

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

TEVA PHARMACEUTICALS USA,
INC.,

Case No.: 23-cv-2584-DDD-SKC

Plaintiff,

v.

MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance, and 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 capacity as members of the Colorado State Board of Pharmacy,

Defendants.

**FIRST AMENDED COMPLAINT FOR DECLARATORY AND
INJUNCTIVE RELIEF**

Plaintiff Teva Pharmaceuticals USA, Inc. (“Teva”) brings this complaint for declaratory and injunctive relief against Michael Conway, in his official capacity as Commissioner of the Colorado Division of Insurance (the “Commissioner”), and Philip J. Weiser, in his official capacity as Attorney General of the State of Colorado (the “Attorney General”) and the members of the Colorado State Board of Pharmacy

(the “Board of Pharmacy” and, together with the Attorney General and the Commissioner, “Defendants”). Teva brings this complaint based on personal knowledge as to all Teva facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. Teva has played a central role in bringing affordable epinephrine auto-injectors to patients across the nation, including in Colorado. Since obtaining FDA approval in 2018, Teva has manufactured generic epinephrine auto-injectors that are just as safe and effective as the branded equivalent, but substantially less expensive.

2. This action seeks to halt an unconstitutional taking of Teva’s auto-injectors by the State of Colorado, pursuant to a recently enacted law, House Bill 23-1002 (“HB 23-1002” or “the Act”). Under the “affordability program” established by HB 23-1002, any time an eligible uninsured Coloradan acquires an auto-injector from a Colorado pharmacy, Teva must send the pharmacy a *free* replacement. Teva’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 Teva could make selling the product to a wholesaler.

3. HB 23-1002’s reimburse-or-resupply requirement plainly effects an unconstitutional “*per se* physical taking” of Teva’s personal property in violation of the Fifth Amendment. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071–72

(2021). If the affordability program is permitted to go into effect, Teva will 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.

4. For these reasons, and as explained further below, Teva seeks a permanent injunction barring Defendants from enforcing HB 23-1002's requirement that Teva reimburse or resupply Colorado pharmacies that dispense Teva'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

5. Teva is a company organized under Delaware law, with its headquarters in Parsippany, New Jersey. Teva improves the lives of patients by, among other things, providing them access to affordable, FDA-approved generic medications. Teva provides American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. In 2018, the FDA granted Teva approval to sell the first generic epinephrine auto-injector in the United States. Teva currently manufactures generic epinephrine auto-injectors in two sizes: 0.3-milligrams and 0.15-milligrams for children.

6. Defendants, named only in their official capacities, are Michael Conway, the Commissioner of the Colorado Division of Insurance, Philip J. Weiser, the Attorney General of the State of Colorado, and the members of the Board of Pharmacy, identified below.

7. Defendant Avani Soni is President of the Board of Pharmacy.

8. Defendant Eric Frazer is Vice-President of the Board of Pharmacy.

9. Defendant Patricia A. Evacko is a member of the Board of Pharmacy.

10. Defendant Ryan Leyland is a member of the Board of Pharmacy.

11. Defendant Jayant Patel is a member of the Board of Pharmacy.

12. Defendant Kristen Wolf is a member of the Board of Pharmacy.

13. Defendant Alexandra Zuccarelli is a member of the Board of Pharmacy.

14. At all relevant times, Defendants, as well as those subject to their supervision, direction, and/or control, will be acting under color of state law.

15. Defendants, as well as those subject to their supervision, direction, and/or control, are responsible for enforcement of HB 23-1002.

JURISDICTION AND VENUE

16. Teva'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.

17. 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).

18. 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.

19. There is an actual controversy of sufficient immediacy and concreteness relating to Teva's rights and legal duties. Beginning January 1, 2024, Colorado pharmacies can demand that Teva reimburse the pharmacy for *the pharmacy's* cost of epinephrine auto-injectors, or demand that Teva supply replacement epinephrine auto-injectors for free.

20. If Teva does not comply with the reimburse-or-resupply requirement, it faces the imminent threat of civil action and fines under an unconstitutional law. HB 23-1002 imposes "a fine of ten thousand dollars for each month of noncompliance" and states that a manufacturer that fails to comply "engages in a deceptive trade practice" under the Colorado Consumer Protection Act, which can be enforced by private plaintiffs as well as the state Attorney General, Colo. Rev. Stat. §§ 6-1-103 (2019), 6-1-113 (1) (2022), and can result in treble damages. § 6-1-113 (2)(a)(III). The harm to Teva as a direct result of the actions and threatened

actions of Defendants is sufficiently real and imminent to warrant the issuance of declaratory judgment and prospective injunctive relief.

21. This Court’s immediate review of the Act’s constitutionality is necessary to prevent an imminent infringement of Teva’s fundamental constitutional rights under the Fifth Amendment.

FACTUAL BACKGROUND

Teva’s Work to Bring Low-Cost Epinephrine Auto-Injectors to Consumers

22. 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. More than thirty years later, in 2018, FDA granted Teva’s application to sell the first generic epinephrine auto-injector in the United States. Ever since, Teva’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

23. 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[.]” § 2, 10-16-160 (2). Teva does not challenge the constitutional validity of this sixty-dollar cap on copayments.

24. The bill also directed the Colorado Division of Insurance to establish 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. § 3, 12-280-142 (3). Eligible individuals can fill out an application form created by the Division of Insurance, 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.

25. Under the bill, 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.* 12-280-141 (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).

26. HB 23-1002 imposes significant penalties for noncompliance. Any manufacturer who fails to comply with the bill is subject to “a fine of ten thousand dollars for each month of noncompliance” and “engages in a deceptive trade practice” under the Colorado Consumer Protection Act, which can be enforced by private plaintiffs as well as the state Attorney General, Colo. Rev. Stat. §§ 6-1-103, 6-1-113 (1), and can result in treble damages. *Id.* 6-1-113 (2)(a)(III).

27. 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. Colorado could impose a similar sixty-dollar price control on all retail sales of epinephrine auto-injectors, which would allow uninsured Coloradans to purchase auto-injectors at the same price they would pay under HB 23-1002's affordability program. What Colorado cannot do is force manufacturers like Teva to bear the entire cost of the program by requiring them to surrender their property without any compensation.

Teva's Sale of Generic Auto-Injectors

28. Teva's auto-injectors are made available to consumers in Colorado through an interstate distribution system involving multiple participants. Teva does not sell its auto-injectors to any purchasers in Colorado. *See* Decl. of Kevin Galownia ("Galownia Decl.") ¶ 4. Instead, Teva sells its auto-injectors to national wholesalers and retail pharmacy distributors, who then re-sell those auto-injectors downstream to pharmacies in Colorado. *Id.* Between June 30, 2022 and June 30, 2023, at least 14,000 epinephrine auto-injectors manufactured by Teva were sold in Colorado. *Id.* ¶ 7.

29. Teva 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. *Id.* ¶ 5. In 2023, Teva sold its 0.3-milligram and 0.15-milligram epinephrine auto-injectors at a WAC of \$300 per two-pack. *Id.* ¶ 3. The WAC for Teva’s auto-injectors is approximately half that for branded versions. *Id.* ¶ 6.

30. The pharmacy’s acquisition cost for Teva’s auto-injectors from wholesalers is not the same as the price Teva 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 necessarily *higher* than the price Teva receives from the wholesaler for those same auto-injectors.

31. If HB 23-1002 is not enjoined before January 1, 2024, Teva will be forced to supply tens of thousands of generic epinephrine auto-injectors *for free* to Colorado citizens. If Teva fails to do so, it will be subject to civil action for violation of the Colorado Consumer Protection Act and substantial penalties of ten thousand dollars per month for each month of noncompliance.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Declaratory/Injunctive Relief—Violation of the Takings Clause of the Fifth Amendment)

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

33. The Takings Clause of the Fifth Amendment provides that “private property [shall not] be taken for public use, without just compensation.” U.S. Const. amend. V. By requiring Teva 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 Teva’s property.

34. “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 Agric.*, 576 U.S. 350, 359 (2015) (rejecting the contention that “personal property [i]s any less protected against physical appropriation than real property”). The affordability program’s requirement that Teva provide free replacement auto-injectors to Colorado pharmacies is clearly a “*per se* physical taking” of Teva’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.

35. It makes no difference that the affordability program requires Teva to deliver free auto-injectors to Colorado pharmacies, rather than the government itself. What matters is that the taking is “government-*authorized*,” not who physically acquires the property. *Id.* at 2073 (emphasis added). Accordingly, the Supreme Court has repeatedly held that a physical appropriation “authorized by state law is a taking without regard to whether the State, or instead a party authorized by the State” receives the property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 432 n.9 (1982); *see id.* at 438 (holding that statute authorizing a cable television company to install cables and boxes on private property effected a taking); *Cedar Point Nursery*, 141 S. Ct. at 2072 (holding that law granting “union organizers a right to physically enter and occupy the growers’ land” effected a *per se* taking).

36. Nor does it matter that the affordability program gives Teva the option of reimbursing pharmacies for the epinephrine auto-injectors, rather than replacing them. The Supreme Court has made clear that a government may not “simply give the owner a choice of either surrendering [the property] or making a payment equal to [the property’s] value.” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013). Moreover, because the price pharmacies pay wholesalers for auto-injectors will almost always be higher than the price that Teva can charge those same

wholesalers, the choice between replacement and reimbursement is really no choice at all. Sending free auto-injectors will be cheaper for Teva than paying pharmacies *more* than Teva could earn if it kept the auto-injectors and sold them.

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

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

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

39. An actual “Case or Controversy” exists because the Act’s unconstitutional provisions create a genuine, credible, and immediate threat that Defendants—acting in their official capacity under color of state law—will violate Teva’s constitutional rights.

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

PRAYER FOR RELIEF

WHEREFORE, Teva prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that section 3 of House Bill 23-1002 (the reimburse-or-resupply

requirement) violates the Takings Clause of the Fifth Amendment of the Constitution of the United States and is therefore void and unenforceable;

B. For preliminary and permanent injunctive relief barring Defendants from enforcing section 3 of House Bill 23-1002, specifically the requirement that Teva reimburse or resupply Colorado pharmacies that dispense Teva'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: October 31, 2023

KIRKLAND & ELLIS LLP

/s/ Alexandra I. Russell

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