

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

AMNEAL PHARMACEUTICALS
LLC.

Case No.: 24-cv-2609

Plaintiff,

v.

PHILIP J. WEISER, in his official
capacity as Attorney General of the
State of Colorado; PATRICIA A.
EVACKO, ERIC FRAZER, RYAN
LEYLAND, JAYANT PATEL,
AVANI SONI, KRISTEN WOLF, and
ALEXANDRA ZUCCARELLI, in
their official capacities as members of
the Colorado State Board of Pharmacy,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Amneal Pharmaceuticals LLC (“Amneal”) brings this complaint for declaratory and injunctive relief against Philip J. Weiser, in his official capacity as Attorney General of the State of Colorado (the “Attorney General”) and Patricia A. Evacko, Eric Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli, in their official capacities as members of the Colorado State Board of Pharmacy (together, the “Board Members”). Amneal brings this complaint

based on personal knowledge as to all Amneal-related facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. Amneal manufactures generic epinephrine auto-injectors that are just as safe and effective as the branded equivalent, but substantially less expensive, thereby helping bring affordable epinephrine auto-injectors to patients across the nation, including in Colorado.

2. This action seeks to halt the ongoing, unconstitutional taking of Amneal’s auto-injectors by the State of Colorado, pursuant to the “affordability program” established by Colo. Rev. Stat. § 12-280-142, which went into effect on January 1, 2024. Under the affordability program, any time an eligible uninsured Coloradan acquires an auto-injector from a Colorado pharmacy, Amneal must send the pharmacy a *free* replacement. Amneal’s only alternative is to reimburse the pharmacy the full price it paid for the auto-injector—an amount that will almost always be *more* than what Amneal could make selling the product to a wholesaler.

3. Amneal received its first replacement request from a Colorado pharmacy on April 16, 2024. As of September 12, 2024, Amneal has sent 304 auto-injectors to Colorado pharmacies that requested free replacements for auto-injectors that the pharmacies dispensed to participants in the affordability program.

4. Colorado’s reimburse-or-resupply requirement plainly effects an unconstitutional, “*per se* physical taking” of Amneal’s personal property in violation of the Fifth Amendment. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071–72 (2021). Pursuant to the requirement, Amneal has been, and will continue to be, forced to provide Colorado pharmacies with free epinephrine auto-injectors, or else risk tens of thousands of dollars in fines and an action for treble damages under the Colorado Consumer Protection Act.

5. For these reasons, and as explained further below, Amneal seeks a permanent injunction barring Defendants from enforcing the requirement that Amneal reimburse or resupply Colorado pharmacies who dispense Amneal’s epinephrine auto-injectors to individuals participating in the affordability program, as well as a declaratory judgment that the reimburse-or-resupply requirement violates the Takings Clause of the Fifth Amendment of the Constitution of the United States.

PARTIES

6. Amneal is a limited liability corporation organized under Delaware law, with its headquarters in Bridgewater, New Jersey. Amneal improves the lives of patients by, among other things, providing them access to affordable, FDA-approved generic medications. Amneal provides American consumers with generic drugs that

are just as safe and effective as their brand-name counterparts, but substantially less expensive.

7. In May 2018, Amneal combined with Impax Laboratories LLC. Impax Laboratories is the registered NDA holder for a generic epinephrine auto-injector sold under the trade name “Adrenaclick.” Adrenaclick is sold in both 0.3-milligram and 0.15-milligram sizes.

8. Defendants, named only in their official capacities, are Philip J. Weiser, the Attorney General of the State of Colorado, and the members of the Colorado Board of Pharmacy: Patricia A. Evacko, Eric Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli. At all relevant times, Defendants, as well as those subject to their supervision, direction, and/or control, have been and will be acting under color of state law.

9. Defendants, as well as those subject to their supervision, direction, and/or control, are responsible for enforcement of the affordability program established by Colo. Rev. Stat. § 12-280-142.

JURISDICTION AND VENUE

10. Amneal’s causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

11. Venue is proper here, as the Act was enacted in this district and will be enforced by Defendants in the performance of their official duties in this district. 28 U.S.C. § 1391(b).

12. The Court has authority under the doctrine of *Ex Parte Young*, 209 U.S. 123 (1908) to enjoin enforcement of the Act, and to grant declaratory relief pursuant to 21 U.S.C. §§ 2201 and 2202.

13. There is an actual controversy of sufficient immediacy and concreteness relating to Amneal’s rights and legal duties. The affordability program has already compelled Amneal to surrender its property without compensation, in violation of the Takings Clause. Colorado pharmacies will continue to demand replacement auto-injectors from Amneal as long as the affordability program is in place.

14. If Amneal does not comply with the reimburse-or-resupply requirement, it faces the imminent threat of civil action and fines under an unconstitutional law. The affordability program imposes a fine of up to twenty thousand dollars for each violation. *See* Colo. Rev. Stat. § 12-280-142(11)(a)(I); *id.* § 6-1-112(1)(a). A manufacturer that fails to resupply or reimburse a pharmacy also “engages in a deceptive trade practice” under the Colorado Consumer Protection Act (CCPA), *id.* § 12-280-142(11)(a)(II), which can be enforced by private plaintiffs, as well as the state Attorney General, and can result in treble damages. *Id.* §§ 6-1-103,

6-1-113(1). The harm to Amneal as a direct result of the actions and threatened actions of Defendant is sufficiently real and imminent to warrant the issuance of a declaratory judgment and prospective injunctive relief.

FACTUAL BACKGROUND

Amneal’s Work to Bring Low-Cost Epinephrine Auto-injectors to Consumers

15. Epinephrine auto-injectors are single-use, spring-loaded syringes that can deliver a dose of the hormone epinephrine (also known as adrenaline) to individuals experiencing anaphylaxis—a potentially fatal allergic reaction that can involve swelling of the throat and tongue, vomiting, and medical shock. FDA first approved the epinephrine auto-injector in 1987. Since Amneal combined with Impax Laboratories in 2018, Amneal’s generic auto-injectors have been available nationwide, including in Colorado, at prices significantly below the prices of branded epinephrine auto-injectors.

Colorado’s Epinephrine Auto-Injector Affordability Program

16. On June 7, 2023, Governor Jared Polis signed HB 23-1002, a bill “concerning the affordability of epinephrine auto-injectors.” The bill began by declaring that “[e]pinephrine auto-injectors are essential because they are the easiest and most efficient way to potentially save the life of an individual exhibiting symptoms of or experiencing anaphylactic shock” and that “[m]any individuals are unable to afford an epinephrine auto-injector because they cannot pay the copayment

amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector.” §§ 1(e)-(f). The bill addressed this affordability problem through two distinct measures. First, the bill provided that “[f]or health coverage plans issued or renewed on or after January 1, 2024, if a carrier provides coverage for prescription epinephrine auto-injectors, the carrier shall cap the total amount that a covered person is required to pay for all covered prescription epinephrine auto-injectors at an amount not to exceed sixty dollars for a two-pack of epinephrine auto-injectors.” Colo. Rev. Stat. § 10-16-160(2). Amneal does not challenge the constitutional validity of the sixty-dollar cap on copayments.

17. The bill also directed the establishment of an “affordability program” by January 1, 2024. All Colorado citizens who (a) have a valid prescription for epinephrine auto-injectors, (b) are ineligible for Medicaid or Medicare, and (c) do not have private health insurance that covers the auto-injectors are eligible for the program. *Id.* § 12-280-142(3). Eligible individuals can fill out an application form, submit the application and proof of Colorado residence at any pharmacy, and obtain a two-pack of epinephrine auto-injectors for no more than sixty dollars. *Id.* § 12-280-142(4)–(7). The initial application remains valid for one year, and there are no limits on the number of epinephrine auto-injectors an individual can obtain under the program.

18. Under the affordability program, the Colorado pharmacy can keep the sixty-dollar payment for the auto-injectors and request *full reimbursement* or *free replacements* from the manufacturer. The bill requires all manufacturers of epinephrine auto-injectors sold in Colorado to “develop a process for a pharmacy to submit an electronic claim for reimbursement” by January 1, 2024. *Id.* § 12-280-142(8)(b). Within thirty days of receiving a reimbursement claim, a manufacturer must either (a) “[r]eimburse the pharmacy in an amount that the pharmacy paid for the number of epinephrine auto-injectors dispensed through the program” or (b) “[s]end the pharmacy a replacement supply of epinephrine auto-injectors in an amount equal to the number of epinephrine auto-injectors dispensed through the program.” *Id.* § 12-280-141(8)(c).

19. The affordability program imposes significant penalties for noncompliance. Any manufacturer who fails to comply with the bill is subject to a fine of up to twenty thousand dollars for each violation, *see* Colo. Rev. Stat. § 12-280-142(11)(a)(I); *id.* § 6-1-112(1)(a),¹ and also commits a “deceptive trade

¹ The Attorney General represented in a public court filing that the Board of Pharmacy has the authority to impose the fine for noncompliance and to generally enforce the requirements of the affordability program. *See* Rule 41 Stipulation of Dismissal, *Teva Pharmaceuticals USA, Inc. v. Weiser*, No. 23-cv-2584, ECF 31 (D. Colo. Nov. 17, 2023). HB 23-1002 provided for a maximum fine of ten thousand dollars, but the Colorado legislature increased the maximum fine to twenty thousand dollars in House Bill 24-1438, which Governor Polis signed into law on June 3, 2024.

practice” under the CCPA, *id.* § 12-280-142(11)(a)(II), which can result in treble damages and can be enforced by both private plaintiffs and the Attorney General. *Id.* §§ 6-1-103, 6-1-113(1).

20. Colorado has other, constitutional means of increasing low-income Coloradans’ access to epinephrine auto-injectors. The other section of HB 23-1002 imposes a sixty-dollar cap on insurance copayments for auto-injectors, which is indisputably within the State’s regulatory authority. What Colorado cannot do is force manufacturers like Amneal to bear the entire cost of the program by requiring them to surrender their property without any compensation.

Amneal’s Sale of Generic Auto-Injectors

21. Amneal’s auto-injectors are made available to consumers in Colorado through an interstate distribution system involving multiple participants. Amneal generally sells its auto-injectors to national wholesalers and retail pharmacy distributors, who then re-sell those auto-injectors to pharmacies in Colorado. From July 1, 2023 to September 12, 2024, more than 19,000 epinephrine auto-injectors manufactured by Amneal have been sold in Colorado.

22. Amneal sells its auto-injectors to wholesalers and distributors at a price based on the drug’s Wholesale Acquisition Cost (“WAC”), less certain discounts and price concessions. In 2024, the WAC for Amneal’s auto-injectors has been

\$300 per two-pack. The WAC for Amneal’s auto-injectors is approximately half that for branded versions.

23. A pharmacy’s acquisition cost for Amneal’s auto-injectors from wholesalers is not the same as the price Amneal receives from its sale of those same products. Because wholesalers typically sell the auto-injectors at a mark-up above the price they pay manufacturers for the products, the price the pharmacy pays its wholesaler-supplier is generally *higher* than the price Amneal receives from the wholesaler for those same auto-injectors.

Implementation of Affordability Program

24. Local media reported that the rollout of the affordability program in early 2024 was “rocky,” with many pharmacies declining to sell auto-injectors at the reduced price because they were unaware of the law’s requirements or did not yet have procedures in place for compliance.²

25. Nonetheless, Amneal began to receive requests from Colorado pharmacies for reimbursement or replacement auto-injectors, beginning on April 16,

² Meg Wingerter, “Rocky rollout for Colorado’s new EpiPen price cap as some pharmacies aren’t honoring \$60 limit,” DENVER POST (Feb. 20, 2024), <https://www.denverpost.com/2024/02/20/colorado-epipen-price-cap-pharmacies/>; *see also* Tony Kovaleski & Kelly Dietz, “Hidden camera tests reveal pitfalls in Colorado law making EpiPens more affordable,” DENVER7 (Mar. 17, 2024), <https://denver7.com/news/investigations/hidden-camera-tests-reveal-pitfalls-in-colorado-law-making-epipens-more-affordable>

2024. As of September 12, 2024, Amneal has received reimburse-or-resupply requests from 52 different Colorado pharmacies, for a total of 304 auto-injectors.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION (Declaratory/Injunctive Relief—Violation of the Takings Clause of the Fifth Amendment)

26. Amneal re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

27. The Takings Clause of the Fifth Amendment provides that “private property [shall not] be taken for public use without just compensation.” By requiring Amneal to either replace the epinephrine auto-injectors that pharmacies dispense or reimburse the pharmacies for their cost, the affordability program effects an uncompensated taking of Amneal’s property.

28. “When the government physically acquires private property for a public use, the Takings Clause imposes a clear and categorical obligation to provide the owner with just compensation.” *Cedar Point Nursery*, 141 S. Ct. at 2071. That obligation to compensate applies with the same force to acquisitions of personal property, including items a business produces for sale, as to acquisitions of real property. *See Horne v. Dept. of Agriculture*, 576 U.S. 350, 358 (2015) (rejecting the contention that “personal property [i]s any less protected against physical appropriation than real property”). The affordability program’s requirement that

Amneal provide free replacement auto-injectors to Colorado pharmacies is clearly a “*per se* physical taking” of Amneal’s personal property that triggers a “simple, *per se* rule: The government must pay for what it takes.” *Cedar Point Nursery*, 141 S. Ct. at 2071–72. Indeed, a court in this District has already held that the reimburse-or-resupply requirement violates the Takings Clause. *See Teva Pharms. USA, Inc. v. Weiser*, 2023 WL 9425675, at *7 (D. Colo. Dec. 27, 2023) (“The affordability program would enact a taking of Teva’s autoinjectors, and the Fifth Amendment renders that taking unconstitutional unless just compensation is provided.”).

SECOND CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

29. Amneal re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

30. By seeking to implement and enforce the Act, Defendants, acting under color of state law, has violated and, unless enjoined by this Court, will continue to violate Amneal’s constitutional rights.

31. An actual “Case or Controversy” exists because the Act’s unconstitutional provisions, and the takings of Amneal’s property that have already occurred under the aegis of the affordability program, create a genuine, credible, and immediate threat that Defendants—acting in their official capacity under color of state law—will violate Amneal’s constitutional rights.

32. Amneal accordingly seeks a declaration that Defendants' implementation or enforcement of the Act would violate 42 U.S.C. § 1983. Amneal also seeks reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, Amneal prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the reimburse-or-resupply requirement of Colo. Rev. Stat. § 12-280-142 violates the Takings Clause of the Fifth Amendment of the Constitution of the United States and is therefore void and unenforceable;

B. For permanent injunctive relief barring Defendants from enforcing Colo. Rev. Stat. § 12-280-142, specifically the requirement that Amneal reimburse or resupply Colorado pharmacies who dispense Amneal's epinephrine auto-injectors to individuals participating in the affordability program;

C. For such costs and reasonable attorney's fees to which it might be entitled by law; and

D. For any other relief that the Court deems just and proper.

Dated: September 20, 2024

KIRKLAND & ELLIS LLP

/s/ Jay P. Lefkowitz

Jay P. Lefkowitz, P.C.
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
lefkowitz@kirkland.com

Alexandra I. Russell
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, NW
Washington, D.C. 20004
alexandra.russell@kirkland.com

Cole Carter
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
cole.carter@kirkland.com

Attorneys for Amneal Pharmaceuticals LLC