely focused on list prices. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC"), which is often referred to as the "list price." While the WAC for each of Amgen's products is in part anchored to a medicine's value-driven price, which represents the value a medicine is likely to deliver to patients, to payers, and to society, the price is frequently established against a competitive backdrop. The list price is the price Amgen charges to wholesalers and distributors who purchase medicines, but it does not reflect the true price of the medicine after the rebates and discounts are negotiated with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, pharmacy benefit managers (PBMs), health plans, and other entities in the supply chain. Such price concessions are often necessary to ensure a medicine's appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition.

Since 2019, Amgen's aggregated net prices have declined by 4.7 percent. Amgen is also taking steps to address patient affordability, including providing $19.9 billion in discounts, fees, and rebates to supply chain intermediaries in 2021. Since 2019, these payments to intermediaries have grown by 65 percent. Again, the list prices of Amgen's medicines reflect, among other things, the economic value delivered to patients, providers and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

Because of the way PBMs structure relationships with pharmacies and patient-enrollees, increases in list prices generally have a limited impact on net prices, while significantly increasing total rebates paid to the PBMs. In light of this environment, Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies. If Amgen had not done so, a likely outcome would have been the removal of Enbrel® from formularies in favor of a competitor who provided a higher rebate to the PBM. Since Enbrel® and its competitor products do not provide the same response in all patients, they are not simply therapeutically equivalent. If taken off formulary, many Enbrel® patients would not have access to the medicine that they and their doctor had determined worked best for them.

For Enbrel®, as of January 4, 2023, the list price is $1,762.34 per weekly 50 mg dose, but, as previously discussed, this does not reflect price concessions. In addition to price concessions, Amgen has invested capital studying Enbrel® for additional indications and introduced new, more patient-friendly formulations and administration methods, such as the easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients.

Again, a significant factor for increases in the list price of Enbrel® is that the market for innovative products is structured in a way to benefit intermediaries and not in a way to get lower prices to patients. Enbrel® is in a highly competitive marketplace that includes a number of other medications that are competing for formulary position with PBMs to enable patient access,

including the largest pharmaceutical product in the world Humira®. In such highly competitive marketplaces, companies are forced to simultaneously compete both on lowest net price (i.e., the "all in" price to the PBM) and highest total rebate. In a competitive market, Amgen often must pay increasingly higher rebates to remain on the formulary, even as list prices rise and the net price to the PBM often decreases.

Patient Affordability is a Result of Numerous Inputs in a Complex System

Unlike other categories of healthcare, the list price serves as a primary basis of determining patient out-of-pocket costs for prescription medicines. As a result, the negotiated savings of the market-based healthcare system do not reach patients at the pharmacy counter, especially as co-payments and deductibles on medicines have increased and as high-deductible health plans become more prevalent. The problem is not that the market-based negotiations are not effective at generating savings, it is that the savings never make their way to patients in the form of reduced out-of-pocket costs.

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (e.g., vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs.

This structure facilitates the current rebate system in the United States, in which companies like Amgen pay billions of dollars in rebates to insurers and PBMs based on the list price, creating a situation in which remaining on-formulary often requires counterintuitive pricing behavior. As discussed later, PBMs can receive lower net prices while consumers see prices increase with little relief at the pharmacy counter, as these savings from the PBMs are rarely, if ever, passed on to any significant extent. While Amgen disapproves of a system where one can lower a medicine's net price and patients pay more and is advocating to change it, this is, unfortunately, the system as it now stands, and Amgen must operate within it to stay competitive and ensure patients have access to Enbrel®.

Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen's patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card[1] was used, cost $10 or

[1] Eligibility criteria program maximums apply. For more information about this program, visit www.AmgenSupportPlus.com.

Appendix K

Enbrel: Rebates, Discounts, and Price Concessions

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives.

The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. (3 CCR 702-9, Part 3.1.E.2.j.i).

Policy: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Staff may also prepare information regarding manufacturer coupons to pharmacies and/or consumers. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for the selected prescription drug for the Board's consideration in the following manner:

- Board staff contracted with SSR Health[1] to receive their proprietary U.S. prescription brand drug pricing and analytics database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net-sales and gross-to-net estimates quarterly for all drugs.[2] The gross-to-net estimates provide a quarterly estimated gross-to-net percent that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.
- Board staff gathered these estimates for Enbrel, which are presented below. The estimates are on a rolling four quarter basis.
- Board staff used publicly available information on patient assistance programs to identify manufacturer coupons and discount programs available to patients.

Data Source(s): Board staff compiled information on rebates, discounts, and price concessions for Enbrel from the following sources:

- SSR Health for estimated gross-to-net sales,
- Results of public input sessions and surveys for patients and caregivers, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations:

- SSR Health data is proprietary and confidential. Estimates are national and do not necessarily reflect rebates, discounts, and price concessions in Colorado.

[1] SSR Health: https://www.ssrhealth.com/

[2] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

- Publicly available patient assistance program information is limited and does not reflect the number of patients who qualify and regularly receive assistance and the process for patients to receive assistance.

Enbrel: Rebates, Discounts, and Price Concessions Evidence

Background

This appendix includes information on gross-to-net estimates, net-sales estimates, and manufacturer financial assistance programs information. For the purposes of this appendix, these terms mean:

- Gross-to-net Sales Estimate means the proprietary estimate as a percentage where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, and coupons provided by manufactures compared to gross sales to get a percentage estimate of all discounts. All gross-to-net sales estimates are provided on a four quarter moving average to provide full annual estimates and smooth quarter to quarter variation.
- Net-sales Estimate means the proprietary estimate of net sales based on sales information from 10-K financial reports and other publically available sources including earnings calls, press releases, and investor presentations.[3]
- Manufacturer financial assistance program Estimate. This is different from the broader "patient assistance program" or "assistance program" terminology used in the Summary Report and in other appendices. While those later terms cover any patient assistance programs, information in this summary just pertains to financial assistance programs offered by the prescription drug manufacturer.

Information for gross-to-net estimates and net-sales estimates are provided first, followed by manufacturer financial assistance program estimates.

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

SSR Health Estimates

Figure K-1

Enbrel Net-Sales and Gross-to-Net Estimates

Figure K-1 shows the net- sales and gross-to-net estimates for Enbrel in 2008. The total gross-to-net estimate in April 2008 was [redacted], which increased to [redacted] in the third quarter of 2023.

Table K-1

Estimated Gross-to-Net for the Third Quarter of 2023

Gross-to-Net Measure	Enbrel	Cimzia	Humira	Remicade	Simponi
Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total less Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-1 shows the gross-to-net estimates broken out by total (all), statutory Medicaid (reflects most Medicaid rebates, but not all such as best price), and total less statutory Medicaid (commercial and Medicare Part D plans). The statutory Medicaid estimate is likely derived from the base 23.1% rebate required under statute[4] and not the Medicaid best price requirement that generates greater discounts. This means that the Medicaid discounts for Enbrel should actually exceed those provided to non-Medicaid entities. Strength and dosage forms of prescription drugs may be associated with different rebate amounts. What is represented in this table is for all strengths and dosage forms.

[4] 42 CFR § 447.509 Medicaid drug rebates (MDR)

Figure K-2

Estimated Total Gross-to-Net Sales

Figure K-2 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Table K-2

Gross-to-Net Estimate (Enbrel and Therapeutic Alternatives)

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2008	[redacted]		[redacted]	[redacted]	
July 2008	[redacted]		[redacted]	[redacted]	
October 2008	[redacted]		[redacted]	[redacted]	
January 2009	[redacted]	[redacted]	[redacted]	[redacted]	

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2009	[redacted]	[redacted]	[redacted]	[redacted]	
July 2009	[redacted]	[redacted]	[redacted]	[redacted]	
October 2009	[redacted]	[redacted]	[redacted]	[redacted]	
January 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
January 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-2 lists the quarterly total gross-to-net estimates from April 2008 to July 2023 for Enbrel and identified therapeutic alternatives. If a cell is left empty, there were no estimates for that drug during that quarter.

Figure K-3
Enbrel Net-Sales Estimate as a percent of Amgen Total Net-Sales Estimate

Figure K-3 shows Enbrel net sales estimates (in purple) as a percent of Amgen total net sales from the first quarter of 2018 through the third quarter of 2023. In the third quarter of 2023, Enbrel accounted for an estimated [redacted] of Amgen's total net sales. Additional information of manufacturer-reported information of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix O.[5]

Table K-3
Quarterly Net-Sales Estimate

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q1	[redacted]		[redacted]	[redacted]	

[5] Appendix O contains information of Enbrel's net sales for national and international sales, whereas this appendix contains estimates for national sales only.

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q2	[redacted]		[redacted]	[redacted]	
2008	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2008	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q1	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q2	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2010	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2012	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2016	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2021	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-3 lists the quarterly estimates in net sales for Enbrel and identified therapeutic alternatives from January 2008 to July 2023.[6] These amounts are the same reflected in Figure K-1 above.

Pursuant to section 10-16-1405(1)(a)(VII), C.R.S., each carrier and PBM must report the fifteen prescription drugs for which the carrier received the largest rebates. In 2021, 14 of 25 carriers indicated that Enbrel was in the top 15 drugs for which the carrier received the largest rebate.

Figure K-4
Carrier's Rank of Enbrel Rebates

[6] Any cells without values do not have estimates in SSR Health

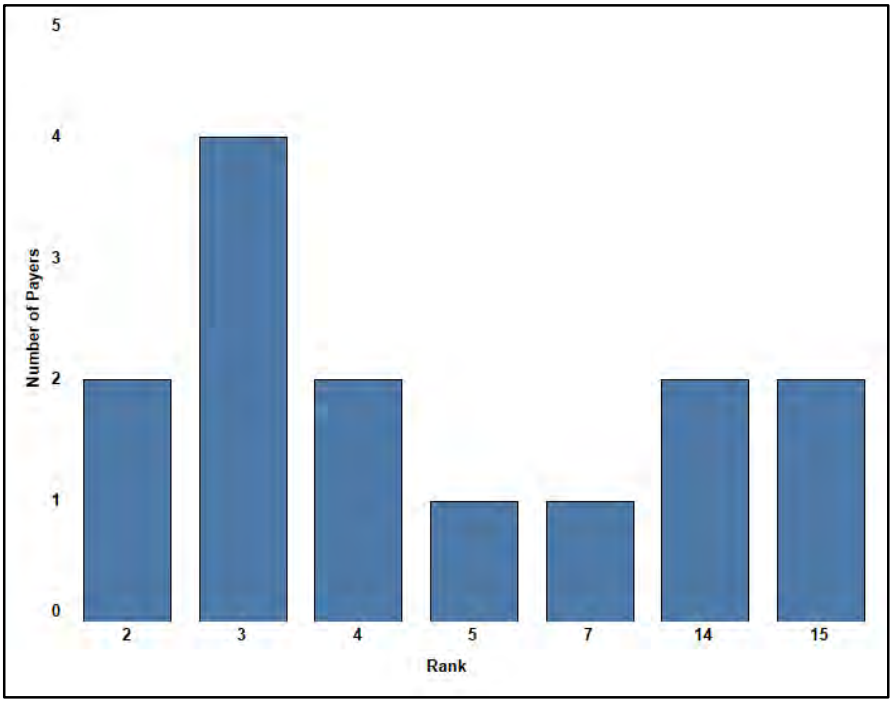

Figure K-4 shows the number of carriers who ranked Enbrel in the top 15 rebated drugs. The x-axis shows the rank and the y-axis shows the number of carriers who ranked Enbrel in that position, for example, two carriers ranked Enbrel as the second highest rebated drug and four carriers ranked it as the third highest drug.

Manufacturer Financial Assistance Programs

As part of voluntarily submitted information from Amgen Inc., the following statement regarding patient assistance was submitted: "Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen's patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month."[7] Additionally, the statement said, "As previously noted, the out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen's co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced – as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month." Amgen Inc. stated the following about uninsured and vulnerable patients: "We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine. Since 2008, the Amgen Safety Net Foundation (ASNF) has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States."[8]

[7] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkI0GmqOe381WN2/view?usp=drive_link
[8] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkI0GmqOe381WN2/view?usp=drive_link

Board staff gathered further information on the Enbrel Co-Pay Program via the drug's public website.[9] According to the website, the co-pay program is open to patients with commercial insurance that covers an Amgen SupportPlus product, regardless of financial need. While there is no income requirement for participation, the maximum program benefit and patient total program benefit are determined by the patient's plan coverage. A patient must meet eligibility criteria for the Amgen Safety Net Foundation assistance including that they: lived in the U.S. or its territories for six months or longer, satisfy income eligibility requirements, and are uninsured or on an insurance plan that excludes the Amgen medicine or its generic/biosimilar. While certain Medicare Part D patients may be eligible, they have to demonstrate inability to afford the medicine and have satisfied all payer guidelines and Prior Authorization (PA) requirements. Patients using Enbrel are able to check if they qualify for assistance through ASNF from their website.[10]

Board staff heard from patients, caregivers, and individuals with scientific and medical training that there are patient assistance programs in addition to the Enbrel Co-Pay Program. See Appendices H, I, and J for more information on both manufacturer financial assistance programs and other patient assistance programs.

[9] https://www.amgensupportplus.com/copay-card-program-terms-and-conditions
[10] https://www.amgensafetynetfoundation.com/eligibility.html

Manufacturer Pricing Information

The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[19] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). Additionally, the 2022 10-K details that Enbrel comprises 17% of total product revenues (p.4). Additional information of estimates of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix K.[20]

[19] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

[20] Appendix K contains information of Enbrel's estimated net sales for national sales only, whereas this appendix contains information for national and international sales.

Appendix P

Data Sources and Limitations

Data sources and limitations are described in detail here. How these data sources are used and component-specific limitations are outlined in each component's appendix.

All-Payer Claims Database (APCD)

The All Payer Claims Database (APCD) receives claims from Medicaid, Medicare Advantage, and over 40 commercial payers and represents over 4.5 million lives and over 75% of insured Coloradans. The APCD does not have claims data for uninsured Coloradans and some commercial payers and plans. For this affordability review, pharmacy and medical claims from January 2018 through December 2022, which were paid through May 2023, were used for analyses. Drugs are identified on pharmacy claims with their National Drug Code (NDC). APCD claims are categorized by the submitting payer and are categorized as Medicaid, Medicare Advantage, and all other submitters are commercial. Enbrel and identified therapeutic alternatives NDC codes found in the APCD and utilized in these analyses were:

Drug Name	NDC
Enbrel	54868-4782-00*****, 54868-5444-00*, 58406-0010-01, 58406-0010-04, 58406-0010-96*[1], 58406-0021-01, 58406-0021-04, 58406-0021-96*, 58406-0032-01, 58406-0032-04, 58406-0032-96*, 58406-0044-01, 58406-0044-04, 58406-0044-96*, 58406-0055-01, 58406-0055-04, 58406-0425-34*, 58406-0425-41*, 58406-0435-01*, 58406-0435-04*, 58406-0445-01*, 58406-0445-04*, 58406-0455-01*, 58406-0455-04*, 58406-0456-01*, 58406-0456-04*.[1]
Cimzia	50474-0700-62, 50474-0710-79, 50474-0710-81
Humira	00074-3799-02, 00074-4339-74, 00074-4339-01, 00074-4339-02, 00074-4339-06, 00074-4339-07, 00074-0243-02, 00074-0616-02, 00074-0817-02, 00074-0067-02, 00074-2540-03, 00074-0124-74, 00074-0124-02, 00074-0554-02, 00074-0554-71, 00074-0124-03, 00074-0124-04, 00074-1539-03
Remicade	57894-0030-01
Simponi	57894-0070-01, 57894-0070-02, 57894-0071-01, 57894-0071-02, 57894-0350-01

[1] (*) inactive NDC. Inactive NDCs were used to gather historical WAC data and any utilization that may have occurred during this time frame if the currently inactive NDCs were active at the time of the claim. Only Enbrel inactive NDCs were included, no inactive NDCs for identified therapeutic alternatives are included.

[2] SSR Health: https://www.ssrhealth.com/

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

Limitations

- As the APCD does not include claims for all Coloradans, it is a conservative estimate, where utilizers, claims, and associated paid amounts are under-represented.
- Annual estimates of utilization are also likely under-represented as individuals change insurance and move and their entire year of utilization may not be captured in the APCD claims.
- Under federal and state privacy laws, information about drugs with fewer than 12 utilizers in the database must be protected, as it is potentially identifiable at such low numbers. Where utilization is below 12 individuals there will be less information available.
- One commercial payer reported inaccurate units for pharmacy claims. These units were removed, and any calculations using units did not include units from this payer. Dollar amounts and utilization information was reported accurately by this payer and were not removed. The only data element in the affordability review that incorporates units is the course of treatment calculation, which excludes this payer and is therefore an underestimate of the course of treatment.
- Pharmacy claims do not include diagnosis codes. As such, utilization and paid amount analyses were conducted for all Enbrel utilization and separate analyses were not conducted for each FDA-approved indication.

First DataBank AnalySource

AnalySource provides WAC and other pricing benchmarks for all NDCs at current rates and historic levels. Enbrel NDC codes found in AnalySource are listed in table P-1 above.

Limitations

- WAC and other data elements from AnalySource are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- WAC data is updated daily, but other data sources have a greater time lag, meaning that there are NDCs for which there is WAC data, but no utilization data. It is noted when these are included

SSR Health

- Board staff contracted with SSR Health[2] to receive their proprietary U.S. prescription brand drug pricing and analytics net price database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net sales and gross-to-net estimates quarterly for all drugs.[3] The gross-to-net estimates provide a quarterly estimated gross-to-net percent rebate that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.

Limitations

- Estimates are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- Gross-to-net sales estimates are inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support, but cannot provide detailed amounts on these discounts.
- Estimates are for national information and are not specific to Colorado.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

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

Plaintiffs,

v.

COLORADO PRESCRIPTION
DRUG AFFORDABILITY REVIEW BOARD;
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.

Civil Action No. 1:24-cv-00810-NYW

JOINT MOTION TO ESTABLISH BRIEFING SCHEDULE AND FOR RELATED RELIEF

Pursuant to Federal Rule of Civil Procedure 7(b), plaintiffs Amgen Inc., Immunex Corporation ("Immunex"), and Amgen Manufacturing, Limited ("AML")

(collectively, "Plaintiffs") and defendants Colorado Prescription Drug Affordability Board, et al. (collectively, "Defendants") jointly move to establish a briefing schedule for this matter as described below:

1. In February 2024, acting pursuant to Colo. Rev. Stat. § 10-16-1401 *et seq.* ("the Act"), members of the Colorado Prescription Drug Affordability Board voted to declare that "use of [Defendants' drug] Enbrel®, consistent with the labeling approved by the FDA or with standard medical practice, is unaffordable for Colorado consumers" and to "select Enbrel® for establishment of an Upper Payment Limit."

2. On March 22, 2024, Plaintiffs filed this action seeking declaratory and injunctive relief with respect to the constitutionality of the Act.

3. For the convenience of the Court and in an effort to streamline proceedings, the parties have conferred pursuant to Local Rule 7.1(a), including via telephone conference on April 9 and May 10, 2024, and agree that this case raises legal questions that may be properly resolved through dispositive motions, without the need for discovery or trial. Accordingly, the parties intend to file cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56.

4. The parties therefore respectfully request that the Court establish the following, agreed-upon schedule for summary judgment briefing:

- Defendants will file an answer and raise affirmative defenses to the Complaint by May 24, 2024.
- Plaintiffs will file their motion for summary judgment by June 24, 2024, not to exceed 40 pages.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitutional Provisions

Statutes

Regulations

Rules

Other Authorities

INTRODUCTION

Innovative medicines have enhanced and extended the lives of countless Coloradans. Recognizing the enormous investment of time and money needed to discover and develop these novel treatments, Congress rewarded those who bring new medicines to market with a period of patent exclusivity and pricing discretion. As binding precedent makes clear and numerous scholars have observed, the economic incentives provided by the federal patent system are crucial to Congress's objective of promoting pharmaceutical research and development.

One such medicine, Amgen's pioneering drug ENBREL® (etanercept), provides life-changing relief to thousands of Coloradans who suffer from arthritis and other autoimmune diseases. Enbrel redefined the clinical course of moderate to severe rheumatoid arthritis, allowing many who would have endured intensifying pain, deterioration, disfigurement, and declining mobility to live years or even decades with less pain and greater function. Amgen's patents provide Enbrel with a time-limited period of exclusivity, enabling Amgen to obtain a fair return on its investment.

Although patent protection allows manufacturers to charge higher prices for innovative drugs during the life of the patent, manufacturers offer many programs that support patients who may have difficulty affording their medicines. For example, for more than 20 years Amgen has sponsored the Amgen Safety Net Foundation, a nonprofit patient assistance program that helps eligible patients in the United States gain access to qualifying Amgen medicines. In 2023 alone, the Foundation provided

$2.5 billion worth of drugs to eligible uninsured or underinsured patients at no cost.[1]

Nevertheless, Colorado enacted legislation in 2021 establishing a "Prescription Drug Affordability Review Board" with sweeping power to deem drugs "unaffordable for Colorado consumers" and subject those drugs to price controls. *See* Colo. Rev. Stat. § 10-16-1401 *et seq*. ("the Act"). In February 2024, after expressing concern that Enbrel's patents protect it from biosimilar competition, the Board declared Enbrel "unaffordable" and voted to "select Enbrel for establishment of an upper payment limit." The Board thus decided to restrict the maximum amount that can be billed or paid for units of Enbrel dispensed or distributed in Colorado. The Board will conduct hearings this Fall to decide the precise payment limit it will impose.

Colorado's price-control scheme is unconstitutional for at least four reasons. ***First***, the federal patent laws preempt Colorado's attempt to regulate the price of patented drugs like Enbrel. To incentivize the immense risk-taking and investment necessary to discover and develop new medical treatments, Congress enacted and has repeatedly refined the federal patent laws, often doing so with a special focus on pharmaceutical patents. This carefully calibrated federal patent system rewards pharmaceutical innovation with a period of market exclusivity and the ability to set prices during that period. Colorado's price-control regime disrupts that finely tuned system by allowing five members of a state-created board to strip away the very

[1] *See* Amgen Safety Net Found., *About*, https://www.amgensafetynetfoundation.com/about.html; Amgen, Environmental, Social & Governance Report 2023, at 10, *available at* https://www.amgen.com/responsibility/environmental-social-and-governance-report.

economic rewards and incentives that Congress sought to provide. The Federal Circuit—whose case law is controlling on issues of patent preemption—has held that a state may not impose price controls on patented drugs, because allowing states to limit "the pecuniary rewards stemming from the patent right" would be "contrary to the goals established by Congress in the patent laws." *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372–74 (Fed. Cir. 2007).

Second, Colorado's scheme violates the Due Process Clause of the Fourteenth Amendment because the statute does not provide any meaningful standards for the Board to apply either when determining whether a drug is "unaffordable for Colorado consumers" or when setting an upper payment limit. The statute contains a long and non-exclusive list of factors the Board may consider, but it neither defines "unaffordable" nor provides any guidance about how the Board should weigh those factors. Without any meaningful standards to constrain the Board's decision-making, manufacturers are deprived of the *sine qua non* of due process—the opportunity to be heard at a meaningful time and in a meaningful manner. The Act also violates the more specific due-process principles that apply to administrative price-control schemes. Because of the serious constitutional concerns they raise, courts have required such schemes to include standards and procedures to guard against arbitrary or discriminatory price-setting and to ensure that regulated parties can earn a reasonable return on their investments. The Act lacks those essential safeguards and leaves regulated parties subject to the whims of the Board.

Third, Colorado's scheme is preempted insofar as the "upper payment limit" applies to federal payors such as Medicare, TRICARE, the Veterans Health Administration, and the Federal Employees Health Benefits Program. Under the Supremacy Clause, states lack the power to regulate federal government activities, and federal law preempts state laws that interfere with the federal government's ability to control its own payment and coverage decisions.

Fourth, Colorado's attempt to control prices in out-of-state transactions violates the Commerce Clause. It is well-established that states cannot directly regulate commerce that occurs entirely out of state. The Act violates that extraterritoriality principle because the "upper payment limit" applies to transactions that occur outside Colorado's boundaries, so long as the drug is ultimately dispensed or distributed in Colorado.

BACKGROUND

A. The Federal Patent System

The discovery and development of new prescription drugs is of vital importance to public health. Innovative medicines save lives and improve patients' quality of life, frequently offering new hope for diseases that were once thought untreatable. But the process of developing new drugs—conducting cutting-edge research, navigating the lengthy FDA approval process, and bringing the drugs to patients in need—is time-consuming, uncertain, and expensive. The average cost of bringing a single new

drug to market is commonly estimated to be more than $2 billion,[2] the process takes an average of 10 to 15 years,[3] and only about 1 in 5,000 potential new drugs obtains approval and reaches patients.[4] Of the medicines approved for patient use, only about 20% ever generate enough revenue to cover their own development costs.[5]

To reward and incentivize the risk-taking and investment necessary for technological innovation, Congress has long relied on the federal patent system. The Constitution vests in Congress the power to grant authors and inventors exclusive rights to their creations for limited times "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. Exercising that constitutional prerogative, Congress has established a comprehensive national system for the granting and maintenance of patents. *See* 35 U.S.C. § 1 *et seq.* Pursuant to the Patent Act, a patent grant confers "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. *Id.* § 154(a)(1).

Under the system Congress designed, "the fundamental purpose of the patent grant" is to "create[] an incentive for innovation" by providing "economic rewards

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[2] Stephen Ezell, Info. Tech. & Innovation Found., Ensuring U.S. Biopharmaceutical Competitiveness, at 30 (July 2020), *available at* https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[3] GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 20, 2019), *available at* https://www.gao.gov/assets/gao-20-215sp.pdf.

[4] Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021), https://doi.org/10.1016/j.csbj.2021.08.011.

[5] Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 665 (2016).

during the period of exclusivity." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). Once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the product's costs. The patent system thus embodies "a careful balance" between "the need to promote innovation" by enabling innovators to set their own prices during the patent term, and the benefits of greater affordability that flow from competition after the term expires. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Congress has deliberately fine-tuned that balance by specifying the duration of exclusivity periods and establishing procedures for adjusting them. *See* 35 U.S.C. § 154.

Congress has especially fine-tuned the rules governing pharmaceutical patents. In 1984, recognizing the unique challenges posed by the costly drug-development process, Congress enacted the Drug Price Competition and Patent Term Restoration Act (known as the "Hatch-Waxman Act"). The Hatch-Waxman Act extended the patent term for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18 (1984); *see* 35 U.S.C. § 156. The statute was designed to "promote medical breakthroughs and drug innovation by granting drug companies up to 5 more years of patent protection for new drugs" to "help compensate for the years of patent life lost" due to the protracted FDA approval process. Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

Congress has promoted competition after the expiration of an innovator drug's patent by creating pathways for competing products to obtain FDA approval. For chemically synthesized, small-molecule drugs, the Hatch-Waxman Act allows generic versions to receive FDA approval without the same level of clinical testing required for new brand-name drugs. *See* 21 U.S.C. § 355(j). For "biologic drugs" (large molecules made from living cells), such as Enbrel, a pathway for FDA approval of "biosimilars" was created by the Biosimilar Price Competition and Innovation Act of 2009 (the "BPCIA"). *See* 42 U.S.C. § 262(k).

B. Colorado's Prescription Drug Price-Control Regime

In the Act, Colorado seeks to strike its own balance, which is different from the one Congress chose. The Act's stated purpose is to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1). To achieve that goal, the Act creates a Prescription Drug Affordability Review Board composed of five members appointed by the governor. *Id.* § 10-16-1402. The Board is directed to "[p]erform affordability reviews of prescription drugs" and "[e]stablish upper payment limits for prescription drugs." *Id.* § 10-16-1403(1). An "[u]pper payment limit" is defined 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." *Id.* § 10-16-1401(23).

As an initial step, the Board identifies, based on certain cost-related criteria, a

list of prescription drugs eligible for an affordability review. *Id.* § 10-16-1406(1); 3 Colo. Code Regs. § 702-9:3.1(C). Next, the Board decides which eligible drugs to select for an affordability review. In making that determination, the Board considers (a) "the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale"; (b) "aggregated data" regarding costs, pricing, expenditures, utilization, and "[h]ealth equity impact"; (c) input from the Board-appointed Prescription Drug Affordability Advisory Council; and (d) "the average patient's out-of-pocket cost for the prescription drug." Colo. Rev. Stat. § 10-16-1406(2); 3 Colo. Code Regs. § 702-9:3.1(D).

Once a drug is selected for an affordability review, the Board's task is to "determine whether use of the prescription drug" is "unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). The statute does not define "unaffordable for Colorado consumers" or otherwise provide any legal standard to constrain the Board's discretion. Instead, it instructs the Board to "consider," "to the extent practicable," a broad and nonexclusive list of factors, including: (a) the drug's "wholesale acquisition cost"; (b) the "cost and availability of therapeutic alternatives"; (c) "[t]he effect of the price on Colorado consumers' access to the prescription drug," (d) the drug's "relative financial effects on health, medical, or social services costs"; (e) the typical "patient copayment or other cost sharing" for the drug under "health benefit plans issued by carriers in the state"; (f) the "impact on safety net providers if the prescription drug is available through section 340B of the federal 'Public Health

Service Act'"; (g) "[o]rphan drug status"; (h) input from "[p]atients and caregivers" and "[i]ndividuals who possess scientific or medical training"; (i) "[a]ny other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide"; and (j) "[a]ny other factors as determined by rules promulgated by the [B]oard." *Id.* § 10-16-1406(4). The Board "may" also "consider any documents and information relating to the manufacturer's selection of the introductory price or price increase," including documents and information related to the drug's "[m]arket competition and context." *Id.* § 10-16-1406(6). The Board has issued a regulation listing a handful of additional factors it will consider, including (i) "estimated manufacturer net-sales or net-cost amounts," (ii) undefined "health inequities in priority populations," (iii) unspecified "analyses" conducted by the state Department of Health Care Policy and Financing, and (iv) information regarding "[n]on-adherence" or "utilization management restrictions" for the drug in question. 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). Neither the statute nor the regulation specifies how any of these factors bears on the ultimate question of "affordability" or how much weight the Board should give to any particular factor.

If the Board determines in its discretion that a drug is "unaffordable for Colorado consumers," it may establish an "upper payment limit." Colo. Rev. Stat. § 10-16-1407(1)(a). Rather than prescribe a methodology for setting that limit, the Act says only that any methodology chosen by the Board "must include consideration of" the cost of "administering," "dispensing," and "distributing" the drug, the drug's

status on FDA's "shortage list," and any impact on "older adults and persons with disabilities"; must not "consider research or methods" that "discount[] the value of a life because of an individual's disability or age"; and must allow pharmacies to charge "reasonable fees" for dispensing the drug. *Id.* § 10-16-1407(2)–(4). Otherwise, the Board is free to adopt whatever methodology it wishes.

The Board has promulgated a regulation purporting to "establish the methodology … for the Board to establish upper payment limits." 3 Colo. Code Regs. § 702-9:4.1(B). But the regulation does not specify a methodology. Instead, it merely states that the Board "shall review" the factors set forth in the statute. 3 Colo. Code Regs. § 702-9:4.1(C)(2). The regulation elaborates on some of those factors without providing additional specificity: For example, it states that "[t]o approximate prescription drug costs," the Board "may consider" "one or more price and cost metrics" that "include but are not limited to" a list of 10 different measures. *Id.* § 702-9:4.1(C)(2)(a). Despite identifying a variety of data points the Board will "consider" or "review," neither the statute nor the regulation explains what methodology, if any, the Board will apply in choosing the amount of an upper payment limit.

C. Amgen's Patent-Protected Drug Enbrel

Enbrel, first approved by the FDA in 1998, is a groundbreaking injectable medicine used to treat certain autoimmune diseases, such as rheumatoid arthritis and psoriatic arthritis. Compl. ¶ 50. Enbrel can help patients with moderate to severe rheumatoid arthritis or psoriatic arthritis reduce joint pain, avoid permanent joint

damage, and dramatically improve their physical function and overall quality of life. *Id.* The active ingredient in Enbrel is a fusion protein called etanercept, which works by attaching to a protein in the body called "tumor necrosis factor" (TNF). *Id.* ¶ 51. When a patient's immune system produces too much TNF, it may lead to inflammation that causes pain, swelling, and joint damage. *Id.* By attaching to TNF, Enbrel inhibits TNF's inflammatory activity. *Id.*

Enbrel is covered by a number of United States patents, including U.S. Patent No. 8,063,182 ("the '182 patent"), which is directed to etanercept and was issued on November 22, 2011, and U.S. Patent No. 8,163,522 ("the '522 patent"), which is directed to methods of making etanercept and was issued on April 24, 2012. Compl. ¶ 52. Those two patents limit competing etanercept biosimilar products from entering the market until 2029 at the earliest. *Id.* ¶ 53. Plaintiff Immunex Corporation is the manufacturer of Enbrel and the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell Enbrel. *Id.* ¶¶ 17, 54. Immunex has granted Plaintiff Amgen Manufacturing, Limited ("AML") an exclusive sublicense to the '182 and '522 patents to manufacture and sell Enbrel, and AML has invested heavily to ensure a safe and reliable supply of Enbrel. *Id.* ¶¶ 18, 54. Both Immunex and AML are subsidiaries of Plaintiff Amgen Inc. This brief refers to Plaintiffs collectively as "Amgen."

D. The Board's Proceedings Against Enbrel

On June 9, 2023, the Board approved the final list of prescription drugs eligible

for affordability reviews. The list included 604 drugs that, according to the Board, met one or more of the statutory eligibility criteria.[6] On August 4, 2023, the Board selected five drugs for affordability reviews, including Enbrel. All of the selected drugs were brand-name drugs covered by unexpired patents.[7]

On February 9, 2024, the Board published its draft affordability review report for Enbrel. Compl. Ex. B. Totaling 499 pages, the report purported to discuss "information from the fifteen statutory and regulatory components the Board considers as part of an affordability review," *id.* at 3, but it followed no discernable methodology. It did, however, highlight Enbrel's patents as a reason for deeming Enbrel "unaffordable" and subjecting it to an upper payment limit. The report observed that "Enbrel has patent protection and is protected from biosimilar competition" due to "patents that prevent the introduction of biosimilar products" until 2029. *Id.* at 26. In contrast, the report noted, "[t]wo of Enbrel's therapeutic alternatives, Humira and Remicade, have recent FDA-approved biosimilar products," and "there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets." *Id.*

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[6] Colo. Div. of Ins., *Colorado PDAB 2023 Eligible Drug Dashboard* (Oct. 19, 2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/0_Navigation?publish=yes ("Drug 'Lookup' Tool").

[7] The other drugs selected were Cosentyx, Genvoya, Stelara, and Trikafta. Each was determined by the Board to be covered by at least one unexpired patent, as the Board acknowledged in its reports for those drugs (which are available at https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

Further emphasizing Enbrel's patent protection, the report included an appendix section devoted to "Patents and Exclusivity." *Id.* at C-9–C-11. The report explained that "[e]valuating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices." *Id.* at C-9. Having identified federal patent rights as a key factor affecting drug prices during the patent term, the report catalogued Enbrel's various patents and highlighted two that it stated currently "prevent the introduction of biosimilar products." *Id.* The report stated that Enbrel's '182 and '522 patents are "'core'" patents that are "considered to be quite strong" and "make the creation of a non-infringing biosimilar drug nearly impossible." *Id.* at C-11. The report noted that "Amgen has protected Enbrel through litigation of its patents in U.S. courts" and that multiple courts had upheld Enbrel's '182 and '522 patents against challenges from potential competitors seeking to market biosimilar drugs prior to the expiration of those patents in 2029. *Id.*

One week later, on February 16, 2024, the Board held a meeting at which it voted to declare that Enbrel is "unaffordable for Colorado consumers." 2/16/24 Mtg. Tr. 103:20-105:18.[8] One member remarked that even though one of Enbrel's therapeutic alternatives had historically been more expensive—in fact, it had topped the Board's list of the "top 10 highest spend eligible drugs," *see* Compl. Ex. C—the

[8] Video recordings of the February 16 and 23 meetings are available at https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board, and transcripts are attached for the Court's convenience.

Board selected Enbrel for an affordability review because unlike Enbrel, the other drug had recently gone off-patent and become subject to biosimilar competition:

> BOARDMEMBER CATHERINE HARSHBARGER: … I think in the graphs that we saw in our report, Humira cost-wise isn't cheaper, I guess is the way I'd put it; it's very expensive as well.
>
> BOARDMEMBER AMY GUTIERREZ: Back in 2022, Cathy, yes. But … whenever something goes biosimilar … that competition lowers the price. … [W]ith this drug … the biosimilars didn't become available until 2023.
>
> CHAIR GAIL MIZNER: And as you may recall, we actually decided not to do an affordability review on Humira because of those biosimilars that had become available.
>
> BOARDMEMBER CATHERINE HARSHBARGER: Right, right, okay.

2/16/24 Mtg. Tr. 33:16-34:11.

On February 23, 2024, the Board held a meeting at which it voted to adopt the final affordability review report for Enbrel, which included the conclusion that Enbrel is "unaffordable for Colorado consumers." 2/23/24 Mtg. Tr. 21:06-22:11. The Board then separately voted to "select[] Enbrel for establishment of an upper payment limit." *Id.* at 36:13-37:3. The Board has scheduled rulemaking hearings for September 6, October 18, and December 6 to determine the amount of that limit.

The Board's final report for Enbrel was made publicly available on March 21, 2024. In a new section titled "Board Deliberation and Vote Summary," the report reiterated the Board's finding that Enbrel is "unaffordable for Colorado consumers" and listed factors the Board had considered in reaching that determination, including

"availability of biosimilars." Compl. Ex. D at 2–3. The final report was otherwise identical to the draft in all relevant respects, including the discussion of Enbrel's patents. *See id.* at 25 and C-11–C-13.

On March 22, 2024, Amgen brought this action seeking declaratory and injunctive relief with respect to the constitutionality of the Act. Defendants are the Chair and members of the Board, the Commissioner of the Colorado Division of Insurance, and the Colorado Attorney General, all in their official capacities.

ARGUMENT

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). The parties agree that Amgen's constitutional claims raise legal questions that may properly be resolved on summary judgment, without the need for discovery or trial. ECF No. 18 at 2. For the reasons set forth below, Amgen is entitled to summary judgment on each of its claims.

I. Colorado's attempt to impose price controls on Enbrel conflicts with the federal patent laws.

1. Under the Constitution's Supremacy Clause, federal statutes are "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. A "fundamental principle of the Constitution" is thus that "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Tuck v. United States*, 2022 WL 833367, at *6 (D. Colo. Mar. 21, 2022)

(Wang, J.) (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)). Preemption is therefore warranted not only when Congress has expressly preempted state legislation or occupied an entire regulatory field, but also when state law stands as "'an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at *8 (quoting *Mt. Olivet Cemetery Ass'n v. Salt Lake City*, 164 F.3d 480, 486 (10th Cir. 1998)). This inquiry "ranges beyond the literal text" of the federal statute and requires an examination of its "'purpose and intended effects.'" *BIO*, 496 F.3d at 1372 (quoting *Crosby*, 530 U.S. at 373).

Although Tenth Circuit precedent is binding on other issues in this case, "Federal Circuit law governs whether federal patent law preempts … state law." *Kim v. Kettell*, 2023 WL 6248878, at *8 (D. Colo. Sept. 26, 2023) (citing *Tavory v. NTP, Inc.*, 297 F. App'x 976, 982 (Fed. Cir. 2008)); *see Vermont v. MPHJ Tech. Invs., LLC*, 803 F.3d 635, 643–47 (Fed. Cir. 2015) (noting Federal Circuit has jurisdiction when party seeks to enjoin state law "on grounds that it is preempted by the patent laws").

2. In enacting the federal patent laws, and especially the laws governing pharmaceutical patents, Congress has long sought to achieve a "careful balance" between competing interests. *Bonito Boats*, 489 U.S. at 146. On the one hand, Congress has recognized "the need to promote innovation" through economic incentives by enabling innovators to earn greater profits during the term of the patent. *Id.* On the other hand, Congress has sought to promote greater affordability by encouraging competition after a patent term expires. *Id.* Congress fine-tunes the

proper balance between economic incentives for innovation and affordability by specifying the duration of patent exclusivity periods and establishing procedures for their adjustment. *See* 35 U.S.C. § 154. "Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *BIO*, 496 F.3d at 1373.

The patent system thus "embodies a carefully crafted bargain" that rewards the creation and disclosure of new technological advances with "the exclusive right to practice the invention for a period of years." *Bonito Boats*, 489 U.S. at 150–51. Federal law does not grant innovators that exclusivity for its own sake. Rather, as the Constitution makes clear, the right to exclude is intended "[t]o promote the Progress of Science and the useful Arts." U.S. Const. art. I, § 8, cl. 8. And the principal mechanism by which the right to exclude accomplishes that aim is by enabling the patent-holder to set its own prices during the patent term, and thus to make more profit than it would without that right. As the Federal Circuit has explained:

> The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

King Instruments, 65 F.3d at 950. The "pecuniary rewards stemming from the patent right" are especially important to incentivize the costly research and development that drives pharmaceutical innovation. *BIO*, 496 F.3d at 1372; *see also Sanofi-*

Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006) (noting that patents "provide[] incentive to … innovative drug companies to continue costly development efforts"); Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 Expert Op. on Therapeutic Pat. 739, 739 (2015) (explaining that patents "have long been considered essential to prescription drug development" due to "the costly, lengthy, and risky nature of innovative [pharmaceutical] research and development").

Congress has accordingly taken particular care to weigh competing interests, and to bolster incentives for innovation, in the pharmaceutical field. As discussed above, the Hatch-Waxman Act extended the patent term for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18. These strengthened protections were designed to compensate manufacturers for the time spent in clinical trials and the lengthy federal approval process. *See id.*; Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

Congress's deliberations on the Hatch-Waxman Act confirm the "central role of enhanced profits in the statutory incentive scheme." *BIO*, 496 F.3d at 1373. As the House Committee on Energy and Commerce observed, "[p]atents … enable innovators to obtain greater profits than could have been obtained if direct competition existed," and "[t]hese profits act as incentives for innovative activities."

Id. (quoting H.R. Rep. No. 98-857(I), at 17); *see also* 130 Cong. Rec. 15,847 (1984) (statement of Senator Hatch) (noting that the legislation "add[s] stimulus for research on new drugs … through an extension of patent life"); 130 Cong. Rec. 24,427 (1984) (statement of Representative Waxman) (explaining that a patent gives the holder "the ability to charge" higher prices until the patent expires and "competition … bring[s] about the result of a lower price for the consumer").

In keeping with those efforts, Congress has also sought to promote affordability by streamlining the FDA approval process for copycat drugs—but, importantly, only *after* the patent term expires. Congress created an approval pathway for generic small-molecule drugs in the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j), and for more complex biosimilar drugs in the BPCIA, *see* 42 U.S.C. § 262(k). Congress has thus struck an intentional balance, ensuring that those who develop innovative medicines are rewarded with a period of federal patent exclusivity and pricing discretion, while encouraging lower prices through competition after the patent term ends.

3. Colorado's new price-control regime for prescription drugs, which does not contain any exemption for patented drugs like Enbrel, is preempted because it frustrates the purposes and objectives of the federal patent laws. Colorado seeks to restrain what it calls "excessive" costs for patented prescription drugs by delegating power to a state board to declare them "unaffordable" and subject them to "upper payment limits." Colo. Rev. Stat. §§ 10-16-1403(1), -1406(3). Colorado's approach would replace the "dictates of the marketplace," *King Instruments*, 65 F.3d at 950,

with the dictates of the Board. And it would upset the balance Congress struck between innovation and affordability by reducing the "size of the carrot" Congress provided in the patent laws—*i.e.*, the economic rewards that are part and parcel of patent ownership. *Id.* By undermining the profit incentives that are so central to Congress's design, the Act impermissibly "re-balance[s] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *BIO*, 496 F.3d at 1374; s*ee Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1305–06 (Fed. Cir. 2003) ("Through the federal patent laws, Congress has balanced innovation incentives against promoting free competition, and state laws upsetting that balance are preempted.").

The Federal Circuit recognized as much in *BIO*, where it struck down a similar price-control law enacted by the District of Columbia. Like the law at issue there, Colorado's statute "is a clear attempt to restrain" what the state considers "excessive prices" for patented drugs, thereby "diminishing the reward to patentees in order to provide greater benefit to [in-state] drug consumers." 496 F.3d at 1374. Congress, however, has already tailored federal patent law to achieve what it considers "the best balance" between the competing interests in rewarding innovation and promoting affordability. *Id.* at 1373. Colorado's attempt to reweigh those competing interests "is contrary to the goals established by Congress in the patent laws." *Id.* at 1374. A state cannot take it upon itself to "second-guess" Congress's design by preventing a patent owner or licensee from charging prices that reflect its federally

guaranteed patent rights. *Id.* (quoting *Bonito Boats*, 489 U.S. at 152). "The underlying determination about the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress." *Id.*

For the same reason, courts have held that state-law claims for unjust enrichment or unfair competition cannot be used as a vehicle to challenge patent-holders' pricing decisions. *See, e.g.*, *Se. Penn. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) (explaining that plaintiffs may not use state law to challenge manufacturer's "exercise of its exclusive patent rights to make pricing decisions" (footnote omitted)); *SanDisk Corp. v. Kingston Tech. Co.*, 863 F. Supp. 2d 815, 835 (W.D. Wis. 2012) (claim challenging "discriminatory pricing" was preempted because "policy decisions about the fair use of patents fall[] to Congress"). "Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing [a manufacturer] to lower its prices" for "the sale of its patented drugs." *Gilead*, 102 F. Supp. 3d at 703. So too, Colorado's attempt to use state law to force Amgen to charge lower prices for its patented drug "stands as an obstacle to the federal patent law's balance of objectives as established by Congress," *BIO*, 496 F.3d at 1374, and is therefore preempted.

4. The conflict with federal law is especially stark because the Board has deliberately targeted Enbrel based on its patent protection. *See* pp. 12–14, *supra*. To be sure, the Act's application to patented drugs would trigger preemption even without that specific targeting. *See Saleh v. Titan Corp.,* 580 F.3d 1, 12 n.8 (D.C. Cir.

2009) ("[I]t is a black-letter principle of preemption law that generally applicable state laws may conflict with and frustrate the purposes of a federal scheme just as much as a targeted state law."); *United States v. California*, 921 F.3d 865, 880 (9th Cir. 2019) ("Obstacle preemption … attaches to any state law, regardless of whether it specifically targets the federal government."). But the Board's focus on patent rights as an important factor justifying the imposition of state price controls makes the Act's interference with federal objectives even clearer.

The Board cannot deny that Amgen's patents were a major, if not the most significant, factor in the decision to subject Enbrel to price controls. Its Chair stated on the record that the Board "decided not to do an affordability review" for a therapeutic alternative that was historically more expensive than Enbrel because that product, unlike Enbrel, had recently become subject to biosimilar competition. *See* p. 14, *supra*. And the Board's affordability report emphasized Amgen's patent rights and their role in limiting biosimilar competition. It included a detailed overview of relevant patents, observing that "Enbrel has patent protection and is protected from biosimilar competition" by patents that will not expire until 2029. Compl. Ex. D at 25; *see id.* at C-11–C-13. It also drew a contrast with "[t]wo of Enbrel's therapeutic alternatives," noting that they "have recent FDA-approved biosimilar products." *Id.* at 25. The Board stated it found consideration of Amgen's patents "helpful" because "intellectual property rights can be associated with increased drug prices." *Id.* at C-11.

Given the Board's close scrutiny of Enbrel's patents, there can be little doubt that the rights guaranteed by the federal patent laws were a key factor in the Board's decision. The Board was open about its desire to use state law to counteract the effect of Amgen's federal patent rights on the price of Enbrel. Although such explicit targeting of federally protected rights is not necessary for preemption, it confirms that Colorado's price-control regime "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of" the federal patent laws. *Crosby*, 530 U.S. at 373 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

II. Colorado's price-control regime lacks meaningful standards and thus violates due process.

Colorado's delegation of virtually unfettered price-setting power to the Board is also unconstitutional because it lacks the procedural safeguards necessary to comport with basic requirements of due process. The Due Process Clause prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. Amgen has a protected property interest in Enbrel. And it is "well-settled" that "the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself" and "within the protection of" due process. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Yet neither Colorado's statute nor the implementing regulations establish any standard to constrain the Board's discretion either in determining whether a drug is "unaffordable" or in setting an "upper payment limit." This lack of ascertainable standards violates due process by denying manufacturers

a meaningful opportunity to be heard and failing to protect them against arbitrary, confiscatory, or discriminatory deprivations.

1. "The core of due process is the right to notice and a *meaningful opportunity* to be heard." *In re C.W. Mining Co.*, 625 F.3d 1240, 1244–45 (10th Cir. 2010) (quoting *LaChance v. Erickson*, 522 U.S. 262, 266 (1998)); *see Mathews v. Eldridge,* 424 U.S. 319, 333 (1976). For a hearing to be meaningful, the law must set "ascertainable limit[s]" on the agency's discretion. *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1185–86 (10th Cir. 2009); *see White v. Roughton*, 530 F.2d 750, 753–54 (7th Cir. 1976) (per curiam) ("The requirements of due process include a determination of the issues according to articulated standards."). "[U]ncontrolled discretion in an agency of government" is "an intolerable invitation to abuse." *Hobbs*, 579 F.3d at 1185 (quoting *Holmes v. N.Y. City Hous. Auth.*, 398 F.2d 262, 264–65 (2d Cir. 1968)). The purpose of due process is to prevent "erroneous deprivation[s]," *Eldridge*, 424 U.S. at 335; but without meaningful standards, there is no yardstick to measure whether a decision is erroneous and no way to hold the agency accountable. "The lack of such standards … deprives any hearing, whether before an agency or a court, of its meaning and value." *White*, 530 F.2d at 754.

Colorado's price-control regime violates due process because the Board's decisionmaking is not governed by any ascertainable standards. The central question the Board must answer is whether a given drug is "unaffordable for Colorado consumers." Yet the statute does not define that term or meaningfully limit the

Board's discretion to deem particular drugs "unaffordable." The Board need only "consider" a multitude of factors "to the extent practicable," and it can name "any other factors" it wants in regulations. Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E). Most of the factors are extraordinarily broad and vague, and neither the statute nor the regulations explain how to assess or weigh those factors. *See* pp. 8–9, *supra*. As a result, the Board's decisionmaking is effectively a black box—as illustrated by the Board's determination that Enbrel, with an average annual per-patient cost of $46,772 and average annual out-of-pocket cost of $3,980, is unaffordable, while Trikafta, an "extraordinarily expensive drug" with an average annual per-patient cost of $234,439 and average annual out-of-pocket cost of nearly $9,000, is not unaffordable.[9] The Board's reports on Trikafta and Enbrel total more than 1,000 pages, yet a reader of those reports can only guess about what specific considerations caused the Board to deem Enbrel unaffordable and Trikafta affordable. At the end of the day, the Board is left to its own "uncontrolled discretion." *Hobbs*, 579 F.3d at 1185.

The Board's discretion in setting an "upper payment limit" for a drug it has deemed unaffordable is similarly standardless. The statute does not impose any meaningful constraint on the Board's power to dictate prices—there is no price floor, nor even any standard of reasonableness or fairness. Colo. Rev. Stat. § 10-16-1407(2).

[9] *Compare* Compl. Ex. D at 2 *with* Colo. PDAB, 2023 Affordability Review Report: Trikafta, at 2–3 (Dec. 15, 2023), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board.

The Board is required only to "consider" or "review" certain factors before choosing a price—but how those factors should affect the Board's decision, if at all, is left unsaid. *See* pp. 9–10, *supra*. Accordingly, at both stages of the administrative process, regulated parties and other stakeholders are subject to the whims of the Board. This scheme violates Amgen's "due process right to be free from" determinations unconstrained by "any publicly-available standard." *Hobbs*, 579 F.3d at 1185.

2. Colorado's regime also violates the more specific due-process principles that courts have applied to administrative price-control regimes. Government price-setting is a potent form of economic regulation that can impose severe burdens on private rights, which in turn can undermine the public interest by creating shortages and reducing incentives for production and innovation. Courts thus have long held that a statute that authorizes an agency to set prices must contain both substantive standards and procedural mechanisms sufficient to "ensure a fair and reasonable rate of return on investment." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 594 (6th Cir. 2001); *see also Guaranty Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990).

A constitutional price must not only allow the seller to recoup its costs; it must also include "compensat[ion] … for the risk assumed." *Mich. Bell*, 257 F.3d at 593 (quoting *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 603 (1944)); *see Tenoco Oil Co. v. Dep't of Consumer Affairs*, 876 F.2d 1013, 1020 (1st Cir. 1989) (rates that do not allow a "fair return on investment" are "confiscatory"). It is not enough that an agency might happen to select a constitutional price; instead, the price-setting

regime must include standards and procedures to *ensure* a constitutionally reasonable price. The Sixth Circuit thus struck down a state law regulating telephone rates because the statute's standards and factors "d[id] not guarantee the constitutionally-required fair and reasonable rate of return." *Mich. Bell*, 257 F.3d at 595–96. The Ninth Circuit likewise invalidated a state law regulating insurance rates because it did not "provide[] any mechanism to guarantee a constitutionally required fair and reasonable return." *Guaranty*, 916 F.2d at 512–15.

Colorado's price-control scheme fails to provide these minimum constitutional safeguards. Neither the statute nor the regulations require that prices set by the Board be sufficient to allow a fair and reasonable return on drug manufacturers' investments. In fact, a fair rate of return is not even listed among the many factors the Board is required to consider when determining whether a drug is "unaffordable" and fixing an upper payment limit. The possibility that the Board might, by chance, set prices at a constitutional level does not satisfy due process. As the Sixth Circuit explained, "it is axiomatic that due process guarantees a fair and reasonable regulatory rate, not just the possibility of acquiring such a rate" through the price-setting authority's discretionary choice. *Mich. Bell*, 257 F.3d at 595 n.4. Far from safeguarding against unconstitutional prices, Colorado's scheme practically invites them by failing to provide any meaningful standards to limit the Board's discretion. Because the Act lacks "any mechanism to guarantee a constitutionally required fair and reasonable return," it violates due process. *Guaranty*, 916 F.2d at 512; *accord*

Mich. Bell, 257 F.3d at 595–96.

III. Colorado's attempt to regulate prices paid by federal healthcare programs is preempted.

Colorado's statute is also preempted insofar as it purports to dictate the prices that federal healthcare programs can pay for Enbrel and other prescription drugs on behalf of program beneficiaries. Under the Act, an "upper payment limit" applies to "*any* financial transaction concerning the purchase of or reimbursement for the prescription drug." Colo. Rev. Stat. § 10-16-1401(23) (emphasis added). There is no exemption for transactions entered into by federal programs such as Medicare, TRICARE, the Veterans Health Administration ("VHA"), and the Federal Employee Health Benefits Program ("FEHB"). Colorado's attempt to govern those federal transactions is preempted under basic constitutional principles prohibiting state regulation of federal activities, as well as under express statutory preemption clauses applicable to certain federal healthcare programs.

1. A basic tenet of our federal system is that the Supremacy Clause "prohibit[s] States from interfering with or controlling the operations of the Federal Government." *United States v. Washington*, 596 U.S. 832, 838 (2022) (citing *McCulloch v. Maryland*, 17 U.S. 316 (1819)). As the Supreme Court has explained, it is "the very essence of supremacy to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments, as to exempt its own operations from their own influence." *Hancock v. Train*, 426 U.S. 167, 178 (1976) (quoting *McCulloch*, 17 U.S. at 427). In other words, "the activities of the

Federal Government are free from regulation by any state." *Id.* (quoting *Mayo v. United States*, 319 U.S. 441, 445 (1943)); *see United States v. Sup. Ct. of N.M.*, 839 F.3d 888, 927 (10th Cir. 2016) (noting "the fundamental importance of the principles shielding federal installations and *activities* from regulation by the States" (quoting *Hancock*, 426 U.S. at 179)).

Colorado violates this principle by seeking to directly regulate the prices that federal healthcare programs pay for Enbrel and other drugs. These programs routinely enter into contracts to purchase or reimburse the purchase of prescription drugs for beneficiaries. Yet under the Act, "[a]n upper payment limit applies to *all* purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state," including purchases and reimbursements by federal healthcare programs. Colo. Rev. Stat. § 10-16-1407(5) (emphasis added). Colorado thus subjects federal programs "to the discretionary authority of a state agency for the terms on which [they] can make arrangements for" the purchase of prescription drugs. *Pub. Utils. Comm'n v. United States*, 355 U.S. 534, 539 (1958). That scheme interferes with the operations of the federal government, which is entitled to control its own payment and coverage decisions "free from regulation by any state." *Mayo*, 319 U.S. at 445. The Act's failure to "exempt [those] operations from [its] influence," *Hancock*, 426 U.S. at 178–79 (quoting *McCulloch*, 17 U.S. at 427), violates the Supremacy Clause.

Perhaps recognizing this problem, in January 2023, the Board issued a non-

binding policy document asserting, without explanation, that "[a]n upper payment limit does not apply to [a] purchase or reimbursement made by Medicare." Compl. Ex. A at 2. That policy document does not solve the constitutional problem. For one thing, it refers only to Medicare and does not address other federal healthcare programs. And even as to Medicare, the Board's assertion is contrary to the plain language of the statute and does not purport to be binding on anyone. It therefore does not provide adequate assurance against preempted applications of the statute.

2. Colorado's attempt to dictate the prices federal healthcare programs can pay for prescription drugs is also preempted under express preemption provisions applicable to several of those federal programs. Start with Medicare. As the Tenth Circuit has recognized, the Medicare Part C and D programs have "broad preemption clause[s]." *Pharm. Care Mgmt. Ass'n v. Mulready* ("*PCMA*"), 78 F.4th 1183, 1205 (10th Cir. 2023). The clauses provide that any "standards established under [Part C or D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to" Part C or D plans. 42 U.S.C. § 1395w-26(b)(3) (Part C); *see id.* § 1395w-112(g) (Part D). This "sweeping" language "is 'akin to field preemption' and precludes States from regulating Part [C or] D plans except for licensing and plan solvency." *PCMA*, 78 F.4th at 1206. Colorado's price-control scheme regulates Part C or D plans, does not pertain to licensing or plan solvency, and is therefore expressly preempted.

Colorado's scheme is likewise preempted under broad preemption clauses

applicable to other federal healthcare programs. The statutes and regulations governing TRICARE, a health benefit program for members of the U.S. armed forces, shield TRICARE from the application of state laws "relating to health insurance, prepaid health plans, or other health care delivery or financing methods." 10 U.S.C. § 1103; *see* 32 C.F.R. §§ 199.17(a)(7), 199.21(o)(2). Similarly, the FEHB's express preemption clause provides that "[t]he terms of any contract under this chapter which relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans." 5 U.S.C. § 8902(m)(1). Even a "general" state law "relates to health insurance" when its "*application* relates to the scope or administration of federal healthcare plans." *Gonzalez v. Blue Cross Blue Shield Ass'n*, 62 F.4th 891, 903–04 (5th Cir. 2023). Accordingly, Colorado's attempt to dictate the prices TRICARE and FEHB plans can pay for prescription drugs is expressly preempted.

IV. Colorado's direct regulation of out-of-state transactions violates the Commerce Clause.

The Act's expansive scope causes it to run afoul of another constitutional prohibition: the rule that a state cannot directly regulate transactions that occur entirely outside its borders. This extraterritoriality principle is inferred from the Constitution's Commerce Clause, which grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. As the Supreme Court has long recognized, that affirmative grant of power to Congress implies "a further, negative

command, one effectively forbidding the enforcement of certain state economic regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (cleaned up).

Under the Commerce Clause, a state law "that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid" per se. *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *see Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 668 (4th Cir. 2018) ("A state law violates the extraterritoriality principle if it … expressly applies to out-of-state commerce."). And "[t]he mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions." *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615 (9th Cir. 2018); *see Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion) ("The Commerce Clause also precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.").

The Act violates that extraterritoriality principle because it directly regulates transactions that occur entirely outside of Colorado. An upper payment limit set by the Board "applies to *all* purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state." Colo. Rev. Stat. § 10-16-1407(5) (emphasis added); *see also id.* § 10-16-1401(23) (upper payment limit applies to "*any* financial transaction concerning the purchase of or reimbursement for the prescription drug" (emphasis added)). The upper payment limit thus applies to

"upstream" transactions—transactions that occur entirely outside of Colorado but involve a drug later dispensed or administered in Colorado (*e.g.*, a sale by a manufacturer in Ohio to a distributor in Illinois). The Commerce Clause does not permit Colorado to dictate prices for those out-of-state transactions.

The Fourth Circuit applied these principles to strike down a similar effort by Maryland to "control[] the price of transactions that occur[red] wholly outside the state." *Ass'n for Accessible Meds.*, 887 F.3d at 671. In that case, Maryland prohibited so-called "price gouging in the sale of an essential off-patent or generic drug." *Id.* (quoting Md. Code Ann., Health-Gen. § 2-802(a)). Although the only drugs subject to the law were those that were ultimately "'made available for sale in [Maryland],'" the court held that the law was "nonetheless invalid because it still control[led] the price of transactions that occur[red] wholly outside the state," *id.* at 671. Maryland's attempt to directly regulate prices in out-of-state transactions was a clear constitutional violation, and "[a]ny legitimate effects the Act may have [had] in Maryland [were] insufficient to protect the law from invalidation." *Id.* at 672.

For the same reasons, a federal district court recently held that a similar Minnesota law violated the Commerce Clause. *Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586 (D. Minn. Dec. 4, 2023), *appeal filed*, No. 24-1019 (8th Cir. Jan. 3, 2024). The law prohibited any "excessive price increase" in "the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state." *Id.* at *1

(quoting Minn. Stat. § 62J.842).[10] While the statute required "some nexus" with Minnesota, *Daniels*, 889 F.3d at 615, it reached transactions that occurred completely outside the state's borders. As the court explained, a state may not "directly regulate a sale that occurs in another state simply because the product eventually makes its way into [the state]." *Ass'n for Accessible Meds.*, 2023 WL 8374586, at *3. The same principle applies here. Colorado may not directly regulate out-of-state transactions simply because the drugs involved are ultimately dispensed or distributed in-state.[11]

Moreover, even if Colorado's attempt to directly regulate out-of-state transactions were not invalid per se, it would violate the Commerce Clause under the *Pike* balancing test, which asks whether a state law imposes a burden on interstate commerce that "is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see Ass'n for Accessible Meds.*, 2023 WL 8374586, at *9. Because Colorado has no legitimate interest in directly regulating transactions that occur entirely outside its boundaries, and because any cognizable local benefits could be achieved by regulating in-state transactions, Colorado's

[10] The Maryland and Minnesota price-control laws in these cases were limited to off-patent or generic drugs. Unlike Colorado, those states did not seek to regulate the price of *patented* drugs, presumably because they recognized that any attempt to do so would impermissibly conflict with the federal patent laws. *See* Part I, *supra*.

[11] As the Minnesota district court and others have recognized, the Supreme Court's decision in *Pork Producers* "did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it." *Ass'n for Accessible Meds*, 2023 WL 8374586, at *3; *see also, e.g.*, *Interlink Prod. Int'l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023).

attempt to regulate extraterritorially fails the *Pike* balancing test.

V. This case presents a justiciable controversy, and the Court should exercise jurisdiction.

Given the strength of Amgen's constitutional claims, Defendants may seek to delay this Court's review by raising unfounded justiciability arguments. Defendants' answer lists several "affirmative defenses," including that Amgen "do[es] not have standing," that its claims are "not justiciable," "not ripe," or "moot," and that "[t]he Court should abstain from hearing this suit under the *Burford* doctrine." ECF No. 23 at 45. It is not clear which, if any, of those arguments Defendants intend to raise in their briefing, but they are all meritless. This case presents a justiciable controversy and does not meet the stringent requirements for *Burford* abstention.

1. With respect to justiciability, "courts have consistently found a case or controversy in suits between state officials charged with enforcing a law and private parties potentially subject to enforcement." *Consumer Data Indus. Ass'n v. King*, 678 F.3d 898, 905 (10th Cir. 2012). In a pre-enforcement challenge to a statute, Article III requires (1) a "threatened injury" that is "certainly impending" or has a "substantial risk" of occurring; (2) a "causal connection" between the injury and the statute; and (3) a "likelihood" that the injury "will be redressed by a favorable decision." *Susan B. Anthony List v. Driehaus ("SBA")*, 573 U.S. 149, 158 (2014) (cleaned up); *see Kane County v. United States*, 928 F.3d 877, 888 (10th Cir. 2019). In short, "[a] plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *BIO,* 496 F.3d at 1370–

71 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). "In pre-enforcement challenges, moreover, standing and ripeness often 'boil down to the same question.'" *Teva Pharms., USA, Inc. v. Weiser*, 2023 WL 9425674, at *5 (D. Colo. Dec. 27, 2023) (quoting *SBA*, 573 U.S. at 157 n.5), *appeal filed*, No. 24-1035 (10th Cir. Jan. 29, 2024).

Amgen faces far more than a "substantial risk" or a "realistic danger" of injury from the Act's operation or enforcement. The Act's express purpose is to reduce what state officials consider "excessive" prescription drug prices, and the Board's *raison d'être* is to effectuate that purpose by imposing "upper payment limits" on drugs the Board deems unaffordable. Colo. Rev. Stat. § 10-16-1403(1). The Board has already engaged in a months-long review of Enbrel that culminated in a 534-page report and two formal votes: one to declare Enbrel "unaffordable for Colorado consumers," and another to "select Enbrel for establishment of an upper payment limit." All that remains to be decided in this autumn's rulemaking is *how much* Enbrel's price will be limited. *See* 3 Colo. Code Regs. § 702-9:4.1(D). And even in the unlikely event that the price reduction is small, "a loss of even a small amount of money" is sufficient to establish standing. *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017). Amgen does "not have to await the consummation of [that] threatened injury to obtain preventive relief." *BIO*, 496 F.3d at 1370–71 (quoting *Babbitt*, 442 U.S. at 298).

Nor does it matter that the Board could, in theory, reconsider its decision to impose an upper payment limit for Enbrel and not complete the rulemaking. There

is no reason to think that, after all the time and resources the Board has invested in declaring Enbrel "unaffordable" and voting to subject it to an upper payment limit, the Board will suddenly change its mind. As the D.C. Circuit has observed, "an agency *always* retains the power to revise" its decisions, so "[i]f the possibility of unforeseen amendments were sufficient to render an otherwise fit challenge unripe, review could be deferred indefinitely." *Am. Petroleum Inst. v. EPA*, 906 F.2d 729, 739–40 (D.C. Cir. 1990) (per curiam). For that reason, "any agency attempt to defeat review by the bare assertion that the agency position may some day change should be summarily rejected." 13B Wright & Miller, Federal Practice and Procedure § 3532.6 (3d ed.); *see, e.g.*, *sPower Dev. Co. v. Colo. Pub. Utils. Comm'n*, 2018 WL 4368612, at *7 (D. Colo. June 18, 2018) (concluding that challenge to agency action was ripe because agency had not "committed to revising or rescinding" challenged rule but had only stated that rulemaking "'may serve as an opportunity to reexamine [its] policies'"). Here, likewise, the theoretical possibility that the Board could reconsider its decision to impose an upper payment limit on Enbrel does not render this challenge unripe.

Moreover, in addition to the threat of injury from imposition of an upper payment limit, Amgen is already suffering (and will continue to suffer) concrete harm as a result of the Board's unconstitutional proceedings. Amgen is being forced to incur substantial costs to participate and defend its interests in a state price-setting process that is preempted and lacks essential due process protections. Amgen's challenge to this process is ripe because "the process itself is preempted … regardless of what the

outcome" might be, and "focus[ing] on the possible ultimate result of the state regulatory process" overlooks that the "process itself can be the preempted burden." *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 342–44 (3d Cir. 2001); *see also, e.g.*, *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 453–54 (9th Cir. 1993) (preemption challenge to state permitting process was ripe because "[t]he hardship is the process itself," which "may impose cost and uncertainty"); *Middle S. Energy, Inc. v. Ark. Pub. Serv. Comm'n*, 772 F.2d 404, 413 (8th Cir. 1985) (similar); *sPower*, 2018 WL 4368612, at *7 (where plaintiff challenges state process as preempted, "[t]he outcome of that process … does not dictate whether [the] claim is ripe" (cleaned up)). Similarly, "a procedural due process claim is instantly cognizable in federal court without requiring a final decision … from the responsible … agency" because "the allegedly infirm process is an injury in itself." *Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 894 (6th Cir. 1991) (cleaned up).

Nothing that happens in the Enbrel rulemaking hearings scheduled for later this year will change any facts relevant to Amgen's claims, which raise "strictly legal issues." *United States v. Ford*, 882 F.3d 1279, 1283–84 (10th Cir. 2018). "A purely legal claim in the context of a facial challenge is presumptively reviewable." *Sanchez v. Off. of State Superintendent of Educ.*, 959 F.3d 1121, 1124 (D.C. Cir. 2020) (cleaned up). The purely legal nature of Amgen's claims means that "waiting for [the rulemaking hearings] to play out" would not "significantly advance [this Court's] ability to deal with the legal issues presented or aid [it] in their resolution." *Sup. Ct.*

of N.M., 839 F.3d at 903–04 (cleaned up). And it would make no sense to force Amgen to incur the costs of an unconstitutional process before challenging that process as unconstitutional. This case is ripe for review now.[12]

2. Defendants' answer also indicates that they may invoke *Burford* abstention, but that doctrine has no application here. Given the "strong federal interest" in having federal rights "adjudicated in federal court," *Burford* abstention is "rare[]" and "represents an 'extraordinary and narrow exception to the duty of the District Court to adjudicate a controversy properly before it.'" *Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706, 728 (1996) (quoting *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 813 (1976)). The Supreme Court has limited *Burford* abstention "to situations where 'there are difficult questions of state law bearing on policy problems … whose importance transcends the result in the case' or 'where the exercise of federal review of the question in a case and in similar cases would be disruptive of state efforts to establish a coherent policy with respect to a matter of substantial public concern.'" *Tavernier v. Colo. State Bd. of Nursing*, 2017 WL 1242995, at *14 (D. Colo. Mar. 17, 2017) (quoting *Oklahoma ex rel. Doak v. Acrisure Bus. Outsourcing Servs., LLC*, 529 F. App'x 886, 897 (10th Cir. 2013)).

This case does not present the "narrow range of circumstances in which *Burford* can justify the dismissal of a federal action." *Quackenbush*, 517 U.S. at 726–

[12] Meanwhile, the Board continues to move forward with proceedings targeting other drugs. Declining to reach the merits now would only mean that Amgen or another affected company would bring the same challenge in a few months.

28. Amgen's "claims both are federal in nature and do not implicate any difficult questions of state law." *Tavernier*, 2017 WL 1242995, at *14 (cleaned up). Nor would Amgen's challenge "disrupt the State's attempt to ensure uniformity in the treatment of an essentially local problem." *Quackenbush*, 517 U.S. at 727 (cleaned up). Notably, "[w]hile *Burford* is concerned with protecting complex state administrative processes from undue federal influence, it does not require abstention whenever there exists such a process, or even in all cases where there is a 'potential for conflict' with state regulatory law or policy." *Id.* For example, "*Burford* abstention is inappropriate where, like here, the plaintiff asserts a well-founded preemption claim." *sPower*, 2018 WL 4368612, at *9–10 (adopting then-Magistrate Judge Wang's recommendation to reject *Burford* abstention); *see Quackenbush*, 517 U.S. at 727 (noting that "federal adjudication" of preemption claim "would not disrupt the State's attempt to ensure uniformity in the treatment of an essentially local problem" (cleaned up)). Preemption is "a pure federal-law question." *Allison v. UNUM Life Ins. Co.*, 381 F.3d 1015, 1027 n.1 (10th Cir. 2004) (cleaned up). The Board can only benefit from knowing, as early as possible, whether and to what extent Colorado's price-control scheme is preempted. *Cf. sPower*, 2018 WL 4368612, at *10 ("[C]lear guidance from this Court on [federal preemption] may actually accelerate and add to [the state agency's] efforts"). For all these reasons, *Burford* abstention is clearly unwarranted.

CONCLUSION

The Court should enter summary judgment in Amgen's favor.

Dated: June 24, 2024

Respectfully submitted,

/s/ Ashley C. Parrish

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CORRECTED TRANSCRIPT

Colorado Prescription Drug Affordability Review Board - February 16, 2024 Meeting

BOARD STAFF LILA CUMMINGS: Callie, it looks like are we still waiting on Chair Mizner?
BOARD STAFF CALLIE ANN SHELTON: Thought I saw her.
BOARD STAFF LILA CUMMINGS: Thanks, everybody, for joining us this afternoon and thanks for your patience while we make sure we got all our Board members present.
BOARD STAFF CALLIE ANN SHELTON: I see her.
CHAIR GAIL MIZNER: Hello, I'm here.
BOARD STAFF LILA CUMMINGS: Hi, Dr. Mizner.
CHAIR GAIL MIZNER: Sorry about that.
BOARD STAFF LILA CUMMINGS: Absolutely fine.
CHAIR GAIL MIZNER: Good. So it is 1:01 p.m., and I would like to call this meeting of the PDAB to order on February 16th. Callie, would you please call the roll.
CALLIE ANN SHELTON: Of course. Dr. Sami Diab.
BOARDMEMBER SAMI DIAB: Present. Hello, everyone.
CALLIE ANN SHELTON: Dr. Amy Guttierez.

BOARDMEMBER AMY GUTIERREZ: Good afternoon. I'm here.
CALLIE ANN SHELTON: Cathy Harshbarger.
BOARDMEMBER CATHERINE HARSHBARGER: Present. Welcome, everyone.
CALLIE ANN SHELTON: Dr. Gail Mizner.
CHAIR GAIL MIZNER: Present.
CALLIE ANN SHELTON: And Dr. Justin VanderBerg.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Present.
CALLIE ANN SHELTON: Madam Chair, we have a quorum.
CHAIR GAIL MIZNER: Thank you, Callie. Do any Board members want to disclose any stakeholder meetings?
BOARDMEMBER SAMI DIAB: Yes, Madam Chair. Sami Diab here. We had a meeting with Colorado Oncology Society and our executive director was present as well.
CHAIR GAIL MIZNER: Thank you, Sami.
LILA CUMMINGS: And then in turn, is there anyone else who would like to do that. Members of the Division of Insurance, so Chief Deputy Commission Kate Harris, as well as myself,

met with representatives from Gilead.
CHAIR GAIL MIZNER: Thank you, Lila. Anyone else? Okay. Do I have a motion to approve the December 8th minutes?
BOARDMEMBER JAMES JUSTIN VANDENBERG: This is Justin VandenBerg. Motion to approve.
CHAIR GAIL MIZNER: Thank you. Do I have a second?
BOARDMEMBER CATHERINE HARSHBARGER: This is Cathy Harshbarger. I second.
CHAIR GAIL MIZNER: Thank you, Cathy. So Dr. VandenBerg moved and Ms. Harshbarger seconded. All those in favor of approving the December 8th minutes, raise your hand and say aye. Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
BOARDMEMBER SAMI DIAB: Aye.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.
BOARDMEMBER AMY GUTIERREZ: Commissioner, I just wanted to -- I know there was the meeting that I didn't attend in December. I just wanted to make sure I know my name is listed. I was just trying to look at my travel

records to make sure that wasn't the day, but if I could just get that clarification.
CHAIR GAIL MIZNER: Lila or Callie, are you able to clarify with whether Dr. Guttierez was at the December 8th.
BOARDMEMBER AMY GUTIERREZ: I believe I was there, but I just wanted to make sure that the record is clear.
CALLIE ANN SHELTON: Let me just double check.
BOARDMEMBER CATHERINE HARSHBARGER: Yeah, I think you came from -- didn't you participate from the airport on one of those days?
BOARDMEMBER AMY GUTIERREZ: Yeah, perhaps. Then I approve.
ATTORNEY ABBY CHESTNUT: Dr. Guttierez, I think you were present for the December 8th meeting, and I think you were not present on December 15th, so we'll have you abstain from the next vote.
BOARDMEMBER AMY GUTIERREZ: Thank you. I approve then, Chair Mizner.
CHAIR GAIL MIZNER: Thank you. Thank you, Abby, too for the clarification. So the

motion passes unanimously and the December 8th minutes are approved.

Do I have a motion to approve the December 15th minutes?

BOARDMEMBER SAMI DIAB: I will approve. Diab.

CHAIR GAIL MIZNER: Thank you. Do I have a second?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Justin VandenBerg, I second.

CHAIR GAIL MIZNER: Thank you. Dr. Diab moved and Dr. VandenBerg seconded. All those in favor of approving the December 15th minutes, raise your hand and say aye with the exception of Amy who will abstain since she was not present. Aye.

BOARDMEMBER CATHERINE HARSHBARGER: Aye.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.

BOARDMEMBER SAMI DIAB: Aye.

CHAIR GAIL MIZNER: Thank you. The motion passes. Commissioner Conway is here to provide opening remarks for todays meeting. Welcome, Commissioner.

COMMISSIONER MICHAEL CONWAY: Thank you, Madam Chair, and it's really not opening remarks; it's more a thank you. So it's been a while since I've come by to thank you all for all of your hard work. And obviously, in recent really kind of months, people have been paying a ton of attention to all of the work that you are doing that are very knowledgeable about PDABs just generally speaking throughout the country. And whenever they reach out to have a conversation, it's always the case that they are incredibly impressed about all of the great work that is being done and how far along the path that you all are.

And it's really a testament to all of the work that you're doing and all of the work that the team at the Division is doing, really the team just across the Board at the Division, the A.G.'s office, everybody. So it's a thank you to everybody, but most importantly, the Board members, and it really has been I think one of the amendments that went on to the legislation back a couple of years ago is to make sure that we appointed and the governor appointed experts on to the Board, and it's a testament to that

amendment that you all are here and that you're doing all the great work that you're doing.

We're incredibly thankful about the work that you're doing. The reason why I think we are moving as expeditiously and as, I think, concretely as you are is because you all are experts in the field and it's impressive every time that I get an update on the work that you're doing from the team, really how far you've gotten.

So really again, it's mostly just a thank you. I'm unfortunately not going to be able to hang out with you all day. I've got to hop off right after that. But like I said, it's been a while since I came and told you directly how thankful I am for all the work that you're doing. I know we don't pay you incredibly well and I know my thanks doesn't go too far, but it's good for me to come in and thank you personally every once in a while.

So again, thank you very much, folks.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you, Commissioner, for allowing us to do the work.

COMMISSIONER MICHAEL CONWAY:

Absolutely.

CHAIR GAIL MIZNER: And thank you, Commissioner, for your support of our work.

BOARDMEMBER CATHERINE HARSHBARGER: And a special thank you to the executive team that we have. You really have some dynamic people working to help support us in our work, and I really can't thank you enough for the level of credibility they lend to this project.

COMMISSIONER MICHAEL CONWAY: Honestly, Cathy, thank you very much for saying that. They don't get to hear that. I tell them that all the time, I know you guys do too, but it's great for them to hear it publicly as well because they're awesome, they're rock stars.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, they are.

COMMISSIONER MICHAEL CONWAY: All right, folks, I'll let you get back to your meeting. But again, thank you. Have a good meeting. I will stop by again soon enough I'm sure.

CHAIR GAIL MIZNER: Thank you very much, Commissioner. We really appreciate your support.

COMMISSIONER MICHAEL CONWAY: Thank you, Madam Chair.
BOARDMEMBER CATHERINE HARSHBARGER: Chair Mizner?
CHAIR GAIL MIZNER: Yes.
BOARDMEMBER CATHERINE HARSHBARGER: I was wondering if we could, at some point, I would like to have an executive session to talk about -- talk with legal, get legal advice on recent correspondence.
CHAIR GAIL MIZNER: Okay. Lila, would you like us to do that now or would you prefer to give your director update first.
LILA CUMMINGS: I'd be happy to run through the director update first, so we can get that out of the way, and then maybe right after that if that sounds okay.
BOARDMEMBER CATHERINE HARSHBARGER: It's fine with me.
CHAIR GAIL MIZNER: Sounds great. Thank you.
LILA CUMMINGS: All right, well, thank you. So I just have two quick updates: 2024 legislative session and affordability review policy changes.

So just want to make you all situationally aware of some of the goings ons of the state legislature and the general assembly, so there's just two introduced bills that I would like to call to your attention: the first is Senate Bill 24-060, and that's a prescription drug affordability Board exempt orphan drugs. It details kind of exactly what the title says and does directly impact your statute. And then another one that is going through is Senate -- or that has been introduced is Senate Bill 24-077, and this is prescription drug manufacturer requirements, so it would require a level of registration for prescription drug manufacturers with the state.
If you have any kind of specific questions on these, be happy to connect you offline with our leg team, but these are two that have been introduced. There may be more this session. We got a couple of more months, so we'll just continue to kind of keep you situationally aware.
And then I will say that as of right now, I believe it's just Senate Bill 60 that has been calendared, so it's going to have its first

committee hearing next Thursday is what it's currently scheduled for.
BOARDMEMBER CATHERINE HARSHBARGER: Lila, who's carrying that bill, please, do you know?
LILA CUMMINGS: I do not know the sponsors offhand; our legislative team does. I should know the sponsors. I could look that up for you.
BOARDMEMBER CATHERINE HARSHBARGER: No problem. I just was curious. I can look it up too, so thank you.
LILA CUMMINGS: Okay, thank you. All right, and we can go to the next one.
Okay, so affordability review policy changes. At your last meeting, actually at the last few meetings, we have talked about potential changes and redlines to both the affordability review rule, as well as policy documents. And these potential changes have really been focused on feedback we've gotten from you all, as well as stakeholders, around the Board's ability to -- or potential ability to consider a prescription drugs orphan drug designation earlier in the process and specifically an ask of could you all

consider it during the selection stage.
Additionally, we've gotten some great feedback, constructive feedback from stakeholders on how we could engage patients and caregivers differently, as well as alternative ways to engage individual with scientific and medical training, so we've begun a redline. I think due to timing we didn't think today was the right meeting to bring that before you all to start looking at and discussing. I think the plan would be for us to do that at your next meeting. And then also note too that it wouldn't impact these affordability reviews; it would be for your next round of affordability reviews.
A question I have and would just like to get a temperature check from Board members is, would you all like to see redlines first and then we reach out to some of the stakeholders to kind of get their thoughts, or would you all like us to kind of present initial drafts of these redlines directly to stakeholders, start to gather their response, and then come to you with redlines. I was kind of curious which direction you'd like us to go.
BOARDMEMBER JAMES JUSTIN VANDENBERG:

Lila, who are the stakeholders that we're thinking of -- I guess it's to ask for their feedback before then it comes to us versus coming to us, possibly tweaking them before going out.

LILA CUMMINGS: Good question. I think so, for orphan drug designation, there are some specific groups, so I'm thinking of the Rare Disease Advisory Council over at CPHE, the National Organization of Rare Diseases. On the alternate ways to engage with patients and caregivers, I think we've just gotten some good feedback from specific conditions, specific consumer groups, so we'd reach out to them.

And then on scientific and medical training, I think we've kind of heard from you all that having a non-clinician in the middle of the conversation between clinicians maybe isn't the most efficient way, so that would probably -- I think will kind of engage in that.

I think with this, if you all -- and we would plan on this at some point. We'd also have just an open to any stakeholder to engage, so probably just a stakeholder meeting, but those are the groups that I think we're thinking about.

BOARDMEMBER AMY GUTIERREZ: Lila, what

would be the staff's recommendation in terms of what you believe would be most effective?

LILA CUMMINGS: I think it might be most efficient if we just go directly to stakeholders first with some of the redlines, and we can bring them to you all kind of after we've vetted them a little bit with stakeholders and kind of identified areas where we agree. And we can also, if we disagree with stakeholders, we can at least explain why we disagree.

So, yeah, I'd say allowing us to kind of go forth and share redlines earlier with stakeholders might be the most efficient.

BOARDMEMBER AMY GUTIERREZ: I don't know about the other Board members, but I'd recommend that we do have you work with the stakeholders first before we saw the redline. I don't know, fellow Board members, what do you think?

BOARDMEMBER JAMES JUSTIN VANDENBERG: I agree with you, Amy, yeah, to get that feedback and not have more of a back and forth, if it's coming to us, then going back out, and now the changes, and then to come back to us. I think you're on the right track.

CHAIR GAIL MIZNER: That sounds fine to me too. I apologize to everyone. I can't make my camera work. I'm working on it.

LILA CUMMINGS: Miss Harshbarger, Dr. Diab, any objections to kind of going out to stakeholders first?

BOARDMEMBER SAMI DIAB: No, I agree with that.

LILA CUMMINGS: Okay. Okay, then we will plan on doing that. And for the stakeholders that are listening in, we'll take a look at kind of calendars over the coming weeks and months and get some things on the website and on the LISTSERV for how we can engage.

And that concludes my updates.

I'll just make one last comment before we move on. Clearly, I think you can hear my voice is a little sore, not quite at 100 percent, so I may be going off camera and on mute more frequently this meeting. Please know I'm still listening, I might just be getting a hot cup of water, so thanks.

CHAIR GAIL MIZNER: Okay. Thank you, Lila. So it sounds like at this point, we should vote about whether we want to go into executive

session. Do I have a motion to meet in executive session to discuss legal questions that Ms. Harshbarger has.

ATTORNEY ABBY CHESTNUT: And actually, Dr. Mizner, if I can just interject.

CHAIR GAIL MIZNER: Yeah.

ATTORNEY ABBY CHESTNUT: So without waiving any privilege, Ms. Harshbarger, if you could just maybe specify with a little bit more detail what you want the topic on legal advice to be. We need to be a little bit more specific in the motion to go into executive session. And we also -- actually, let's just start there, Cathy, if you don't mind. Which correspondence were you wanting to get legal advice on?

I'm sorry, you're on mute.

BOARDMEMBER CATHERINE HARSHBARGER: Can you hear me now?

ATTORNEY ABBY CHESTNUT: Yes.

BOARDMEMBER CATHERINE HARSHBARGER: Okay. I just don't know where my camera went, but anyway...

I wanted to talk about the -- and that's what I had switched to, in specific, the letter received from Community Access National

Network.
ATTORNEY ABBY CHESTNUT: Okay. So I believe since that public comment letter was received for one of these affordability reviews, we're happy to provide legal advice on that, and I can help kind of formulate the motion. But since Dr. Diab has a conflict with that drug, I believe it's Genvoya, but please correct me if I'm mistaken. So since Dr. Diab has a conflict with that drug, we'll just ask that the remaining four Board members vote. Dr. Diab, you're welcome to vote us into executive session, but we won't have you join us.
So then I'll kind of phrase the motion, but Cathy, please correct me if this is not correct. So are you asking that the Board move into executive session to receive legal advice from its attorneys regarding the public comment letter received relating to Genvoya, pursuant to Section 24-6-402(3)(a)(II)?
BOARDMEMBER CATHERINE HARSHBARGER: Yes, I am. Thank you.
ATTORNEY ABBY CHESTNUT: Okay.
BOARDMEMBER AMY GUTIERREZ: I'll second Cathy's motion.

CHAIR GAIL MIZNER: So moved.
ATTORNEY ABBY CHESTNUT: Okay.
BOARDMEMBER AMY GUTIERREZ: And I'll second, Amy Gutierrez.
CHAIR GAIL MIZNER: Thank you. So sorry, who -- Ms. Harshbarger moved and Dr. Guttierez seconded to convene in executive session. We need to vote on that, so all in favor, please raise your hand and say aye.
BOARDMEMBER AMY GUTIERREZ: Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
BOARDMEMBER JAMES JUSTIN VANDENBERG: Aye.
BOARDMEMBER CATHERINE HARSHBARGER: Aye.
CHAIR GAIL MIZNER: Thank you. The motion passes and the Board will now convene in executive session. The public is now excused.
LILA CUMMINGS: And just note for members of the public, the slide will be up and we will be back when this is done.
(00:19:09 Executive Session begins)
(00:33:36 Executive Session ends)
CHAIR GAIL MIZNER: Thank you everyone,

we're back. The Board has adjourned its executive session. The Board received legal advice regarding responding to public comment on Genvoya. The Board conducted no formal business within the meeting.
Next on the agenda is a discussion of Enbrel. Before we begin discussion of the affordability review data, Board members will need to disclose conflicts of interest related to the prescription drugs on today's agenda, Enbrel and Genvoya. Callie will do a roll call.
CALLIE ANN SHELTON: Dr. Sami Diab.
BOARDMEMBER SAMI DIAB: Yeah, I have conflict with both drugs.
CALLIE ANN SHELTON: Thank you, Sami. Dr. Amy Gutierrez.
BOARDMEMBER AMY GUTIERREZ: No conflicts.
CALLIE ANN SHELTON: Cathy Harshbarger.
BOARDMEMBER CATHERINE HARSHBARGER: No conflict.
CALLIE ANN SHELTON: Dr. Gail Mizner.
CHAIR GAIL MIZNER: No conflict.
CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: No conflict.
CHAIR GAIL MIZNER: Thank you. So we do have a quorum of four people to proceed. Before we begin deliberation, I'd like to note that all Board members were present at the December 8th meeting when staff presented draft evidence for the Enbrel affordability review. I'd like to also note that the Board members were provided with the entire unredacted draft report on February 9th. I'm sure everyone has read that, as have I.
To ensure that all Board members have had an opportunity to review the information in the draft report, I'd like to ask if any Board member feels we do not have sufficient information to deliberate regarding unaffordability for Enbrel today. Is there anybody who feels that we need further information before deliberating?
BOARDMEMBER CATHERINE HARSHBARGER: Nope.
CHAIR GAIL MIZNER: Okay. If there are no concerns, are there any objections to moving forward with deliberation?

BOARDMEMBER CATHERINE HARSHBARGER: No from Cathy.
CHAIR GAIL MIZNER: Okay, good. Lila, let's move forward with deliberation.
LILA CUMMINGS: All right. Thank you, Chair Mizner. We can go to the next slide.
So I will note that we have received several suggestions for redlines. Board members, that was those redlines were shared in your confidential protected folder, so you have the unredacted confidential version.
I also have on my desktop a redacted public version and was planning to open those documents up and we will go to them to walk through the changes as we go throughout the report but do let me know if you kind of would like the cadence to go any differently.
So we'll just start with therapeutic and utilization profile overview. I will say that, you know, the next I believe 40 slides are really just copy and paste or screenshots from the report itself, so we will defer to you on how much time you would like to spend discussing each slide. To save my voice, I'm not going to read each slide, but we'll leave it up on the screen

for a bit, and then you all can kind of discuss as you see fit.
I will note that when it comes to potential redlines to the report, the redlines that I'll share on my screen and that you all have in your folder, the redlines that we made were really around pulling up data sources. So we received some recommendations from Board members individually to kind of highlight things in appendices or to pull more data from source materials that were already footnoted and cited, so that's what today's redlines really focus on.
Before next Friday, if you all are in a space where you are ready to adopt the final report, I will note that there are a number of typos and grammatical errors that we do plan on fixing that we've not redlined for you today. But then also would encourage, if there are style or tone changes that you all would like to see in the final report, we will continue accepting edits there.
So these are for the therapeutic and utilization profile view includes information about Enbrel's clinical efficacy and the people who use it. Information is provided regarding

its indication, utilizer profile, health equity impact, and therapeutic alternatives, and these are the appendices with that information is pulled from. We can go to the next slide.
So Enbrel has six indications, six FDA approved indications: rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile idiopathic arthritis. And then October of 2023, an additional indication was FDA approved, and that's polyarticular juvenile idiopathic arthritis.
And actually, I'm going to pause here. This is actually -- apologies -- this is inaccurate. Juvenile idiopathic arthritis, and it's accurate in your report, juvenile idiopathic arthritis is not one of the indications; it's juvenile psoriatic arthritis. And so, we can get into that in future slides, but in your report, it is accurate. Apologies for this. Okay, next slide.
Orphan drug status. So Enbrel is classified by the World Health Organization Anatomical (ATC) as a tumor necrosis factor alpha (TNF) inhibitor. And the FDA granted orphan drug

designation in 1998 for polyarticular-course juvenile rheumatoid arthritis, which is now referred to as polyarticular juvenile idiopathic arthritis.
BOARDMEMBER AMY GUTIERREZ: So, Lili, just a comment. The orphan drug designation is only for one indication.
LILA CUMMINGS: Correct.
BOARDMEMBER AMY GUTIERREZ: Not for all of them.
LILA CUMMINGS: Correct. Next slide.
And then here is information on utilization of Enbrel according to the All Payer Claims Database from 2018 to 2022. And I will note Appendix D, we've talked about kind of considerations and limitations with APC data before and further details are outlined in Appendix B.
Next slide.
So we do have some utilization and All Payer Claims Database about payer type, so you'll see here information on utilization across commercial markets, Medicaid and Medicare Advantage, as reported in the APCD.
BOARDMEMBER CATHERINE HARSHBARGER: I

think the one thing that really does indicate too is that the out-of-pocket costs and copays are probably going to be, as we're going to see later, are going to show that that impacts people more than it usually does because it's more of the private commercial insurances are paying the majority of the claims, I guess is the way I want to say it.

CHAIR GAIL MIZNER: You mean with more associated copays and deductibles and like that.

BOARDMEMBER CATHERINE HARSHBARGER: Right, yeah.

LILA CUMMINGS: Okay. Any other comments on this slide? Okay, next slide.

And then here it's visualized a different way, the same information but a slightly different format. Okay, next slide.

So there was some research done and it's kind of much more comprehensive in the appendix, in the associated appendix, but we did summarize a bit of a health equity literature review in the body of the summary report, but I know Board members have looked at the full appendix as well.

I will note something that is noted in

the report, which is it is difficult to find drug-specific health equity data most times. And so, a lot of what this research focuses on and summarizes is the specific conditions and indications that Enbrel treats and is not necessarily specific to Enbrel itself.

BOARDMEMBER CATHERINE HARSHBARGER: I think that one thing that was interesting is finding out that the Hispanic and Black patients were usually undertreated and underdiagnosed as a beginning factor of that. I thought that was of interest and I thought that there's a map that shows that really, there's quite a bit of disparity within the different counties in the state as far as being able to access this medication.

CHAIR GAIL MIZNER: There are a paucity of rheumatologists in many rural areas.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER AMY GUTIERREZ: We did, however, have the SVI score numbers and in 2022, almost 50 percent of the patients lived in a county with a higher SVI score than the statewide average.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: Go to the next slide.

BOARDMEMBER CATHERINE HARSHBARGER: Really speaks volumes.

CHAIR GAIL MIZNER: Yeah. That would seem to indicate that there may be people in those purple counties, if I'm interpreting this correctly, that are either not diagnosed or diagnosed and unable to access certain medications.

LILA CUMMINGS: And also I apologize for not saying this earlier. We are joined today by a number of in-house and contract colleagues who are on hand to answer any questions you might have. I think they'll be kind of more in the coming slides, but we have Kate Davidson, our manager of insurance data science, as well as folks from the program on regulations, therapeutics, and law portal, specifically Dr. Ben Rome and Dr. Aaron Kesselheim are here today to answer any questions you might have. So welcome and apologies for not introducing you all earlier.

BOARDMEMBER CATHERINE HARSHBARGER: I

think these purple areas also -- I just read some of my notes. It said that the low-income people are also not as likely to have access to this drug as well.

LILA CUMMINGS: I don't know if we necessarily had information specific to Enbrel on access. I believe the research just pointed out that access generally to medications (sound glitch) across race and ethnicity.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: All right, so we'll get into therapeutic alternatives. So I will say you all made a decision with previous drugs to -- I guess I should just say this is the first time that kind of a deeper dive into therapeutic alternatives is before you all.

So here are the in-class therapeutic alternatives -- brand name therapeutic alternatives. You'll see them up there on the screen. I will not read through them.

I will note in the affordability review summary report, we did include additional information regarding Humira and Remicade having biosimilars. I'll let you all kind of have this

discussion a bit, then I'm going to show you my screen and pull up the redlined information that was added. But we just wanted to acknowledge that there is -- you know, that Humira and Remicade do have biosimilar products that have been introduced within the past five years.

But then I'll also note that the utilization of those biosimilars, because of the lag in claims data, was very, very small, so there was not an analysis done from the APCD data of biosimilars.

BOARDMEMBER AMY GUTIERREZ: I'd like to echo that. One of the things I noted, Humira was not available in biosimilar form when this analysis was done, but it was done for our neighbors fund release. And payers do have different -- from my experience, payers have different types of access depending on the drug.

The other thing that strikes me as I look at this is, most of these are probably pharmacy benefit drugs with the exception of Infliximab Remicade, which is an infusion. So as we start looking at copays and what the -- they're under a different benefit structure than the pharmacy benefit, the regional pharmacy

benefit. So I think we need to keep that in mind as we go down the road in looking at costs.

CHAIR GAIL MIZNER: So, Amy, you feel that Infliximab Remicade is sort of less comparable because it requires in-house infusion.

BOARDMEMBER AMY GUTIERREZ: It's usually typical -- and Justin chime in -- but usually medical benefits and pharmacy benefits have different copay structures, so it's kind of different. It's really hard to compare them as one-to-one when we start looking at copay and co-insurance.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Most of the thinking along -- absolutely right, Amy, but also thinking too of the access of even a location of an infusion center to where one could even be administered, especially in more of your rural areas; whereas, as a self-injection, subcutaneous has its own other access benefit. So just keeping that in mind too as we move down. But, yeah, as far as the pay structure, it's going to be very different.

LILA CUMMINGS: Okay. I think we can move on to the next slide. And then here is information on the utilization of both Enbrel and

its therapeutic targets over five years. So we'll just leave this up for a second.

BOARDMEMBER CATHERINE HARSHBARGER: I think noticing that Humira is by far twice the amount of people are utilizing that versus Enbrel. I don't know this, but probably as pharmacists you do, but is Humira maybe the first line or is there anything that's basically considered first line?

CHAIR GAIL MIZNER: There really isn't, Cathy, no. I mean, there's a huge armamentarium of rheumatoid arthritis and autoimmune drugs and there is no -- nothing that particularly says that you should use one over another.

BOARDMEMBER AMY GUTIERREZ: However, when we look at some of the patient comments and feedback we got in the report, there were some comments where we had to go back to step therapy. So my guess is given the fact that Humira is now biosimilar, at least in today's market, that that may be a workhorse for a lot of payers just because of the price comparison, and they may be using it as first line versus escalation.

I think Gail's right. There's a lot of inter-variability, but if you're newly diagnosed,

you got to stop somewhere, so I think they're probably utilizing the biosimilars more.

CHAIR GAIL MIZNER: I'm sure it depends in part on which drugs will be approved by their insurance. You know, there's a simple difference between Enbrel and Humira, which is that Humira is injected every two weeks normally and Enbrel injected every week normally, so few times having to inject yourself, you know. But there isn't a sort of this is what you start first, this is what -- unless you're looking at methotrexate, which has been traditionally what is often started first, but that's not actually necessarily current practice for I think many rheumatologists.

BOARDMEMBER CATHERINE HARSHBARGER: And I'm not sure totally on the cost, but I think in the graphs that we saw in our report, Humira cost-wise isn't cheaper, I guess is the way I'd put it; it's very expensive as well.

BOARDMEMBER AMY GUTIERREZ: Back in 2022, Cathy, yes. But after the -- it's kind of like whenever something goes biosimilar, it's kind of like a generic competition; you have multiple vendors that come up or pharmaceutical

manufacturers that come into the playing field. So just that competition lowers the price. That's kind of -- this is an unusual situation with this drug, given that the biosimilars didn't become available until 2023.

CHAIR GAIL MIZNER: And as you may recall, we actually decided not to do an affordability review on Humira because of those biosimilars that had become available.

BOARDMEMBER CATHERINE HARSHBARGER: Right, right, okay.

CHAIR GAIL MIZNER: It came out in the very expensive range as well, but that was the reason we did not decide -- we decided not to do an affordability review of it.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that's for that review.

LILA CUMMINGS: And they're just echoing something that I believe Dr. Guttierez said. We, in talking with patients and caregivers and looking at the survey results, formulary placement seemed to -- that was something we heard from patients that impacted them across Enbrel and therapeutic alternatives was the different formulary placements.

BOARDMEMBER AMY GUTIERREZ: I think I read them saying that I was stabilized on Enbrel, but because the insurance wanted me to go try another agent again, I had to go do that before I could get access to it. I think I recall reading that.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that happens unfortunately. You know, it's hard for patients and providers because they want to go with the drug they believe is going to be the best one, but that cost factor comes into play.

LILA CUMMINGS: We can keep moving along. So that kind of summarizes the therapeutic and utilization profile. There's more information in the report. And actually, I'm thinking that maybe one of the structures could be we'd go through all the slides for each drug, I will share my screen because I just want to make sure everybody specifically sees the redlines that we've proposed so far. So we'll get through all the slides and then I'll verbally mention them as we go. And we'll come, I'll share my screen and show you the redlines that we've made based on your input because you all

also have some good information for us.

So price and cost profile overview is next. This profile includes information on why different entities along the prescription drug supply chain or what do they charge for Enbrel, as well as what different entities pay. Information is also provided regarding Enbrel's financial effects on health, medical, and social services costs. You'll see there's a number of appendices that this relies on.

I will just call out in particular Appendix D, relative financial effects. Because Enbrel has, you know, six indications and five in particular that have had, you know, prior FDA approval prior to this past October, there is a lot of detailed information from across a number of national/international organizations, as well as from the manufacturer themselves regarding the relative financial effects of Enbrel. They are not summarized in a table in the summary report. Instead, we've encouraged Board members to go read Appendix D in full because there's a lot of great information there. So just noting that, that that's the kind of one time we said please go read this appendix. That's sounded a little

weird. I know you all read the appendices, but that one in particular has the information.

So next slide.

All right, so here is some summary statistics regarding both price and cost per person statistics, as well as statewide price and cost statistics as of January 1st, 2024. And then I'll just note since Enbrel's introduction, the WAC has increased over 1500 percent. So we'll leave this up for a bit, see if there's any questions, see if there's any clarifications that are needed.

BOARDMEMBER CATHERINE HARSHBARGER: I think the total -- yeah, I think the total out-of-pocket costs we showed was annually about 3,980, right, when you combined that with the copays.

LILA CUMMINGS: Yes. We do have, like, a deeper dive into out-of-pocket costs in a couple of slides. And you're correct, so there are times where -- and this is noted in the report -- there are times where Medicaid patients out-of-pocket costs are included in a statistic and there are times when it is not.

And we note that this is because

Medicaid patients typically pay zero to $3.00, so it could potentially, if you're trying to focus in on what the average commercially insured patient is paying, if you include Medicaid data, it's going to skew the results. And so, this average patient paid per person per year out of pocket of $2,295; that is including Medicaid patients. But then later in the report, we do specifically call out the average out-of-pocket for just commercially insured patients and that is that number you were mentioning, Cathy.

And then, Kate Davidson, correct me if I'm wrong on any of this.

KATE DAVIDSON: I do have a slight correction. This is still not including Medicaid for any average, we're not including Medicaid. This is including the Medicare Advantage folks, and so that's why this is different than that $3900 number that you referenced, Cathy, which is only commercially insured folks.

BOARDMEMBER CATHERINE HARSHBARGER: Okay. Still a significant number. When I looked at this, it said in the surveys that you did -- I believe it's the surveys, somebody can correct me -- that zero to $50 was paid by 57 percent of the

respondents, .3, and then the rest of it they paid between $9,8- -- some were as high as $9,850 to almost $10,000, 990, so those are significant variabilities in the cost to the patient that I just wanted to bring up. Because total patient paid out, it was, like, $9.8 million, significant number. Oh, it's right there on that page, total patient paid. I find that significant.

BOARDMEMBER JAMES JUSTIN VANDENBERG: What was the number of outliers again that had this severe -- or, like, the very, very high out-of-pocket costs, Cathy, like what you had mentioned?

BOARDMEMBER CATHERINE HARSHBARGER: Well, there was 57.3 percent that were zero to 50, and then those that paid the 9850 -- Lila, can you help me with that -- or is it the difference?

KATE DAVIDSON: So this is from the APCD claims and kind of just bucketing how many people paid within a $50 bucket. So it was 57 percent of people paid between zero and $50, and then a number of people that I can't tell you because it is 12 or fewer paid in that large chunk. And in the report, it shows kind of that

histogram, which is very, very skewed to a lower dollar amount, but swings all the way out to some small number of individuals who paid that much.

BOARDMEMBER AMY GUTIERREZ: The APCD database, if they were getting manufacturer patient assistance, would it show up still as a patient paid amount?

KATE DAVIDSON: It depends on how the assistance comes across, but it's very possible those individuals at the very high tail of that were receiving some sort of assistance and that's just not something that we're able to see in that database.

BOARDMEMBER AMY GUTIERREZ: So the survey information that Cathy referenced might be a better indicator of what's really happening with patients.

BOARDMEMBER CATHERINE HARSHBARGER: And I guess I see too that if 57 percent have a zero to $50, that's nice, but then there's still a huge amount of people that are paying more, you know, there's still a significant number there.

BOARDMEMBER AMY GUTIERREZ: Agreed.

CHAIR GAIL MIZNER: As I recall in the patient surveys, a significant number of patients

reported that the amount they had to pay was problematic for them.

BOARDMEMBER CATHERINE HARSHBARGER: Yes, they said that. And they also said that sometimes they were going without other things they needed in their lives to be able to afford that medication in those patient surveys. In fact, I actually put those numbers down: 52 percent of the people said they had to adjust for cost of medications in their budgets basically, and 21 percent said that they had medical debt as a result of that, and that was compared to nationally. Nationally, the 52 percent as compared to 27 percent nationally, and 21 percent medical debt in Colorado versus 13 nationally, so a higher amount of people are actually in medical debt as a result of this medication.

CHAIR GAIL MIZNER: You mean it seems worse in Colorado than it does nationally.

BOARDMEMBER CATHERINE HARSHBARGER: Correct.

CHAIR GAIL MIZNER: Because that was 21 out of 38, I believe.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah. I took the different percentages because

it speaks to it, yeah.
LILA CUMMINGS: We can actually keep moving along because I think these slides will get into some of the survey results and patient out-of-pocket response.
BOARDMEMBER CATHERINE HARSHBARGER: Sorry about that, Lila.
LILA CUMMINGS: Oh, no, please don't be sorry. Okay, so out-of-pocket estimates. So you know, we've got the All Payer Claims Database, as well as information from survey responses. Here is one way to visualize differences between Enbrel and its in-class therapeutic alternatives across the average copay, average deductible, and average total out-of-pocket cost.
So there's a lot on this slide, so I'm just going to give a moment and turn it over to you all.
BOARDMEMBER AMY GUTIERREZ: When I look at this slide, this is what made me make that comment about the Remicade being different because I think it's a different structure. When I look at the bottom, Enbrel, Humira, Cimzia, and Simponi, those are more the pharmacy benefit. I see them kind of in the same benefit structure

versus Remicade.
CHAIR GAIL MIZNER: So even if we take out Remicade, we still are seeing that Enbrel, in terms of out-of-pocket costs is second only to Humira, which of course, this is 2022, the most recent data may be -- is likely changing given the biosimilars at least that people are accessing biosimilars of Humira. And so, Enbrel does look relatively more expensive in terms of out-of-pocket costs for what patients in Colorado are paying.
BOARDMEMBER AMY GUTIERREZ: I agree with you, Gail.
CHAIR GAIL MIZNER: Any other comments on this before Lila moves on? Kate, anything to add?
BOARDMEMBER CATHERINE HARSHBARGER: There was, on one of those surveys, it did mention 10 patients, but, you know, we're talking about 22 or 23 people that were surveyed, that they still had trouble paying for their medication, so I thought that was pretty significant too out of the total number that we had -- well, almost half of the people were having trouble paying for it.

CHAIR GAIL MIZNER: I think you may have that slide coming up, right, Lila?
LILA CUMMINGS: All right, so here is information. This is just a better breakdown of the average month. And so, in the average month, what is someone paying across different types of out-of-pocket costs. Kate, before I speak, please remind me, is this commercial only or this got commercial and Medicare Advantage?
KATE DAVIDSON: I believe this is commercial only. Yes, this is commercial only.
LILA CUMMINGS: Okay.
BOARDMEMBER AMY GUTIERREZ: When we look at the out-of-pocket costs for Remicade, given that it is an infusion, is that just the drug or is it the drug with the IV solution and all of that, or do we know?
KATE DAVIDSON: I think it's everything. So the claim itself will include all of the costs associated with the infusion, so this is the copay associated with that medical distribution of the drug, if you will, so it does include that difference.
DR. BEN ROME: Dr. Guttierez, this is Dr. Rome from PORTAL. We've looked at this

separately as separate claims in prior studies and the cost of -- usually, you know, the out-of-pocket cost is mostly for the drug claim, the code that's for the drug; that includes the administration of the drug too. But there is a separate code, an administration code, that's like a sort of generic administration of an IV solution for cancer or for non-cancer, and it depends on the time and how long it takes. So those can generate additional out-of-pocket costs, but they tend to be small relative to the out-of-pocket costs of the drug itself.
BOARDMEMBER AMY GUTIERREZ: It does include the labor and everything for infusing; that's where I was kind of going with it.
DR. BEN ROME: Yeah. I mean, it includes the storage and delivery of the drug; there is a separate administration cost there that, you know, healthcare facilities can bill to insurance company. Obviously, that might vary by payer or how that's negotiated and whether they're allowed to bill that.
BOARDMEMBER AMY GUTIERREZ: Thanks.
BOARDMEMBER CATHERINE HARSHBARGER: The only comment I want to make on this is the

average total out-of-pocket per month is $373, and I always think that in relationship to what does it cost to have your house, what does it cost to buy groceries every week, especially right now. And so, $373 is a lot of out-of-pocket per month, it really is a lot, especially if you start talking about single-parent families or any of that going on as well.

CHAIR GAIL MIZNER: And in this review of just commercial insurance, Enbrel is the most expensive of the therapeutic alternatives.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

CHAIR GAIL MIZNER: Any other comments on this before Lila moves on?

LILA CUMMINGS: Okay. And so, this is similar information shown in a different way, but I will note this is annual. So this table shows the annual change and the annual average out-of-pocket amounts comparing Enbrel, which is in dark purple, to its therapeutic alternatives. Each line is labeled with the name of the therapeutic alternative and then the percent change from 2018 to 2022, and Enbrel has the third highest increase in total out-of-pocket costs with a 77.8

percent increase.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I mean, it doesn't seem like the story has really changed much on each slide that we've gone to. You know, I think any normal person, they're seeing Cimzia, like financial, you know, seem to be problematic to that level of having to pay an out-of-pocket cost there. I think that's where Amy was asking earlier about where does the copay cards come in or any kind of patient assistance. But even if it is adding in there, that's still - - well, I guess that's not reflective in this, so if it's showing that amount with that copay card, let's say if it was integrated, how much would that bring that 77.8 percent down.

I think that's kind of where it's that missing puzzle piece to see is that truly a large impact, a sufficient impact to say that it's making a change or making a dent for patient access or ability to pay. I don't know, that's kind of some of the pieces I'm trying to look for and tease out from the information here.

BOARDMEMBER AMY GUTIERREZ: I think Cathy said it earlier and I agree with you. Cathy said earlier that in the patient comments,

I think 30 percent of them said they still had trouble affording Enbrel, like paying their rent. And they would know about -- I mean, patient manufacturer programs are out there, so we still have -- and that's a big percentage. To have 30 percent have to decide between paying their rent or food or transportation versus their drug, it's a big chunk.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Absolutely.

CHAIR GAIL MIZNER: And I think, you know, there were also patient comments about the difficulty of having to be on the phone all day to access the patient assistance. It doesn't sound like the programs are particularly easy or that they always cover enough. I mean, just going back to one of the first slides, it's just impressive that the WAC would have increased 1500 percent; that is...

BOARDMEMBER JAMES JUSTIN VANDENBERG: Is that year over year or is that from when it first came to...

CHAIR GAIL MIZNER: When it first came out, which was a long time ago.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I

just want to clarify on that one. I'm, like, did it go from (crosstalk) and then it went up to that? But still, long run, you know...

CHAIR GAIL MIZNER: Yeah.

BOARDMEMBER AMY GUTIERREZ: And, Lila, are we going to have a slide -- I'll hold my question then -- on rebates, because I know that's the next section on the report.

LILA CUMMINGS: We do have a slide with those confidential, so I'd be happy to kind of -- if you all would like to go into executive session. I will just reemphasize for folks. So we have rebate estimate data that we obtained through an organization called SSR Health. We are not allowed to share that information publicly. Board members cannot discuss if it is a high or a low rebate drug.

So Board members, you have access to that information, but you can't give specific percentages. Can't say if, in your opinion, it is high or low. You can say if a rebate has increased or decreased over time, so that can be said publicly. But, unfortunately, I would have to hop into executive session, which we absolutely can do if you all would like.

BOARDMEMBER AMY GUTIERREZ: Where I was going with this had nothing to do with the amount of the rebate. It had to do with the manufacturer, a letter that we received, where there was a contention that as the rebates go up, the drug price goes up. And I just wanted to see from Ben if there's any -- his thoughts on that. Because it was a pretty -- I mean, they even had diagrams in there about, well, when the rebate goes up, we have to increase our price to keep up or we're out of the market, so I just wanted to get the take, Ben, on what that comment was.

BOARDMEMBER CATHERINE HARSHBARGER: Is that the letter with the PBMs piece in it; are you talking about that one, Amy?

BOARDMEMBER AMY GUTIERREZ: Yeah, the payers. What they were alleging is the payers are getting or the PBMs are getting more of a rebate so they have to keep increasing the price. I just wanted to get some insight on that from our expert.

DR. BEN ROME: Sure. I mean, without talking specifically about Enbrel, in general what we've seen over the last decade or two has been that list prices for many brand-name drugs

have increased faster than inflation and rebates have gone up as well. There's been a widening gap, therefore, between sort of list and net prices. You know, it depends on the drug obviously in terms of what the net effect is on sort of net prices or after rebates and discounts. Although, you know, just to be clear, perhaps it's our health and all sorts of other estimates; this includes all sorts of discounts other than rebates as well and the supply chain.

So the net price is really the price that's received by the manufacturer but doesn't include sort of supply chain costs, of which there are always some supply chain costs to deliver a drug from the manufacturer to the patient, including the pharmacy fees and other sort of costs that, you know, everyone I think recognizes normal costs of doing business.

So that's just sort of some, like, general comments as you're sort of reviewing the rebate data. You know, there are many examples where the net prices have gone up despite increasing rebates, and, you know, just in other words, the increases and rebates did not fully offset the increases in list prices; that's just

sort of some general comments and for context.

BOARDMEMBER AMY GUTIERREZ: And I just brought it up just because we got it as a public comment and I wanted to understand that. Thank you.

CHAIR GAIL MIZNER: Do Board members feel the need to go into executive session to discuss confidential information?

BOARDMEMBER CATHERINE HARSHBARGER: No.

BOARDMEMBER AMY GUTIERREZ: No.

CHAIR GAIL MIZNER: Good.

LILA CUMMINGS: We can keep moving along, but if you change your mind, just let us know.

All right, so here is information on the relative financial effect. Not going to read the slide but will leave it up for a little bit. So there's really a couple of areas where we gather this input: input from patients and caregivers, input individuals with scientific and medical training, as well as review of different national and international health technology assessment organizations that do both clinical effectiveness research and summarization, as well as cost effectiveness, which we'll get to in a

second.

And then I'd also note too that we pulled information from the manufacturer, voluntarily submitted manufacturer documents with information they provided on the health effects of Enbrel.

I'll leave this up to just -- I was not going to read through but really want to leave time to highlight the input that was received from patients and caregivers on the health effects of Enbrel.

BOARDMEMBER AMY GUTIERREZ: Justin and Gail, since you're the other clinicians on here, what I recall reading is that Enbrel was the only one that worked in juvenile, is that right, or the others were actually more for the adult patients.

CHAIR GAIL MIZNER: I'm not sure it's the only one that works in juvenile. I think it's the only one approved.

BOARDMEMBER AMY GUTIERREZ: Approved, got it, okay.

CHAIR GAIL MIZNER: So it's not that other drugs aren't used.

BOARDMEMBER AMY GUTIERREZ: Are used

off label, yeah, got it.
CHAIR GAIL MIZNER: But I'm not a pediatrician, but that was my understanding.
LILA CUMMINGS: And I believe we can dive into appendices if we want. In Appendix I, input from individuals with scientific and medical training, we highlighted what was heard particularly around off-label usage.
BOARDMEMBER AMY GUTIERREZ: If you were going to use --
CHAIR GAIL MIZNER: That's what I think.
BOARDMEMBER AMY GUTIERREZ: If you had a patient with juvenile, the FDA approved indication would be use Enbrel.
LILA CUMMINGS: And I think a combination -- and be happy to pull these up -- a combination of the therapeutic alternatives appendix where it's listed which of the therapeutic alternatives are approved for specific indications, the six indications Enbrel is approved for, and then that Appendix I with input from individuals with scientific and medical training.
I will say staff did not conduct

research to identify -- you know, we really looked at each drug and its therapeutic alternative and what its FDA approved indications were. We did not do an indication-specific search where we looked at an indication and then looked at which prescription drugs were also approved.
BOARDMEMBER CATHERINE HARSHBARGER: I think you guys did a great job on that section, so thank you for that. I feel pretty good about it.
CHAIR GAIL MIZNER: I don't feel like we have to spend a lot of time on health effects. Enbrel is, it's clear Enbrel is an effective drug from a number of indications. There are a few patients who never find it effective, but there are other patients who find it extremely effective, and that's what the data shows. I mean, it's not news. It's a good drug. It's part of the armamentarium of rheumatologic agents.
DR. BEN ROME: This is Dr. Rome. Just on Table 4 of the report, it does list your therapeutic alternatives and the indications, as Lila was saying. So I think Golimumab or Simponi

received FDA approval for pediatric juvenile idiopathic arthritis in 2020.
LILA CUMMINGS: Thank you, Dr. Rome.
BOARDMEMBER CATHERINE HARSHBARGER: Thanks, Ben.
LILA CUMMINGS: Okay, we can move on to the next slide.
So here is a summary of the information gained from individuals with scientific and medical training, and we'll leave it up for a while as well.
BOARDMEMBER CATHERINE HARSHBARGER: The only thing is these are the same things we would see in the other drugs as well, right, because this is the indications that they have for any of them to be considered effective.
LILA CUMMINGS: Go ahead, Chair Mizner. Apologies.
CHAIR GAIL MIZNER: Detailing through the information, the appendices that have to do with this, I didn't feel we saw any evidence that Enbrel was less good or better than the therapeutic alternatives. Again, it's a good and effective drug.
BOARDMEMBER CATHERINE HARSHBARGER: I

think there was one report where it said Enbrel was inferior to Humira, but then there was another one that said it was superior to Remicade, but it was only a small amount of people, a small study, so there were still other alternatives basically.
CHAIR GAIL MIZNER: Yeah. I think that's clear, there are a variety of alternatives, both in just looking at TNF inhibitors and then looking at other kinds of (indiscernible) and biologics. But, you know, it's not a drug where I think we have to question that it's a worthwhile medication.
BOARDMEMBER CATHERINE HARSHBARGER: No, not at all.
CHAIR GAIL MIZNER: It's an effective medication.
BOARDMEMBER CATHERINE HARSHBARGER: Absolutely.
LILA CUMMINGS: I think we can move to the next slide because that...
And then this is what I was mentioning earlier. And Ms. Harshbarger, what you just mentioned is exactly from this appendix. If there's anything in the appendix you would like

us to touch on, happy to pull it up if you need, but we'll just leave this here for now.

We can keep moving on. I believe financial effects is next.

So here is one of the -- I think the full survey results from patients is found in Appendix H. It's coming in at 285 pages with kind of the full unedited answers. Something that we were really appreciative of is there were stakeholders that helped us get the word out when we reopened the survey in January, and so, I think we were pretty pleased with the response rate. But we did notice that there were, you know, a number -- there was a difference between national and Colorado, and so we've pulled that out here for a number of the questions.

I will say we got a suggestion to do exactly what you did on your own, Ms. Harshbarger, and put in percentages, so our plan would be to do that kind of through the appendices, as well as the report, to make it a little easier particularly when comparing national responses versus Colorado responses.

And when I pull up the edited version of the report, you'll see Table 12 around

utilization management, we've put in percentages. And then we're going to go through and do that for a number of -- any time there's a comparison between national and Colorado, we'll put the percentages in.

BOARDMEMBER AMY GUTIERREZ: I was going to recommend that same thing, Lila, so good. I've had both at my calculator and started doing those.

BOARDMEMBER CATHERINE HARSHBARGER: But I have to tell you this information was very helpful in the format that you gave, so I mean, I just did a little math; that was all.

CHAIR GAIL MIZNER: And just to say what we already said, that 20 out of 38 felt that the cost of medication had caused them to have to cut costs in other areas of their life is significant I think.

BOARDMEMBER CATHERINE HARSHBARGER: I agree. And Coloradans struggle more so than even the national level, so that to me was also important to see.

CHAIR GAIL MIZNER: Right, even though the national level is still, you know, significant, but Colorado is even higher

percentage.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Speculation obviously. Do you think that has more to do with just the higher cost of living? Again, I mean, you know, like, the housing market, et cetera has gone up, I mean, exponentially to where you're comparing this market to homes in California. And I'm just -- again, now we're getting into a different area, but I'm just trying to think, like you said, having a higher percentage here from the responses to there, you know, what other factors are coming into play, and that one just pops into my mind immediately.

BOARDMEMBER CATHERINE HARSHBARGER: I think it's a good question. I think the biggest thing that I would remark is that we tend to do national markers against other metrics in healthcare, and so this is just one more that we take that national average basically and say here's what we think. So there's states that are higher and states that are lower, you know, because California is always one that you can

look at, but there's other states that are high, New York and those kinds of areas as well, and yet we're still outpacing it in the wrong direction.

CHAIR GAIL MIZNER: And our basic charge is to decide whether this medication is unaffordable for Coloradans, so that Colorado data, I'm glad that you separated it out.

BOARDMEMBER CATHERINE HARSHBARGER: I like that we had a national one to look at as comparison, absolutely very important.

BOARDMEMBER AMY GUTIERREZ: Even the national one at 28 percent or 27 percent, it's still a lot. It's like 50 percent in Colorado, even though we are twice as high, it's still an issue across the country.

BOARDMEMBER CATHERINE HARSHBARGER: Right.

CHAIR GAIL MIZNER: Should we move on?

LILA CUMMINGS: Sorry, I was on mute. But, yes, happy to.

Okay, so then here is information from individuals with scientific and medical training. We'll leave it up for a moment for you all to take a look at, and then also survey responses

and summarize of meetings are in Appendix I as well.

BOARDMEMBER AMY GUTIERREZ: To me, looking at this kind of confirms what we were just talking about: there is affordability issues with this drug, given the amount of out-of-pocket expenses, the difficulty in getting it, patient assistance programs; it's kind of reiterating the same thing.

CHAIR GAIL MIZNER: That last comment is interesting to me. People who are undocumented can access financial assistance programs despite not being a U.S. citizen. There are -- certainly, there may be sometimes 340B programs that assist those patients, not all. And I really would be interested to know -- maybe that's confidential information, I don't know, for Enbrel; I don't think it should be confidential. Some assistance programs require a social security number and some do not, and that actually is a piece of information I would like to know.

BOARDMEMBER JAMES JUSTIN VANDENBERG: You're right, Gail. Every program is completely different. They can set whatever rules that they

want. I've seen it very specific, excludes a lot of areas; then I've seen some that are completely open. I mean, some of the easiest ones you just apply and essentially, you can get it, assuming you hit those little markers.

As far as what the requirements are, that is public knowledge to where we could ask staff to look that up as far as for Enbrel, if that's important in our review at this point, or would that be later on down the road.

CHAIR GAIL MIZNER: Well, I think it does -- would tell us something about affordability. If Enbrel is one of the programs that requires a social security number, therefore, requires you to be documented, that does exclude a significant number of people who might need it. So if that is information we can get from staff, that would be very useful I think. It's probably something somebody could look up very quickly just going on the Enbrel site actually.

LILA CUMMINGS: We pulled the information from Amgen's letter; they provided information tailored to us. We also looked at their website and what was publicly posted. That

is summarized, I believe, in Appendix K with rebate, discounts, and price concessions where we do a summary of manufacturer assistance programs.

BOARDMEMBER CATHERINE HARSHBARGER: I think for me, today anyway, I don't know that while that is important to note at some point, I don't know that it's going to get in the way of our decision today relative to Enbrel. And I say that because we still have statistics that show that people that are United States citizens and Coloradans are struggling. And so, for me, I see that as that's our core mission is to look at what is not affordable for people.

BOARDMEMBER AMY GUTIERREZ: And I agree with you, Cathy, especially if you look at that third bullet. Even if they aren't always aware and they have difficulty navigating the process, I would think that would be even more difficult for someone that's not a U.S. citizen to have to try figure all that out.

CHAIR GAIL MIZNER: Oh yeah, extraordinarily difficult.

And, Lila, this was an individual with scientific and medical training who said that the annual maximum copay amount that's awarded

decreased significantly in the last couple of years.

LILA CUMMINGS: My screen is a little...

CHAIR GAIL MIZNER: Looking at the fourth bullet there.

BOARDMEMBER CATHERINE HARSHBARGER: Annual maximum copay awarded.

CHAIR GAIL MIZNER: So I would summarize this input from individuals with scientific and medical training, essentially we're talking about rheumatologists and pharmacists who work with rheumatologic meds that this is proving to be pretty costly for people.

BOARDMEMBER CATHERINE HARSHBARGER: I'm guessing it's prohibited for some; some are even there that would like to be on Enbrel.

LILA CUMMINGS: Okay, we'll keep moving along. It's still financial effects. So this is a similar one around really taking a look at Appendix D for the specific cost effectiveness studies by indication. So if there's anything there that you would like to talk about?

I would say the summary of it was pretty similar to Chair Mizner, what you've

already said that some situations where folks have found it, where institutions have found it more or less, kind of right there in the middle. But if you have specific questions, I reference Appendix D.

We note this in the appendix. There's more research on cost effectiveness for the indications that utilize Enbrel more frequently, so rheumatoid arthritis and ankylosing spondylitis, those have kind of more research where some of the smaller utilization populations had less research.

CHAIR GAIL MIZNER: Anybody need more information there?

BOARDMEMBER CATHERINE HARSHBARGER: No.

LILA CUMMINGS: Next slide. So we've moving on to the third and final profile.

So this is the access to care profile, and it examines potential access concerns related to Enbrel and whether there's evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile includes an examination of potential relationships with changes between utilization, price and costs, as well as information about safety net providers,

utilization management requirements, and health benefit plan design. And these are the appendices where that information is pulled from.

Okay, next slide.

All right, so we'll start here with price effect on access. So this is just simply showing the change in Enbrel's wholesale acquisition costs since its introduction, as well as the change, the percent change in inflation.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I guess I'm curious. It's a very large number, but I'm curious to see what that compares to maybe the class of (indiscernible). But, like, are all of them doing that? Not saying it's right, but is this setting apart a higher rate than its competitors to where it seems -- I mean, just in general looking at it, it seems astronomical. But I don't know, just seeing it, like -- I don't know how to say the right word to it, but just trying to put it into a better context. Is every single drug out there going up at 1500 since it came out or that have been out on the market this long? My guess probably no, but I don't know, just wanted to...

CHAIR GAIL MIZNER: Looks like Dr. Rome

may have something to say.

DR. BEN ROME: I was going to add just one thing, which is that I know this graph only shows -- this is WAC data for Enbrel. Congress has released, you know, a public investigation comparing the WAC prices for Enbrel and Humira and shown that they increased sort of at the same rate, so this actually sort of stepwise increase with those two drugs. I don't think they looked at the other drugs, other therapeutic alternatives in the class. These are obviously the two most commonly used ones, but that gives you context within the class.

I think your other question (indiscernible) outside of the class is this abnormally high, and I think it is on the high end. There's, again, pretty good data that sort of looks at average price increases and it tends to be more in the, like, you know, 10 percent range per year on average for brand name drugs, so this is higher than average.

LILA CUMMINGS: I do want to highlight that in Appendix A for Enbrel, WAC, it's confidential, but there is information regarding the specific wholesale acquisition costs change

for Enbrel and all of its therapeutic alternatives, so you can access that information. It doesn't show percentage change; it just shows -- that's why it's confidential -- it shows the actual change in the wholesale acquisition cost.

BOARDMEMBER CATHERINE HARSHBARGER: My comment is it's high; that's what it is. It's high and even comparing with Humira, they both are high; that's my feedback from having read that appendix.

BOARDMEMBER AMY GUTIERREZ: Oh, go ahead, Cathy.

BOARDMEMBER CATHERINE HARSHBARGER: No, no. Ben's basically said that as well. I mean, the question with that always is what should it be, and the thing I keep saying to myself, it shouldn't be 1500 percent; that's what it shouldn't be. What it should be is up for debate, but it shouldn't be 1500 percent.

BOARDMEMBER AMY GUTIERREZ: I seem to recall reading somewhere they had something like 36 price hikes over this time period too, I mean, in terms of increases. I'm trying to find it on the report.

BOARDMEMBER JAMES JUSTIN VANDENBERG:

Amy, I'm trying to think, Amy, for some of the -- tying this into patients out-of-pocket, if it's a percentage. Oftentimes, on the commercial side, it's going off of AWP, not necessarily the WAC, and it's a percentage of that. And I'm just trying to think of -- but I assume you're not going to have an AWP that's below the WAC costs, so I guess you would see it in some degree fall in line with that. I'm just trying to match that up to then what's going to then translate to the patients either out-of-pocket.

BOARDMEMBER AMY GUTIERREZ: I'll bet if we graphed AWP, Justin, I'll bet we'd see the same type.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I'll bet you're right. You're right, okay.

BOARDMEMBER AMY GUTIERREZ: Because (sound glitch) increase.

BOARDMEMBER CATHERINE HARSHBARGER: Is AWP, isn't it something that is considered after the price is set by the manufacturer or no? I don't...

BOARDMEMBER JAMES JUSTIN VANDENBERG: It's the average wholesale price, so I mean, it can certainly change depending on the product and

depending on how your charging is working, the charging model, that can certainly change everything. You go off of WAC or AWP, but typically AWP is more than your wholesale acquisition cost because you're buying it for the acquisition, so that's going to be lower and then the wholesale price is going to be closer to what you're going to be selling it at.

BOARDMEMBER AMY GUTIERREZ: It's also set, Cathy, AWP is how pharmacy reimbursements are set. It's AWP minus a certain percentage and that determines pharmacy reimbursement, which in turn goes to the patient.

BOARDMEMBER CATHERINE HARSHBARGER: Right, okay. I knew that. I just wasn't sure which one was the egg and the chicken, so to speak, on that.

CHAIR GAIL MIZNER: So I think this is, you know, a percent increase of 1500 is very impressive, but going back to what I think is most important is whether this is proving to be unaffordable for Coloradans. So I'd suggest we move on to the next slide.

BOARDMEMBER CATHERINE HARSHBARGER: Agreed.

LILA CUMMINGS: One thing I want to note too, and we can think about maybe at your future meetings changing this, there's a lot of context that's in the reports that we're not pulling out for these slides. So we can kind of see next meeting if you all would like us to just run through the report.

I'll note on the previous slide that a different 1500 number was listed in the text and in the graphic, and that's because, as is noted in the report, one is analysis of change in WAC to today, but then the figures are these five-year lookbacks, and so, the analysis stopped in December of 2022. And so that's why that number is 1502, it's slightly because in January of this year, there was an increase in the WAC, and so you'll see discrepancies like that. We footnote them in the report, but feel free to ask us if you've got any clarifications.

BOARDMEMBER CATHERINE HARSHBARGER: I'm okay with your PowerPoints the way they are, just for my feedback.

LILA CUMMINGS: Then we can move on to the next slide. All right, so here is information regarding the therapeutic

alternatives.

So Humira and Remicade, as we mentioned before, have recent FDA approval by similar products. So while this affordability review doesn't contain that information, we do have information for the four other therapeutic alternatives. So this figure shows the monthly number of utilizers for Enbrel and therapeutic alternatives. And you'll note that general utilization of Enbrel has stayed consistent from January 2018 to December 2022, and it's the second highest utilized drug after Humira, which has increased significantly within that timeframe, though you'll see what could be a slight dip towards the end and to the point that you all have made, the introduction of biosimilars.

BOARDMEMBER AMY GUTIERREZ: This makes a big deal of the formularies. Like in the news, I guess it's public information, but CVS Caremark has actually taken Humira off their formulary, so they're basically going to biosimilar only. So that is effective April 1st, 2024, they announced it.

LILA CUMMINGS: Okay. Any other

questions? We'll keep moving along.
All right, now here are some statistics that were pulled kind of in accordance with your rule on policy about the potential effects of price on access.
So you've got information here just summarized largely from other places in the report. They really look at patient count changes over five years, the total paid amount, the average paid per person, this includes both out-of-pocket costs, as well as the plan paid, and then that breakdown of total plan paid and average out-of-pocket costs.
And then WAC per unit, you all have access to but it's been redacted on this slide.
BOARDMEMBER AMY GUTIERREZ: So the average per person paid went up $13,000 in four years, $1,000 a month.
BOARDMEMBER CATHERINE HARSHBARGER: Thanks, Lila.
LILA CUMMINGS: Absolutely.
CHAIR GAIL MIZNER: The average out-of-pocket just is high. The average out-of-pocket is high. It did go down a little bit between '22 and '21, but for people to be having to pay over

$2,000 a year for one medication is a lot.
BOARDMEMBER CATHERINE HARSHBARGER: Yeah, and there are some that are paying $1,000 a month, so that's -- as their copay, it sounded like, from some of the professionals that we had give us feedback.
LILA CUMMINGS: Okay. I think we can move on to the next slide.
All right, so here's some information on safety net providers, utilization management, and health benefit plan design. So one thing, and I do want to share this. I believe this is maybe the last slide for Enbrel, so we'll switch to the redlines that we made and I'll run through.
So there's complications with the 340B program in terms of providers are not allowed to disclose the discount in their 340B price. So we did talk with some safety net providers, but no voluntarily submitted information around utilization was provided. Though we did -- and Dr. Guttierez, I'll turn it over to you - we did pull information on just not specific to Enbrel, but the number of 340B covered entities in Colorado and specifically by entity type.

We also pulled information on the number of distinct and unique addresses that are in Colorado. So that information, Board members, you have it, it's in your confidential folder. I'll share it. There's nothing actually confidential in that document itself. But just to paint a picture of the number of 340B providers in the state, and it's information that Dr. Guttierez put out is easily accessible. So not specific to Enbrel, but just that contextual understanding of 340B providers in Colorado.
Dr. Guttierez, anything you'd like to add?
BOARDMEMBER AMY GUTIERREZ: Yeah. First, I just maintained a database that you can actually query for the state by provider, by active participation. It even includes the authorizing official, the contact information, and it's updated every year usually through recertification, but there is a national database.
I just want to make sure the report outlined that that did exist and we could actually reach out to 340B if we desired to do so in the future. I think, Lila, you had found the

website and you were able to pull some data.
I think you're on mute, Lila.
LILA CUMMINGS: Thank you. So thank you for that, Dr. Guttierez. And so as an additional to research around 340B were staff access data around the benefit plan coverage design and formula structure. Data was pulled for carriers and the individual small group markets for which the division receives annual rate filings.
And so of note of the 10 carriers that submitted filings, eight carriers cover four or more dosage forms of Enbrel. All carriers that cover Enbrel require prior authorization, and in total, 576 plans provide coverage for Enbrel. And the majority of carriers place Enbrel on the highest two formulary tiers, meaning a higher portion of the drug is paid by patients than prescription drugs on lower tiers until the out-of-pocket maximum is met.
BOARDMEMBER JAMES JUSTIN VANDENBERG: As far as, I guess as far as safety net, you know, the medication is not on some sort of restricted formulary. It's going to be dictated by the payer on what's covered. So I don't know

how much you would really gather from a safety net component because they're not choosing it; the payer plan is. If it's step therapy, like we talked about before, you have to try X and fail before you can try Y.

But it would be going through the provider would write the prescription for the patient, it would go to the pharmacy, they would process, it would adjudicate, and either the claim would reject because it's not covered or prior auth needed to go through, you know, whatever the steps are, or it would go through per the contract and then that's what then the patient, if they had a copay, would have to pay to pick up the medication. Does that make sense? But it really is independent of what a safety net or 340B would even be; that's not going to drive it.

BOARDMEMBER AMY GUTIERREZ: I think Justin's right. In fact, the governor I think in 2022 signed a bill that really removes payers from paying 340B entities any differently than anybody else, so it's a law that's on the books right now.

BOARDMEMBER CATHERINE HARSHBARGER:

it and do it this way. That's not really what's going to be driving it. It's the payer plan on the prescription benefit.

CHAIR GAIL MIZNER: Oh, I see. So if it's a 340B entity, if the patient is insured at least, the fact that they may be getting that particular drug through a 340B with a 340B discount doesn't really affect what the patient pays.

BOARDMEMBER JAMES JUSTIN VANDENBERG: It's whatever is set with that contract or with the payer, your copay is going to be X amount of dollars, and that's what they're going to have to pay regardless of that additional discount potentially with 340B.

CHAIR GAIL MIZNER: And if the patient is uninsured, then what happens with most 340B providers, do you know?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Now you're going a different process, but yes. So it's going to depend, but it could be -- oftentimes, it's looking which one has a patient assistance to where you could get it for free, and there may be a team within pharmacy maybe that works on that paperwork to help that

Yeah. I'm not surprised that came around.

BOARDMEMBER JAMES JUSTIN VANDENBERG: But that's probably why you didn't get anything from a safety net was they probably didn't feel like they had much to really offer, I guess.

CHAIR GAIL MIZNER: Can you go over that again, Justin? I'm not sure I'm following.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yeah. So, I mean, if you're at a safety net versus a for-profit if you're looking at a pharmacy, you're going to have your provider, you're going to decide, okay, I want to start this drug for this patient, it's a pharmacy benefit. I'm going to send the prescription to the pharmacy. They're going to fill it and run it through the claims. It'll adjudicate, so it'll go through the contract with the payer and either the payer is going to reject it because maybe it's not first line and it'll usually say in the rejection, you know, patient needs to try this or to call the plan, or it'll go through and then the patient pays the specific copay.

But that's not going to drive a, you can't have this drug for this reason because we get a better price on it, we're going to change

patient; if they're not there, then it might be medical assistant or even the patient themselves that then completes that form to get approved from the manufacturer to where then they can get that for free or at a significant discount. That's going to drive that component.

I know that with pharma, they're changing the model a little bit to where if it's a prescription benefit, they almost have these cards, almost like an insurance card if you will and it changes, but it's for the patient assistance program. So even that is kind of changing right now of how some of these are covered, but that may drive.

So if you had three drugs, but one has the copay assistance, well that's the only way that the patient can pay for it, that's going to be driving -- for the provider is going to be driving not so much that, oh, well, this is the most expensive, this is the cheapest. You know, that could come down further down. But from a prescription benefit, that's typically what these newer and more expensive agents, the first direction that the pharmacy would go so that the patient could get it.

CHAIR GAIL MIZNER: So most 340B entities are not -- for example, if they're getting Enbrel for very -- obtaining Enbrel for very little money, they're not necessarily passing that savings on to an uninsured patient or an insured patient is what you're saying.

BOARDMEMBER AMY GUTIERREZ: I would imagine that there are some clinics, Gail, that maybe serve a lot of uninsured that probably drive your formulary around the 340B savings.

I think what Justin was referring to is more the insured status.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

BOARDMEMBER AMY GUTIERREZ: For the uninsured, I think it's going to be really different.

CHAIR GAIL MIZNER: Yeah, got it.

BOARDMEMBER AMY GUTIERREZ: I know. I used to be with the County of Los Angeles. There's a lot of uninsured patients and our formulary was all centered around 340B low priced drugs.

CHAIR GAIL MIZNER: Yeah.

BOARDMEMBER JAMES JUSTIN VANDENBERG:

And that can change on a quarterly basis, which makes it tough. So within a quarter, that discount that could be pretty good could go away and then it goes up to a high -- and it might have a marginal discount, so you're kind of playing in that.

CHAIR GAIL MIZNER: Yeah, okay. Thank you both very much for that remedial lesson. In any case, it sounds like we're just not going to know a lot.

LILA CUMMINGS: Drug-specific information turns out to be a little tricky to get, not because of some confidentiality components. But I'm actually going to share my screen in a second. We've got one more slide on access to care and then I'll share my screen just to very publicly go over the redlines that were sent to you all.

So here was the results, very similar of questions around utilization management that we received from patients and caregivers. I know some of this had already been discussed too.

So with that, I am going to share my screen, and I will just show you things that we have already discussed. I just want to show you

what the changes were. Can you all see my screen?

Okay. So looking at the changes to just two portions of your report: one was the summary report, and one was Appendix F, which is input from safety net providers. And so, in the Enbrel report, summary report itself, so here is the information that was added about just acknowledging that there are biosimilar products available for both Humira and Remicade, and it includes the biosimilar's name, as well as the date that they began to be marketed. So we have information for another source around the date that they were, again, to be marketed. So that information you have, we will post as well.

And then I'm scrolling through. I will note you'll see some purple as I scroll, but we have taken out anything that needs to be redacted so there's no information that is being disclosed.

And then the only other change is towards the bottom of the report. Apologies for just the scrolling. And this is just we put in percentages, so we will go through. We put in percentages here and we're going to plan to go

through and do that for the remaining of the situations where we have both national response and Colorado response side by side, so we'll put in some percentages there.

Then the next change that was made was to Appendix F, impact on safety net providers. And so, here, you will see where we've pulled the information from HRSA's website. So we provide a little information about the database that exists, some summary statistics. And there are 108 unique active covered entity names in Colorado -- we did a filter by active -- with an associated 535 unique addresses. We also note that there are approximately 2,974 approved and participating contract pharmacies. I will note we did not do an assessment of if there were duplicates to addresses; that's just the number that was listed on HRSA's website.

And then here we provide information, again, not specific to Enbrel or dispensing Enbrel, but information around the number by entity type of 340B entities in Colorado, so you'll see the categories here.

We also make a note of the due to the differences in form and manner in which

information is submitted to HRSA versus All Payer Claims Database, we did not conduct an analysis of which of these. You know, it's nearly impossible to connect an analysis of which of these reported dispensing Enbrel in the APCD just because the data sources are so different.

We did note here that, in accordance with HHS's 340B drug pricing program ceiling price, prescription drug manufacturers are only allowed to charge a penny for prescription drugs when it's 340B ceiling price calculation results in an amount that is less than a penny. This penny pricing, as it is often referred to, occurs when a manufacturer raises the price of a drug substantially more quickly than the rate of inflation.

And so, we'll note here, this is not information that has been disclosed to us, so we just are calling out here the image that shows the change in inflation and the change in the WAC, and noting that Enbrel's WAC has risen significantly higher than inflation, though we have not done an analysis on the rate of change, just the fact that it has risen higher than inflation. So just kind of our two cents on the

penny policy. Apologies for that.

BOARDMEMBER AMY GUTIERREZ: Lila, I would just add if you're going to put that in there is put quarterly, 340B quarterly ceiling price calculation in that sentence. Because it is -- it's not like it's a penny forever, it's calculated every quarter. I think Justin mentioned that earlier.

LILA CUMMINGS: Absolutely. Okay, so those are the redlines that have been made. I will stop sharing my screen. And then I think we've got some, I believe public comment is up next.

CALLIE ANN SHELTON: We have three opportunities for public comment today: one for Enbrel, one for Genvoya, and then general public comment period at the end. So if you'd like to provide comment, please fill out the form in the chat, and I have a couple of people already lined up, so we'll get that started.

LILA CUMMINGS: And, Callie, will you remind us if there's a limit on the number of people, correct?

CALLIE ANN SHELTON: Yes, 10.

LILA CUMMINGS: Okay, thank you.

CALLIE ANN SHELTON: Thank you. First up, we have Bridget Serrett. Bridget, are you here?

BRIDGET SERRETT: Yes, I'm here. I would like to sign up at the end for general public comments.

CALLIE ANN SHELTON: Okay, thank you. And then, Jen (indiscernible), I have you signed up, but I'm assuming you want to go for Genvoya? That's before I put the other option.

JEN: Correct, thank you.

CALLIE ANN SHELTON: Tiffany Westrich-Robinson.

TIFFANY WESTRICH-ROBERTSON: Yes, hello. Robertson, I'm here.

CALLIE ANN SHELTON: You can go ahead, Tiffany.

TIFFANY WESTRICH-ROBERTSON: Okay, thank you. Hello, and I am representing the patient voice and also the International Foundation for Autoimmune & Autoinflammatory Arthritis, or AiArthritis for short. I'm also a person living with these diseases that can be treated by Enbrel.

I had a lot of planned comments, but

I'm frankly going to change all of them and talk about what I heard today because I am extremely, extremely concerned, more concerned than I was coming in, based on the conversation that I heard.

One of the things that I'm really concerned about is that the data that was presented was only based on a handful of people. And on October 3rd of last year, AiArthritis had submitted information that demonstrated that the survey that you're citing today was severely flawed, so the information that is being used is not even going to result in correct data.

For example, the question have you ever skipped a dose, stretched out a dose due to affordability, that question is severely flawed. I know because I was in the listening session for Cosentyx, and I said I can't answer this because it cost me zero dollars, but yes, I've skipped or stretched. The affordability comes with step therapy. The affordability comes with being switched by the insurance company, and then they tell you you can pay more for it because it's on a higher tier. None of that information was collected from patients, so I'm very, very

concerned that that's even being cited today.
The answer -- the other thing that I just really wanted to say is the conversations, there were a lot of questions that were asked that seemed to be conversations that should have been having months ago. I really encourage the Board, please pause, let's look back at these transcripts, publish them, give all of us an opportunity to clarify the conversations that you had and some of the points because they were not clarified. They were not. Please, I'm asking you, pause this decision until the transcripts can be out and we can come back and provide you with correct information and the potential to ask more patients why it is unaffordable. Thank you.
CALLIE ANN SHELTON: Thank you, Tiffany. Brett Johnson.
BRETT JOHNSON: Hi, thank you. Brett Johnson representing Amgen. Just to kick it off, I just want to call your attention to the process concerns that we've raised in our letters dated February 1st and December 4th, which include: first, public comments by a member of the Board in multiple meetings regarding off-the-record conversations with unnamed persons regarding

Enbrel's affordability; and second, the inconsistency in standards and procedures applied by the Board, including a lack of clarity about what those standards are and the inconsistent applications of what stated policies have been adopted.
To this second point, assessing the various reasons the Enbrel draft report posted over the past week, at least three of which we are aware, we're having trouble reconciling how some of the data points have been treated among the different medicines reviewed in just this first cohort.
For instance, can you help us understand why the percentage of patients paying $50 or less out-of-pocket per month feature so prominently in the Trikafta report at 51 percent but not in the Enbrel report at 57.3 percent, with the latter set focusing on the aforementioned results of the survey, about which we also have very serious real questions concerning the instrument used and the methodology. And even with those survey results, roughly half of the patients paying $100 or below out-of-pocket did not report trouble ever

affording their medicine, and it was ever affording their medicine.
Can the Board explain the standard it applied with respect to these data and, more broadly, how they factor into a decision about what constitutes affordability. For example, can you clarify what specific data has the Board reviewed and in what manner is that data being considered to support statements made today about formulary placement and its impact on patients.
And then finally with regards to the discussion today about patient assistance, which isn't reflected in the key claims data that's been discussed. It's important to distinguish between, one, copay card programs for which there's a streamlined access, it's online, it's very easy, and commercially insured patients with Enbrel are eligible, but generally not those covered by federal programs. For these programs, not a single Coloradan of the nearly 2,000 that applied last year were denied.
And then the need-based safety programs, which are different, which I assume is what was being referred to with some of the phone waiting and other complications. But due to

these in-common insurance verification requirements, which are required by rules that can be a challenge to some patients; they must be U.S. residents and either uninsured or have Medicare Part D with affordability gaps and household incomes up to three times the federal poverty line.
Even with this more thorough review process, the current average wait time for callers is 33 seconds. And through these programs, the Amgen Safety Net Foundation has provided approximately $2.5 billion in medicines just last year.
So if there are any questions or anything we can provide further information on, please do use us as a resource and, you know, we hope to be an aid to understanding some of these key points that appear to be a point of misunderstanding based on today's discussion, so thank you.
CALLIE ANN SHELTON: Thank you, Brett. Hope Stonner, please.
HOPE STONNER: Hello, my name is Hope Stonner. I'm the policy manager at the Colorado Consumer Health Initiative. Appreciate this

opportunity for public comment.
I also had some comments prepared, but also would just like to add. I think, as a local consumer advocacy organization who has a lot of experience engaging in sort of these, like, state regulatory processes, we have been very impressed with the way that the PDAB has been conducting this work, and I think there has been ample opportunity throughout this process for stakeholders kind of across the entire supply chain to engage in this work. And so, just wanted to raise that and reflect our gratitude for that.
I think some other things that the Board members have already called attention to that I just kind of wanted to reemphasize were the reports detailing of patients struggling to afford Enbrel even with access to financial assistance, which confirms concerns that CCHI had previously raised regarding the reliability and accessibility of manufacturer patient assistance programs for all patients across the board.
And I think that this is related to the report's findings that members also called out that Enbrel's prices have increased a whopping 36

times since its introduction, and we think that given this history and the fact that the last of Enbrel's patents are set to expire in 2039, the Board had a really important opportunity and authority to course correct today by deeming Enbrel unaffordable and initiating an upper payment limit process.
Thank you.
CALLIE ANN SHELTON: Thank you, Hope. Steven Newmark.
STEVEN NEWMARK: Hi, how are you. Sorry, give me a moment as I struggle with the unmute button.
Hello, I'm Steven Newmark and I'm the policy director for the Global Healthy Living Foundation, a patient organization, that works to help chronically ill patients around the 50 states, including Colorado. These patients are chronically ill, as I said, and many rely on the medication such as Enbrel to live their lives.
We have concerns over access issues to these medications that the Board is -- and some of the considerations that the Board is undertaking, and most notably, savings that will actually be realized by patients, but I'll let

our written comments stand on these points.
But for the oral comments, I just want to add that you raised some issues on copay cards and how it affects affordability, but there seemed to be a little bit of a trail off in the discussion. I don't know how deep you have spoken to patients directly about this issue. Further, I didn't understand the limited and partially non-public discussion on rebates. The slide itself said confidential. To not focus on rebates when dealing with drug cost issues is like trying to build muscles, but refusing to lift weights. I mean, that's a big part of dealing with the affordability issues.
But just for now, I just want to say that we at GHLF are eager to hear more about your plans for engagement with patients and caregivers mentioned at the top of this meeting. I hope it's not too little too late. As seen today, too often, the parent-caregiver voice is left out of these discussions, and we are hopeful that you will engage in robust discussions directly with these important stakeholders.
We look forward to hearing more about these engagement ideas and stand ready to share

them with our Colorado patients. Thank you for all that you do.
CALLIE ANN SHELTON: Thank you, Steven. I don't have anyone else signed up specifically for Enbrel, but I'll give you another moment. I'll put the link in the chat again, and again, if you'd like to provide comments specifically on Enbrel. I'm not seeing any more. We can close this public comment period.
LILA CUMMINGS: Then we probably need to go to the next slide.
CALLIE ANN SHELTON: Somebody just signed up for Enbrel.
LILA CUMMINGS: Oh, okay.
CALLIE ANN SHELTON: Jerry Cunningham. Jerry, are you there?
JERRY CUNNINGHAM: Okay. Can you hear me now?
CALLIE ANN SHELTON: I can hear you now.
JERRY CUNNINGHAM: Okay, great. My comment might be out of turn. Is Enbrel the potential replacement drug for Remicade, or was that conversation and Enbrel something else?
LILA CUMMINGS: Remicade is one of the

identified therapeutic alternatives for Enbrel in this affordability review.

JERRY CUNNINGHAM: Okay. So I suppose I could ask a question before I make public comment because I don't want to speak out of turn. So I have a family member, actually it's my brother, who uses Remicade. Is the Board considering Remicade as, you know, under its affordability -- you know, the umbrella or just Enbrel?

LILA CUMMINGS: This affordability review is specific to Enbrel.

JERRY CUNNINGHAM: Okay. Well, if you give me 30 seconds, I'll say what I was going to say, and then I will go ahead and just listen to the rest of the public comments.

I really have paused, someone just spoke earlier about how this meeting today has really set them back, and that goes for me as well, and I spoke on this before. I just want to reiterate that when public comment notifies you as professional individuals in the medical space, being doctors, also having an oath to not do any harm, I feel like there are smarter people than me that you all have access to that you can ask

that if a small pharmacy in Yuma, Colorado decides not to carry Enbrel or Remicade for my brother and that information leads to, you know, legal action, I can't see the Board not personally being liable because of the oath to do no harm.

So I just caution all of you to please speak to people that are way smarter than me because my brother already has a hard time getting Remicade because of the insurance loopholes and, you know, hoops that he has to jump through, and it is determined that someone is making it difficult for him to get medicine that he believes is lifesaving, that's harmful, and I can't see that not being something that people could come after everybody individually for.

That's all I will say. Thank you for giving me my time and I will go back on mute.

CALLIE ANN SHELTON: Thank you, Jerry. Bridget, have you changed your mind and you want to speak on Enbrel specifically? If so, you can.

BRIDGET SERRETT: Yes. Sorry, you'll have to forgive me. I'm fresh out of neurosurgery, so the brain is not quite checking

the way it should.

My concerns with this are going to be the stakeholder process clearly. I don't feel like we are doing our best to engage stakeholders to get as much information. I feel like the data process, the questions are very flawed and don't necessarily reflect why patients are having trouble accessing Enbrel, and I do also want to make sure that we make decisions that aren't going to hurt access for patients. There is still nothing in this process that I can see that is going to make these drugs more affordable for the end user, the patients, and I want to be sure that we keep that in mind as we go further into this.

Thank you.

CALLIE ANN SHELTON: Thank you, Bridget, and happy healing. Take care of yourself. Anyone else would like to speak specifically on Enbrel, maybe one more moment.

LILA CUMMINGS: And then we can move to the next slide.

CALLIE ANN SHELTON: Yeah, go ahead.

LILA CUMMINGS: Chair Mizner, we'll turn it back over to you.

CHAIR GAIL MIZNER: Thank you, Lila, and thank you everyone for your comments.

Is there any further deliberation about -- that the Board would like to undertake about Enbrel? Are you comfortable -- are Board members comfortable moving forward with determining whether Enbrel is unaffordable with the information presented?

BOARDMEMBER AMY GUTIERREZ: Yes.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Any further deliberation? Lila, do you want to make any comment about some of the issues that were raised about our outreach to stakeholders?

LILA CUMMINGS: Yeah, I'd be happy to. I think, you know, there is a tension between needing to treat all drugs equally and then hearing from consumers that they would like tailored surveys. And so, that's something that I think, you know, we want to gather information as consistently as possible across drugs.

I will say for surveys, we always left

an option open for patients to kind of provide any information they would like, and we did get specific feedback from patient groups on the design of the survey, so our aim was to have a patient-friendly survey. That being said, we are -- you know, as we've talked about, we are open to continued improvement. I think we feel confident and we work to post the links so the Board members, I know you all have listened to the unedited audio from the public meeting with patients and caregivers for Enbrel.

And then we also posted unedited survey replies, so I think we feel that as staff that is accurate that you all have access to unedited information from us. I think we feel confident in it and to the degree that in the future, processes might change; that is always the conversation we're willing to have, but confident in what we've provided for Enbrel.

CHAIR GAIL MIZNER: Thank you, Lila.

BOARDMEMBER CATHERINE HARSHBARGER: One little comment. Even though we didn't talk about the confidential information, we had access to that and read that, and I just want to emphasize that to the public. There's some things that we

just knew what they had already said and so, therefore, we didn't need to deliberate further on it.

BOARDMEMBER AMY GUTIERREZ: I have something I want to add on to Cathy's comment. I think the staff did a great job at putting this report together. It was very comprehensive. There's a lot of information, a lot of work that was done on outreach, so I feel very confident in the work that they've done and I think we need to rely on that when we deliberate, make our decision.

BOARDMEMBER CATHERINE HARSHBARGER: Agreed.

CHAIR GAIL MIZNER: The staff did an enormous amount of outreach and was able to get a lot more input on their second attempt from patients and caregivers, as well as to my understanding some of the medical experts.

BOARDMEMBER CATHERINE HARSHBARGER: I'm comfortable with moving forward with a vote, Gail, when you're ready.

BOARDMEMBER AMY GUTIERREZ: So am I.

CHAIR GAIL MIZNER: Then I need a Board member to make a motion if there's no further

deliberation and having considered the evidence before us relating to each affordability review component. Do I have a motion regarding a vote on the unaffordability of Enbrel?

BOARDMEMBER CATHERINE HARSHBARGER: I'll make the motion. My motion is that the use of Enbrel is consistent with the labeling approved by the FDA or with standard medical practice and is deemed unaffordable for Colorado consumers.

BOARDMEMBER AMY GUTIERREZ: I will second Cathy's motion.

CHAIR GAIL MIZNER: Okay. Then Ms. Harshbarger moved and Dr. Guttierez seconded that we move that use of Enbrel consistent with the labeling approved by the FDA or with standard medical practice is unaffordable to Colorado consumers. Did I get that right, Cathy?

BOARDMEMBER CATHERINE HARSHBARGER: Yes, you did.

CHAIR GAIL MIZNER: Okay. Then I'm going to roll call a vote. Callie, are you going to call on people one by one?

CALLIE ANN SHELTON: Yeah, we can do that. Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Yes.

CALLIE ANN SHELTON: Cathy Harshbarger.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

CALLIE ANN SHELTON: Dr. Gail Mizner.

CHAIR GAIL MIZNER: Yes.

CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Okay. Then, Lila, please finalize the affordability review report for Enbrel by adding a high-level summary of our deliberations today, our determination that use of Enbrel is unaffordable for Colorado consumers, and correcting any clerical errors you all identify. We will vote to approve the final report at our next meeting.

LILA CUMMINGS: Absolutely. Thank you, Chair Mizner. And I'll just note for the public, the next meeting will be posted to the website. The next meeting of the Board will be next Friday, February 23rd at 10:00 a.m. So thank you, and we will do that.

CHAIR GAIL MIZNER: Thank you all. We

will now break. I'm thinking we need to make this 15 minutes, Lila.
LILA CUMMINGS: Okay, absolutely.
CHAIR GAIL MIZNER: We'll now break for 15 minutes, so be back at 2:39.
LILA CUMMINGS: Okay, great. Thank you.
(2:24:11 -- Break Begins)
(2:39:37 -- Break Ends)
CHAIR GAIL MIZNER: It's 3:39, but I'm not sure I see Dr. Guttierez and Ms. Harshbarger back with us yet.
BOARDMEMBER AMY GUTIERREZ: I'm here, Gail.
BOARDMEMBER CATHERINE HARSHBARGER: I'm here.
CHAIR GAIL MIZNER: Okay, great. Then let's get started. Welcome back, everyone.
We're now going to turn to consideration of Genvoya. Board members disclosed conflicts at the top of the meeting. Dr. Diab is the only Board member with conflicts and he will not participate in the deliberation.
Before we begin deliberation, I'd like to note that all Board members were present at

the December 8th meeting when staff presented draft evidence for the Genvoya affordability review. I'd like to also note that the Board members were provided with the entire unredacted draft report on February 9th.
To ensure that all Board members have had an opportunity to review the information in the draft report, I'd like to ask if any Board member feels we do not have sufficient information to deliberate regarding unaffordability for Genvoya today. Does anyone have concerns about that?
BOARDMEMBER JAMES JUSTIN VANDENBERG: I do not.
BOARDMEMBER CATHERINE HARSHBARGER: No.
BOARDMEMBER AMY GUTIERREZ: No.
CHAIR GAIL MIZNER: So if there are no concerns, are there any objections to moving forward with deliberation?
BOARDMEMBER JAMES JUSTIN VANDENBERG: Not from me.
BOARDMEMBER CATHERINE HARSHBARGER: No.
BOARDMEMBER AMY GUTIERREZ: No concerns.
CHAIR GAIL MIZNER: Lila, let's move

forward with deliberation.
LILA CUMMINGS: Okay. Thank you, Chair Mizner.
I think my first question would be, there were some more redline edits that were suggested, so both in the summary report for Genvoya, Appendix B, Appendix F, and Appendix M with HCFA, so I'd ask would you like to do the same thing where we showed them at the end or would you like me to show them at the top?
CHAIR GAIL MIZNER: You guys have any feelings about that?
BOARDMEMBER CATHERINE HARSHBARGER: I don't have strong feelings either way.
LILA CUMMINGS: Okay. Then I might just show them at the top because they're relatively small, but then that way -- so I'll plan on showing them, but the we can maybe save them for discussion at the appropriate point throughout. So I will share my screen first and then I will hop back to the PowerPoint slides.
So in the summary report itself, we did pull out some information, and this is under the indication that Genvoya treats. So we pulled out some information from the clinical guidelines

which are cited in Appendix D, so we pulled out information here.
And, Chair Mizner, this was kind of at your direction, so if you have any comments on this, we welcome that.
CHAIR GAIL MIZNER: Let me read it quickly. Thank you.
LILA CUMMINGS: And if you'd like to save your comments for the appropriate spot in the discussion, absolutely on that too.
CHAIR GAIL MIZNER: Yeah. I think what I was wanting to highlight is that Genvoya is not for patients who are na?ve to -- who have never been on any retroviral therapy before, that there are a couple of other regimens that are considered preferred, that Genvoya is included in the list of alternative regimens.
BOARDMEMBER CATHERINE HARSHBARGER: So it's not first line; it's kind of like a...
CHAIR GAIL MIZNER: Yeah, I mean, but there are only two that are listed as the preferred and then, you know, there are others that follow and Genvoya is among the others that follow, but I think that is important information. And the other little clinical piece

is that Genvoya does, because of the cobicistat in it, have more drug interactions, but those are just, you know, pieces of information that I think are relevant.

As we've seen with the information presented, Genvoya is an effective medication that is used by a number of patients still, even though it's not listed among the preferred agents.

BOARDMEMBER AMY GUTIERREZ: Gail, when you say preferred, it's by clinical evidence or resistance patterns or...

CHAIR GAIL MIZNER: It's largely based on the fact that the two preferred regimens contained integrase inhibitors that have higher barriers of resistance to viral mutation and, therefore, a development of drug resistance.

BOARDMEMBER AMY GUTIERREZ: I don't (sound glitch) with this drug class with this. They just keep changing; they keep adding those resistance to both. We add other drugs over time since HIV was first identified.

CHAIR GAIL MIZNER: And the integrase inhibitors are essentially the most recent widely used category and are very, very effective and

very beneficial for people, and Genvoya contains an integrase inhibitor.

LILA CUMMINGS: And then the only other change we made here, and we appreciate our partners at PORTAL, it was a tiny one -- you'll see it in the therapeutic alternatives appendix as well -- a tiny, but important.

So here just clarifying the mechanism of action for Dovato we had written to is, in fact, one, so that was the only other change.

CHAIR GAIL MIZNER: I thought it was one of the two drugs -- it's a two-drug regimen, as opposed to a three-drug regimen, so I was just wanting to make sure we were correct on that.

LILA CUMMINGS: So now I will minimize this. So in the therapeutic alternatives appendix, you'll see just the same -- that last change that we mentioned is also in there when you scroll down to Dovato. So the only change here is that corresponding change from two to one, so that's the only redline in this appendix.

Then impact on safety net providers. This is the same, very similar changes to what you've already reviewed, and I'd say there is more information here that we'll get into

regarding Ryan White. But we provided information from that HRSA database regarding covered entity types and number of unique addresses, again, not specific to Genvoya, but we have this information in here as well.

And, Lila, let's add that quarterly on there as well.

LILA CUMMINGS: Great.

BOARDMEMBER CATHERINE HARSHBARGER: That's 340B.

LILA CUMMINGS: There we go. Thank you. Fantastic.

And then the only other change here is in information from the Department of Health Care Policy and Financing. We have pulled out that there is a published report that mentions Genvoya. That is something we work with our partners at HCFA to identify, and it had to do with the fact that Genvoya is listed on potential drugs for importation for the HCFA's Canadian Drug Importation Program. I'll note that that is not approved yet by the FDA; it's an ongoing conversation.

So we had information on there on Genvoya, but then Chair Mizner said are there any

other HIV drugs that are also on that list. So we have pulled the information from the same source regarding the fact that there are other -- and it's on HCFA's website, it's drug category HIV. We did not do further analytics in terms of class or doses, but this is the information that was presented there, and then we've cited the source as well.

CHAIR GAIL MIZNER: Thank you, Lila.

LILA CUMMINGS: Yeah, absolutely. Okay, so those are the redlines, so I will stop sharing. Happy to come back to any of these if you would like. But with that, we can proceed back to the slides.

In the interest of time, I'm not going to reread some of these. We'll start with therapeutic and utilization profile, and I think you all are familiar with the appendices where we pull this information from. We can go to the next slide.

So indication, Genvoya has one indication, HIV-1, and so there's information up here from the FDA's website. I'll pause. Any questions on indication? We can go to the next slide.

So here is utilization data for Genvoya, and we've combined here two types of information. You've got the raw numbers, but then you also have information based off of utilization for just Genvoya; there is information on general utilization for Genvoya and its therapeutic alternatives. But for just Genvoya, here's how utilization has changed since 2018 across commercial, Medicaid, and Medicare Advantage plans, as reported in the APCD.

BOARDMEMBER CATHERINE HARSHBARGER: That's a significant reduction in utilization, isn't it? Is there -- we probably don't know why that is, or did somebody...

CHAIR GAIL MIZNER: I think we kind of do. It's that other medication combinations became available that were viewed as being either better tolerated or more effective, so it's basically that. As I mentioned before, Genvoya does have cobicistat, which makes it so that you cannot take a statin with it. And as HIV patients, age, cardiovascular disease becomes more and more of a concern, and so many people need to be on a statin, so that would be one potential reason that someone might switch away

from Genvoya.

So there are, you know -- I hate to be acting as the expert again, but that has been the tendency is with newer regimens coming out, people, for one reason or another, get switched.

BOARDMEMBER CATHERINE HARSHBARGER: Okay.

LILA CUMMINGS: And I would say note too that Chair Mizner, Dr. Mizner has been incredibly helpful. Because, you know, one of the sources that was used for this is the clinical guidelines, so she's been incredibly helpful in making sure that we appropriately translate some of the clinical guidelines.

Next slide.

All right, so again, same information just presented in a different way, in terms of utilization of Genvoya by payer type over five years.

Okay, next slide.

Health equity. So priority populations -- and this is just a note for folks that the Board has defined priority populations in your rules. So if folks are kind of wondering why we're using that term, it's just an all-

encompassing term where specifically priority populations are listed out; that's why we're using that language and would just encourage folks to look at the rule if they want to know specifically.

But HIV disproportionately impacts priority populations, particularly sexual minorities and communities of color. HIV disparities persist and the number of new HIV diagnosis linkage to care and treatment and retention and care, there's a pretty thorough overview of health equity literature related to HIV. We also heard from patients and caregivers that accessing HIV-related medications for people living with HIV, there's a historical context.

That is important that we heard that and patients submitted information to that context about particularly the disproportionate impact they felt in health equity and accessing prescription drugs in the past, and then kind of persisting potential health equities. So there's a lot more information in the health appendix as well, as well as input from patients and caregivers and individuals with scientific and medical training and voluntarily submitted

information.

And then another thing too that I'll note specific to Genvoya is that we heard a lot from patients and caregivers around stigma associated with HIV and how that might impact access to medications and access to care.

We can go on to the next slide.

So here is a map of utilizers of Genvoya in 2022. You've seen this map before, and so I'll just leave it here to pause to see if Board members have any kind of comments or thoughts or discussion.

CHAIR GAIL MIZNER: For the counties that are not counted ones where we don't have any patients as far as we know taking Genvoya?

LILA CUMMINGS: Correct. (Indiscernible) on here, they're in the claims database. There is no...

CHAIR GAIL MIZNER: Okay.

LILA CUMMINGS: Thank you.

CHAIR GAIL MIZNER: I think we can move on.

LILA CUMMINGS: All right. And then here are the therapeutic alternatives that were identified, so these are in-class single-dosage

form therapeutic alternatives. I'll leave it here for any discussion. I see on the slide it says two, not one, for Dovato. You've seen the change in the report.

BOARDMEMBER CATHERINE HARSHBARGER: Biktarvy, I guess I keep thinking that that one's kind of a preferred starting point. I think it said that in the report for new HIV patients, they tend to use that as their first choice.

CHAIR GAIL MIZNER: So the preferred agents listed by DHHS are Biktarvy or the combination of dolutegravir and tenofovir emtricitabine called Descovy. And so, that second combination is two pills taken just once a day, which for many people isn't a big problem. But that was not included in this just because it's two pills instead of one, so it wasn't felt to be quite comparable.

But, you're right, Biktarvy came out more recently in 2018 and has been very popular. It's a small pill that's easy to swallow, highly, highly effective, everything in one, and so it has been quite popular and it is listed as one of the first line.

BOARDMEMBER CATHERINE HARSHBARGER: It

of the patient out-of-pocket, it's about 2600 per year; is that how I'm interpreting this?

LILA CUMMINGS: Yes. Go ahead, sorry.

BOARDMEMBER AMY GUTIERREZ: That's over $200 a month, that's quite a bit.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, it quite a bit. Go ahead.

CHAIR GAIL MIZNER: Is this just commercial insurance or commercial plus Medicare?

KATE DAVIDSON: Yeah, it's commercial plus Medicare Advantage.

LILA CUMMINGS: And then something that I will note, like, I think we were going to get to it in a few slides, but since you all are discussing out-of-pocket costs. So in Appendix F, which is the impact on safety net providers, we spoke a couple of months ago with our peers at CDPHE who oversee the state drug assistance program, and they provided us with information on how the programs run, as well as what services and what kind of assistance is available.

So a summary -- and I said state drug assistance program, or SDAP, Ryan White, the federal Ryan White HIV/AIDS Program is kind of what that's referring to. Frequently, clinics

has lower side effects too; is that correct?

CHAIR GAIL MIZNER: What's that?

BOARDMEMBER CATHERINE HARSHBARGER: It has lower side effects.

CHAIR GAIL MIZNER: Probably it may cause a little more weight gain for some patients than, for example, Genvoya does. But generally, really most of these drugs are very well tolerated at this point.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you.

LILA CUMMINGS: I've actually just moved forward to the next slide where we have utilization data for Genvoya, Biktarvy, Dovato, Scribid, and Trimeq and total as well. Okay. Any questions on indication utilization or information about therapeutic alternatives and their utilization?

All right, so price and cost profile. I'll just leave this up here for a second, and we can go on to the next slide.

Here are the WAC and cost statistics that you've seen a similar version before. We'll leave it up for folks to discuss.

BOARDMEMBER AMY GUTIERREZ: So in terms

are referred to as Ryan White Clinics, but there's more information in Appendix F, and specifically, I want to highlight information about the state drug assistance program and the income eligibility chart that is there. And so, that is highlighting the certain kind of income eligibilities in which you can receive financial assistance to access drugs, including drugs like Genvoya.

And I'll just note that there is assistance that is available for up to 500 percent of the federal poverty line, and that is something -- so that access to that assistance is not reflected in claims data.

BOARDMEMBER AMY GUTIERREZ: Do we have any idea, Lila, how many of the commercially insured patients have access to that federal poverty level limit?

LILA CUMMINGS: That is --

BOARDMEMBER AMY GUTIERREZ: (Sound glitch) in this.

LILA CUMMINGS: Yeah, that is not something that we did an analysis of. Kate, correct me if I'm wrong, I do not believe there's any information in the APCD that could estimate

income levels.
KATE DAVIDSON: That's correct.
BOARDMEMBER CATHERINE HARSHBARGER: We probably wouldn't be able to get that because they probably do that on a one-on-one basis and keep it pretty confidential, so I would imagine that would be hard to get.
CHAIR GAIL MIZNER: So let me see if I can do a couple of clarifications. So that SDAP program or ADAP/SDAP program is available whether the patient -- as long as the patient is enrolled on the western slope, it's Western Colorado Health Network, so they can see a provider who's not a Ryan White provider and still be prescribed medications and receive them under SDAP. I know that because I'm not a Ryan White provider and most of my patients receive their medications under SDAP.
And that organization as well does an enormous amount to help get patients who can be on insurance on insurance and insurance that does cover the medication.
So I am, based on my experience, which is of approximately, must have taken care of at least 200 patients with HIV in the past three,

four, five years, I've never seen a patient have to pay $2,600, but I don't see wealthy patients either. So I'm a little surprised by that out-of-pocket number is what I'm saying.
I don't know, Kate, if you have commentary on that.
KATE DAVIDSON: Just reiterating what Lila said, that this is what the claims says, not necessarily what was experienced by the patient with all of the funding.
BOARDMEMBER AMY GUTIERREZ: The reason I asked the question, Gail, was out of that 2600 is the SDAP program available to them or are we really looking at patients that are insured, because there are quite a bit of insured commercial patients on here. Is that what their out-of-pocket is really 2600? That's why I asked that question.
CHAIR GAIL MIZNER: Yeah. And are they getting somehow other assistance.
DR. BEN ROME: Yeah. One point just about the 2600 is a mean, just to remind you all too, and I think we saw it with Enbrel and with this drug too. Like most drugs, these costs are not distributed such that -- you know, it's not

true that, like, half of patients are paying more than 2600, right. The mean tends to be driven by some skews on the very high cost, so, you know, there's going to be a range of patient out-of-pocket costs when you analyze these data.
LILA CUMMINGS: And I'd say we really appreciate the stakeholders that engaged in this process because, particularly in voluntarily submitted information, they pointed to very -- like, where assistance programs, you might not have full info- -- like, in manufacturer assistance program, you might not have full information on utilization. But in the case of Genvoya in particular, there are federal and state level policies around copays, and we'll get to that; that's in a few slides.
The patients survey results I think tell -- we will get to those in a few slides -- tell their experience, and then the Ryan White program. So there are a couple of very established, very transparent data in terms of what the rules and policies are that impact patient out-of-pocket costs is what we heard from stakeholders.
BOARDMEMBER JAMES JUSTIN VANDENBERG:

And I think that's really important. What you're noting, Lila, here is you have state, you have federal, you have patient assistance program. There's quite a few different pieces in there that are highlighting, as well as the stakeholders, of the ability to gain access to this medication.
BOARDMEMBER CATHERINE HARSHBARGER: You did have a pretty big WAC increase that it's noted on here.
BOARDMEMBER JAMES JUSTIN VANDENBERG: And I'm curious, looking at the graph that you had before and seeing that trend, the downward trend, I'm curious if we're almost catching this on the back end of it almost sunsetting itself, to some degree. As we were talking before, as new agents are coming out, as there is resistance and you're having to shift the medication, is it naturally kind of going to continue to go down and then probably, you know, bottom out to some degree a little bit.
But as far as our data collection, we're getting it on the tail end of this, so it encompasses here. But if were to, let's say, run this again in five years, my guess is Genvoya

wouldn't be coming up to this -- coming on to our radar as being one of the top medications would be my guess looking at the trajectory that it's going. Does that make sense?

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, it makes sense.

CHAIR GAIL MIZNER: Yeah. So I think what you're saying, Justin, is that it's likely that utilization is going to continue to decline as new medications come out, et cetera. So that total costs, you know, if we're looking at total costs for the state, those costs should probably go down for insurance carriers or whoever, just because of fewer numbers of patients.

I don't think we can predict that for sure. It might stabilize because there certainly are people who have been on Genvoya a long time and it works well for them and they like it and they want to stay on it. So I think it's hard to predict, but certainly, we do see a trend overall, but a tendency that as newer medications come out that have advantages, people get switched.

BOARDMEMBER CATHERINE HARSHBARGER: Would I be making a wrong assumption to ask

whether or not if people are on Genvoya, is it because they were potentially resistant to the other drugs available at the time and/or (sound glitch) side effects? I don't know.

CHAIR GAIL MIZNER: Not so much because it's not really, it's not a drug that you -- not one of the ones you turn first when you have a patient with drug resistance. When it first came out, it was very popular, which like I say, has worked well for some people, but other people had reasons to switch.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you.

BOARDMEMBER AMY GUTIERREZ: And, Lila, are you going to go after Table H1, which talks about out-of-pocket costs, because I was looking at because 90 percent of the out-of-pocket costs are under $50, at least from the survey of 22 patients you did. But you may already be presenting that later.

LILA CUMMINGS: I believe that's one of the slides or we can go to the report.

BOARDMEMBER CATHERINE HARSHBARGER: We can go to that part, yeah.

LILA CUMMINGS: Okay, we'll keep moving

along. Here is information in terms of a month, what was paid in a month. But again, note that this out-of-pocket costs for the month does not take into account SDAP funding.

Okay, we will keep moving on but can always come back.

So again, put a different way -- and we will get into this when we're getting into kind of patient and caregiver input, as well as individuals with scientific and medical training -- financial effects input. But again, this is information from the claims database around co-insurance deductible and copayment amounts and total out-of-pocket costs, but does not include SDAP or any other assistance program but specifically calling that one out.

BOARDMEMBER CATHERINE HARSHBARGER: That's where the patient data becomes so important to what they say is going on for them, meaning the patient's feedback. I'm sorry, I said that kind of wrong, patient's feedback.

CHAIR GAIL MIZNER: So the general gestalt of this for me is that there's not a big rise in out-of-pocket costs over the last few years.

BOARDMEMBER CATHERINE HARSHBARGER: Correct.

LILA CUMMINGS: Okay, next slide. So we've got here health effects, this is from Appendix D, so we have done some summarization here. There was one indication, so it was a little more concise, but also encourage you, Appendix D, H, I, and J are where the vast majority of these slides information come from. And again, we have linked to the Zoom for the public meeting for Genvoya with patients and caregivers, as well as their survey responses.

I'm noticing a typo on here, so apologies for that. I think the top line, apologies, that is Enbrel, but I think that was just something that wasn't deleted, that top area.

So moving on to health effects for patients and caregivers. The majority of patients aid their treatment goal was to remain undetectable and achieve overall physical health. They spoke to the importance of whole person wellness, in addition to medical outcomes. And they discussed the differences in Genvoya and other drugs under review, namely that Genvoya

treats a communicable disease and interruptions in treatment could lead to worries of a broader public health issue.

For health effects, I'm not going to read through this necessarily. I'll just leave it up there for folks to take a look at.

CHAIR GAIL MIZNER: Any questions on that, comments? I think we can move on.

LILA CUMMINGS: Okay. All right, so here is a summary of the health effects of Genvoya. It is both from -- we surveyed six different or reviewed six different health technology assessment organizations. We also noted if (sound glitch) was used in Appendix D, but here's the summary from both Canada and Germany.

I will note here that something we kind of consistently found in review was sometimes there are head-to-head studies with different drugs, but then kind of frequently, there were -- it was a comparison to a placebo. But those are cited, so you can investigate as you see fit.

CHAIR GAIL MIZNER: So really HIV drug studies are not done in comparison to placebo because that would be immoral; they're compared

to other drugs and that's just the way it has to be.

LILA CUMMINGS: And I think I just transcribed what I meant to say in my previous statement. Sorry, yes, apologies. Thank you.

BOARDMEMBER CATHERINE HARSHBARGER: The one thing to remember in all of this is the health effects, it seems like some of them are the norms for people if they're going to get it: diarrhea, nausea, things that you can get treated for, for the side effects if you wanted to. The one thing that's different about Genvoya is the effect it has on -- I don't know whether it's liver or just on the fact that you can't have a statin if you needed it.

CHAIR GAIL MIZNER: It's the drug interaction with the statin. It's complicated.

BOARDMEMBER CATHERINE HARSHBARGER: I'll trust you on that.

LILA CUMMINGS: I think Chair Mizner, correct me if I'm wrong, that is what we pulled up from the cited clinical guidelines into the body of the report.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: All right, so here's some information on financial effects. And again, all of this is in the appendices, so the information from surveys regarding the financial effects of the drug. Also, we've pulled some information from individuals with scientific and medical training appendix where they've provided information from their experiences on patient's ability to afford Genvoya.

BOARDMEMBER CATHERINE HARSHBARGER: I sit and ask myself the question about the 4 out of 22 or 18 percent, that the medication reduces the amount of time. Oh, wait, I'm talking about due to the cost of this medication, they cut costs in other areas.

And so, it makes me wonder if those are people that are on insurance, for one, and secondly, do they not know about other program because there's so many programs out there. I don't know that answer, or maybe they don't qualify for them. So even if they -- I don't know what that is, but at least 18 percent of the people have some impact relative to having to cut costs in their lives to afford the medication.

LILA CUMMINGS: And something I will

add to say here that feedback we received that we did discuss in December but we'll reiterate is, we received feedback from a number of organizations that are patient kind of focused organizations for people living with HIV. And we heard that because of the historical and current stigma associated with HIV, that there were some concerns about responding to surveys, and so that is something we've heard.

And I will note too that, you know, and we reopened the surveys at your direction in January, where we received a tremendous amount for other drugs. I will say for Genvoya, we did not receive any additional responses.

BOARDMEMBER CATHERINE HARSHBARGER: Which also makes me wonder how concerned they are about it. I don't know that answer exactly. I think the stigma definitely is part of the issue. People just don't want to be associated necessarily, have people associate them with their health issue in this case.

BOARDMEMBER AMY GUTIERREZ: For the second bullet under there, Lila, where it says some participants highlighted IQVIA lab data. I'm not sure IQVIA has lab data. It's probably

more -- they're looking at qualities and affordability. Do we validate that, that 85 percent of people have a copay of less than or equal to $5.00?

LILA CUMMINGS: We did not. So any voluntarily submitted information, we did not do an independent assessment of. And I will note that IQVIA is a clearinghouse that also does analytics, including claims-based analytics that, to our understanding, is based on claims data they receive from a number of organizations, but not state All Payer Claims Databases. So no, we did not; that's not something that we validated.

BOARDMEMBER CATHERINE HARSHBARGER: But this is from one of our scientific or medical trained people.

LILA CUMMINGS: Something that they provided, yup. And I believe this one in particular was the manufacturer who had individuals with scientific and medical training present at meetings.

BOARDMEMBER JAMES JUSTIN VANDENBERG: And didn't they just change this year. Sorry, this is bullet three, I'm jumping to the next one. I thought they got rid of copays for

Medicaid patients.

LILA CUMMINGS: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: So that line is probably outdated.

LILA CUMMINGS: So for particular, and we'll touch on that in a little -- I believe it's on this slide; if it's not, we'll touch on it. Yes, for individuals covered by -- who are insured through commercial insurances regulated by the State of Colorado, there is new legislation that prevents copays for any HIV medication.

BOARDMEMBER CATHERINE HARSHBARGER: Can anybody tell me, because I don't know what it is now, what's the federal poverty level this year; does anybody know?

LILA CUMMINGS: The information on who qualifies is in Appendix F for 2024.

BOARDMEMBER CATHERINE HARSHBARGER: Okay, thank you. I don't remember seeing it.

LILA CUMMINGS: I've got a lot of tabs open.

BOARDMEMBER CATHERINE HARSHBARGER: That's okay. I can look at it.

LILA CUMMINGS: I'd be happy to share

my screen if you would like.

CHAIR GAIL MIZNER: Just want to clarify for people too that the ADAP coverage includes undocumented, uninsured people, and this is very important from a public health standpoint. You don't want people uninsured because -- I mean, untreated because they can then transmit the virus; whereas, somebody who's well treated with an undetectable viral load will not transmit the virus.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, that's a social issue for sure.

CHAIR GAIL MIZNER: And I have no patients for whom I cannot get antiretroviral medication because of that excellent ADAP coverage and the excellent work of the Ryan White programs.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: I think we can move on to the next slide. All right, so there was just one organization that had done kind of a summary of the financial effectiveness of Genvoya.

I will note, and we've noted this, that, you know, no assessment was done on

comparing the price Canada pays or the average reimbursement to Colorado-specific data. So for Canada, you'll see here that they said that Genvoya is similar in costs or less costly than other single tablet or commonly used treatment regiments for adolescents and adults in Canada.

Okay, we can keep moving.

All right, so moving on to the access to care profile. You've seen these appendices, you've seen the description, so we can keep moving.

All right, so here is the graphic that shows change in WAC versus change in annual inflation. And apologies, I think we've -- Google Drive shut down on us this morning, so we had some issues with saving some of the text properly. And so, you'll see there that is right, but on a previous slide, it was not, so this is good for Genvoya.

CHAIR GAIL MIZNER: Any comment on that?

BOARDMEMBER CATHERINE HARSHBARGER: No.

BOARDMEMBER JAMES JUSTIN VANDENBERG: No.

LILA CUMMINGS: The similar graphic to

what you've seen in the report. We have change in patient count, change in total paid, average paid for person, total patient, then average out-of-pocket costs.

Okay. Any discussion here?

BOARDMEMBER CATHERINE HARSHBARGER: Well, the graph does show us from 2018 to 2022, it's become I guess less costly for individuals, you know, the Colorado consumer, as well as just in general, the cost has gone down.

CHAIR GAIL MIZNER: Well, the total paid has gone down, but the number of patients using it has gone down.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah, sorry. Yeah, there's a correlation, sorry.

CHAIR GAIL MIZNER: So I'm still sort of a little bit alarmed by that out-of-pocket cost, but I also think that with this particular medication, we know that, whereas unlike with some other medications where you simply -- it's hard to know if there are patients who need it and just simply aren't accessing it at all.

With this, because of the robustness of the ADAP program with possibly a few exceptions of patients who are afraid to -- have so much

stigma that they're afraid to approach the program or enter into care that people who need a drug are getting it.

Dr. Rome, what did you want to...

DR. BEN ROME: I was just going to add one more thing, Gail, just as you're thinking about that number. It includes copayments, coinsurance, and deductibles. So, you know, many patients do pay a deductible of a few hundred dollars at the beginning of the year. And if the person who has HIV but no other medical conditions, you know, the deductible will probably go towards Genvoya if that's the medicine they're using, and so, that also is counted here.

So just as you're sort of conceptualizing this number, that's another maybe reason why it might be a little higher than you were expecting because patients may not see that as a cost, you know, as a specific barrier to Genvoya. And obviously, the benefit design is such that it isn't, but if that's their only drug or their most expensive drug, it'll probably get applied.

CHAIR GAIL MIZNER: Right. Thank you.

BOARDMEMBER AMY GUTIERREZ: I think they key is too that 500 percent federal poverty level. Anyone above that will not apply.

CHAIR GAIL MIZNER: Right. That's a pretty generous amount, though, that it is 500 percent above federal poverty level is inclusive of quite a few people probably.

BOARDMEMBER AMY GUTIERREZ: I think I'm just looking it up, Cathy. I think it was 15,060 in 2023 FPL.

BOARDMEMBER CATHERINE HARSHBARGER: Right, thank you.

LILA CUMMINGS: And I would just note too that we don't have it on a slide, but in the summary report, particularly I believe it's Page -- or it begins on Page 25, there is information on monthly utilization for Genvoya's therapeutic alternatives. There's information for monthly total paid and average total paid.

And then there's also information from the survey responses, acknowledging that there were only 22 survey responses regarding patient self-reported out-of-pocket costs and any concerns with costs affecting access. And all patients reports that their out-of-pocket cost

per month was zero to 50 or 50 to 100.

And then there's also information on cost effectiveness on access where the majority said that cost did not affect access, and that's Table 12 in the summary report.

CHAIR GAIL MIZNER: I'm at the F-3, which is the Colorado State Drug Assistance Program income eligibility chart. So for a single person family size of one, 500 percent of federal poverty level is $75,300.

BOARDMEMBER CATHERINE HARSHBARGER: Oh, my math is right; that's what I calculated.

CHAIR GAIL MIZNER: And it goes up if you have more in your family. Can we move on?

LILA CUMMINGS: Yup, we sure can. So patients, caregivers, and clinicians provided input that treatment for HIV may be received at a clinical provider's office who receives funding from the Ryan White HIV/AIDS Program and that many, if not all, of these clinics are registered as covered entities.

I would say here that in the Appendix F where we list the different covered entity types, some of the clinics or one of the -- some of the covered entity types are specifically Ryan White

clinics or Ryan White adjacent. So that information, while we didn't do an assessment of was there utilization or couldn't do an assessment of was there utilization of Genvoya at those clinics, I think just due to the nature of there's a specific category for these providers under covered entities in the 340B programs is notable.

Individuals also provided input that these clinics receive funding in a number of programs, including SDAP, to lower the cost of prescription drugs. I won't read this. You've already talked about it and discussed the specific levels.

But then do also want to note, and Dr. VanderBerg, you mentioned this, so Colorado Senate Bill 23-189 requires Medicaid and state regulated commercial plans that cover health services related to STIs to include coverage for HIV prevention drugs or cover HIV treatment like Genvoya without step therapy or prior authorization requirements.

Additionally, at the federal level, Medicare requires Part D plan sponsors to include on their formulary all drugs in six categories,

including antiretrovirals like Genvoya, and they may not be subject to prior authorizations or step therapy requirements.

BOARDMEMBER CATHERINE HARSHBARGER: But probably would be subject to, like for Medicare, their copays and things like that -- not copays, their deductibles, right? Well, they can go to those programs as well, the Ryan White programs, state programs.

LILA CUMMINGS: And then here are the survey responses regarding utilization management and requirements from patients and caregivers.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Amy, do you think the second-to-last one is probably on there only offers 30-days. Was it my understanding a lot of that has to do with compliance and putting this into almost the specialty bucket because of the high cost? So they want to make sure there's adherence so they're not just going to give a three-month supply, and so they want to have a tighter check in, I think was my understanding on there. Not saying it's right. I'm just -- but I believe that's the rationale behind that.

CHAIR GAIL MIZNER: It's pretty common.

I'm almost surprised it's not higher than that.

BOARDMEMBER AMY GUTIERREZ: I agree. I think it's just -- that way, you at least don't wait three months to find out they're not taking their medication and you don't intervene, but I agree.

LILA CUMMINGS: I believe this is the last slide, so I'll pause here. And anything on the slides or in the report, right, the slides kind of touch on most areas. But if there's anything you'd like to discuss from the report through the appendices, I'm happy to do that.

BOARDMEMBER AMY GUTIERREZ: Lila, the report was well done.

BOARDMEMBER CATHERINE HARSHBARGER: Yeah.

LILA CUMMINGS: Okay. Then with that, I believe we can move on.

CHAIR GAIL MIZNER: Okay. Any more comments before we move on then to public comment? Any more comments from the Board or deliberations from the Board?

BOARDMEMBER JAMES JUSTIN VANDENBERG: Can't think of...

CHAIR GAIL MIZNER: Great. Then we

will now take public comment regarding Board deliberations on Genvoya only. Callie will put the sign up form in the chat and we will take comments from up to 10 people today and each speaker will be given two minutes to speak. As a reminder, this period of public comment is limited only to comments related to the Board's deliberations on Genvoya. A time for general public comment will be available at the end of the meeting.

CALLIE ANN SHELTON: The link is in the chat. I have a few people signed up already, and we'll start with Jen Laws.

JEN LAWS: Thank you, dear. I hope your throat is doing all right. I'm going through the same thing.

I'm Jen Laws, President and CEO of Community and Access National Network. We participated in small group meetings and really tried to participate throughout this process. We're a 27-year-old national patient advocacy organization focused on HIV, Hepatitis C, and substance use disorder.

I, myself, am a transgender man living with HIV, so this particular issue was very, very

important as we engaged on this, including working with local partners over at CORA and a Colorado-based HIV patient advocacy organization as well.

I do want to clarify a point that might have been a little confusing for folks listening when Lila was going over the first part of this, saying that patients have sometimes run into issues around prescription medications for HIV. That is a historical health equity point because prior to the ACA, our drugs weren't covered, payers weren't required to do so, and we were adamantly discriminated against. It's the entire point of the AIDS Drug Assistance Program.

So that health equity and access piece around medication influences a lot of what you hear from patients around medication access and HIV. A lot of us have been dealing with this for a very, very long time before these protections were made available, and so we're facing what we're facing right now.

I do want to respond to what Dr. Rome had to say about not seeing it because of the deductible and everything else. I'm going to keep myself well behaved right now. The SDAP

actually helps with premiums and deductibles, not just as out-of-pocket costs, so that's a huge piece on this.

And I think this is the most important part of when we talk about system costs, not just that individual cost, because I'm going to tell you right now there are not patients in Colorado that meaningfully have an issue accessing Genvoya based on cost. We deal with those things, and we deal with those things nationally because HIV is a public health issue.

So to that end, with regard to 340B-based programs or 340B-covered entities, including Ryan White Clinics and the AIDS Drug Assistance Program itself and certain hospitals, what a UPL would do there is not reduce the ability for that entity to access the discounted cost, but will reduce the value of the rebates in which those entities are able to reinvest in their communities.

A UPL will dramatically increase issues of health disparities because it reduces those income availability, that program revenue availability to reinvest in communities. If UPL is instituted on any drug on an ADAP formulary,

what you are going to have as a result is a reduced ability for that program to serve people in need, and when that comes to the ADAP specifically, you are talking about your priority population too. You're talking about people living with HIV in marginalized communities, people who are impoverished. It is hard. This is a complicated process.

I believe in good faith that everyone here is trying to make sure that there is equitable access to care, not just poor people living with HIV, but across the spectrum and this is complicated. It is my sincere desire that as you approach legislative report back, that what you tell the legislature, so UPL is not the right tool for the job.

Thank you. Thank you, Callie. I know I went a little over.

CALLIE ANN SHELTON: Hey, Jen, I hope you get to feeling better. Natalie Rose. Natalie, you're muted.

NATALIE ROSE: Good gracious, that mute button. Thank you for letting me know.

My name is Natalie Rose. I am speaking as a medical value and evidence liaison with

Gilead Sciences. I respectfully ask that the committee protect all HIV medications, not deem them unaffordable, or place an upper payment limit on them, including Genvoya.

The draft report affirms that Coloradans with HIV have robust and affordable access to Genvoya. In its review of payer data and input from patients from stakeholders, the report included many examples of how Genvoya is affordable to Coloradans with HIV across all payer types with a significant portion of patients with low or even zero copays. We also appreciate that the report acknowledges the combined role of both federal and state safety net programs to assist with access to medications.

The affordability of Genvoya is further underscored by its low abandonment rates. Whereas, patient affordability or non-adherence may be an indication of patient affordability issues, the report found that three or fewer respondents to the patient survey indicated that the cost of Genvoya has ever affected adherence. This finding comports with our understanding that the abandonment rate for Genvoya is 50 percent

lower than rates seen across other specialty drug classes in 2022.

Furthermore, the further affirms Genvoya is accessible. The report found that of the 10 carriers in the market, all 10 carriers covered this medication with unrestricted access, and the majority of carriers placed Genvoya on the middle-to-lower tier, meaning a lower portion of the drug is paid by patients.

Lastly, the report includes many quotes from respondents who attest to the wide availability of assistance programs, and an overwhelming majority of patients surveyed reported using an assistance program. As affirmed here by the data presented in the Board's affordability report, Genvoya is affordable and accessible. Colorado can do its part to end the HIV epidemic.

I respectfully ask that the Board not find any HIV medication, specifically Genvoya, unaffordable and not set an upper payment limit within the HIV class. Thank you so much for your time today. I appreciate it.

CALLIE ANN SHELTON: Thank you, Natalie. Mark Thrun.

MARK THRUN: My name is Mark Thrun. I work with Natalie at Gilead Sciences. I direct HIV strategy at the present moment for the United States, but I'm a Coloradan. I am a public health infectious disease doc who's had 24 years of experience providing HIV care in Colorado. I used to direct the Sexual Health HIV Prevention Services at Denver Health, long time advisor to CDPHE, HCFA, and CDC mostly on matters related to sexual health and HIV.

And I wanted to touch on a couple of the things that you all have already brought up, and that is stigma and the importance of continuity of care. As was shown in the affordability reports, HIV is increasingly being diagnosed in persons who might also have challenges accessing and persisting in care, including disproportional new infections in Black, Latino, and MSM populations.

As you all noted, 60 percent of people on Genvoya are in counties that have an above average social vulnerability score. There remain significant challenges to accessing ongoing HIV care in a state in which most of the providers -- Dr. Mizner, you excepted -- are actually in the

front range.

Stigma is incredibly important as well, as you've just heard from Jen. HIV not only impacts those who are in marginalized communities, but HIV itself is a marginalizing disease. Many people living with HIV have not disclosed to their family and friends, they're reticent to seek care in HIV-specific settings, they're anxious as they go to Quest and LabCorp that somebody might mention it out loud, and they're reticent to go to a pharmacy to pick it up and to have the pharmacist mention the medication aloud. It's difficult for these folks to remain meaningfully engaged in care, and any potential disruption of care can be harmful.

The same stigma, as you've already talked about, likely played an impact in the number of respondents on the survey. On the website, it said that you all could not guarantee anonymity to the survey and certainly, I suspect that played a role in the few number of respondents.

Finally, as a public health doc, I really have to mention -- that I would be remiss in not mentioning, I should say, the need for

continuity of care. If someone stops their HIV medications, their viral load becomes detectable, then they can transmit virus; whereas, if they remain on their medications continuously and their virus is undetectable, there's zero likelihood of forward transmission to other Coloradans.

For all these reasons, we at Gilead support those in the community who have advocated for treatment choice, allowing a patient and provider to opt for the treatment regimen that works best for them and allows for them to remain on it without interruption. We at Gilead remain committed with all of you, based on your comments, to ending the epidemic for everyone everywhere, and we believe that access to appropriate tailored treatment regimens is central to that.

Thank you for the opportunity to speak. Thank you, Lila, for opportunities previously to share our insights with you.

CALLIE ANN SHELTON: Thank you, Mark. Christopher Zivalich, please.

CHRISTOPHER ZIVALICH: Hello there, hi. Thank you for letting me make comments today. My

name is Chris Zivalich, I use he and his pronouns, and I'm speaking to you today as a community member with extensive experience in HIV treatment and prevention, including my role as a volunteer co-chair for 5280 Fastrack Cities, a local HIV coalition.

I want to stress that placing an upper payment limit on Genvoya would render it less accessible, which puts a person living with HIV's ability to self-direct their own care at risk. As we've mentioned, 60 percent of people living with HIV taking Genvoya live in a county with high social vulnerability. My interpretation of that is that many people taking this drug are dealing with overlapping inequities and social determinants to health. So making something that is stable in their life like Genvoya less accessible could impact them more disproportionately than a person living with HIV in a less vulnerable county.

Also being on a medication that really works for someone living with HIV helps them maintain their adherence and ultimately achieve an undetectable viral load, which does eliminate the possibility of HIV transmission, so this

really is a public health matter.

And I want to emphasize that a person's HIV medication should always be the byproduct of a shared decision-making process between the provider and the patient.

I'd also like to emphasize, just as someone who's enrolled people in the past in a lot of these programs, that yes, Genvoya is eligible for copay support, usually with or without income limits; that will cover the entire cost of the drug, so it will not place an affordability burden on nearly all patients. However, the burden of being forced to a new drug, that could be a significant interruption. So while therapeutic alternatives exist, that switch really being forced on someone could be pretty distressing and destabilizing and it's very different when they choose to do that.

So I hope with this information you'll recognize how Genvoya access is critical and that decisions on this should really always center, first and foremost, the autonomy of the person living with HIV so they, you know, decide for themselves in consultation with their doctor or provider which drug is currently meeting their

care needs.

Thank you so much for the opportunity to speak today.

CALLIE ANN SHELTON: Thank you, Christopher. Sorry I did such a bad job pronouncing your last name.

CHRISTOPHER ZIVALICH: That's okay, I'm used to that.

CALLIE ANN SHELTON: Michael Deroche please.

MICHAEL DEROCHE: Thank you for letting me speak today. I'm a person who's living with HIV for 37 years, I believe. I can't most of the drugs because even though I'm always adherent with my medications, it's a smart little bugger virus.

I really think that HIV should not be one of the disease categories for this program. I think it's great what you're doing, but I just think that you need to be hands off of HIV. You know, a lot of drugs do help a lot of people in a lot of ways, but this drug is -- HIV drugs are essential to stay alive. If I stop taking my medication, it's just a matter of time until I'm going to get sick and die; it's as simple as

that.

I'm on this crazy regimen. By the way, I just want to correct you. You can take statins. I'm on a statin. I'm not on Genvoya and I'm not on cobicistat, but I'm on Ritonavir, which is the same thing; it's a sensory A inhibitor, which boosts levels of my (sound glitch) producing inhibitor. My prescription for Rosuvastatin is 10 milligrams instead of 20. If I ever go off that drug, I'm going to have to go back to 20 milligrams, so that just isn't really correct. And then I also take it in the middle of the day because I take my Ritonavir with breakfast and with dinner, so I take my (indiscernible) with lunch.

I just think it's really -- you know, first of all, Genvoya is on the way out, it really is; it's an older drug. And I'm a peer educator, I'm involved in the AIDS Treatment Activist Coalition and Treatment Education Net- --which is a national organization, and Treatment Education Network, which is a local organization. I'm a peer educator. We provide programs with people with HIV.

You know, people will say, hey, what do

you think of blah, blah, blah, blah. They ask me for advice because they know I stay up on everything. And I say, well, why would you take a drug that has cobicistat in that, which has toxicities and it's not an antiretroviral, why would you take that if you don't have to. You know, I mean, Biktarvy, which is the same manufacturer, is a great option, and really Genvoya is on the way out.

It was interesting how well (indiscernible), which was (indiscernible), is an integrase inhibitor that wasn't even on your comparator list. I just think it's so important. If you need to have an HIV drug on your -- you know, if you need to target one -- you need one HIV drug to target, there's Crofelemer, which was developed for people with HIV that have diarrhea; it's a questionable drug, it's very expensive, but you're not going to die if you don't take it. There's also Egrifta, which is for sub-q hardened belly fat, which I think isn't diagnosed properly, but you know, it's really expensive but it doesn't keep you alive.

I think that's all I have to say. I know I was going to say other things, but you

know how your mind goes whatever. Thank you for this opportunity.

CALLIE ANN SHELTON: Thank you, Michael. Scott Bertani.

SCOTT BERTANI: Hey, thank you again. Hey, I am Scott Bertani and the director of advocacy for Health HIV. I'm the lead for the National Coalition for LGBTQ Health, and a former DG patient myself. And I mention the latter because I'm so glad that Dr. Mark Thrun was on there; in fact, he was my prescribing doc back in the day. And I can't ever remember him saying to my NP, Scott, oh yeah, switch his meds to meet my cost profile needs. It's just a communicable disease. Ignore that there are statutes on the doctors too. Shared clinical decision making just isn't that important.

So from that place, you know, facing challenges long before current protections, we've navigated the evolving landscape of healthcare and particularly in Colorado where HIV treatment access remains largely unimpeded by cost. It's thanks to vital national public health efforts and subsidies and patient programs that erase the premiums and the deductibles.

And the stigma likely contributed to the low response rate in the survey mentioned where anonymity really couldn't be guaranteed, and it highlights the challenges we have in engaging this population in care and research. And the ongoing dialogue, you know, it really underscores the importance of 340B programs and ADAP with a looming threat of UPLs potentially reducing rebate values that's essential for community reinvestment and it not exacerbating health disparities.

My personal journey as an HIV positive individual, it underscores the necessity of maintaining access to treatment so that I could be here today to help speak after Dr. Mark Thrun and emphasize that cost containment measures, they impact patient wellbeing and the healthcare ecosystem. And despite Colorado's healthcare legacy and the Denver principles that are patient centric where autonomy is a focus, the current strategies risk making crucial medications like this inaccessible and it undermines Medicare's protections and all the 340B programs benefits.

So I appreciate the conversations, and it really does call for a broader stakeholder

engagement and a reevaluation of data representation so that our healthcare decisions align with our needs and there are equitable access to treatments. So I appreciate the time, thank you.

CALLIE ANN SHELTON: Thank you, Scott. Dr. Mizner, that is everyone who signed up for Genvoya comments.

CHAIR GAIL MIZNER: Great. Thank you all. Are Board members comfortable moving forward with determining whether Genvoya is unaffordable with the information presented?

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

BOARDMEMBER AMY GUTIERREZ: Yes.

BOARDMEMBER JAMES JUSTIN VANDENBERG: I am.

CHAIR GAIL MIZNER: Good. If there's no further deliberation and having considered the evidence before us relating to each affordability review component, do I have a motion regarding a vote on unaffordability of Genvoya?

BOARDMEMBER AMY GUTIERREZ: I'll make a motion. The use of Genvoya consistent with the labeling approved by the FDA or with standard

medical practice is not unaffordable for Colorado consumers.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Justin VandenBerg, I second that.

CHAIR GAIL MIZNER: Thank you. Dr. Guttierez moved and Dr. VandenBerg seconded that the use of Genvoya consistent with the labeling approved by the FDA or with standard medical practice is not unaffordable for Colorado consumers.

I am going to call for a roll call vote again. Callie, would you please call the names.

CALLIE ANN SHELTON: Of course. Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Yes.

CALLIE ANN SHELTON: Cathy Harshbarger.

BOARDMEMBER CATHERINE HARSHBARGER: Yes.

CALLIE ANN SHELTON: Dr. Gail Mizner.

CHAIR GAIL MIZNER: Yes.

CALLIE ANN SHELTON: And Dr. Justin VandenBerg.

BOARDMEMBER JAMES JUSTIN VANDENBERG: Yes.

CHAIR GAIL MIZNER: Thank you. Lila,

please finalize the affordability review report for Genvoya by adding a high-level summary of our deliberations today, our determination that use of Genvoya is not unaffordable for Colorado consumers, and correcting any clinical errors you all identify. We will vote to approve the final report at our next meeting.

BOARDMEMBER AMY GUTIERREZ: Can I just say I want to thank all those that stood up and provided public testimony, including those who even disclosed personal details about their own illnesses and such and really thank you for taking the time to provide us with really valuable input from the public, so just a thank-you to you.

CHAIR GAIL MIZNER: So I want to second that.

LILA CUMMINGS: And just something I want to -- and I'll give my kind of closing comments about timing, and then we'll turn it over to public comment.

So the next Board meeting will be next Friday, February 23rd, from 10:00 to 11:00 a.m. is what is scheduled, and there will be kind of a couple of actions that could take place. We will

present kind of these final draft affordability reviews taking into account changes and a summary of your deliberations today and the vote, so for each of the drugs, there will be that.

For Enbrel, you all will also be taking a vote on Friday on whether or not you would like to initiate the rulemaking process for establishing an upper payment limit, so that is a decision that is before you next Friday. And then we will also come with a proposed timeline for what that could look should you all choose to move forward with that.

BOARDMEMBER CATHERINE HARSHBARGER: Lila, I will be -- as I mentioned to you I think before, I will be out of state and I was going to attend via Zoom like we do anyway. I will do my very best to be there at that time. I'll let you know if I have any problems with it, okay?

LILA CUMMINGS: Okay, we'll follow up. Thank you.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you.

LILA CUMMINGS: Okay. So now we'll turn it over to general public comment.

CALLIE ANN SHELTON: A few folks signed

up already, but if anybody else wants to sign up, click the link in the chat. Amy Goodman.

AMY GOODMAN: Thank you. First, I want to say that as the PDAB decides whether to set an upper payment limit on Enbrel since it has deemed it unaffordable, Colorado Bioscience Association continues to stress that government and price controls and caps are the wrong solution for patients. Government price controls will not lower costs for patients and risk serious unintended consequences, including limiting patient and prescriber choice and reducing investments in new medicines.

Also, I would just like to ask a question to clarify the process regarding the small group meetings that have happened with scientific and medical experts. At this time, the current draft affordability review reports do not include links to recordings of staff meetings with scientific and medical experts, and the draft reports also do not include a list of scientific and medical experts with (indiscernible).

What is going to be publicly shared about those meetings, which inform the

affordability review reports. We think these meetings should be made visible to the public, so I hope that we can get more insight into that soon. Thank you.

CALLIE ANN SHELTON: Thank you. Mannat Singh. Mannat, are you still here?

MANNAT SINGH: Hello. Sorry, my microphone was being a little glitchy. Thank you.

My name is Mannat Singh, and I am the executive director of the Colorado Consumer Health Initiative. I use she/her pronouns. As a consumer advocacy organization, it's CCHI's priority to make sure that Coloradans can access the prescription drugs that they need.

The findings today illustrate that the Board's work is very useful and very necessary. We appreciate the Board's care in discussing the complex and nuanced nature of access to Genvoya in Colorado at this time.

We're also encouraged by the designation of Enbrel as unaffordable, particularly the acknowledgement of racial health disparities in discussing affordability. We hope to see an upper payment limit process initiated

for Enbrel so that patients can get the financial relief that they deserve from this high-cost drug.

Upper payment limits are the only tool that Colorado has to address the root causes of the high cost of prescription drugs. PDAB is a really important opportunity to make meaningful policy choices that promote health over profit. CCHI remains optimistic about the Board's potential to create long-overdue accountability as one overall goal, to increase access to the highest (sound drops) drugs in our state. Thank you.

CALLIE ANN SHELTON: Thank you. And lastly, Katelin Lucariello.

KATELIN LUCARIELLO: Good afternoon, now evening, everyone. This is Katelin Lucariello, deputy vice president of state policy with pharma. First of all, thank you, of course, for the opportunity to provide public comment. We really appreciate that at this meeting, you've made time for public comment following deliberations and before votes on affordability.

We'd like to ask that the general comment period be moved to the beginning of your

meetings so that those considerations raised in public comment or questions, like some of those that had been asked this afternoon, can be deliberated or discussed by the Board at the meeting.

We'd also like to ask that the Board include a comment period at every meeting, including their shorter meetings to finalize the affordability reviews. At the meeting on 12/15, the Board did not have public comment and under PDAB's policies and procedures, the Board has said that they'll provide an opportunity for public comment at every meeting. It is really one of the few ways I think that we've seen the impact that stakeholders can really communicate directly with the Board in real time and provide input on deliberations. And so, we would greatly appreciate your consideration of those two suggestions.

Thank you very much and have a great weekend.

CALLIE ANN SHELTON: Thank you, Katelin. And we have one more, Bridget Serrett.

BRIDGET SERRETT: Hello. First, I want to thank you guys for all the work that you are

putting into this. I definitely would not want to be in your situation right now because I know it's a very difficult task to balance affordability and everything that's coming at you.

First, I want to address maybe some problems or some issues that I see with the process. For instance, the upper payment limit doesn't necessarily describe what this is. The PDAB bill was sold and I quote, "This bill is projected to save Coloradans up to 75 percent on the most unaffordable drugs and will pave the way for a more equitable healthcare system that prioritizes the wellbeing of patients over profits for the pharmaceutical industry."

But the more that I am involved with this process, I realize that upper payment limits are reimbursement caps. We have not changed what the manufacturer can charge for the medication, and so that means our specialty pharmacies may not be able to stock it if they can't get reimbursed for what it costs for them to get it and stock it.

So this bill seems to be geared towards shifting the process, rather than giving them

back to actual Coloradans, and I feel like insurance companies and pharmacy benefit managers are going to be the biggest winners in this and that is concerning.

I do want to also bring awareness to the transparency of this. The process is incredibly rushed, and, while I absolutely appreciate you guys reopening the surveys for Enbrel, we weren't given very much notice. And we had two and a half -- you know, we had four or five days to kind of rally everybody in only two and a half weeks for the surveys to be open, and that ultimately is not a long period of time, especially when you're dealing with medically complex community members and this was over a holiday, which made it even more difficult to find people to take part in this.

The data collection, the surveys don't actually prompt the patients to -- they answer questions about affordability and the value of the medication, but it doesn't ask about did you have less hospitalizations, were you able to work more, were you able to get off disability.

LILA CUMMINGS: Bridget, I apologize. We're at the limit on the time.

BRIDGET SERRETT: Oh, okay. Well, thank you very much. You guys have a good weekend.

CALLIE ANN SHELTON: Thank you, Bridget.

CHAIR GAIL MIZNER: Okay. I want to thank everyone for their participation today, staff, my fellow Board members, members of the public, experts. It's been quite an afternoon.

The next PDAB meeting will be held at 10:00 a.m. next Friday, February 23rd. And so, unless there is any objection, the meeting is now adjourned. Thank you all very much.

LILA CUMMINGS: Thank you, Board members, and thank you to members of the public.

BOARDMEMBER CATHERINE HARSHBARGER: Thank you everyone.

CALLIE ANN SHELTON: Lila, you cool if I end it?

LILA CUMMINGS: Yup. Thank you.

CERTIFICATION

I, Sonya Ledanski Hyde, certify that the foregoing transcript is a true and accurate record of the proceedings.

Date: JUNE 1, 2024

Sonya Ledanski Hyde

CORRECTED TRANSCRIPT

Colorado Prescription Drug Affordability Review Board - February 23, 2024 Meeting

BOARD STAFF LILA CUMMINGS: I'm going to shoot the other Board members a message just to see if they're having any tech troubles. One moment.

All right. Just heard from Dr. Diab. He should be able to get in soon. He's having some tech issues with his work computer, and then still working on Ms. Harshbarger. So, Dr. Diab should be here soon.

BOARDMEMBER DR. SAMI DIAB: Sorry I am late.

BOARD STAFF LILA CUMMINGS: Thanks for joining, Doctor.

CHAIR GAIL MIZNER: Lila, do you want -- should we wait for Ms. Harshbarger? Are we...

BOARD STAFF LILA CUMMINGS: I think we can go ahead.

CHAIR GAIL MIZNER: I haven't heard back from her.

BOARD STAFF LILA CUMMINGS: I think we might want to -- I'll keep reaching out to her. We could go out of order on the agenda if we want to try and see if we can get her. Let me keep calling. I'll give her a call again.

CHAIR GAIL MIZNER: Okay.

BOARD STAFF LILA CUMMINGS: So maybe we could wait just a moment. And also, there are some things on the agenda that could go first, if she needs a little bit more time, so let me see where she's at. One moment.

CHAIR GAIL MIZNER: Okay, thanks.

BOARDMEMBER DR. SAMI DIAB: And Madam Chair, I have a patient in the room, so, can I just -- I'm going to leave for five minutes. I'll be right back.

CHAIR GAIL MIZNER: Okay. Thank you, Sami.

BOARDMEMBER DR. SAMI DIAB: Madam Chair, I am back.

CHAIR GAIL MIZNER: Great. Thank you. Lila, should we proceed, and maybe change the order of our agenda? Or do you want to wait a few more minutes for Ms. Harshbarger?

BOARD STAFF LILA CUMMINGS: I was not able to get in touch with her. But I might propose we go a little out of order on the agenda. We can do some of the updates first. And then, Dr. Diab, we might be able to get you in a situation where you can help, potentially, vote where you can, and then you can leave a

little early on some of the things where there's a conflict, so we can work on that.

BOARDMEMBER DR. SAMI DIAB: Sounds good. Thank you.

BOARD STAFF LILA CUMMINGS: So, we will, I think what we can do is, we'll start out with the, actually, last agenda item. So, we'll do the Ad Hoc Work Group Meeting for General Assembly Report, so we can give some background on that and talk about a Board staff suggestion. And then, kind of be going reverse order and talk about the Cosentyx and Stelara and then, but back go Enbrel and Genvoya.

CHAIR GAIL MIZNER: Okay. So, I'm going to call the meeting to order. It is 10:10 AM. And the February 23, PDAB Meeting is called to order. Callie, would you please call the roll?

BOARD STAFF CALLIE ANN SHELTON: Of course. Dr. Sami Diab?

BOARDMEMBER DR. SAMI DIAB: Present.

BOARD STAFF CALLIE ANN SHELTON: Dr. Amy Gutierrez.

BOARDMEMBER AMY GUTIERREZ: Present.

BOARD STAFF CALLIE ANN SHELTON: We are

still waiting on Cathy Harshbarger. Dr. Gail Mizner?

CHAIR GAIL MIZNER: Present.

BOARD STAFF CALLIE ANN SHELTON: And Dr. Justin Vandenberg?

BOARDMEMBER JAMES JUSTIN VANDEBERG: Here.

BOARD STAFF CALLIE ANN SHELTON: Thank you. Madam Chair, we have a quorum.

CHAIR GAIL MIZNER: Thank you, Callie. Okay, Lila, you want to move first to discuss the Ad Hoc Work Group Meeting in preparation for General Assembly Report?

BOARD STAFF LILA CUMMINGS: Yeah, absolutely. And so, Sabrina, if you would scroll to the end of the PowerPoint. There we go. Go back one more. There we go.

So, it's kind of approaching time for the Board's annual General Assembly Report. So, you can see here on the screen that your statute outline said on or before July 1, 2023, and every July 1 thereafter, the Board shall submit a report summarizing the activities of the Board during the preceding calendar year to the Governor, House Health & Insurance Committee, and

Senate Health & Human Services Committee. And so, this report that is coming out July 1 of this year, will summarize your events from 2023, including any work that you all conducted on affordability reviews and upper payment limits.

We've outlined some potential goals here. And really, on the next slide, we'll talk about, I think, what we've heard from Board members as well as from Advisory Council members, of some extra thought that you might want to put into the report. And it wasn't so much around summarizing your activities; it was, there's a section in the statute that says you all can make policy recommendations.

And so, we've put together kind of a potential timeline goal. On the next slide, we'll revisit some of the policy recommendations that you all have brought up in the past, and then just want to open it up to discussion on what Board members think the right cadence is, between now and July 1, for drafting this report.

So, the staff proposal here is that sometime, kind of in early April, we could help facilitate an Ad Hoc Meeting, that would include Board members, Advisory Council members; could

also include members of the public, and a public comment period, to discuss the report contents. I will say we had three members from the Advisory Council volunteer for, if there was an Ad Hoc Work Group created, they volunteered to serve on that. And so, that was -- the Chair, Dr. Kimberly Jackson, Edward Dauer and Nathan Wilkes. So those three Advisory Council members volunteered to help support in this discussion.

Then, if we have that meeting, Ad Hoc meeting in early April, we could then bring to the Board a kind of final draft, still in draft form, of the report contents for your April 26 meeting. And then incorporate any changes you'd like to see for, hopefully, at your June 7 meeting, a kind of finalization of the report. And then we could send that off to the General Assembly.

So, that's the general timeline that we're looking at. And if we could go to the next slide. So, what we anticipate this report and this Ad Hoc Work Group, would really focus on the space. So, there's space in the report for recommendations the Board may have for the General Assembly, concerning legislative and

regulatory policy changes to increase the affordability of prescription drugs, and reduce the effects of excess costs on consumers and commercial health insurance premiums in the state.

The Board had brought up some topics last year that you said you might want to revisit and continue to think through. So, one of these was the role of group purchasing organizations and the supply chain; research into prescription drug costs and indications that may signal a prescription drug is unaffordable. And then potential ways to better understand topics that are typically hard to know. So, prescription drug challenges for the uninsured, impact of utilization management and prior auth on prescription drug access, and prescription drug manufacture assistance programs, advertisement discovered and utilization information.

So, those are some topics from last year. And we anticipate that these work group meetings would focus mainly on this component. Board staff can work to summarize your activities, and absolutely kind of clear that with Board members and make sure we're

summarizing it properly. But in our minds, this Ad Hoc Work Group could really focus on drafting these recommendations. And Board staff would work you all as well, before the April 26 and June 7 meetings, where we could bring kind of final recommendations for discussion. And so I think we can go to the next slide.

So, here we, I'd say, first, I would love to hear from Board members on kind of what, any questions about the General Assembly Report? Do you like this idea of an Ad Hoc Work Group? We've got this slide up here, if you'd like us to kind of go that direction, but we'll pause here for conversation.

CHAIR GAIL MIZNER: What does everyone think?

BOARDMEMBER AMY GUTIERREZ: I think it's a good idea to be able to provide some more directed (indiscernible) on potential areas that we could be looking into, to make sure that our decision is, decisions that we make are as tight as possible. So, I think it's a great idea.

BOARDMEMBER DR. SAMI DIAB: Yeah, Sami here. I second that. I think it's really great for discussion-generating ideas, you know, and

really moving forward. So, I totally support that.
CHAIR GAIL MIZNER: Justin?
BOARDMEMBER JAMES JUSTIN VANDEBERG: No, I like that. I think where I'm thinking is, and maybe I'm putting the cart before the horse as far as how often are they going to meet? Do we have a set number so that it gives them enough time to produce a quality report and not just, you know, we meet one afternoon and that's it. But no, I think it's a great idea to be able to put more time and not thoughtfulness, but I think that time of being able to, you know, create a more robust report on that. I certainly agree.
CHAIR GAIL MIZNER: I agree too. In fact, I think there may be ideas that arise from board members or from PDAAC members that are not even listed by Lila, and that maybe we actually would need more than one meeting to discuss those, Lila. Maybe we should even aim for the first meeting of an Ad Hoc Committee in March. What do you think about that?
BOARD STAFF LILA CUMMINGS: We can build time for that.
CHAIR GAIL MIZNER: Okay.

BOARD STAFF LILA CUMMINGS: And I'm also wondering, and we could check with Dr. Jackson. There is a PDAAC meeting scheduled for April 11. So, I'm also wondering if there might be some synergy, if we've got a March meeting of an Ad Hoc work group, if we kind of -- if there's some piggybacking we could do with the Advisory Council meeting. We can look into that.
CHAIR GAIL MIZNER: Okay. And Lila, do we need to decide now which Board members would be on the Ad Hoc Committee?
BOARD STAFF LILA CUMMINGS: I think that would be the hope, is which one of you would like to volunteer to put extra meetings, to be on the Ad Hoc Committee?
CHAIR GAIL MIZNER: So it can be only one person?
BOARD STAFF LILA CUMMINGS: No, it can be multiple.
CHAIR GAIL MIZNER: Okay. Okay.
BOARDMEMBER DR. SAMI DIAB: Sami here. I'm happy to volunteer, but if anybody else wants to do it or, you know, happy to do that as well.
CHAIR GAIL MIZNER: I'm also interested in being on the Ad Hoc Committee. Justin? Amy?

What are your thoughts?
BOARDMEMBER AMY GUTIERREZ: I'd volunteer too, but is it going to -- can all of us be on it or (indiscernible)?
BOARDMEMBER JAMES JUSTIN VANDEBERG: That's why I was just keeping my mouth shut for a second, because I'm like -- see where it went so that it wasn't, yeah, just turned into a full -- full blown meeting thing.
CHAIR GAIL MIZNER: Right, right.
BOARDMEMBER DR. SAMI DIAB: So, you know, if there's interest, I withdraw my name at this point, if somebody else wants to do it, since there's already a physician on it. That's totally fine.
CHAIR GAIL MIZNER: Okay. Thank you, Sami. All right. So, we need to formally delegate Board members to form an Ad Hoc Work Group to help prepare a draft for the General Assembly. Let me -- so, it's sounding like Dr. Gutierrez and I are the ones who would -- are most keen on being on this Ad Hoc Group. Do I have a motion to delegate Dr. Gutierrez and myself, Dr. Mizner, to form an Ad Hoc Work Group to help prepare a draft General Assembly Report?

BOARDMEMBER DR. SAMI DIAB: I so move.
CHAIR GAIL MIZNER: Thank you. Do I have a second?
BOARDMEMBER JAMES JUSTIN VANDEBERG: Justin Vanderberg, I second.
CHAIR GAIL MIZNER: Okay. Thank you. Dr. Diab move and Dr. Vandenberg seconded. All those in favor of forming an Ad Hoc Work Group to help prepare a draft General Assembly Report, raise your hand and say aye.
BOARDMEMBER DR. SAMI DIAB: Aye.
BOARDMEMBER AMY GUTIERREZ: Aye.
BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.
BOARD STAFF LILA CUMMINGS: Aye.
CHAIR GAIL MIZNER: Okay. I think that's unanimous, with the exception of Ms. Harshbarger, who's not here. Any opposed, say nay. Okay. The motion passes. So, we will be forming an Ad Hoc Work Group with some members of the PDAAC, and with myself and Dr. Gutierrez as the Board representatives, to help prepare a draft General Assembly Report. Great. Lila, where do we want to go next?
BOARD STAFF LILA CUMMINGS: I think

next we can go Cosentyx and Stelara, though I am, I think there might be kind of an emergency that has taken Ms. Harbarger away, so we'll talk about Cosentyx and Stelara, and then proceed, kind of at the top of the agenda. And it looks like Ms. Harshbarger might not be able to join.

So, (indiscernible), if you could go a couple of slides -- thank you.

Okay, and so here, I do know that we need the brief, Cosentyx and Stelara, the next slide, conflict of interest disclosure.

CHAIR GAIL MIZNER: Okay, so are there any Board members who have a conflict of interest with either Cosentyx or Stelara? Should we do a roll call on that?

BOARD STAFF CALLIE ANN SHELTON: Dr. Diab?

BOARDMEMBER DR. SAMI DIAB: I believe I have conflicts.

BOARD STAFF LILA CUMMINGS: And actually, counsel, would you be able to help Dr. Diab here with, I believe it's just one.

BOARD STAFF SARA STULTZ: Yes, no problem. Dr. Diab, we believe, based on your prior disclosures, you have a conflict of

interest with Cosentyx. Does that still sound...

BOARDMEMBER DR. SAMI DIAB: Yeah, nothing has changed. Thank you for the help.

BOARD STAFF SARA STULTZ: No problem.

BOARD STAFF CALLIE ANN SHELTON: Dr. Gutierrez?

BOARDMEMBER AMY GUTIERREZ: No conflicts.

BOARD STAFF CALLIE ANN SHELTON: Thank you. Dr. Mizner?

CHAIR GAIL MIZNER: No conflicts.

BOARD STAFF CALLIE ANN SHELTON: And Dr. Vandenberg?

BOARDMEMBER JAMES JUSTIN VANDEBERG: No conflicts.

BOARD STAFF LILA CUMMINGS: All right. We can go to the next slide. Okay, so here, and we just want to check with you all to see if there's any objections. I'm not necessarily asking for a formal vote. But we just want to see if there were any objections to us as staff, gathering additional information for Cosentyx and Stelara, in the same way you all directed us to, for Genvoya and Enbrel. And this was due to the kind of lower survey and stakeholder engagement

responses. So, in an effort to gather more input from, so two different groups.

So, first of all, input from individuals with scientific and medical training. So, staff plan to reopen the surveys for individuals with scientific and medical training for probably two to three weeks, as well as outreach to physicians and pharmacists who are actively prescribing and dispensing Cosentyx and Stelara, for additional information on the health and financial benefits of the drug. So, we'll plan on doing that, unless there's any concern. And then, for input from patients and caregivers, we do plan to reopen the survey for the same amount of time as the other surveys, to gather additional input.

BOARDMEMBER AMY GUTIERREZ: Can I ask a question? I know, in some of the comments, public comments that we got, there was a question about conflict of interest with professionals that are providing us survey responses. Are we planning on having individuals disclose those when they do provide us with responses?

BOARD STAFF LILA CUMMINGS: That's a -- we can look into that. It's something where, in

policy documents, we encourage people to disclose. But there's not a requirement that individuals disclose. And because we haven't required that disclosure previously, I think we might have some hesitancy to do it now. But there is this general, we encourage folks to disclose. But that is something we could talk about.

BOARDMEMBER AMY GUTIERREZ: Okay. Thank you.

CHAIR GAIL MIZNER: Yeah, I agree with you. Amy, I think that's important to know. And you know, this -- what we're doing here is a process, and we are trying to constantly improve it. So, I would encourage us to require disclosure on the part of medical professionals about any connection to the manufacturer.

I also realize that we have gotten some public comment and feedback regarding the surveys themselves. And I wonder whether we would want to -- I know we've had expertise already, in developing the surveys, but I wonder whether we should take a second look; maybe get an outside survey expert, if we can find the funds for that, to just review before we send out those surveys,

to make sure that they are as well developed as possible, given the feedback that we've gotten. I'm not saying the feedback is necessarily correct, but I do think we should get somebody with real expertise to take a second look at that.

BOARD STAFF LILA CUMMINGS: Okay, okay. Something we can do -- I think we're just mindful of wanting to have the surveys open for a number of weeks, with enough time to take the results to present. But I think that if we -- we can look into both the conflict-of-interest disclosure requirement, as well as kind of the -- somebody looking at the surveys for potential edits. And what we will do is we can get back to you with answer on that for your next meeting; which means that the surveys would not reopen till after March 15. But we can look at that in an effort to try and get answers to those questions. And then, when you all are ready, we might be able to kind of open the immediately after March 15, because we want to ensure we can leave the open while still having time to interpret the results. So, we'll plan on gathering some of that information for March 15.

CHAIR GAIL MIZNER: Great.

BOARD STAFF LILA CUMMINGS: Any other discussion about the surveys or gathering additional input? Great. Well, then I think -- Chair, I think we can probably move to the top of the agenda. It does look like Ms. Harshbarger will not be able to join us today.

CHAIR GAIL MIZNER: Okay. That's too bad. All right. Before we vote on the final versions of the affordability review reports for Enbrel and Genvoya -- actually, should we -- I know there's some -- I would like to hold an executive session for legal advice on public comments that we've received on Enbrel. Do we, should we do this conflicts of interest first, or should we go straight into voting about whether to do an executive session?

BOARD STAFF LILA CUMMINGS: Sara?

BOARD STAFF SARA STULTZ: Sure. We should just go ahead and do the conflicts, and then we can do executive session. Again, Dr. Diab can still vote us into executive session, but if he has a conflict with one of the drugs, Enbrel, then he won't be able to go into the session with us.

CHAIR GAIL MIZNER: Okay, great. Thank you, Sara. So, I would like to move to, that we move into executive session to receive legal advice on public comments received on Enbrel, pursuant to section 24-6-402(3)(a)(III), CRS. Do I have a second?

BOARDMEMBER AMY GUTIERREZ: I'll second, thank you.

CHAIR GAIL MIZNER: Thank you, Dr. Gutierrez. So, I, Dr. Mizer moved, and Dr. Gutierrez seconded, that we move into executive session to receive legal advice on public comments received on Enbrel. All those in favor, please raise your hand and say aye. Aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: I think I heard Dr. Gutierrez and Dr. Vandenberg. I'm not sure if Dr. Diab --

BOARDMEMBER DR. SAMI DIAB: Aye.

CHAIR GAIL MIZNER: Okay, thank you. The motion passes. The Board will convene in executive session. The public is now excused.

[EXECUTIVE SESSION / NOT RECORDED]

CHAIR GAIL MIZNER: Okay, the Board has adjourned its executive session. The Board received legal advice regarding public comments received relating to Enbrel. The Board conducted no formal business within the meeting.

And so, let's go back up our agenda. So, next on the agenda would be to adopt the affordability review report for Enbrel. Before we vote, I'd like to note that all Board members were present at the February 16 meeting, when the Board voted that use of Enbrel is unaffordable for Colorado consumers. To ensure that all Board members have had the opportunity to review the summary of deliberations and changes made by staff from the draft report, I'd like to ask if any Board member has objections to moving forward with approval of the final report? None. Okay. Do I have a motion to adopt the final Affordability Review Report for Enbrel, with the changes as discussed?

BOARDMEMBER AMY GUTIERREZ: So moved.

BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vanderberg. I second.

CHAIR GAIL MIZNER: Thank you. Dr. Gutierrez moved and Dr. Vandenberg seconded. All

those in favor of adopting the final Affordability Review Report for Enbrel raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

CHAIR GAIL MIZNER: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: That was the three of us. All opposed say nay. The motion passes. Staff, please publish a clean version of the report.

We will now take public comment regarding whether to select Enbrel for establishment of an Upper Payment Limit. Callie will put the sign-up form in the chat. We will take comments from 10 people today. And each speaker will be given two minutes to speak, only two minutes please. So, say exactly what you need to say.

As a reminder, this period of public comment is limited only to comments related to whether Enbrel should be selected for establishment of (indiscernible). Okay, Callie, I'm going to let you call the roll. Or I mean, open the public discussion.

BOARD STAFF LILA CUMMINGS: Before Callie does that, I just want to check. I know we're approaching time, and I assume that Board members are okay if we run a little bit long, to allow for public comment in the remainder of your potential votes. Okay. Thank you. Okay, back to you, Callie.

BOARD STAFF CALLIE ANN SHELTON: First up we have Tiffany Westrich-Robertson.

TIFFANY WESTRICH-ROBERTSON: Hi. Can I go ahead and start?

BOARD STAFF CALLIE ANN SHELTON: Please.

TIFFANY WESTRICH-ROBERTSON: Okay. First of all, I just want to thank the Board and Callie and Lila, for this opportunity to give public comment. My name is Tiffany Westrich-Robertson. I am a patient living with autoimmune arthritis disease, and a person who couldn't use Enbrel. I'm also with the International Foundation for Autoimmune & Autoinflammatory Arthritis, or AiArthritis, representing the 3,400-plus patients in Colorado using Enbrel.

I just wanted to first mention that we are the organization that submitted several

reports. I have approximately 40 pages identifying flaws in the survey and listening session question design. And we do appreciate that that has been recognized. We did, some of the highlights of that is during the affordability deliberation that the Board did view total numbers of the respondents of the 38; actually 50 percent were on Medicare and Medicaid, which significantly impacted the results, because they were all analyzed together. I wanted to mention that nine of the 17, the 53 respondents who reported that zero of 50 of out of pocket was too expensive for Enbrel.

I want to make sure that it's clear that as far as the UPL, that it is known that the Colorado PDAB Upper Payment Limit Policy and Procedures, document section 10-16-1407 CRS, states that Medicare and Medicare programs are not subject to the policies of the Board, including a policy applying a UPL limit. Therefore, half of the data that was analyzed is being used to date to judge for that.

AiArthritis urgers the Board to vote against a UPL for Enbrel. We believe a restriction will only benefit payers and will not

address any of the affordability expressed by patients in Colorado. For those who Enbrel works for, they should not lose access to it. For those who are responding, it should be up to the patient and their rheumatologist to decide to switch or not to switch to a drug.

Again, I wanted to thank you for this opportunity, and in knowing that information needs to render the unaffordability decision is incorrect, or at least potentially incorrect, moving forward, voting in favor of our UPL would be premature.

Finally, I want to give public kudos to Callie and Lila who have been absolutely amazing in this process. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Tiffany. Brett Johnson, please.

BRETT JOHSNON: Thank you. Can you see and hear me?

BOARD STAFF CALLIE ANN SHELTON: We can, Brett.

BRETT JOHNSON: Okay. Yes, Brett Johnson with Amgen. And I'm here to say that we're here to urge your no vote on proceeding with the UPL. Considering the very real

potential consequences to patients and providers who are concerned with the notion that you must vote to pursue an Upper Payment Limit, in order for us to understand what that might actually look like in Colorado. For instance, there's been discussion of methodology on how a UPL will be developed, and no discussion of the scope of application to the supply chain, among many other fundamental aspects of a UPL policy. We should have answers to these fundamental questions before voting to move forward on such a policy. Again, the prospect of not doing so could be very real unintended consequences for patients and provides in Colorado. And this is not just a concern for Amgen. These concerns have been shared by others in the patient and provider communities.

Based on what little we do know about the intent for a UPL, we fail to see how this will actually improve out-of-pocket affordability for patients. And the focus really should be about what patients are paying out of pocket. For instance, we know those that pointed out and submitted comments that substantial issues with the patient survey process and the instrument

itself, and the cost-sharing figures discussed by the Board, and in the report, did not account for assistance being provided to patients to reduce out-of-pocket cost. As we've noted previously, every eligible Coloradan, nearly 2,000 of whom applied for copay card assistance last year were approved. And more broadly, the Amgen Patient Safety Net Foundation provided $2.5 billion in medicines last year, to the uninsured and those experiencing Part D affordability gaps; for roughly two-thirds of Enbrel prescriptions to those with commercial coverage, including those for whom a co-pay card was used, patients ultimately paid $10 or less per month, and only 14 percent of those prescriptions cost more than $100 per month.

Patients, instead, need reforms that help lower the price patients pay for medicines, such as making monthly costs more predictable, ensuring cost-sharing assistance is applied to a plan's out-of-pocket spending requirements, and sharing the negotiated savings on medicines with patients at the pharmacy counter. We're here to help you and other policymakers work through what these reforms might look like.

BOARD STAFF CALLIE ANN SHELTON: We're at two minutes. Apologies.

BRETT JOHNSON: Okay. And we believe that process starts here with a no vote. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Brett. Corey Greenblatt.

COREY GREENBLATT: Hello everyone. Can you hear me and see me today?

BOARD STAFF CALLIE ANN SHELTON: We can, Corey, go on.

COREY GREENBLATT: Great. Hello. My name is Corey Greenblatt. I'm speaking on behalf of, today, of the Global Healthy Living Foundation. We're a nonprofit patient organization advocating for patients with chronic pain and autoimmune disease. Many in our community rely on medications like Enbrel and are very worried that the decision to move forward with UPL today will risk their access to the medication that they rely on to live their lives as pain free as possible.

I'd like to start today by simply asking this Board to take a pause before making any further determinations. As you debate

whether to add an Upper Payment Limit to Enbrel, I'd like to remind you that your stated purpose, and the stated purpose of this Board, is to reduce the cost of prescription medications. We live in a world where there are many different costs related to the medication, but to us as a patient group, we believe the one that matters most is the price that the patient pays. And in this regard, Upper Payment Limits do nothing to reduce the out-of-pocket costs for patients. In fact, the term 'Upper Payment Limit,' is one of many misnomers in healthcare, that sound beneficial, but in reality, could really harm patients. In practice, these limits often act as a reimbursement cap. These caps will likely be significantly lower than the list price and will result in local pharmacies either stocking this medication at a loss, or not stocking it at all, which will drive patients to rely on national specialty pharmacies, many of which are owned by the insurance companies that use them, due to vertical integration, which will further reduce accessibility for patients.

While there may be many other medications that treat patients, similar to

Enbrel, it is not as easy for patients to switch between biologics, as it is to simply switch between a brand and a generic. Patients spend, on average, over a year, to find a medication that works for them. And if they suddenly lose access to that medication, it could lead to a windfall of unforeseen costs due to worsening health.

Short of outright voting no today, I am again asking this Board to take a pause and evaluate what the impact on accessibility will be on patients, should you continue to press forward. Thank you for the opportunity to comment today and have a good day.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Corey. Brian Warren?

BRIAN WARREN: Hi. Good morning, Board members. Brian Warren with the Biotechnology Innovation Organization. I would like to reiterate our concern that rather than improving access to medicines for patients, implementation of an Upper Payment Limit will not save money, most patients money, and it will create supply chain problems that could impact all patients needing medicine, subject to the UPL. The UPL

will not improve affordability because it will not change the most important factor in determining what patients pay; their cost-sharing as determined by insurance benefit design. Instead, a UPL would likely have the biggest impact on the first in-state purchaser of a drug. In most cases, this would be a Colorado hospital, clinic, or pharmacy, purchasing from a national distributor or wholesaler. These entities would be prohibited from paying more than UPL for their product, even if their product is not available at that price.

We've seen what happens when, for example, pharmacies are required to purchase drugs subject to a maximum allowable cost, which is a maximum reimbursement amount. And oftentimes, providers lose money as a result. The UPL would theoretically function somewhat similarly, and it would have the force of law.

We know you did not design the law you are tasked with implementing, or the concept of a UPL. And perhaps you believe that other actions could be taken that would have a more significant impact on patient affordability. Now is your opportunity to say, that even though you have

determined a medicine to be unaffordable, the UPL is not the right tool at this time, because we still do not really know how it will be implemented, or how to prevent unintended consequences on patient access. Thank you.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Brian. Emily Zadvorny.

EMILY ZADVORNY: Hi everyone. Thank you for the opportunity to weigh in. Thanks to the Board. I'm not here today to comment on whether or not there should be an Upper Payment Limit consideration for Enbrel specifically, but just echoing some of the concerns that we have to the Board for many years now. And I reference a letter sent to the Board in January of '23. As pharmacists, of course, we want nothing more than patients to have access to their medications, and as affordably as they can. But I do implore you to consider all the aspects of operationalizing any drug that you might consider selecting for an Upper Payment Limit. We don't need to look much further than what's going on with EpiPens right now, where, you know, the pharmacies are faced with either losing money or not providing access to a drug, and it's a real problem that we're

seeing actually happening right now in our state.

So, we simply just can't have a situation that puts our frontline providers, as pharmacists, or the pharmacies, at a disadvantage financially, where they have to lose money or, potentially, not have the financial support to provide access to these medications.

Thank you so much for letting me be the broken record on the record. Thanks so much.

BOARD STAFF CALLIE ANN SHELTON: Thank you, Emily. Hope Stonner.

HOPE STONNER: Hi. My name is Hope Stonner. I'm with the Colorado Consumer Health Initiative, appreciate this opportunity for public comment today. I would just like to say that the Colorado Consumer Health Initiative, which works to protect and promote access to affordable and equitable healthcare in the state, believes that the comprehensive process of the affordability review, and the process outlined in the statute for the UPL, has appropriate guardrails in place to protect patient access, because we believe, overall, that the goal of the PDAB is to encourage access to drugs in the state, that we know that folks may be struggling

to, or cannot access at this time.
We believe that the UPL process can work alongside other policies that folks have called out in public comment, that are already being implemented in the state, to meaningfully lower drug costs for patients in the system. And due to Enbrel's high cost to the to the healthcare system, particularly when the report stated that the drug remains out of reach or is unaffordable for so many Coloradans, we believe that Enbrel is a perfect example of the need for a PDAB in the first place, and an appropriate candidate for a UPL. Thank you.
BOARD STAFF CALLIE ANN SHELTON: Thank you, Hope. And I'll put the form in the chat, and this is the last call for public comment. Madam Chair, I'm not seeing any more public comments.
CHAIR GAIL MIZNER: Okay, thank you, Callie. And thank you to everyone who gave us public comment, both written and the recent couple of comments you just gave. Is there any deliberation on the part of the Board on whether to select Enbrel for establishment of an Upper Payment Limit?

BOARDMEMBER AMY GUTIERREZ: Can I ask for a clarification? Because I thought we already selected Enbrel. What is the action that we're doing?
CHAIR GAIL MIZNER: We already determined that Enbrel was unaffordable for Coloradans.
BOARDMEMBER AMY GUTIERREZ: Got it. Okay.
CHAIR GAIL MIZNER: Now what's before us is whether, is to determine whether to initiate the process of setting an Upper Payment Limit for Enbrel. And I think I'd like to remind the Board and the public that a vote to initiate the UPL process, does not mean that we are bound to complete the Upper Payment Limit process. So, we could, at any point, if we, if the data presented to us indicated to us that it wasn't appropriate, to move forward with setting a UPL, we could stop the process at any point in the future. I think the other thing to keep in mind that has been outlined by staff is that we're looking, we're not looking at making a decision about a UPL in a month. We're looking at probably a six-month process of data gathering

and discussion. So, that's kind of the -- that plan that's been outlined that I think is wise, that we would not proceed rapidly.
BOARDMEMBER AMY GUTIERREZ: Thanks Gail, for that clarification. Do you need a motion?
CHAIR GAIL MIZNER: Yes, I do, unless there's further deliberation.
BOARDMEMBER JAMES JUSTIN VANDEBERG: No, I think that clarification that you had set up was, I think, a good reminder as far as the process for, you know, everyone in the meeting. I'm good to let the motion to approve, to work on establishing a Upper Payment Limit for Enbrel.
CHAIR GAIL MIZNER: Okay.
BOARDMEMBER AMY GUTIERREZ: I'll second the motion, Chair Mizner.
CHAIR GAIL MIZNER: Thank you. So, Dr. Vandenberg moved and Dr. Gutierrez seconded. All those in favor of selecting Enbrel for establishment of an upper payment limit, raise your hand and say aye.
BOARDMEMBER AMY GUTIERREZ: Aye.
CHAIR GAIL MIZNER: Aye.
BOARDMEMBER JAMES JUSTIN VANDEBERG:

Aye.
CHAIR GAIL MIZNER: That's the three of us. Opposed, say nay. The motion passes. As a reminder, the Board establishes UPLs through a rulemaking proceeding. Our vote today to establish a UPL for Enbrel, initiates a rulemaking process that will involve multiple public hearings. Do I have a motion to direct staff to initiate rulemaking, to establish a UPL for Enbrel, with the Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule?
BOARDMEMBER AMY GUTIERREZ: I move that we direct staff to initiate rulemaking to establish an Upper Payment Limit for Enbrel, with the Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule.
BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vandenberg, I second.
CHAIR GAIL MIZNER: Thank you. Dr. Gutierrez moved, and Dr. Vandenberg seconded. All those in favor of directing staff to initiate rulemaking to establish a UPL for Enbrel with the

Secretary of State, so that we can hold our first rulemaking hearing at a future meeting that accommodates the Board's overall schedule, raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: Aye. The motion passes. Staff, please work with us in future meetings regarding timing of the UPL rulemaking hearings for Enbrel, and to initiate rulemaking to establish a UPL with the Secretary of State, in line with those discussions.

Okay. Now, we are scheduled to move onto Genvoya. Board members disclosed conflicts at the top of the meeting. Dr. Diab is the only Board member with a conflict of interest for Genvoya and will not participate in the deliberation.

Also, before we vote, I'd like to note that all Board members were present at the February 16 meeting, when the Board voted that use of Genvoya is not unaffordable for Colorado consumers. To ensure that all Board members have had the opportunity to review the summary of

deliberations and changes made by staff from the draft report, I'd like to ask if any Board member has objections to moving forward with approval of the final report.

BOARDMEMBER JAMES JUSTIN VANDEBERG: I do not.

CHAIR GAIL MIZNER: Do I have a motion to adopt the Final Affordability Review Report for Genvoya with the changes as discussed?

BOARDMEMBER JAMES JUSTIN VANDEBERG: This is Justin Vanderberg. I motion to adopt the Final Affordability Review Report for Genvoya with the changes as discussed.

BOARDMEMBER AMY GUTIERREZ: Amy Gutierrez, second.

CHAIR GAIL MIZNER: Thank you. Dr. Vandenberg moved and Dr. Guitierrez seconded. All those in favor of adopting the final affordability review report for Genvoya, raise your hand and say aye.

BOARDMEMBER AMY GUTIERREZ: Aye.

BOARDMEMBER JAMES JUSTIN VANDEBERG: Aye.

CHAIR GAIL MIZNER: Aye. Okay. The motion passes. The Board's vote concludes this

round's affordability review process for Genvoya. Staff, please publish a clean version of the report. Lila, did you want to now go through a UPL rulemaking timeline with us?

BOARD STAFF LILA CUMMINGS: Yes. Yeah, absolutely. We can go to the next slide. So, here is what we are going to propose and how we'll propose to proceed unless we hear differently from you all in terms of kind of some of the next steps for Upper Payment Limit rulemaking.

So, at your next meeting, on March 15, we will save a portion of the time, probably not a large portion of the time, we're thinking maybe half an hour, to just revisit and reacquaint ourselves and everyone with the Upper Payment Limit rule and policy that already exists, that you all promulgated and adopted over a year ago.

So, we'll spend some time just reacquainting ourselves with the rule and policy, answering any questions that you all may have, and then continue to save some time at your April 26 meeting as well, for continued kind of conversation. So, not really looking at specific data for Enbrel, just really looking at the rule

and policy, answering any questions that you might have, and just thinking about how you want some of the data gathered.

Then, you'll see on here, there is a potential hold here for a meeting on May 3, but we anticipate that would be, like today, really focusing, only if needed, on conversation about Cosentyx and Stelara.

Then, on June 7, would potentially be the first rulemaking hearing for Enbrel. And then, that would be kind of that formal process with testimony, both written and verbal testimony provided, and then moving on. And we would strongly recommend a second rule-making hearing, at a minimum, on July 19.

And so, if things are kind of moving this way, and we can start this way, but if there's a time as you all mentioned, where you'd like to slow down, or where you'd like to speed up, we can absolutely adjust as needed, but this is kind of how we propose at this point to proceed.

And then the only other thing I'll note is, in the past, any time you all have done rulemaking, we have held separate stakeholder

meetings to gather input and really talk with individuals and stakeholders directly to get their feedback, so we can converse with them before the rulemaking hearing. We would plan on doing the same thing.

So, we don't exactly have a date yet for when those stakeholder meetings would be, but we would anticipate sometime between April and June, and heading even into the summer, as your rulemaking continues, and your rulemaking hearing continues. The staff hosts meetings with stakeholders to answer questions. The Board members would not need to attend, but that will host those meetings so folks can ask questions.

Any kinds of concerns or thoughts or comments on this proposed timeline for now? We'll continue to check in at each meeting to make sure kind of this is the right cadence. Chair Mizner, you were on mute.

CHAIR GAIL MIZNER: My feeling is that as long as we're able to slow down at any point where we feel that we need to, to gather more information, more input, whatever, I think that makes sense. I want to be sure that both Board has enough time for every meeting to read and

incorporate all the information gathered into their thinking, and also that we have enough time for public comment and stakeholder meetings. I think those are just key. Amy and Justin, do you have other thoughts about this timeline?

BOARDMEMBER JAMES JUSTIN VANDEBERG: No. I think you state it very well, just as far as being able to -- I don't want to say flexibility, but maneuverability, based on the data as is presented.

BOARDMEMBER AMY GUTIERREZ: I agree as well, Gail, with your comments. And I think it's going to be important on the flexibility because it's the first time we've done this, so it will be important to be flexible on some of the timelines agreed.

CHAIR GAIL MIZNER: All right. Great.

BOARD STAFF LILA CUMMINGS: Great. Then we'll proceed with this, but we'll check in with you at every meeting, kind of, if this is the right timeline. I believe that's all I have and I think we did the next two agenda items at the top, so I believe you're done.

CHAIR GAIL MIZNER: Okay. And I think we are done with our work today. Thank you to

everyone. The next PDAB meeting will be held at 10:00 AM on Friday, March 15. And unless there's any objection, the meeting is now adjourned. Thank you all very much.

BOARDMEMBER DR. SAMI DIAB: Thank you Board members.

CERTIFICATION

I, Sonya Ledanski Hyde, certify that the foregoing transcript is a true and accurate record of the proceedings.

Date: May 31, 2024

Sonya Ledanski Hyde

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC, et al.,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, et al.,

Defendants.

DEFENDANTS' COMBINED CROSS-MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT AND RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

PAGE

CASES

TABLE OF AUTHORITIES

PAGE

TABLE OF AUTHORITIES

PAGE

TABLE OF AUTHORITIES

PAGE

STATUTES

TABLE OF AUTHORITIES

PAGE

TABLE OF AUTHORITIES

PAGE

FEDERAL RULES

STATE REGULATIONS

TABLE OF AUTHORITIES

PAGE

OTHER AUTHORITIES

TABLE OF AUTHORITIES

PAGE

INTRODUCTION

Every day in Colorado, people are forced to make the unconscionable choice between paying for groceries or rent and paying for necessary medication. The excessive costs of prescription drugs hamper both the financial and physical health of Coloradans.

The prescription drug supply chain is rife with dramatic asymmetries in bargaining power, with manufacturers and middlemen raising costs that consumers must pay to receive life-changing and life-saving medicine. The complexity of the supply chain results in opaque drug prices for Colorado consumers. And supply chain actors can inflate prices to capture a share of the profit of the trillion-dollar pharmaceutical industry as the drugs make their way to the consumer, while consumers are left without information or leverage to negotiate lower prices.

The Constitution does not dictate that states stand idly by while their consumers grapple with these wrongs. States not only have the authority, but the duty, to protect the health and welfare of their citizens by addressing the harms inuring to the consumers and entities in their borders caused by these prescription drug market failures. Colorado has done just that with the creation of the Prescription Drug Affordability Board.

The Board is empowered to address the lack of access to affordable prescription drugs in Colorado, cutting through the obfuscated drivers of prescription drug costs, holding supply chain actors accountable, and shifting power back to those in Colorado most harmed by unaffordability. To that end, the Board is authorized to conduct affordability reviews of particular drugs and, if the Board finds those drugs unaffordable,

establish upper payment limits on what certain consumers, providers, pharmacies, and insurance companies may pay for those drugs dispensed in Colorado.

The work of Colorado's Board is a necessary, careful, and tailored exercise of the state's police power to help alleviate the threat that unaffordability of prescription drugs poses to Coloradans. Plaintiffs (referred to herein as "Amgen"), manufacturers of Enbrel, seek to end this work. But no harm befalls Amgen from the Board's affordability review or the ongoing upper payment limit setting, so Amgen cannot demonstrate ripeness, standing, or violations of federal law. The Board's work is a constitutional effort at transparency and regulation of transactions occurring directly in response to Colorado consumers filling their prescriptions. Defendants are entitled to summary judgment.

BACKGROUND

The Prescription Drug Market

The physical prescription drug distribution chain is generally unremarkable. The pharmaceutical "distribution chain starts with the manufacturer who sells to a wholesaler for the wholesale acquisition cost ('list price'). Wholesalers 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 Pracs. & Antitrust Litig.*, 44 F.4th 959, 965 (10th Cir. 2022).

Amgen is a pharmaceutical manufacturer. *See* ECF No. 1 ¶¶ 16-18. Substantially all of Amgen's sales in the United States are to pharmaceutical wholesale distributors, which serve as the principal means of distributing Amgen's products to healthcare

providers.[1] Amgen sells its products to wholesalers for the list price or "wholesale acquisition cost."[2] The wholesalers then sell Amgen's products to the wholesalers' customers, which include physicians or their clinics, dialysis centers, hospitals, and pharmacies.[3]

While physical drug distribution is straightforward, the flow of funds in the prescription drug market is not. "Drug pricing is a complex and often confusing issue" involving "multiple transactions among numerous stakeholders."[4]

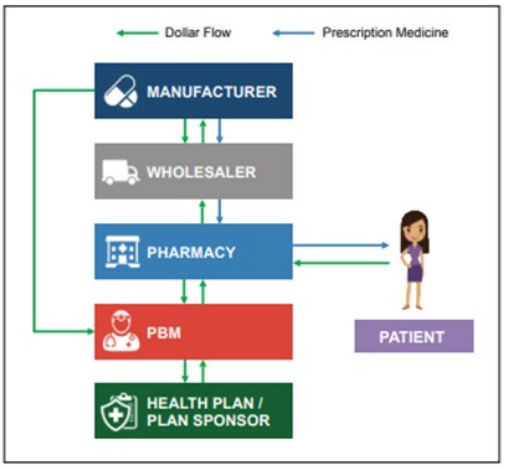

Fig. 1. Visual representation of distribution of prescription drugs in supply chain and flow of payments amongst stakeholders. See PhRMA, Follow the Dollar at 1.

In addition to the manufacturers, wholesalers, pharmacies, and patients, there are two other important players in the prescription drug market.

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[1] *See* Amgen 2023 Form 10K at 2, 76, available at https://investors.amgen.com/static-files/eeb1013b-5d9a-4ff3-934f-3905972207f3. 79% of Amgen's 2023 worldwide gross revenues were based on sales to three wholesalers. *See id*. at 2.
[2] *See* Amgen, Paying for Enbrel, available at https://www.enbrel.com/enbrel-cost.
[3] Amgen 2023 Form 10K, supra note 1, at 42.
[4] PhRMA, Follow the Dollar 1 (2017), available at https://tinyurl.com/bdfrt945.

First, there are the health plans or "payers." Insured patients access prescription drugs through health plans—such as individual health insurance purchased on the state insurance exchange or employer-sponsored plans—that offer prescription-drug benefits. *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023). The cost of the drug is shared between the patient and their health plan, and the amount the patient pays depends on the scope of their prescription drug benefit. *In re EpiPen*, 44 F.4th at 965. The health plan sets this 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.

Second, there are pharmacy benefit managers or "PBMs." Health plans typically hire PBMs to formulate and oversee the health plans' prescription-drug benefits. *Id.*[5] When a patient goes to a pharmacy to fill a prescription, the pharmacy checks with the PBM to determine whether the drug is covered and what the patient's payment will be. *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 84 (2020). The PBM then reimburses the pharmacy on behalf of the health plan, and the PBM is compensated by the health plan with reimbursements and fees. *Id.; see also* FTC PBM Report at 9-13. PBMs also contract with manufacturers to negotiate rebates on drugs. *See Mulready*, 78 F.4th at 1188. According to one estimate, these rebates and discounts now exceed $100 billion each year. PhRMA, Follow the Dollar at 1. This rebate system is coming under increasing

[5] *See also* Fed. Trade Comm'n, Pharmacy Benefit Managers at 9-10, available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (hereinafter, "FTC PBM Report").

scrutiny given its apparent anticompetitive effects. *See* FTC PBM Report at 66 ("[O]ur initial review of these contracts shows rebate structures that may impede and impair competition and patient access to affordable medicines."). Further, since nearly 80 percent of prescriptions filled in the U.S. are managed by the three largest PBMs, PBMs also exert substantial influence over independent pharmacies and the contractual terms of their pharmacy networks and reimbursement agreements. *Id.* at 1, 9-11. Despite the significant impact these middlemen have on the access to prescription drugs, PBM business practices remain extraordinarily opaque. *Id.*

Given this web of rebates and reimbursements, PhRMA[6] argues "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." PhRMA, Follow the Dollar at 1. This system is supposed to generate cost savings. In practice, it does not. According to Amgen's CEO, "[c]ompanies in virtually every other industry compete by offering the lowest price. Unfortunately, the current rebate system in the U.S., created with good intent, now often leads to a situation in which not getting kicked off formulary requires matching a competitor's higher price."[7] According to Amgen, "[p]rescription drug list prices increase so that manufacturers can absorb more and more

[6] PhRMA is a "voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies." ECF No. 27 at 1. Amgen is a member of PhRMA and Amgen's CEO serves on PhRMA's Board of Directors. *See* https://phrma.org/en/About.

[7] *Unsustainable Drug Prices: Testimony from the CEOs (Part II): Hearing Before the H. Comm. on Oversight and Reform*, 116th Cong. at 5 (2020) (Statement of Robert Bradway, CEO, Amgen) available at https://tinyurl.com/mtj35txr (hereinafter "Bradway Testimony").

payer demands for rebates and other discounts."[8] "Higher list prices can mean higher out-of-pocket costs for patients, since rebate dollars aren't passed on to patients at the pharmacy counter."[9]

Manufacturers like Amgen blame intermediaries like the PBMs for rising drug prices. PBMs, in turn, blame the manufacturers.[10] But at the end of the day, consumers are the ones left hurt. In 2022, prices for branded drugs in the U.S. were 422% of the prices in other parts of the world.[11] In fact, according to PhRMA, "[s]ometimes a patient's cost-sharing amount may exceed the price the health plan actually pays for a medicine or exceed what the patient would pay at the pharmacy counter without using insurance (ie, by paying in cash)" and pharmacies can be contractually prevented from telling consumers about the lower cash price. Follow the Dollar at 6.

The Prescription Drug Affordability Board Program

In 2021, Colorado created the Prescription Drug Affordability Board.[12] The legislature found it "imperative" to "take measures to reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs," thus creating the Board "with

[8] Amgen, Inside the Drug Pricing Loop, available at https://tinyurl.com/37d6p5tk.
[9] *Id*.
[10] According to the Pharmaceutical Care Management Association, which represents PBMs in the United States, drug companies abuse "the patent system to keep more affordable alternatives from entering the marketplace, which allows those companies to increase prescription drug prices for far longer than Congress contemplated when it established patent and exclusivity periods." *Testimony of Juan Carlos Scott to U.S. H. Comm. on Oversight* at 3, available at https://tinyurl.com/mrybaczf.
[11] International Prescription Drug Price Comparisons: Estimates Using 2022 Data, Assistant Secretary for Planning and Evaluation, U.S. Dept. of Health & Human Services at 3 (2024) available at https://tinyurl.com/uawhpeuc.
[12] SB 21-175, 73rd Leg., Reg. Sess. (Colo. 2021) (hereinafter, "SB 21-175"). Two other bills have subsequently modified the Board's authority: HB 23-1225 and SB 24-203.

the authority to review prescription drug costs and protect Colorado residents and entities who purchase or reimburse for prescription drugs from the excessive costs of prescription drugs." SB 21-175 at 2-3.

The Board is comprised of five medical and pharmacy experts and performs two main functions: (1) conducting affordability reviews of eligible drugs to determine whether use of those drugs is unaffordable for Colorado consumers, and (2) for drugs it deems unaffordable, potentially establishing upper payment limits in certain transactions for drugs dispensed in Colorado. §§ 10-16-1402(1), (2)(a); 10-16-1403(1), C.R.S. The Board implemented procedures for these statutory directives through rules (3 C.C.R. § 702-9:1.1 to 702-9:5.1) and policies[13] (referred to generally herein as the "Affordability Program").

Affordability Reviews

Pricing in the prescription drug market is notoriously opaque. Since this lack of transparency prevents policymakers and Coloradans from understanding the true costs of prescription drugs and hinders accountability, the legislature charged the Board with conducting "affordability reviews." *See* SB 21-175 at 2; §§ 10-16-1405 –1406, C.R.S.

Choosing from eligible generic and brand-name drugs alike (§ 10-16-1406(1), C.R.S.), the Board conducts affordability reviews by analyzing over a dozen mandatory factors and additional permissive criteria set forth in statute and rule (§ 10-16-1406(4)-(6), C.R.S., and 3 C.C.R. § 702-9:3.1), to determine if use of a prescription drug is

[13] *See* Prescription Drug Affordability Board Policies 01 to 05, available at https://tinyurl.com/djct93ch.

unaffordable for Colorado consumers (§ 10-16-1406(3), C.R.S.). The factors the Board considers are centered on the consumer experience, including:

- Cost and availability of therapeutic alternatives[14] to the drug;
- Effect of the price on Colorado consumers' access to the drug;
- Patient co-payment or other cost sharing associated with the drug and typically required pursuant to health benefit plans;
- Input provided by patients and caregivers affected by the condition or disease that is treated by the drug;
- Whether patients receive financial assistance from the manufacturers; and
- Impact of the affordability challenges on health equity.

§ 10-16-1406(4)(b), (c), (e), (h)(I), (j), C.R.S.; 3 C.C.R. § 702-9:3.1.E.2.j.

To establish the factual basis for these factors, the Board developed an affordability review process that provides ample opportunity for Coloradans, supply chain actors, and manufacturers alike to provide information to the Board about the affordability of a drug. *See* 3 C.C.R. § 702-9:3.1; Enbrel Affordability Review Report.[15]

The goal of the affordability review is not to determine the appropriateness of a manufacturer's price. Rather, the Board considers and flexibly weighs robust, contextual factors[16] to determine whether use of a drug, consistent with standard medical practice or the FDA label, is unaffordable for Colorado consumers. § 10-16-1406(3), C.R.S. The

[14] "Therapeutic alternatives" is a technical term for a drug that may contain different therapeutic agents, but is in the same therapeutic class and similarly treats a condition as the drug under review. *See* 3 C.C.R. § 702-9:1.1.C. This is not to be confused with a "therapeutic equivalent" which encompasses, for example, a generic competitor to a brand-name drug because such a drug is a "pharmaceutical equivalent[] for which bioequivalence has been demonstrated." 3 C.C.R. § 702-9:1.1.C

[15] *See generally* Prescription Drug Affordability Board, Enbrel Affordability Review Report, available at https://tinyurl.com/yc5u94h3.

[16] These contextual factors allow the Board to evaluate the circumstances and market behavior surrounding use of a particular prescription drug, treating specific diseases or conditions, in Colorado, and the unique attendant affordability challenges they may pose.

result of an affordability review is a report that details the Board's analysis of the required factors, supporting documents, and a determination of whether the drug is unaffordable for Colorado consumers.

Importantly, the Board's determination regarding unaffordability does not impact any rights or obligations of anyone selling or purchasing the prescription drug. The unaffordability determination is not a final agency action. § 10-16-1408(1)(c), C.R.S. The General Assembly made clear that the affordability reviews serve standalone purposes of transparency and accountability and may be an end unto themselves. *See* § 10-16-1407(1) and § 10-16-1407(9), C.R.S. The Board's determination of unaffordability may conclude its review of a prescription drug.

Upper Payment Limits

To re-balance the bargaining power in Colorado's prescription drug market, the legislature also empowered the Board with the Affordability Program's second major component: establishing upper payment limits ("UPLs"). The Board may only set a UPL for a drug it has determined is unaffordable.[17] UPLs are intended to "reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs." SB 21-175 at 2-3. A UPL is not a regulation on the manufacturer but rather a limit on what someone can pay—in particular, what in-state actors and actors doing business in Colorado can pay—for a drug that is dispensed or administered in Colorado.

[17] The Board does not have to set a UPL for a drug it has deemed unaffordable and the two processes—affordability reviews and UPLs—are not only distinct but explicitly severable. §§ 10-16-1407(1), 10-16-1407(9), C.R.S.; *see also* § 2-4-204, C.R.S.

An upper payment limit is "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado" and applies to a consumer's purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies' and providers' purchases of the prescription drug. § 10-16-1401(23), C.R.S.; 3 C.C.R. § 702-9:4.2.C. The legislature intended UPLs to specifically apply to entities such as state and local governments, contractors and vendors, commercial health plans, providers, and pharmacies. SB 21-175 at 3. The statute also directs the Board to consider the costs of "administering," "dispensing," and "distributing" the prescription drug in Colorado in establishing a UPL, putting into sharp focus for the Board the costs incurred by the entities the UPL was designed to apply to: providers, pharmacies, and wholesalers, respectively. § 10-16-1407(2), C.R.S. Put simply, a UPL is a payment restriction on entirely downstream actors for actual sales and reimbursements of a drug dispensed to Colorado consumers.

The statute should not be read to apply otherwise. The legislative history underscores this intent that a UPL not apply to a wholesaler's purchase from a manufacturer. In introducing the bill in committee, one of the bill's sponsors explained the purpose of the downstream applicability as follows:

> "The reason we did this is because we wanted to impact the entities in Colorado that are purchasing these drugs and give them the support they need to get better pricing from the industry. The way we anticipate this working is that the current relationship between pharmaceutical manufacturers and wholesalers will largely remain unchanged. . . . [Wholesalers] will purchase drugs at the wholesale acquisition cost. They will sell it to pharmacies or hospitals at the UPL or whatever negotiated price is lower than that – which may be the case. Our hope is that negotiations continue and there will be lower prices that are below the UPL. But they'll sell them at that lower price and then they will be made whole on the back-

> end by the pharmaceutical manufacturer. So we really don't believe in-state purchasers are stuck in the middle in this bill. What we believe is this bill is giving them the air support they need to get the better prices in the first place."
>
> Prescription Drug Affordability Review Board: Hearing on SB 21-175 Before the House Comm. On Health & Insurance, 73rd Sess. (2021) (statement of Rep. Chris Kennedy).

UPLs are also limited to only the transactions where Colorado's authority to regulate is clear. The Board adopted a policy that states a UPL does not apply to Medicare and other purchases and reimbursements made by federal or sovereign actors.[18] UPLs also do not apply to self-funded plans regulated pursuant to Employee Retirement Income Security Act ("ERISA") (§ 10-16-1413, C.R.S.) or where a carrier is required under state or federal law to purchase or reimburse a payer for a prescription drug (§ 10-16-1411(5), C.R.S.) above a UPL.

The Board establishes UPLs through rulemaking, and a rule establishing a UPL is an appealable final agency order. §§ 10-16-1408(2), 24-4-103, 24-4-106(2), C.R.S. The Board may also terminate a rulemaking proceeding at any time. 3 C.C.R. § 702-9:4.1.D.1.; *see also* § 24-4-103(4)(d), C.R.S. A UPL does not go into effect until at least six months after the Board's adoption of the rule. § 10-16-1407(5), C.R.S.

A UPL established by the Board is subject to judicial review (§ 10-16-1408(2), C.R.S.), and may also be subsequently repealed by the legislature through a direct repeal (§ 10-16-1414(3)(b), C.R.S.) or through the rule review process under the state Administrative Procedure Act (§ 24-4-103(11)(d), C.R.S). Judicial review of a UPL rule

[18] PDAB Policy 05, Upper Payment Limit Policy and Procedure, available at https://tinyurl.com/djct93ch (hereinafter "PDAB UPL Policy").

may also include a challenge to the affordability review determination. §§ 10-16-1408(2); 24-4-106(7)(b), C.R.S.

The Attorney General is exclusively authorized to "enforce [§§ 10-16-1401—10-16-1416, C.R.S.] on behalf of any state entity or any consumer of prescription drugs." § 10-16-1411(3), C.R.S. However, he may not enforce the Affordability Program against "a carrier or state agency that is required pursuant to state or federal law to purchase or reimburse a payer for a prescription drug for which the board has established an upper payment limit." § 10-16-1411(5), C.R.S. The Attorney General has expressly stated that if it is ever necessary to bring an enforcement action, he will enforce a UPL set by the Board according to the applicability of UPLs as established by the Board. *Exhibit 1,* Decl. of Nathan Blake at 1-2.

The Board has not yet established any UPLs, nor has the Attorney General or Commissioner[19] initiated any enforcement actions concerning the Affordability Program.

Enbrel

In 1998, Enbrel was approved by the FDA to treat autoimmune diseases such as rheumatoid arthritis. ECF No. 1 ¶ 50. While Enbrel is covered by patents, those patents are held by a different company; Amgen merely licenses the commercial rights for use of the patents in the United States. *See id.* ¶ 54; *Immunex Corp. v. Sandoz Inc.,* 964 F.3d 1049, 1054-55 (Fed. Cir. 2020).

[19] The Commissioner of Insurance may impose a penalty on a manufacturer that fails to comply with certain notice requirements upon withdrawal. § 10-16-1412, C.R.S.

Between its launch in 1998 through January 2024, "Enbrel's [list price] has increased 1,582.24%," significantly outpacing inflation for the same period. Enbrel Affordability Review Report at 2. The current list price for Enbrel is at least $1,850.46 per weekly 50 mg dose.[20] According to Colorado data from 2022, Colorado entities and consumers paid over $159,305,653 that year for Enbrel, and the average cost per patient of a year's supply was $46,772. Enbrel Affordability Report at 2. In that same year, the average annual out-of-pocket cost for Coloradans with commercial insurance was $3,980 annually. *Id.* at 2. Over half of insurance carriers who submitted information to Colorado under section 10-16-1405, C.R.S., reported that Enbrel was one of the top 15 prescription drugs that raised premiums for all covered lives. *Id*.

Enbrel's list price did not increase by 1,582.24% over this time because of "innovation." Amgen's CEO told Congress that "the primary reason the list price of Enbrel® has increased as much as it has" is because the market "is structured in a way to benefit intermediaries and not in a way to get lower prices to patients."[21] Amgen often has to "pay higher and higher rebates to remain on formulary" and "increases in list prices generally have limited impact on net prices but significantly increase total rebates paid to the PBMs." *Id*. So, "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*. The net effect of this "counterintuitive pricing behavior" is that PBMs receive lower prices,

[20] *See* Amgen, Paying for Enbrel, available at https://www.enbrel.com/enbrel-cost.
[21] *Testimony of Robert A. Bradway, Chairman and Chief Executive Officer Amgen Inc., Before the U.S. H. Comm. on Oversight and Reform* at 7 (hereinafter, "Bradway Written Statement") available at https://tinyurl.com/mufwzev3.

but "consumers instead see prices go up and see little relief at the pharmacy counter since these savings from the PBMs are often not passed on." *Id.* at 8.

The Board's Proceedings Relating to Enbrel

In 2023, the Board began implementing the Affordability Program. Out of 604 eligible drugs, the Board selected Enbrel and four other drugs for affordability reviews. Enbrel Affordability Review Report at 3.

The Board then conducted its affordability review for Enbrel deliberately and thoroughly over a period of six months, with Amgen participating in the process at every step. The affordability review occurred across three public Board meetings—December 8, February 16, and February 23—and included voluminous stakeholder feedback, including from Amgen.[22] Before and between these meetings, the Board gathered stakeholder input and analyzed each of the required factors. Amgen voluntarily submitted information in October, 2023, that was included in the Board's Affordability Review Report. *Exhibit 2,* Decl. of Elizabeth Cummings at 1; Enbrel Affordability Review Report at J3-J11, J23-J49. Amgen also participated in a September 19, 2023, stakeholder meeting facilitated by Board staff where it provided robust input from its medical experts. Enbrel Affordability Review Report at I-4. Amgen provided verbal comments at the December 8, February 16, and February 23 Board meetings and written comments in advance of the February 16 and 23 Board meetings.

[22] Links to recordings from 2023 Board meetings are available at https://drive.google.com/file/d/1kKX96Z4vzczf5McTx-MJsf_X4OqBb5lp/view, and links to recordings from 2024 Board meetings are available at https://drive.google.com/file/d/1Mh7-0Bmd0_t_IPO8IOT_GQgYUO1JOHfb/view.

The Board deliberated on the over 500-page draft affordability report for Enbrel and determined that use of Enbrel was unaffordable for Colorado consumers at its February 16 meeting. This report contains a separate appendix devoted to each of the required factors the Board is directed to consider in determining unaffordability of a drug for Colorado consumers. In addition, it contains information the Board may permissively consider, including pricing information for Enbrel. § 10-16-1406(6)-(7), C.R.S. Four pages out of the 534-page report mention Enbrel's patent protections. *See* Enbrel Affordability Review Report at 25, C-11-13. During the February 16 meeting, for less than 15 minutes over the span of an almost two-hour deliberation, the Board discussed Enbrel's status as a patented drug and how that lack of competition from biosimilars might impact Colorado consumers' affordability and access. The remaining substance of the Board's report and the deliberation reflects the true focus of the Board: unaffordability for Colorado consumers. The summary report presents the Board's most salient considerations in reaching its unaffordability determination including Enbrel's higher out-of-pocket costs compared to therapeutic alternatives and self-reported affordability concerns from Colorado consumers. Enbrel Affordability Review Report at 2-3.

The Board approved the final affordability review report for Enbrel on February 23. The Board then voted to initiate rulemaking to establish a UPL for Enbrel. The Board has not yet begun the rulemaking and it anticipates holding rulemaking hearings, at a minimum and at the earliest, at its September 6, October 18, and December 6 meetings.[23] The Board may terminate these proceedings at any time without setting a UPL.

[23] The timeline was affirmed by the Board at its April 26 and July 3 meetings.

LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) states, "The court shall grant summary judgment 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." When presented with cross-motions for summary judgment, [the court] "'must view each motion separately,' in the light most favorable to the non-moving party, and draw all reasonable inferences in that party's favor." *United States v. Sup. Ct. of New Mexico*, 839 F.3d 888, 906–07 (10th Cir. 2016) (citations omitted). And if the parties dispute factual matters, "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986).

State legislative acts are presumed to be constitutional. *Villanueva v. Carere*, 85 F.3d 481, 487 (10th Cir. 1996). In evaluating facial challenges to a state law, courts consider implementing regulations as well as any limiting construction an agency has proffered. *See, e.g.*, *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 494 n.5 (1982); *Ward v. Rock Against Racism*, 491 U.S. 781, 795 (1989). "Claims of facial invalidity often rest on speculation" and "facial challenges threaten to short circuit the democratic process by preventing duly enacted laws from being implemented in constitutional ways." *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2397 (2024) (quotations omitted). Furthermore, "[f]acial challenges also run contrary to the fundamental principle of judicial restraint that courts should neither "'anticipate a question of constitutional law in advance of the necessity of deciding it'" nor "'formulate a rule of constitutional law

broader than is required by the precise facts to which it is to be applied.'" *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (citations omitted). Accordingly, the Supreme Court has "made facial challenges hard to win." *Moody*, 144 S. Ct. at 2397. "[A] plaintiff cannot succeed on a facial challenge unless he establishes that no set of circumstances exists under which the law would be valid, or he shows that the law lacks a plainly legitimate sweep." *Id.* (quotations and alterations omitted).

I. Amgen's case must be dismissed because this court lacks subject matter jurisdiction.

This court lacks subject matter jurisdiction because Amgen, as a manufacturer, does not have standing as it cannot demonstrate that it is directly injured by the Board's work, and this case is not ripe as the Board has not, and may never, set a UPL.

A. Amgen lacks standing.

As an initial matter, Amgen's claims must be dismissed because it lacks standing to bring suit. To establish standing to bring an action, a plaintiff must show that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo v. Robins*, 578 U.S. 330, 338 (2016). Here, Amgen cannot demonstrate either of the first two required elements: injury in fact and causation.

i. Amgen fails to identify an injury in fact.

First, any injury to Amgen is based on conjecture of what effects may flow from a downstream UPL that does not apply to Amgen; this is insufficient to demonstrate standing. "To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or

imminent, not conjectural or hypothetical.'" *Spokeo,* 578 U.S. at 339. (citations omitted). For an injury to be concrete, "it must actually exist." *Id.* "A claimed injury that is contingent upon speculation or conjecture is beyond the bounds of a federal court's jurisdiction." *Tandy v. City of Wichita*, 380 F.3d 1277, 1283-84 (10th Cir. 2004). Additionally, "where an injury is threatened rather than actual, '[a]llegations of *possible* future injury are not sufficient' to establish standing." *Tennille v. Western Union Co.,* 809 F.3d 555, 560 (10th Cir. 2015) (citation omitted).

Amgen does not suffer any concrete injury to a legally protected interest from a possible downstream payment regulation affecting third-party entities. 3 C.C.R. 702-9:4.2.C. Neither the affordability review nor the UPL impacts what the manufacturer can charge or who the manufacturer sells its drugs to; Amgen fails to identify a legally protected interest. Nor does Amgen suffer an injury from fear of an enforcement action. Because a UPL does not apply to a wholesaler's purchase from a manufacturer, the Attorney General could not enforce a UPL against Amgen. § 10-16-1411(3), C.R.S.; *Exh. 1*. There is also no concrete harm to Amgen; the Board may never set a UPL.

Finally, to the extent Amgen argues its injury arises from the Board's mere determination that Enbrel is unaffordable, it does not allege a cognizable injury. Allegations of "a bare procedural violation, divorced from any concrete harm" cannot satisfy the injury in fact requirement under Article III. *Spokeo,* 578 U.S. at 341; *Summers v. Earth Island Inst.,* 555 U.S. 488, 496 (2009).

ii. Amgen fails to demonstrate causation.

Moreover, Amgen's alleged injury arises not from the Board's actions, but from the possibility that independent supply chain actors may try to negotiate a lower price from the manufacturer. But to demonstrate causation of an injury when the plaintiff is not the object of the government's action, standing is "substantially more difficult" to establish, because the plaintiff must show that the "unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or predict" "have been or will be made in such a manner as to produce causation and permit redressability of injury." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992). Amgen cannot make such a showing here.

Any UPL set by the Board would apply to downstream actors including consumers, PBMs, insurance carriers, pharmacies, and providers. Given the complexity of the pharmaceutical supply chain, how intermediaries throughout the supply chain will respond to a UPL is a matter of pure speculation, particularly as no other state has established a UPL. What's more, the business decisions these intermediaries make in response to a UPL is for them alone to make. Any incidental and indirect impacts they may choose to try to pass on to manufacturers is a contractual matter between the manufacturer and those entities. The potential for indirect impact does not transform a UPL into a regulation on the manufacturer and does not show causation necessary to establish standing.

B. Without a UPL, this suit is not ripe.

Because a UPL for Enbrel has not yet been set, and may never be set, this suit is not ripe. In determining whether a case is ripe, courts look to two main factors: (1) fitness of the issues for judicial decision, and (2) hardship to the parties from withholding court

consideration. *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003); *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 148-49 (1967).

First, the issues here are not fit for judicial decision because there is no final agency action and judicial intervention would inappropriately interfere with further administrative action. The basic rationale of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Lab'ys*, 387 U.S. at 148-49. Whether an action is fit for review concerns whether the question presented is purely legal, whether the agency action is final, and whether further factual development would significantly advance the court's ability to deal with the legal issues presented. *Merit Energy Co., LLC v. Haaland,* Nos. 21-8047, 21-8048, 2022 WL 17844513 at *5-6 (10th Cir. Dec. 22, 2022).

An agency action is final when it represents the consummation of the agency decision-making process and determines the parties' rights or obligations or creates legal consequences. *Id.* at *5. There is no such final agency action here. The affordability review does not determine any person's rights or obligations or otherwise create legal consequences. *See infra II.B.* A UPL does not determine Amgen's obligations in any case, but particularly when the administrative process to establish a UPL for Enbrel has

not even formally begun, let alone reached its consummation.[24] Amgen has not felt any effects from the Board's Affordability Program.

Second, there is no legal hardship to the parties if the court waits to decide the constitutionality of the Affordability Program—particularly its authority concerning UPLs—until the Board actually establishes a UPL. To demonstrate hardship, a party must demonstrate adverse effects of a "strictly legal kind" which would be suffered by the party if the case is not decided until a later time, such as significant financial costs it would incur, or a concrete action taken by defendants impairing a plaintiff's interests. *Nat'l Park Hosp. Ass'n*, 538 U.S. at 808; *see also Wyoming v. Zinke*, 871 F.3d 1133, 1143 (10th Cir. 2017). But here, Amgen cannot show it would reasonably incur legal adverse effects of a UPL that may never be set and that would never apply to it. Amgen may bring each of its legal challenges at the time an actual controversy exists.

Defendants argue that this case can be decided now on purely legal grounds and summary judgment in their favor is appropriate. However, to the extent the court disagrees that summary judgment for Defendants is appropriate, Amgen's claims are not yet fit for judicial review. If summary judgment is denied, further factual development is needed to determine whether any constitutional violation has occurred, specifically whether a UPL concretely harms Amgen. *See United States v. Doe*, 58 F.4th 1148, 1154-55 (10th Cir. 2023) ("If waiting to decide a case would put us in a better position to resolve

[24] At the Board's July 3 meeting, the Chair reminded the public that "the establishment of an UPL . . . is a process and one that we can decide to terminate at any point."

the dispute, such as when further factual development would help us adjudicate the case, the case may be unripe and therefore nonjusticiable.").

Even if a UPL had been established for Enbrel, any injury to Amgen would be speculative and indirect, at best. Absent a definitive UPL, this case is not ripe for review.

II. Even if this court has subject matter jurisdiction, Defendants are entitled to summary judgment because the Affordability Program is a constitutional exercise of Colorado's police powers.

The Affordability Program is constitutional as a matter of law. Because any UPL would not apply to Amgen, it does not displace federal patent law. Enshrined nowhere in federal patent law is a principle that a state may not regulate downstream transactions for the health and welfare of its citizens after a patent holder has sold its product. In fact, the opposite is clear: once Amgen sells its patented product, its rights and benefits under the federal patent law system are exhausted.

The Affordability Program does not impact Amgen's rights in any form and complies with due process. The statute provides the Board with the standards it applies in its work, and the Board has provided for not just sufficient, but robust, opportunities for public participation and review throughout its processes.

Further, consistent with legislative intent, the Board has stated that any UPL would not apply to purchases or reimbursements made by the federal government. Thus, any question regarding whether such application of a UPL is preempted is moot.

Finally, any UPL would also not violate the dormant Commerce Clause because it applies only to transactions clearly involving a drug being dispensed or administered in Colorado and does not impose discriminatory burdens on interstate commerce.

A. The Affordability Program is not preempted by federal patent law.

Amgen argues that the Affordability Program is preempted by the federal patent laws. *See* ECF No. 1 ¶¶ 66-74. According to Amgen, the Affordability Program "frustrates the purposes and objectives of the federal patent laws" and is, therefore, "preempted by federal law, regardless of its outcome, because it is fundamentally inconsistent with the congressional design." *Id.* ¶ 71; *see also* ECF No. 24 at 19-23. However, since the doctrine of patent exhaustion forecloses Amgen's patent preemption claim, summary judgment should be granted to Defendants.

i. Patent exhaustion and state police powers limit patent rights.

Federal law preempts contrary state law. *See, e.g., Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150, 162 (2016). Under so-called "conflict preemption," a state law is preempted "when it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See, e.g.*, *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1326 (Fed. Cir. 2017).

Patent law has three main objectives. It seeks to: (1) "foster and reward invention"; (2) "promote[] disclosure of inventions" and "permit the public to practice the invention once the patent expires"; and (3) "assure that ideas in the public domain remain there for the free use of the public." *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Consistent with these objectives, patent law provides patentees and their assigns with "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States" during a specific period of time. 35 U.S.C. § 154(a)(1).

But the right to exclude is a negative right with clear limits. For over 160 years, the doctrine of patent exhaustion has served as one "uniform and automatic" limit on patent rights. *See Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 370, 377 (2017). Under the patent exhaustion doctrine, when "a patentee chooses to sell an item, that product is no longer within the limits of the monopoly" granted by a patent. *Id.* at 370. (quotations omitted). "A patentee is free to set the price and negotiate contracts with purchasers, but may not, by virtue of his patent, control the use or disposition of the product after ownership passes to the purchaser." *Id.* (quotations omitted). "The sale terminates all patent rights to that item." *Id.* (quotations omitted). Thus, patent law does not give patentees the right to set or control prices of the product after the first authorized sale. *See, e.g., United States v. Univis Lens Co.*, 316 U.S. 241, 252 (1942); *Impression Prods.*, 581 U.S. at 372-73 (discussing *Univis* and other cases).

In addition, once a product enters a state, its sale is subject to state regulation, even if the product is patented. As the Supreme Court explained over 140 years ago, "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits." *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880). It is well-established that states can regulate patented products in their borders. *See, e.g.*, *Patterson v. Kentucky*, 97 U.S. 501, 503-5 (1878) (regulation prohibiting sale of patented illumination oil); *Webber*, 103 U.S. at 347 (tax on patented products).

ii. There is no patent preemption because a UPL would regulate purchases of Enbrel after Amgen's patent rights have exhausted.

Here, Amgen and the amici repeatedly argue that Congress struck a "careful balance" in the patent laws that rewards innovation with the exclusivity. *See* ECF No. 24 at 16-17. Amgen argues that the only limitation on its economic rewards during exclusivity should be the dictates of the marketplace. *See id.* at 17. But invoking these principles does not help Amgen because "[e]xhaustion extinguishes that exclusionary power." *Impression Prods.*, 581 U.S. at 374. Amgen sells Enbrel to its wholesalers for the list price. Those wholesalers, in turn, sell Enbrel to Colorado pharmacies, which in turn, sell Enbrel to Colorado consumers. The moment Amgen sells Enbrel to its wholesalers, the "careful balance" Congress struck is satisfied. Amgen has received its economic reward and its patent rights automatically exhaust. After the sale to the wholesaler, Amgen has "no exclusionary right left to enforce."[25] *Id.* at 375. After the sale, Amgen cannot use patent law to control the prices downstream in the chain of commerce.[26] *See Univis*, 316 U.S. at 252. After the sale, Amgen cannot use patent law to exempt its products from state regulation. *See Patterson*, 97 U.S. at 505.

The Affordability Program does not regulate the transactions between Amgen and its wholesalers. Rather, if a UPL for Enbrel is set, that UPL will only apply to: (i) a Colorado

[25] Amgen does not own the '182 patent or the '522 patent and instead is the exclusive licensee of the commercial rights to those patents in the United States. *See* ECF No. 1 ¶ 54. Since Amgen is the exclusive licensee, the patent rights are exhausted when Amgen sells Enbrel to the wholesaler. *See Impression Prods.*, 581 U.S. at 376 ("That licensee's sale is treated, for purposes of patent exhaustion, as if the patentee made the sale itself.").
[26] Indeed, any attempt by Amgen to fix or control downstream prices would likely violate antitrust law. *See, e.g.*, *United States v. Parke, Davis & Co.,* 362 U.S. 29, 45 (1960). The patent "monopoly" does not give patentees the right to monopolize.

consumer's purchase from a pharmacy; (ii) an insurance company or PBM's reimbursement to the pharmacy; and/or (iii) the pharmacy's purchase from the wholesaler. *See* 3 C.C.R. § 702-9:4.2.C. In other words, the UPL would regulate transactions downstream in Colorado, at the pharmacy level after Amgen has already sold Enbrel to the wholesaler. This is firmly within the state's power. "It is universally recognized that the state has authority under the police power for the protection of the public health and welfare to regulate the practice of pharmacy and the sale of drugs." *Moore v. Dist. Ct. In & For City & Cnty. of Denver*, 518 P.2d 948, 952 (Colo. 1974); *see also Pharm. Rsch. & Mfrs of Am. v. McClain*, 95 F.4th 1136, 1143-44 (8th Cir. 2024). Consistent with this authority, states, like Colorado, routinely regulate the prices that pharmacies and health plans can charge consumers for prescription drugs.[27] Indeed, the Supreme Court recently affirmed the power of states to regulate the rates at which PBMs reimburse pharmacies for prescription drugs. *See Rutledge*, 592 U.S. at 80. The Affordability Program is a straightforward exercise of these police powers. [28]

[27] *See, e.g.*, §§ 10-16-151 and 12-280-139, C.R.S. (payment and cost-sharing caps on insulin); §§ 10-16-160, and 12-280-142, C.R.S. (payment and cost-sharing caps on epinephrine auto-injectors); § 10-16-104(18.1), C.R.S. (requiring insurance plans to provide coverage for total cost of contraception); § 10-16-104(18), C.R.S. (requiring insurance plans to provide coverage for total cost of preventative health services, including certain vaccinations and HIV prevention drugs).

[28] The Affordability Program is designed to protect the health, safety, and welfare of Coloradans by helping to reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs. *See* S.B. 21-175. Excessive drug costs are a life-or-death issue that extract a real human and economic toll. Excessive drug costs are also a problem recognized universally by governments, stakeholders, and entities throughout the U.S. healthcare system, including Amgen itself. *See, e.g.*, Bradway Written Statement at 3-4; Inside the Drug Pricing Loop. Colorado has the power to address this real problem.

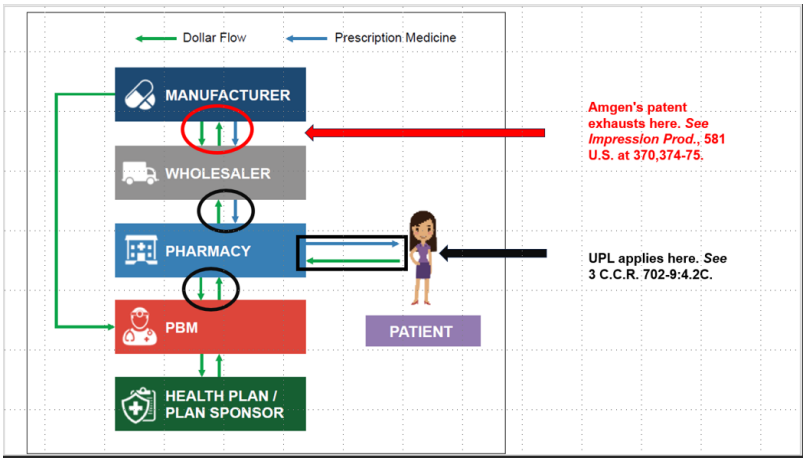

Fig. 2. Visual representation of which transactions UPL regulates in prescription drug supply chain. See PhRMA, Follow the Dollar at 1.

In short, there is no patent preemption because the UPL would regulate downstream transactions after Amgen's patent rights have been exhausted. There is simply no conflict between patent law and the Affordability Program because the Affordability Program is an exercise of the state's police power in an area where Amgen's right to exclude does not apply.

iii. Amgen's arguments do not overcome the exhaustion bar.

In their filings, Amgen and the amici make three principal arguments for patent preemption, none of which avoid the "uniform and automatic" patent exhaustion bar.

First, Amgen argues that the Federal Circuit's decision in *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) ("*Bio*"), dictates the result here. *See* ECF No. 24 at 19-21. But *Bio* involved a regulation that made it unlawful for "any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price."

Id. at 1365. Therefore, the regulation in *Bio* on its face directly targeted the manufacturers' ability to set their own price with the wholesaler. *See id*. at 1374. But as the author of the *Bio* decision later explained, the *Bio* decision rested on the specifics of that particular regulation. *See Biotechnology Indus. Org. v. D.C.*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Gajarsa, J. concurring). *Bio* does not stand for the proposition that any state law regulating the prices of patented pharmaceutical products is preempted. *Id.* at 1348.

Unlike the regulation in *Bio*, the Affordability Program does not regulate the price the manufacturer sets.[29] As discussed above, it regulates transactions involving the pharmacy after Amgen sells Enbrel to its wholesaler customers. This key difference means that patent exhaustion would have occurred by the time Enbrel would be subject to a UPL; *Bio*'s rationale simply does not apply here.

Second, Amgen and the amici repeatedly point to the Hatch-Waxman Act and the Biosimilar Price Competition and Innovation Act ("BPCIA") as evidence of the central role "enhanced profits" purportedly have in the patent scheme. *See, e.g.*, ECF No. 24 at 18-19; ECF No. 27-1 at 11-12. It is true that Hatch-Waxman and BPCIA extended the term of patent exclusivity for pharmaceuticals and created a pathway for generics. But neither law altered the patent exhaustion doctrine nor placed a limit on the states' power to regulate products within their borders. As the Supreme Court noted *after* Hatch-Waxman and the BPCIA were passed, "Congress has not altered patent exhaustion at all; it

[29] *Bio* is also distinguishable because the regulation in *Bio* applied exclusively to patented products, *see Bio*, 496 F.3d at 1374, which is not the case for the Board's Affordability Program. The Affordability Program applies to branded and generic drugs alike and so is not targeted at anyone's patent right.

remains an unwritten limit on the scope of the patentee's monopoly." *Impression Prods.*, 581 U.S. at 378. Amgen receives its "enhanced profits" when it sells Enbrel to its wholesalers. At that point, the extended term of exclusivity granted by Hatch-Waxman and the BPCIA are exhausted. Therefore, Amgen cannot rely on Hatch-Waxman or the BPCIA to invalidate downstream government regulations, such as the Affordability Program, after that point.

Finally, Amgen argues that the Affordability Program is preempted because it would "reduc[e] the 'size of the carrot' Congress provided in the patent laws – *i.e.*, the economic rewards that are part and parcel of patent ownership." ECF No. 24 at 20. Amici adopt a more apocalyptic tone, arguing that the Affordability Program would "create less favorable terms for investment, causing researchers to scale back certain development programs" and "will hinder continued biopharmaceutical innovation, ultimately harming patients reliant on the industry." ECF No. 27-1 at 15-16. But these dubious policy arguments do not save Amgen's patent preemption claim.

The Supreme Court heard similar arguments in *Impression Prods., Inc. v. Lexmark Intn'l, Inc,* and considered whether patent exhaustion applied to foreign transactions. 581 U.S. at 370 (2017). In *Impression Prods.,* the Federal Circuit held that foreign sales did not exhaust patent rights since patentees were entitled to a particular "reward from sales in American markets." *Lexmark Int'l, Inc. v. Impression Prods., Inc.*, 816 F.3d 721, 761 (Fed. Cir. 2016). The respondent argued that foreign exhaustion should not apply since "a patentee selling in a foreign market may not be able to sell its product for the same price that it could in the United States, and therefore is not sure to receive 'the reward

guaranteed by U.S. patent law.'" *Impression Prods.*, 581 U.S. at 379. In its amicus brief in *Impression Prods.*, PhRMA argued that permitted foreign exhaustion would result in "downward pricing pressures on pharmaceutical sales in the United States" which "would hinder pharmaceutical companies from using the patent exclusivity period to recover their research and development costs." Br. for PhRMA as Amicus Curiae in Support of Respondent, *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360 (2017) (No. 15-1189) 2017 WL 894890, at *12. PhRMA also argued that, since some foreign governments impose price controls on patented drugs, a foreign exhaustion rule would "effectively usurp Congress' policy judgment about the proper balance between innovation and access to medication" and would "permit foreign price controls or patent policy to encroach on the U.S. market." *Id.* at 14.

The Supreme Court rejected all of these arguments. The court explained that "the Patent Act does not guarantee a particular price, much less the price from selling to American consumers." *Impression Prods.*, 581 U.S. at 380. "Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive." *Id.* at 382. All that the right to exclude ensures is that a patentee receives "one reward" for every item that is sold. *Id.* at 380. Once a patentee decides to sell, it receives that one reward and the sale automatically exhausts the patentee's patent rights domestically and internationally. *See id.* at 377, 382.

The same logic applies here. The Patent Act does not guarantee Amgen a particular price for Enbrel or give Amgen the unfettered right to extract the maximum profits possible from Coloradans. The Patent Act does not relieve Amgen of potential

downward pricing pressures from downstream entities. The Patent Act does not care about the size of Amgen's "carrot." The Patent Act simply entitles Amgen to one reward, which Amgen receives the moment it sells Enbrel to its wholesalers. Once that happens, the purposes of patent law have been achieved and patent law is no longer concerned with the product or the effects of downstream regulations. Patent rights do not "stick remora-like" to Enbrel as it moves through the chain of commerce. *Id.* at 382.

Amgen may prefer for its products to be totally free from state regulation. Amgen may prefer to continue raising its list price for Enbrel to pay more rebates to PBMs, even if that means that the Coloradans who need Enbrel will see little relief at the pharmacy counter. But "[i]t is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent." *Bio*, 505 F.3d at 1346 n.1 (Gajarsa, J. concurring). That the Affordability Program may make it uncomfortable for Amgen to engage in what it euphemistically calls "counterintuitive pricing behavior" does not mean the Affordability Program is preempted by patent law. Since the doctrine of patent exhaustion forecloses Amgen's patent preemption claim, summary judgment should be granted for Defendants.

B. Amgen's due process claim fails because the Affordability Program does not implicate Amgen's due process rights.

Neither the Board's affordability review nor UPL processes impact Amgen's protected property rights. Even if they did, the Board's Affordability Program affords the appropriate level of process required by the Due Process Clause. While Amgen argues that these processes are "standardless," such an allegation is insufficient to make out a

due process claim when Amgen cannot identify how the Affordability Program impacts or adjudicates its rights. The legislature's grant of discretion to subject-matter experts in an administrative agency comports with due process.

"When determining whether the government has deprived an individual of his due process rights, the court engages in a two-pronged inquiry. First, we ask whether the individual possessed a protected interest giving rise to due process protection." *Garcia v. City of Albuquerque*, 232 F.3d 760, 769 (10th Cir. 2000). If yes, then courts "proceed to the second inquiry: whether the government afforded the individual an appropriate level of process." *Id.* Here, Amgen has neither a protected interest nor a deprivation. And it has received or will receive an appropriate level of process as part of the Board's affordability review and UPL proceedings. The Board has not violated Amgen's due process rights.[30]

i. Amgen lacks a protected interest or a deprivation as part of the Board's Affordability Program proceedings concerning Enbrel.

To have a protected property interest, "a person clearly must have more than an abstract need or desire" and "more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Town of Castle Rock, Colo. v. Gonzales*, 545

[30] Amgen is not clear in whether it attempts to bring a procedural due process claim or a substantive due process claim. If a substantive due process claim, Amgen has not satisfied its burden to show that "the challenged government action shocks the conscience of federal judges." *Klen v. City of Loveland, Colo.,* 661 F.3d 498, 512-13 (10th Cir. 2011) "An arbitrary deprivation of a property right may violate the substantive component of the Due Process Clause if the arbitrariness is extreme" and of "a degree of outrageousness and a magnitude of potential or actual harm that is truly conscience shocking." *Id.* But Amgen does not allege that the Board's actions were borne of "corruption, self-dealing, or bias against any protected group or activity." *Onyx Props, LLC v. Bd. of Cnty. Commn'rs*, 838 F.3d 1039, 1050 (10th Cir. 2016). And the possibility that the Board will establish a UPL that Amgen deems "unfair" or "arbitrary" does not shock the conscience, particularly when such a UPL is reviewable.

U.S. 748, 756 (2005). "A property interest includes a 'legitimate claim of entitlement' to some benefit created and defined by 'existing rules or understandings that stem from an independent source such as state law.'" *Crown Point I, LLC v. Intermountain Rural Elec. Ass'n*, 319 F.3d 1211, 1216 (10th Cir. 2003) (quoting *Bd. of Regents v. Roth*, 408 U.S. 564, 577 (1972)). Amgen does not have a legitimate claim of entitlement to dictate downstream prices of its products after it sells its drug to a wholesaler.

Amgen does not identify how the Board's work impacts its protected property interests. While Amgen argues it has the right to "fix the price at which [an owner] of property will sell," it does not address how the Affordability Program interferes with that right. Nothing in the affordability review impacts Amgen's ability to choose to whom it sells its product, set the list price, or dictate the terms of its sales to distributors. The Board's determination that use of a drug is unaffordable for Colorado consumers does not, on its own, impact anyone, let alone Amgen. It is simply a determination. And it is not even a final agency action. § 10-16-1408(1)(c), C.R.S.

Similarly, if the Board sets a UPL for Enbrel, that UPL would still not dictate what Amgen may charge. Because a UPL does not apply to a purchase from Amgen, Amgen is a third-party whose property rights are not at issue. *See Martin Marietta Materials, Inc. v. Kansas Dep't of Transp.*, 810 F.3d 1161, 1177 (10th Cir. 2016) (rejecting a due process claim from a plaintiff who was "not a party to the contract and so cannot claim a property interest arising from that contract").

Amgen's lack of identifiable property right being impacted by the Board's work should end the due process inquiry.

ii. Even if Amgen has a protected interest, it has been afforded the appropriate level of process.

Even if this Court finds that the Board's work impacts Amgen's property rights, the Affordability Program affords an ample level of process and commensurate mechanisms for review of the Board's actions. An essential principle of due process is that deprivation of a protected right "'be preceded by notice and opportunity for hearing appropriate to the nature of the case.'" *Mullane v. Central Hanover Bank & Trust Co.,* 339 U.S. 306, 313 (1950). But the purpose of the notice requirement is to satisfy the "fundamental principle in our legal system" "that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.,* 567 U.S. 239, 253 (2012); *see also Blanca Tel. Co. v. Fed. Commc'ns Comm'n*, 991 F.3d 1097, 1116 (10th Cir. 2021) (citations omitted) ("Due process requires fair notice for two reasons. First, regulated parties need to know what is required of them so they may act accordingly. . . . Second, it prevents officers or agencies who enforce the law from acting in an arbitrary or discriminatory manner."). But neither the affordability review (which does not regulate anyone) nor the establishment of a UPL (a quasi-legislative action that does not apply to Amgen) requires the typical notice central to quasi-judicial proceedings. Nevertheless, both these processes provide ample and transparent opportunities for stakeholder engagement and robust reviewability mechanisms. Neither run afoul of due process.

a. Though it need not, the Board provides notice and opportunity to be heard in the affordability review.

If the purpose of the Due Process Clause's notice requirement is to let regulated persons or entities know what is forbidden or required, such protections are inapposite

for affordability review proceedings. By the affordability review, the Board is not proscribing or compelling any activity. Rather, the affordability review is the process by which the Board, using numerous criteria established by statute and rule, reaches a fact-specific and contextual determination regarding unaffordability of a drug for Colorado consumers. This does not trigger due process protections.

Amgen attempts to make out a due process violation embedded in this affordability review process by alleging that the Board lacks uniform standards it applies across these affordability reviews. But due process does not require every delegation by the legislature to an administrative agency to contain precise, formulaic instructions on how to reach determinations across nuanced contexts. Indeed, if that were the case, regulatory bodies comprised of subject-matter experts would serve little purpose. Instead, administrative agencies made up of industry participants or experts must routinely reach generalized determinations. *See, e.g.,* § 10-16-107, C.R.S. (directing the insurance commissioner to review rates for health insurance products to ensure they are not "excessive, inadequate, or unfairly discriminatory"); §§ 12-240-120(1)(b), -121(1)(j), C.R.S. (directing the Colorado Medical Board to discipline licensees for failing "to meet generally accepted standards of medical practice"). Valid delegations do not run afoul of the Due Process Clause simply because they give an agency discretion.

Here, the Board evaluates whether *use* of a drug is unaffordable, not whether a drug is fairly priced. And to do so it must conduct a fact-intensive inquiry using statutory and regulatory factors that depend on how the drug is actually used and accessed by Colorado consumers. Neither the legislature nor the Board saw fit to turn this inquiry into

a formulaic, binary determination because the conclusion the Board must reach is complex and inherently different on a drug-by-drug basis. For instance, a drug with no therapeutic alternatives that is administered by a physician as an injection every few months to treat a rare disease may present entirely distinct considerations relating to unaffordability than a drug that may be taken orally, at home, and daily to treat a common condition and for which a patient may have many choices amongst alternatives. The grant of discretion to the Board to consider these nuances is not unconstitutional.

That "unaffordability" may not be evaluated in a methodically identical way for each drug does not render the Board's work standardless. The Board evaluates the same criteria, as much as data availability allows, across each of the drugs it reviews. That data is set forth in detail in its publicly available reports, which include a summary of the Board's deliberations, which themselves are public.[31] The Board's unaffordability determinations are not only based on clear and explicit standards, but they are reviewable if the Board proceeds with a UPL. § 10-16-1408(2), C.R.S.

But even if some opportunity to be heard is required in the affordability reviews, Amgen had it and used it. Amgen repeatedly engaged with the Board through supplying oral and written comments across multiple meetings; directly engaging in a stakeholder meeting concerning Enbrel's health and financial effects; and providing evidence the Board considered as part of its affordability review determination. *See generally* Enbrel

[31] *Compare* the Enbrel Affordability Review Report at 1-30 *with* Affordability Review Summary Report sections of the Board's Affordability Review Reports for Trikafta, Genvoya, Stelara, and Cosentyx, available at https://tinyurl.com/2tv6xyfr.

Affordability Review Report Appx's I, J. In fact, 35 pages of the Board's 534-page report is comprised of materials Amgen submitted for the Board's consideration. *See Exh. 2.*

b. Establishing a UPL through rulemaking is sufficient to safeguard the ability to participate in the Board's process.

Similarly, establishing a UPL is a quasi-legislative process that need not provide notice and opportunity to be heard. While rulemaking affords sufficient opportunity for stakeholder participation and reviewability, typical due process protections do not attach when an administrative agency acts in a quasi-legislative capacity. *Onyx Props, LLC*, 838 F.3d at 1045-48 (holding that the discretionary implementation of a prospective, generally applicable zoning plan was a quasi-legislative proceeding and did not require a hearing before the agency took action); *see also Denver Bible Church v. Azar*, 494 F. Supp. 3d 816, 840 (D. Colo. 2020) ("procedural due process in the form of individual notice and hearing is typically not required for the government to implement a generally applicable rule that affects the public at large, rather than a specific individual or a small group."). A UPL is a generally applicable, prospective, setting of a payment limit. *AviComm, Inc. v. Colo. Pub. Utils. Comm'n*, 955 P.2d 1023, 1030 (Colo. 1998); *see also Carroll v. Barnes*, 455 P.2d 644, 647 (Colo. 1969) ("When the making of rates for the future is delegated to an administrative agency, it functions in a quasi-legislative capacity."). Thus, UPL setting is a quasi-legislative act, subject to all the robust protections of the state APA. § 10-16-1407(5), C.R.S.; *see generally* § 24-4-103, C.R.S.

The Board's UPL process also provides adequate standards. The statute directs the Board to create a methodology in rule for establishing UPLs and provides factors the Board must consider including the costs of administering, dispensing, and distributing the

drug, as well as factors the Board is prohibited from considering such as analyses relying on quality-adjusted life years. § 10-16-1407, C.R.S. The Board promulgated that rule, which outlines the data and information it will evaluate in establishing a UPL. 3 C.C.R. § 702-9:4.1. Far from rogue, standardless discretion, the Board has publicly identified what it will consider in establishing a UPL, in accordance with the guardrails and emphases established by the General Assembly.

Amgen cites *Michigan Bell Tel. Co. v. Engler,* 257 F.3d 587 (6th Cir. 2001) and *Guaranty Nat'l Ins. Co. v. Gates*, 916 F.2d 508 (9th Cir. 1990)—involving challenges to definable statutory rate freezes—for the proposition that agencies must "ensure a fair and reasonable rate of return on investment." ECF No. 24 at 26. But Amgen fails to demonstrate how the Board's ongoing process to potentially establish a UPL for Enbrel, results in the *statute* being deemed confiscatory and facially unconstitutional. Neither case Amgen cites establishes a test used in the Tenth Circuit, but regardless, both cases discuss a critical component to the due process inquiry that is clearly present in the Board's Affordability Program: due process requires a mechanism to challenge the rates. *Michigan Bell Tel. Co,* 257 F.3d at 593; *Guaranty Nat'l Ins. Co.,* 916 F.2d at 513 (finding reviewability mechanisms limited by the insolvency provisions at issue and so not sufficient for due process).

Any UPL established by the Board is reviewable in at least three ways. Such a rule could be challenged under the state APA's judicial review procedures. § 24-4-106(2), (7), C.R.S. Additionally, the legislature could, on its own, repeal a rule establishing an UPL. § 24-4-103(11)(d), C.R.S. And finally, the statute specifically authorizes a joint House and

Senate committee of the General Assembly to pursue legislation to discontinue any UPL. § 10-16-1414(3)(b), C.R.S. Amgen's argument that the Board's discretion is unfettered is belied by the numerous statutory pathways for review.

Finally, Amgen faces no risk of arbitrary enforcement. Indeed, it faces no risk of enforcement at all because any UPL would not apply to it. None of the Affordability Program impacts Amgen's rights regarding when, where, to whom, and for how much it can sell Enbrel. Due process protections, while crucial to our democracy, simply are not applicable to the Board's work in the way Amgen suggests. Defendants are entitled to summary judgment because the Affordability Program complies with due process.

C. Amgen's claim that the Board is preempted is moot because a UPL would not apply to federal programs and payers.

Amgen's claim that the Board is preempted from applying its UPLs to federal programs such as Medicare, TRICARE, and the Federal Employee Health Benefits Program (FEHB) (ECF No. 24 at 28) is moot because the Board has explicitly stated that UPLs do not apply to these programs. There is no active controversy.[32] A case is moot when "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Already LLC v. Nike, Inc.,* 568 U.S. 85, 91 (2013). A claim for declaratory relief is moot when the relief would not affect the behavior of the defendant toward the plaintiff. *Smith v. Becerra*, 44 F.4th 1238, 1247-48 (10th Cir.

[32] Amgen's claim regarding preemption applies only to the Board's authority to create—and the Attorney General's authority to enforce—UPLs in certain instances. Amgen has not asserted that the Board is preempted from conducting affordability reviews to create transparency in this exceptionally opaque market. Nor could it. There is no federal law preempting states from evaluating whether a drug is unaffordable for its consumers.

2022). Because the Board, through its UPL Policy, and the Attorney General, have disclaimed the applicability of a UPL to federal programs and payers, any relief requested by Amgen and granted by this court on this claim would have no effect. PDAB UPL Policy at 2; *Exh. 1* at 2.

While section 10-16-1407(5), C.R.S., does not enumerate each transaction to which a UPL does or does not apply, the statute's text shows the legislature did not intend for UPLs to apply to federal payers or purchasers, or entities otherwise regulated by the federal government. In SB 21-175's legislative declaration, the legislature specifically identified the need to impact drug costs for "commercial health plans" and "state and local governments" SB 21-175 at 2-3. The Attorney General's enforcement authority is also limited by a prohibition on enforcement against "a carrier or state agency that is required pursuant to . . . federal law to purchase or reimburse a payer for a prescription drug for which the Board has established [a UPL]." § 10-16-1411(5), C.R.S. The statute further provides a mechanism for self-funded health plans—which would otherwise be subject to regulation by the federal government under ERISA—to *opt-in*, suggesting the law's default application is that a UPL would *not* apply. §§ 10-16-1407(8), -1413, C.R.S. In short, the legislature never intended to create conflicts with federal law.

And so, neither did the Board. In January, 2023, the Board promulgated its UPL Policy to clarify that a UPL would not apply to Medicare or self-funded plans subject to ERISA that did not opt-in. On July 19, 2024, the Board expanded that clarification to state:

> An upper payment limit does not apply to the purchase or reimbursement by any federal agency, federal program, Indian Tribe, or non-participating self-funded health benefit plans, including but not limited to, purchases or

> reimbursements made by Medicare, TRICARE, or the Federal Employee Health Benefits program.
>
> PDAB UPL Policy at 2.

This is a valid, constitutional interpretation of the Board's statute, and it is sufficient to render this case moot.[33] A defendant's voluntary cessation will moot a case if the defendant "carries the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Brown v. Buhman*, 822 F.3d 1151, 1166 (10th Cir. 2016). The Board's UPL Policy, which clarifies the Board's original position to avoid application of any UPL in a manner that conflicts with federal law, squarely addresses the relief sought by Amgen. The policy change forecloses any reasonable chance that a UPL would be applied to the federal purchases raised by Amgen. *See, e.g.*, *Prison Legal News v. Fed. Bureau of Prisons,* 944 F.3d 868, 881-82 (10th Cir. 2019); *Mink v. Suthers*, 482 F.3d 1244, 1256-57 (10th Cir. 2007). Although the Board amended its UPL Policy during the pendency of this matter, "[a] government official's decision to adopt a policy in the context of litigation may actually make it more likely the policy will be followed, especially with respect to the plaintiffs in that particular case." *Brown*, 822 F.3d at 1171.

In addition to the Board's constitutional interpretation, giving effect to the legislative intent, the Attorney General has explicitly stated that he will only enforce a UPL according

[33] Consistent with well-established principles of constitutional avoidance, the Board appropriately interpreted its statute to not apply to transactions that may create a conflict with federal law. *See Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018) ("Under the constitutional-avoidance canon, when statutory language is susceptible of multiple interpretations, a court may shun an interpretation that raises serious constitutional doubts and instead may adopt an alternative that avoids those problems.").

to the applicability established by the Board. *Exh. 1* at 2. These clarifying statements regarding UPL applicability and enforceability by the Board and Attorney General were issued prior to any enforcement of the statutes and thus represent the good faith intention of Defendants to interpret and apply the statutes in a constitutional manner.

In any case, the statute itself is not preempted, as there is no explicit application to the federal government. Rather, preemption here is a question of whether individual UPLs, as applied by the Board and enforced by the Attorney General may be preempted in certain circumstances involving the federal government. Effecting a constitutional and valid reading of the statute's text, structure, and legislative history, Defendants have now answered: a UPL does not apply in those circumstances. This renders Amgen's claim moot and summary judgment is appropriate for Defendants.

D. Upper payment limits do not violate the dormant Commerce Clause.

The dormant Commerce Clause is not a license for courts to invalidate any state law that might impact commerce outside of a state. "[P]reventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme delicacy,' something courts should do only 'where the infraction is clear.'" *See Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 390 (2023) (quotations omitted). "*Extreme caution* is warranted before a court deploys" this principle to strike down a state law. *Id* (emphasis added) (quotations omitted). Amgen's attempt to invalidate the Board's UPL authority[34] cannot overcome this heavy burden.

[34] Amgen does not argue that affordability reviews violate the dormant Commerce Clause. And indeed, nothing about providing a detailed report regarding a medication's costs to a state's consumers implicates the dormant Commerce Clause.

i. UPLs apply equally to in-state and out-of-state competitors.

The Commerce Clause empowers Congress to "regulate Commerce … among the several states." U.S. Const. art. I, § 8, cl. 3. The Supreme Court has held that the clause implicitly prohibits states from enacting laws that seek to protect in-state interests from their out-of-state competitors: the "dormant Commerce Clause." *See Ross,* 598 U.S. at 368-71. "[T]his antidiscrimination principle lies at the 'very core' of [the Supreme Court's] dormant Commerce Clause jurisprudence." *Id.* at 369. (citations omitted).

Upper payment limits do not implicate this "core" dormant Commerce Clause concern because they do not discriminate against interstate commerce. A UPL does not give an in-state company an advantage relative to its out-of-state competitors. Rather, the same UPL that applies to an in-state pharmacy's purchase of a medication dispensed in Colorado applies to an out-of-state pharmacy's purchase of the same medication dispensed in Colorado. *See* § 10-16-1401(23), C.R.S. (defining "upper payment limit" by focusing on whether a drug is dispensed or distributed in Colorado, not a seller's location); 3 C.C.R. § 702-9:4.2.C.2. Similarly, a pharmacy's purchase from a wholesaler for drugs dispensed in Colorado is subject to the same UPL regardless of the wholesaler's location.

Because a UPL applies equally and maintains a level playing field for all market competitors, the Board's authority does not implicate the anti-discrimination concerns that form the "very core" of the dormant Commerce Clause.

ii. UPLs do not impact the prices charged in other states.

A UPL also does not violate the dormant Commerce Clause just because it may impact transactions occurring outside of Colorado. The Supreme Court has resoundingly

rejected such an approach.

Nearly ten years ago, then-Judge Gorsuch examined the Supreme Court's cases that had invalidated state laws under the dormant Commerce Clause on the theory that they had impermissible extraterritorial impacts. He noted that the cases had three "essential characteristics": (1) a price control or price affirmation regulation, (2) that linked in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses. *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1173 (10th Cir. 2015). As the Tenth Circuit Court of Appeals explained, "only price control or price affirmation statutes that link in-state prices with those charged elsewhere and discriminate against out-of-staters" are subject to a *per se* invalidity rule. *Id.* at 1174.

Last year, now-Justice Gorsuch, writing on behalf of a majority of the Supreme Court, reached the same conclusion. In *Ross*, the Court concluded its extraterritoriality cases all involved "statutes [that] had a *specific* impermissible 'extraterritorial effect'—they deliberately 'prevent[ed out-of-state firms] from undertaking competitive pricing' or deprive[d] businesses and consumers in other States of 'whatever competitive advantages they may possess.'" 598 U.S. at 374 (quoting *Healy v. Beer Inst., Inc.*, 491 US. 324, 338-39 (1989)). That rule applied in the extraterritoriality cases—and the same rule Amgen asks the Court to apply here, ECF No. 24. at 32 (citing *Healy*, 491 U.S. at 336)—addressed "price control or price affirmation statutes that tied the price of … in-state products to out-of-state prices." *Id.* (quoting *Pharm. Rsch. & Mfrs. v. Walsh*, 538 U.S. 644, 699 (2003)).

A UPL, however, does not tie the price of medications sold in Colorado to the price

of those medications when sold outside of Colorado, which was the specific concern in other extraterritoriality cases. *See, e.g., Healy*, 491 U.S. at 336-39 (striking down a Connecticut law that made it illegal for beer importers to sell in-state at a higher price than beer sold in a bordering state, because the law effectively set a floor in every bordering state). Instead, the Board must consider various data and independently determine (1) whether to set a UPL, and (2) if a UPL is appropriate, what the limit should be. § 10-16-1407(1), (2), C.R.S.; 3 C.C.R. § 702-9:4.1.C.2. None of that impacts what a person pays in another state. Thus, UPLs do not violate the extraterritoriality prong of the Supreme Court's dormant Commerce Clause jurisprudence.

iii. Colorado can prohibit the sale of drugs purchased in violation of a UPL from being dispensed and distributed in Colorado.

Amgen argues that a UPL violates the extraterritoriality principle because Colorado is attempting to "directly regulate transactions that occur entirely outside its borders." ECF No. 24 at 31. This argument is both limited in scope and incorrect.

On scope, Amgen's dormant Commerce Clause arguments are limited to "transactions that occur entirely outside [Colorado's] borders." *Id.* at 31, 34. Implicitly, then, Amgen concedes that its argument does not apply when part of the transaction is in Colorado. For example, if a pharmacy sells a drug to a consumer located in Colorado—regardless of where the pharmacy is located—the transaction is not wholly out of state. Similarly, if a distributor sells a drug to a provider located in Colorado, the transaction is

not wholly out of state.[35] Further, because a drug must be administered or dispensed in Colorado for a UPL to apply, it is not possible for the UPL to apply to a patient-level transaction occurring entirely outside of Colorado. §§ 10-16-1401(23), 10-16-1407(5), C.R.S. The reality then, is that Amgen's argument is limited to situations where an out-of-state pharmacy purchases a drug from an out-of-state distributor and dispenses or distributes that drug in Colorado.

Even there, however, a UPL does not violate the dormant Commerce Clause. In *Ross,* California prohibited pork products being sold in California if the producers failed to comply with specific requirements for how they treated their pigs. 598 U.S. at 363-64. The producers argued that California's attempt to dictate how they had to raise their pigs outside of California to be able to sell their products inside California violated the dormant Commerce Clause because California's law would significantly increase costs for producers who wanted to sell their products in California. *Id.* at 371.

The Court disagreed. In the lead opinion, a plurality of the Court recognized that California was telling pork producers only that *if* they wanted to sell their products in California, then they had to treat their pigs in a specific manner. *Id.* at 384. If they did not want to sell their products in California, they did not have to comply with California's requirements. Or they could separate the pigs intended to be sold in California to comply with California's laws, while they raised the remaining pigs however they saw fit. *Id.* That did not violate the dormant Commerce Clause because all California was doing was

[35] Importantly, this concession means that even if the Court agreed with Amgen's dormant Commerce Clause arguments, the only relief to which Amgen would be entitled is an injunction preventing the application of UPLs to wholly out-of-state transactions.

regulating the products that could be sold in California. *Id.* at 390-91.

The same is true here. Wholesalers, pharmacists, and providers can sell and buy drugs at any price. But if the price exceeds the UPL that applies to a drug that is dispensed or distributed in Colorado, then those drugs cannot be sold in Colorado. This leaves purchasers with choices, like the choices faced by the producers in *Ross*. They can purchase drugs for prices above the UPL and not sell them in Colorado. Or they can purchase some drugs at prices that comply with the UPL and sell those in Colorado, while purchasing others at prices over the UPL and selling those elsewhere. Or they can choose not to sell a drug that is subject to a UPL into Colorado altogether. Giving out-of-state purchasers these choices does not violate the dormant Commerce Clause because all a UPL does is regulate products that companies choose to sell in Colorado. *Id.* at 376 n.1.

The cases Amgen cites do not require a contrary result. *See* ECF No. 24 at 32-33. *Association for Accessible Medicines. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), is a Fourth Circuit case that is not controlling on this Court, that pre-dates *Ross*, and whose holding is no longer good law. In *Frosh*, the Fourth Circuit rejected Maryland's argument that the principle against extraterritoriality was limited to price affirmation statutes and relied on cases, such as *Healy*, to conclude that the law violated the dormant Commerce Clause. 887 F.3d at 669-70. As discussed above, however, the Supreme Court has since limited the extraterritoriality case law to price control and affirmation statues that tie the price in one state to the price in another, directly undermining *Frosh's* analysis.

Amgen also points to *Association for Accessible Medicines. v. Ellison*, No. 23-CV-2024, 2023 WL 8374586 at *3-4 (D. Minn. 2023) for support. Not only is that decision not

binding on this Court and on appeal, it is also distinguishable. In *Ellison*, Minnesota admitted that its statute would apply to a transaction between a manufacturer and a distributor so long as the drug was eventually dispensed in Minnesota, even if the manufacturer did not know that the drug would be dispensed in Minnesota and even if the manufacturer actively tried to keep its drugs out of Minnesota. *Id.* at *3. The district court expressed concern over the tenuous connection of the law: "[t]he only requirement for [a transaction] to be subject to the Act is that somehow, someday, in some way, someone who is *not* a party to the transaction must sell, dispense, or deliver the drugs to any consumer in Minnesota." *Id.* at *4.

A UPL does not apply that broadly. Indeed, to the extent a particular purchaser is not responsible for a drug being dispensed or distributed into Colorado, liability under the statute cannot reasonably attach. It is only the pharmacy or provider that purchases a drug that is subject to a UPL and then avails itself of the Colorado market by dispensing or distributing that drug who must comply with a UPL. The dormant Commerce Clause does not prohibit Colorado from exerting control over that purchaser.

iv. UPLs do not impose a substantial burden on interstate commerce under *Pike*.

Finally, Amgen argues that even if a UPL does not violate the dormant Commerce Clause *per se* through its extraterritorial effect, the Board's UPL authority fails the *Pike* balancing test because the burdens of a UPL are "clearly excessive in relation to the putative local benefits." ECF No. 24 at 34 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). Amgen argues "Colorado has no legitimate interest in directly regulating transactions that occur entirely outside its boundaries" and that any local benefits "could

be achieved by regulating in-state transactions." *Id.*

Amgen's argument misses the mark. First, it forgets that the core of dormant Commerce Clause jurisprudence is the prevention of discrimination against out-of-state interests. UPLs do not discriminate against out-of-state commerce, placing Amgen's argument in a tenuous position from the start. *Ross*, 598 U.S. at 379-80.

Second, Amgen has failed to specifically identify a burden on interstate commerce, much less one that would support its argument under *Pike*. When performing the *Pike* analysis, the focus is on "the burdens on interstate commerce that exceed the burdens on intrastate commerce." *V-1 Oil Co. v. Utah State Dep't of Pub. Safety*, 131 F.3d 1415, 1425 (10th Cir. 1997). Here, Amgen points to no burden on interstate commerce that exceeds those on intrastate commerce, and indeed, there are none. *See Ross,* 598 U.S. at 391 (noting the petitioners "would have [the Court] prevent a State from regulating the sale of an ordinary consumer good within its own borders on nondiscriminatory terms—even though the *Pike* line of cases they invoke has never before yielded such a result").

The dormant Commerce Clause is a judicially created doctrine intended to prevent discrimination against interstate commerce. It should be deployed with extreme caution when being used to invalidate a state law. Colorado's UPL authority does not discriminate against interstate commerce and only apply to transactions involving medications that a purchaser chooses to later dispense or distribute in Colorado. The dormant Commerce Clause does not prohibit Colorado from setting a UPL and summary judgment is appropriate for Defendants.

CONCLUSION

There is no doubt that Enbrel is an effective—and extremely profitable—drug that can dramatically change the quality of life for its users. And the parties agree that affordable access to medications is critical. *See* ECF No. 24 at 1-2; *see generally* Enbrel Affordability Review Report at 2-3. But Amgen misunderstands the impact of a UPL in Colorado to be on the manufacturer. Rather, any UPL in Colorado will directly apply to the very actors Amgen argues are to blame for rising costs, like PBMs and the commercial insurance plans they operate on behalf of. 3 C.C.R. § 702-9:4.2.C. The Board's interest in addressing these excessive costs for Colorado consumers appears aligned with Amgen's understanding of where a market failure is occurring. And yet, Amgen claims that a Colorado UPL will up-end federal patent law and completely reverse incentives for innovation. Amgen may choose to jeopardize access to Enbrel in Colorado because of a downstream regulation on what certain people can pay for it, but the Board is not altering these incentives for manufacturers. The Board is not regulating Amgen at all.

Colorado has both the authority and a duty to protect Coloradans by ensuring access to affordable prescription drugs. Downstream payment regulations—even on a patented product—are a legitimate and constitutional exercise of its police powers. Colorado empowered the Board with tools to peel back the curtain on prescription drug costs in Colorado through affordability reviews and restore power back to those consumers, pharmacies, providers, and insurance companies paying for those drugs through UPLs. The Affordability Program is not targeting Amgen and is constitutional. Defendants request this court grant summary judgment in their favor.

DATED at Denver, Colorado this 9th day of August, 2024.

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Attorney General

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC., et al.

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, et al.,

Defendants.

DECLARATION OF NATHAN BLAKE

I, Nathan Blake, pursuant to 28 U.S.C. § 1746, state as follows:

1. I am the Deputy Attorney General for the Consumer Protection Section in the Colorado Attorney General's Office. Attorney General Philip Weiser has granted me authority to testify on his behalf regarding the above-captioned lawsuit's challenge to the constitutionality sections 10-16-1401 to 10-16-1416, C.R.S.

2. Pursuant to section 10-16-1411(3), C.R.S., the Colorado Attorney General is authorized to enforce part 14, title 10, C.R.S., on behalf of any state entity or any consumer of prescription drugs.

3. Pursuant to sections 10-16-1406 and 10-16-1407, C.R.S., the Prescription Drug Affordability Review Board is the agency charged with conducting affordability reviews and setting upper payment limits. Further the Prescription Drug Affordability

EXHIBIT 1

Review Board is the agency responsible for interpreting the statutes governing affordability reviews and upper payment limits.

4. The statements in this declaration are all based upon my own personal knowledge or information.

5. As of the date of this declaration the Colorado Attorney General's office has not taken or initiated any enforcement actions under section 10-16-1411(3),C.R.S.

6. The Colorado Attorney General's Office will only enforce part 14, title 10, C.R.S., in accordance with the regulations and policies adopted by the Prescription Drug Affordability Review Board.

7. The Colorado Attorney General does not intend to enforce part 14, title 10, C.R.S., against Plaintiffs in the above-captioned matter, or against any others similarly situated to Plaintiffs, in a manner that is inconsistent with the regulations and policies adopted by the Prescription Drug Affordability Review Board.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 7th day of August, 2024.

s/ Nathan Blake
Nathan Blake

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC.; et al.,

Plaintiffs,

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GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board; et al.,

Defendants.

DECLARATION OF ELIZABETH CUMMINGS

I, Elizabeth Cummings, pursuant to 28 U.S.C. § 1746, state as follows:

1. I am Deputy Commissioner of Health Policy at the Colorado Division of Insurance.

2. From November 22, 2021 to present, I also served as the Prescription Drug Affordability Director.

3. My duties as the Prescription Drug Affordability Director included receiving and compiling confidential information submitted for inclusion in the Prescription Drug Affordability Board's ("Board") affordability review for the prescription drug, Enbrel.

4. On October 2, 2023, Amgen, Inc. confidentially submitted information for inclusion in the Board's affordability review of Enbrel.

EXHIBIT 2

5. This confidential submission was included in the Board's affordability review report for Enbrel and appears at pages J23-J49 in Appendix J of the Board's report.

6. This submission was redacted in the public version of the report, pursuant to Board Rule and Policy. *See* 3 C.C.R. 702-9:3.1.F.7; Prescription Drug Affordability Board Policy and Procedure, Policy 04 Affordability Review Policy and Procedure at 11. The submission was provided to the Board without redactions.

7. The statements in this declaration are all based upon my own personal knowledge or information.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 31st day of July, 2024.

s/Elizabeth Cummings
Elizabeth Cummings

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' COMBINED REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Defendants do not dispute that the Board has formally voted to impose a price cap on Amgen's patented drug Enbrel. Nor do they dispute that a core purpose of the federal patent laws is to incentivize innovation by enabling the patent owner to receive, during the life of the patent, the "pecuniary rewards stemming from the patent right." *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007). By capping Enbrel's price, the Board is directly inhibiting those rewards and upending Congress's deliberate balance between promoting affordability and providing incentives for innovation. Colorado's price-control scheme is also unconstitutional because it lacks the procedural safeguards required by due process, interferes with federal healthcare programs, and violates the Commerce Clause.

Seeking to delay consideration of these issues, Defendants assert Amgen lacks standing to challenge the imposition of a price cap on its drug because, under Defendants' interpretation of one of the Board's regulations, the cap will apply only to Amgen's wholesalers and distributors, not to Amgen itself. That interpretation is contrary to the statute, but even if it were correct, it would not affect Amgen's standing. As a matter of basic economics and common sense, a price cap on a product will harm the product's manufacturer, irrespective of where in the supply chain the cap is imposed. The less wholesalers can charge for Enbrel "downstream" (to pharmacies and providers), the less they will pay for it "upstream" (to Amgen). Defendants know this: They even quote a statement by a legislative sponsor

explaining that wholesalers impacted by the cap will "be made whole … by the pharmaceutical manufacturer." Def. Br. 10-11 (quoting *Hearing on S.B. 21-175 Before H. Comm. on Health & Ins.* (Colo. 2021) (statement of Rep. Kennedy)). Amgen thus faces at least a "substantial risk" of harm from the price cap. *Susan B. Anthony List v. Driehaus* ("*SBA*"), 573 U.S. 149, 158 (2014) (quotation marks omitted).

Defendants also argue that Amgen's challenge is unripe because the Board could, in theory, revisit its decision to cap Enbrel's price. But the mere possibility that an agency could change course cannot bar review. After months of deliberation, the Board voted to declare Enbrel unaffordable and select it for imposition of a price cap. Defendants offer no reason to think the Board will not follow through on its decision, and the precise amount of the cap is irrelevant to Amgen's purely legal constitutional claims. Defendants' demand for delay ignores that having to participate in an unconstitutional administrative process is itself an injury—and that all stakeholders, including the Board and the citizens of Colorado, will benefit from knowing as soon as possible whether the Act's price-control scheme is unconstitutional.

Defendants fare no better on the merits. ***First***, as to the conflict between Colorado's scheme and the federal patent laws, Defendants do not dispute that *BIO* is correctly decided and binding authority, and they have no answer to Amgen's argument that *BIO* prohibits the Act's price-control scheme. The crux of their response is once again their contention that the price cap applies only to downstream sales. Just as that atextual limitation cannot defeat Amgen's standing, it cannot be

used to circumvent federal preemption. What a state cannot do directly, it cannot do indirectly. And Defendants' reliance on patent exhaustion is misplaced because Amgen does not claim any right to use its patent to control downstream prices; it seeks only to prevent *the Board* from dictating those prices and thereby undermining the financial incentives provided by federal patent law.

Second, as to due process, Defendants fail to identify any standards in the Act or its implementing regulations that ensure a meaningful opportunity to be heard or safeguard against arbitrary, confiscatory, and discriminatory price-setting. They insist that the Board must be allowed to apply different standards to every drug it considers, and they do not even try to explain the Board's conclusion that Enbrel is unaffordable but another, *more expensive* drug is affordable. They instead focus on arguing that a manufacturer has no cognizable interest in whether a price cap is imposed on its product, a position that is contrary to precedent and common sense.

Third, Defendants concede Colorado's scheme cannot constitutionally apply to federal payors. The Board's recent, non-binding policy statement, however, does not meet the high bar for demonstrating mootness based on voluntary compliance.

Fourth, as to the Commerce Clause, Defendants' suggestion that the Supreme Court recently overruled the longstanding prohibition on direct regulation of out-of-state transactions has been rejected by every court to consider the issue. And their claim that the Act applies only to those who cause a drug to be distributed in Colorado is yet another invalid attempt to save the statute by rewriting it during litigation.

ARGUMENT

I. Amgen has standing and this case is ripe for review.

Despite Defendants' attempts to muddy the waters, Amgen's standing is straightforward, and this case is ripe for review.

1. In a pre-enforcement challenge to a statute, Article III requires only (1) a "threatened injury" that has a "substantial risk" of occurring; (2) a "causal connection" between the injury and the statute; and (3) a "likelihood" that the injury "will be redressed by a favorable decision." *SBA*, 573 U.S. at 158 (cleaned up). Amgen faces far more than a "substantial risk" of injury from the Board's decision to subject Enbrel to a price cap. *See* Amgen Br. 36–39.

Defendants do not dispute that economic harm is a classic Article III injury or that Amgen is already incurring "substantial costs to participate and defend its interests" in the price-setting process. *Id.* at 37. Nevertheless, they contend (at 17–19) that Amgen's injuries are conjectural because the price cap will apply only to sales by Amgen's wholesale and distributor partners, not to sales by Amgen itself. That contention lacks any statutory basis. Under the Act, an upper payment limit applies to "*any financial transaction* concerning the purchase of or reimbursement for the prescription drug," Colo. Rev. Stat. § 10-16-1401(23) (emphasis added). This plainly includes Amgen's sales of Enbrel to wholesalers.

Ignoring the statute, Defendants rely on their interpretation of a Board regulation. That regulation states that an upper payment limit applies to "a

consumer's purchase" and to "any pharmacy … or provider's purchase" of the drug. 3 Colo. Code Regs. § 702-9:4.2(C). Nothing in the regulation says that the upper payment limit applies *only* to those transactions or that it does *not* apply to a wholesaler's purchase from a manufacturer. To the extent the regulation is ambiguous in that regard, it must be construed to be consistent with the statute. *See Canyon Fuel Co. v. Sec'y of Labor*, 894 F.3d 1279, 1291 (10th Cir. 2018). And even if the regulation were unambiguous, it cannot trump the statute. Under settled principles, "[a]n agency regulation or rule may not modify or contravene an existing statute, and any regulation that is inconsistent with or contrary to a statute is void." *McCool v. Sears*, 186 P.3d 147, 151 (Colo. App. 2008).

But even if the upper payment limit applied only to downstream sales, that would not eliminate or even diminish the impact on Amgen. Courts evaluating standing need not ignore "[c]ommon sense and basic economics." *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 (D.C. Cir. 2017). No rational economic actor, including a wholesaler or distributor, will buy a product for a price higher than that for which it can lawfully sell the product; so capping prices downstream will naturally reduce prices upstream. *See, e.g.*, *Caldwell Wholesale Co. v. R J Reynolds Tobacco Co.*, 781 F. App'x 289, 291 (5th Cir. 2019) (per curiam) (noting that each party in the supply chain "must sell its [product] for a higher price [than it paid for it] to make a profit"); *Money Mailer, LLC v. Brewer*, 449 P.3d 258, 265 (Wash. 2019) (en banc) (noting that court "need not delve into the details of economics" to observe that "a wholesaler

charges a retailer a higher price than the wholesaler paid the supplier for the goods").

Affording standing on this basis is hardly unusual: As the Supreme Court has recognized, "government regulation of a third-party … business" is often "likely" to cause "upstream economic injuries to others in the chain, such as … manufacturers." *FDA v. All. for Hippocratic Med.* ("*AHM*"), 602 U.S. 367, 384–86 (2024). And even "[w]hen the plaintiff is an unregulated party," the plaintiff has standing if "third parties will likely react" to the challenged regulation "in predictable ways that in turn will likely injure the plaintiff[]." *Id.* at 383 (quotation marks omitted).

It is thus "well settled that a provider of goods or services has standing to challenge government regulations that directly affect its customers and restrict its market." *Wedges/Ledges of Cal., Inc. v. City of Phoenix*, 24 F.3d 56, 61 (9th Cir. 1994) (collecting cases). In *Wedges/Ledges*, for example, the city banned new licenses for an arcade game manufactured by the plaintiff. The city argued that the plaintiff "lacked standing … because [it was] the manufacturer" of the game "rather than an [arcade] owner/operator" and therefore "could not have been injured directly by the City's policies." *Id.* Rejecting that argument, the court found it obvious that the plaintiff would suffer "economic harms" such as "lost profits" and "lost business opportunities" as a result of the city's downstream regulation. *Id.* (quotation marks omitted).

Similarly, in *Energy Future Coalition v. EPA*, 793 F.3d 141 (D.C. Cir. 2015) (Kavanaugh, J.), the EPA argued that ethanol producers lacked standing to challenge a fuel regulation because the regulation was "directed at vehicle manufacturers, not

biofuel producers." *Id.* at 144. But that did "not undermine petitioners' standing" because a downstream regulation on a product impacts the manufacturer of that product; for instance, a "hot dog manufacturer ha[s] standing to sue" when a city "makes it harder for concession stands to sell hot dogs." *Id.* In such cases, both the manufacturer and the downstream entity are "object[s] of the [regulatory] action," so there is "little question that they have standing." *Id.* (quotation marks omitted).

Defendants insist (at 17) that Amgen must show it will be "directly injured." But "Article III standing does not follow the causation principles of tort law; an injury may be fairly traceable to an agency action that is not the very last step in the chain of causation." *Me. Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 592–93 (D.C. Cir. 2023) (quotation marks omitted). Even assuming the price cap applies only to downstream entities, Amgen's standing rests on "the predictable effect of [the Board's] action on the decisions of" those entities. *Dep't of Commerce v. New York*, 588 U.S. 752, 767–68 (2019); *see Growth Energy v. EPA*, 5 F.4th 1, 33 (D.C. Cir. 2021) (per curiam) ("'reasonably predictable' third-party conduct suffices" to establish standing); *Kane County v. United States*, 928 F.3d 877, 889 (10th Cir. 2019) (environmental group had standing to challenge widening of road because it would lead to greater usage of road by third parties).

No crystal ball is needed to see that 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. The effect on

Amgen is a matter of "common sense," *Carpenters*, 854 F.3d at 6, "firmly rooted in the basic laws of economics," *Growth Energy*, 5 F.4th at 33. If there were any doubt, the attached declaration confirms that "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." Ex. A, Decl. of Patrick Costello ¶ 12. Moreover, addressing this issue with wholesalers will entail administrative costs, which independently supports Amgen's standing. *Id.* ¶ 14; *see BIO*, 496 F.3d at 1371.

Perhaps recognizing that their position defies common sense, Defendants allude vaguely (at 19) to the "complexity of the pharmaceutical supply chain" as a source of uncertainty. But the fact that a supply chain involves multiple actors does not mean it is exempt from basic economics. And the impact on Amgen is hardly complex: As Defendants acknowledge (at 3), Amgen sells Enbrel to wholesalers, who then sell it to pharmacies and providers in transactions that Defendants agree are subject to the price cap. Defendants cite nothing suggesting that the wholesalers are so irrational or impervious to basic market forces that they will agree to *sell* Enbrel at a reduced price without *buying* Enbrel at a reduced price, whether in the form of an up-front discount or an after-the-fact refund.[1] On the contrary, Defendants

[1] While purporting to provide an overview of the pharmaceutical market, Defendants neglect to mention the role of "chargebacks"—routine payments from manufacturers to wholesalers to compensate them for discounts obtained by downstream purchasers. *See* Costello Decl. ¶¶ 6–7; Andrew Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships 23 (Oct. 2021), *available at* https://aspe.hhs.gov/reports/prescription-drug-supply-chains.

concede (at 30–31) that the price cap will cause Amgen to face "downward pricing pressures from downstream entities" that will reduce Amgen's "profits."

Defendants' account of the Act's legislative history confirms as much. As they acknowledge, a leading sponsor of the bill explained that the impact of a price cap would fall on manufacturers because wholesalers "will sell [the drug] to pharmacies or hospitals … at that lower price *and then they will be made whole on the back-end by the pharmaceutical manufacturer*." Def. Br. 10–11 (emphasis added) (quotation marks omitted). In other words, wholesalers will not be "stuck" with a reduced price, but will be empowered to demand "better prices in the first place" from the manufacturer. *Id.* (quotation marks omitted). Defendants' suggestion that a price cap will not affect manufacturers like Amgen thus contradicts Defendants' own account of how legislators expected the law to work. Because Amgen faces a substantial risk of harm from "a predictable chain of events leading from the [Board's] action to the asserted injury," *AHM*, 602 U.S. at 385, it has Article III standing.

2. Defendants alternatively invoke the prudential ripeness doctrine, which multiple Tenth Circuit judges have noted "may no longer be good law." *McAuliffe v. Vail Corp.*, 69 F.4th 1130, 1157 n.4 (10th Cir. 2023) (Eid, J., concurring in part). The Supreme Court, too, has questioned the doctrine's "continuing vitality" in light of federal courts' "virtually unflagging" "obligation to hear and decide cases within [their] jurisdiction." *SBA*, 573 U.S. at 167 (quotation marks omitted). Even if the doctrine were good law, it would not apply here.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*, *Plaintiffs*, v. GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*, *Defendants*.	**DECLARATION OF PATRICK COSTELLO**

DECLARATION OF PATRICK COSTELLO

I, Patrick Costello, declare as follows:

1. I am over the age of eighteen, and I am competent to provide this declaration.

2. I have worked for Amgen since 2007, holding roles of increasing responsibility in Amgen's finance, marketing, and value and access organizations. Since 2007, I have held the following roles: Accounting Manager

(2007 to 2008); Finance Manager (2008 to 2011); Finance Sr. Manager (2011 to 2016); Finance Director (2016 to 2019); Marketing Director (2019 to 2020); Contracts and Pricing Director (2021); Executive Director, United States Value and Access (2021 to June 2024). Since June 2024 I have been in my current role, Associate Vice President, United States Value and Access.

3. My professional experiences and leadership roles at Amgen have given me significant knowledge about how the pharmaceutical supply chain works, including standard industry practice for the pricing and distribution of prescription drugs. I am also well acquainted with Amgen's pricing and distribution practices for Enbrel, including with respect to wholesalers, pharmacies, and health care providers.

STANDARD INDUSTRY PRACTICE

4. As a general matter, pharmaceutical manufacturers sell drugs to wholesalers and other distributors ("direct customers"), which in turn sell the drugs to other downstream purchasers, such as pharmacies and hospitals ("indirect purchasers"). The price at which manufacturers sell their drugs to wholesalers is typically referred to as the "Wholesale Acquisition Cost" or "WAC." The WAC is a national list price that does not reflect any reductions, including the (often substantial) rebates demanded of manufacturers by pharmacy benefit managers (PBMs), or discounts applicable to pharmacies, hospitals, and other entities that purchase drugs from wholesalers.

5. Wholesalers typically sell drugs to indirect purchasers at WAC or at a price lower than WAC. Wholesalers' profit margins generally come from discounts they obtain from the manufacturer for prompt payment and/or from administrative or service fees they charge to the manufacturer for managing distribution of its drugs.

6. Wholesalers are at times required to provide discounts or other price reductions at the point of purchase (*e.g.*, when a drug is sold by the wholesaler to an indirect purchaser, it may include a discount indicated by the manufacturer). The wholesalers then seek reimbursement from the manufacturer for such discounts. This standard practice is known in the industry as a "chargeback."

7. As a general matter, Amgen is contractually obligated to reimburse wholesalers for certain discounts, deductions, rebates, and/or allowances the wholesalers provide to indirect customers (*e.g.,* discounts to 340B covered entities or other government purchasers, or Amgen's contracted discounts to commercial indirect customers, such as hospitals and pharmacies). Accordingly, Amgen utilizes chargebacks to credit wholesalers for the amount of such discounts for drugs the wholesalers sell to indirect customers. Without that reimbursement, wholesalers would lose money. Buying high and selling low is unprofitable in any industry, but it is especially so with respect to

pharmaceutical wholesalers, which operate on extremely thin margins and generally do not have the capacity to absorb uncompensated discounts.

THE COLORADO LEGISLATION

8. I am aware of the legislation Colorado enacted in 2021 creating a new Prescription Drug Affordability Board with the power to impose price controls, termed "upper payment limits," on sales of prescription drugs dispensed or distributed in Colorado. I am also aware that the Board has voted to select Amgen's drug Enbrel for imposition of an upper payment limit.

9. I understand that the statute defines an upper payment limit 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).

10. Amgen's sales of Enbrel are financial transactions concerning the purchase of or reimbursement for a prescription drug. I understand, however, that Colorado has claimed in this lawsuit that an upper payment limit would apply to sales made by Amgen's wholesalers and distributors but not to sales made by Amgen itself.

THE EFFECTS OF THE LEGISLATION ON AMGEN

11. Even assuming that the upper payment limit applies only to "downstream" transactions (such as wholesalers' transactions with indirect purchasers), it will have predictable and negative effects on Amgen.

12. First, based on my experience in the industry, and as a matter of basic economics and common sense, if an upper payment limit is imposed on wholesalers' sales of Enbrel, 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. Indeed, Amgen is contractually required to reimburse wholesalers for such legally required discounts.

13. Second, as described above, Amgen cannot reasonably expect wholesalers to purchase products at WAC, without any discount or reimbursement from Amgen, if Colorado dictates that wholesalers must sell the products for less than WAC. Like any other rational economic actor, wholesalers will not agree to purchase a product for more than what they can lawfully recover from reselling that product.

14. Third, if for some reason Amgen and its wholesalers are unable to come to an agreement regarding how to approach an upper payment limit for Enbrel, Amgen would still be negatively impacted. Amgen would lose revenue due to the loss of sales, as its wholesalers would choose to purchase an alternative product not subject to an upper payment limit. And whether or not

an agreement is ultimately reached, Amgen would incur administrative costs negotiating with its wholesalers over these issues.

15. I am therefore certain that Amgen will incur costs as a result of the imposition of an upper payment limit on "downstream" sales of Enbrel. There is no scenario in which an upper payment limit for Enbrel would not negatively affect Amgen.

16. In sum, irrespective of where in the supply chain the upper payment limit on Enbrel is applied, it will disrupt the market for Enbrel and reduce the amount of revenue Amgen can obtain from sales of Enbrel.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this fourth day of September, 2024.

By: Pat Costello
Patrick Costello

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC, et al.,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, et al.,

Defendants.

DEFENDANTS' REPLY IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Colorado's Affordability Program is a constitutional, measured exercise of the state's police powers to study the affordability of certain medications for Colorado consumers and to potentially set an upper payment limit (a "UPL") for those medications on transactions in Colorado. One can only speculate about the potential impact of a UPL, should the Prescription Drug Affordability Board ("Board") choose to set one for Enbrel, and that is insufficient to invoke the jurisdiction of this court. Furthermore, the Affordability Program, with its downstream application, is constitutional.

I. The complexities of the prescription drug supply chain highlight the speculative nature of Amgen's claims.

The pharmaceutical supply chain is not as "common sense" as Amgen would have this court believe. Despite Amgen's claim that "[n]o rational economic actor, including a wholesaler or distributor, will buy a product for a price higher than that for which it can lawfully sell the product" (ECF No. 35 at 5), that is, in practice *exactly* what routinely happens with prescription drugs. According to Amgen, after purchasing from manufacturers at the wholesale acquisition cost or "WAC", "[w]holesalers typically sell drugs to indirect purchasers at WAC or at a price lower than WAC." ECF No. 35-1 ¶¶ 4–5. "Wholesalers' profit margins generally come from discounts they obtain from the manufacturer for prompt payment and/or from administrative or service fees they charge to the manufacturer for managing distribution of its drugs." *Id.* ¶ 5.

It is so commonplace for wholesalers to sell a drug for less than it paid that manufacturers and wholesalers have developed established business practices of administrative fees, discounts, and chargebacks to sustain their mutual business

interests. *Id*. And "biosimilar manufacturers typically sell their products to wholesale distributors pursuant to pre-negotiated, long-term bulk contracts that cover a range of products for resale nationwide." *Ass'n for Accessible Meds v. Ellison*, 704 F. Supp. 3d 947, 952 (D. Minn. 2023). And wholesalers do not simply make money off individual purchases of drugs from manufacturers, but also receive fees from manufacturers for other services including financial management, inventory management, distribution services, and data processing. *See PhRMA,* Follow the Dollar 3 (2017).

Amgen asserts that it is obvious that a downstream UPL inevitably would be directly felt at the wholesaler and manufacturer levels. But this ignores the economic realities that these contractual relationships are built on economies of scale, diverse services provided by wholesalers, and fees, discounts, and rebates manufacturers already provide to wholesalers. It is not at all a foregone conclusion that a *potential* downstream payment limitation impacting some wholesalers, applying to *some purchases*[1] of *one drug* in *one state* would result in *any* impact to Amgen whatsoever.

Whether a UPL will ever be set and whether the Board would set it at an amount that results in any, let alone a material, loss to wholesalers is pure speculation. What a wholesaler will decide to contractually do with such an impact will be a negotiated business decision between it and the manufacturer.

II. UPLs are limited by statute to downstream transactions.

[1] At a minimum, a UPL would not apply to reimbursements from Medicare (covering approximately 10.5% of Coloradans) or under employer-sponsored insurance plans (covering 49.4% of Coloradans) regulated by ERISA (which is more than half of employer-sponsored insurance plans) that do not opt in to a UPL. *Colo. Health Institute*, 2023: Colo. Health Access Survey: Insurance Coverage, available at https://tinyurl.com/23ykz2kr.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

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GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' NOTICE OF RESCHEDULING OF UPL RULEMAKING HEARING

On December 18, 2024, Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited (collectively "Amgen") filed a notice to inform the Court that Colorado's Prescription Drug Affordability Review Board had formally commenced the rulemaking process to establish an upper payment limit for Enbrel and had scheduled the first rulemaking hearing for January 17, 2025. Plaintiffs submit this supplemental notice to inform the Court that that hearing has been rescheduled for March 7, 2025. *See* Exhibit A. Board staff stated that the hearing was postponed to allow the Board time to comply with certain requirements of the Colorado Administrative Procedure Act. *See* Colo. Rev. Stat. § 24-4-103(4)(a) & (4.5)(c) (regulatory analysis must be made available five days before hearing);

id. § 24-4-103(2.5)(a) (cost-benefit analysis must be made available ten days before hearing).

Dated: January 9, 2025

Respectfully submitted,

/s/ Paul Alessio Mezzina

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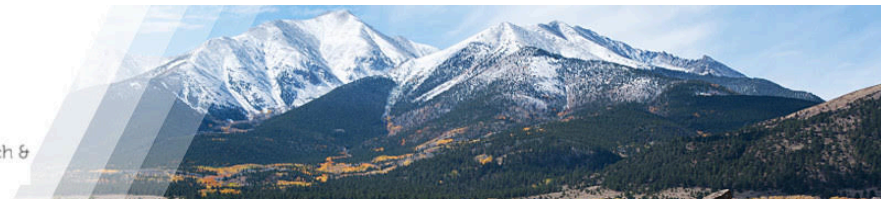
EXHIBIT A

Colorado.gov

COLORADO
Department of Regulatory Agencies
Colorado Office of Policy, Research & Regulatory Reform



Detailed Rulemaking Information

Department/Agency

Department: Department of Regulatory Agencies

Rulemaking Agency: Insurance

Proposed Rule Changes

Rule Type: New Rules

Title or Subject: UPPER PAYMENT LIMITS

Short Description: REVISED HEARING DATE: Upper payment limit

CCR Number: 3 CCR 702-9

Statutory Authority: sections 10-16-1403(1)(c), 10-16-1403(5), 10-16-1407(1)(a), and 10-16-1407(5), 10-16-1407(6), C.R.S.

Website for Current Agency Rules:

Subject Matter/Purpose: WEBINAR ONLY: The purpose of this rule is to establish an upper payment limit for the prescription drug, Enbrel, pursuant to section 10-16-1407, C.R.S., and part 4.1 of these rules. The Board performed an affordability review of Enbrel and determined it was unaffordable for Colorado consumers pursuant to section 10-16-1406, C.R.S., and part 3 of these rules.

Colorado Register Publish Date: 12/25/2024

Text of Proposed Changes: Draft Enbrel Proposed Rule - Part 4.doc (45K, Microsoft Word)

Submitted for Review: 12/13/2024

Rulemaking Hearing

Hearing Date: Friday, March 7, 2025 10:00 am

Hearing Covers: Single Rule

Hearing Location: Webinar or 1560 Broadway, STE 850
Denver, CO 80202

Hearing Notes: Due to concerns with the spread of COVID-19, this Permanent Rulemaking Hearing will be held via WEBINAR. Please register here to attend the hearing via webinar on March 7, 2025:

https://us06web.zoom.us/meeting/register/tZAkdOigqjkuG9wIhrT5AqppQ7J2DTJ-VJm8

The Board will receive oral testimony regarding this permanent rule on March 7, 2025, beginning at 10:00 AM. Please visit https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board for additional information related to hearing dates and deadlines for written submissions regarding this rule.

Contact Information

Public Contact

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Subject Information

Related Subject Area(s): Insurance

Review

Review Date: 12/31/2024

Review Outcome: Cost-Benefit Analysis Required

Review Findings:	Cost-benefit analysis required as requested.
Deadline for Public Cost-Benefit Analysis Request:	Monday, December 30th, 2024 The deadline for public cost-benefit analysis requests has passed.

Cost-Benefit Analysis

Cost-Benefit Analysis Pending

 **New Search**

1560 Broadway, Suite 1550, Denver, CO 80202 Email

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' NOTICE OF RESCHEDULING OF UPL RULEMAKING HEARING

Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited submit this notice to inform the Court that the first rulemaking hearing to establish an upper payment limit for Enbrel, previously scheduled for March 7, 2025, has been rescheduled for April 11, 2025. *See* Exhibit A.

Dated: February 28, 2025

Respectfully submitted,

/s/ Paul Alessio Mezzina

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Colorado.gov

COLORADO
Department of Regulatory Agencies
Colorado Office of Policy, Research & Regulatory Reform

Detailed Rulemaking Information

Department/Agency

Department: Department of Regulatory Agencies

Rulemaking Agency: Insurance

Proposed Rule Changes

Rule Type: New Rules

Title or Subject: UPPER PAYMENT LIMITS

Short Description: NEW HEARING DATE: Upper payment limit

CCR Number: 3 CCR 702-9

Statutory Authority: sections 10-16-1403(1)(c), 10-16-1403(5), 10-16-1407(1)(a), and 10-16-1407(5), 10-16-1407(6), C.R.S.

Website for Current Agency Rules:

Subject Matter/Purpose: WEBINAR ONLY: The purpose of this rule is to establish an upper payment limit for the prescription drug, Enbrel, pursuant to section 10-16-1407, C.R.S., and part 4.1 of these rules. The Board performed an affordability review of Enbrel and determined it was unaffordable for Colorado consumers pursuant to section 10-16-1406, C.R.S., and part 3 of these rules.

Colorado Register Publish Date: 12/25/2024

Text of Proposed Changes: Draft Enbrel Proposed Rule - Part 4.doc (45K, Microsoft Word)

Submitted for Review: 12/13/2024

Rulemaking Hearing

Hearing Date: Friday, April 11, 2025 10:00 am

Hearing Covers: Single Rule

Hearing Location: Webinar Only

Hearing Notes: This Permanent Rulemaking Hearing will be held via WEBINAR ONLY. Please register here to attend the hearing via webinar on April 11, 2025:

https://us06web.zoom.us/meeting/register/tZEkcumhrz8qGNQvJHFJh18quqSZKYadcE-S#/registration

The Board will receive oral testimony regarding this permanent rule on April 11, 2025, beginning at 10:00 AM. Please visit https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board for additional information related to hearing dates and deadlines for written submissions regarding this rule.

Contact Information

Public Contact

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Subject Information

Related Subject Area(s): Insurance

Review

Review Date: 12/31/2024

Review Outcome: Cost-Benefit Analysis Required

Review Findings: Cost-benefit analysis required as requested.

Deadline for Public Cost-Benefit Monday, December 30th, 2024

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' NOTICE OF APPEAL

Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited hereby appeal to the United States Court of Appeals for the Federal Circuit from the Memorandum Opinion and Order (Doc. 49) and Final Judgment (Doc. 50), both dated March 28, 2025, granting Defendants' motion for summary judgment and dismissing Plaintiffs' complaint without prejudice for lack of subject matter jurisdiction, and from all interlocutory or other orders and rulings subsidiary or relating thereto.

Dated: April 8, 2025

Respectfully submitted,

/s/ Paul Alessio Mezzina

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