IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; 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.

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

PLAINTIFF'S REPLY IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION

CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Defendants' opposition brief does not dispute that the epinephrine auto-injector affordability program will take property in violation of the Takings Clause by requiring manufacturers like Teva to either resupply pharmacies with free replacement auto-injectors or reimburse pharmacies in full for the auto-injectors' acquisition cost. In other words, it is undisputed for purposes of this motion that the program at issue—which is set to take effect on January 1, 2024—is unconstitutional.

Defendants nonetheless seek to fend off an injunction on various procedural grounds, but none of their objections have merit. ***First***, the Eleventh Amendment is no barrier to a suit seeking prospective injunctive relief. ***Second***, there should be no question that Teva has sued the proper parties, as the Pharmacy Board defendants have now been added to the complaint, and the Attorney General has a duty and demonstrated willingness to enforce the Colorado Consumer Protection Act (CCPA). ***Third***, Teva has standing to mount a pre-enforcement challenge because there is a near certainty that at least one of the thousands of auto-injectors Teva ships to Colorado each year will be purchased by a participant in the affordability program. ***Fourth***, injunctive relief is appropriate because "the legal remedy of damages is not 'complete, practical, and efficient'" when a statute authorizes an indefinite series of takings, as the Eighth Circuit recently held in a case concerning a materially identical

law. *PhRMA v. Williams*, 64 F.4th 932, 945 (8th Cir. 2023) (quoting *Terrace v. Thompson*, 263 U.S. 197, 214 (1923)).

I. THIS COURT HAS SUBJECT-MATTER JURISDICTION OVER TEVA'S SUIT FOR INJUNCTIVE RELIEF.

A. The Eleventh Amendment Does Not Bar Teva's Request for Injunctive Relief.

Defendants acknowledge that Teva "seeks only equitable relief," ECF No. 20 ("Opp.") at 4, but they nonetheless argue that "*if* Teva reframes its claim as one for just compensation … Eleventh Amendment sovereign immunity bars such a claim because it would 'impose a liability which must be paid from public funds[.]'" *Id.* at 5 (quoting *Edelman v. Jordan*, 415 U.S. 651, 663 (1974)) (emphasis added). Defendants' argument is irrelevant because Teva has not, and will not, "reframe[ ] its claim as one for just compensation." Opp. 5. As Teva has explained, it seeks injunctive relief because after-the-fact suits for just compensation cannot adequately remedy the series of continuous takings authorized by the affordability program. *See infra*, Section II.

Defendants also assert that the Eleventh Amendment "bars Teva's Fifth Amendment Takings Clause claim for just compensation … regardless of the fact that it is couched as one for only equitable relief." Opp. 6–7. But Teva is not bringing a claim for just compensation "couched as" a request for an injunction, as in the cases cited by Defendants. *See Williams v. Utah Dep't of Corr.*, 928 F.3d

1209, 1214–15 (10th Cir. 2019) (denying putative request for "injunctive relief" to pay interest on inmate funds); *Los Molinos Mut. Water Co. v. Ekdahl*, 2023 WL 6386898, at *8 n.7 (E.D. Cal. Sept. 29, 2023) (denying putative request for injunctive relief "to compel compliance with … compensation requirements when defendants carry out the taking in the future" (emphasis omitted)). Here, Teva only seeks an injunction against the enforcement of the reimburse-or-resupply requirement, which will not require the payment to Teva of any money from the state treasury.

Teva's request for injunctive relief falls squarely within the *Ex parte Young* exception to Eleventh Amendment immunity for "suit[s] against individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law"—or, as here, an imminent violation—"and the plaintiff seeks prospective relief." *Williams*, 928 F.3d at 1214 (quoting *Muscogee (Creek) Nation v. Pruitt*, 669 F.3d 1159, 1166 (10th Cir. 2012)); *see PhRMA*, 64 F.4th at 948–49 (holding that the *Ex parte Young* exception applied to a materially identical suit). Defendants' invocation of Eleventh Amendment immunity, which relies on a supposed request for just compensation that Teva has not made, is meritless.

B. The Proper Officials Are Defendants.

Under *Ex parte Young*, a plaintiff may seek to enjoin the enforcement of an unconstitutional statute by filing suit against the state officials with "a particular duty to 'enforce' the statute in question and a demonstrated willingness to exercise that

duty." *Hendrickson v. AFSCME Council 18*, 992 F.3d 950, 965 (10th Cir. 2021) (quoting *Prairie Band Potawatomi Nation v. Wagnon*, 476 F.3d 818, 828 (10th Cir. 2007)). Defendants argue that Michael Conway, the Colorado Commissioner of Insurance, has no duty to enforce the affordability program's reimburse-or-resupply requirement, even though the statute tasks the Colorado Division of Insurance with administering the program and appropriates funds to the Division for that purpose. *See* HB 23-1002 at § 3, 12-280-142 (4); § 3, 12-280-142 (9); § 5. Instead, Defendants say, the members of the Colorado Pharmacy Board are responsible for enforcing the reimburse-or-resupply requirement, including by imposing the ten-thousand dollar fine for each month of noncompliance. *See* Opp. 8–9.

Teva agrees that, if the Pharmacy Board has the enforcement authority for the affordability program, and the Division of Insurance lacks any, then the Board members are proper defendants, and the Commissioner of Insurance is not. Accordingly, Teva has added the Board members to its complaint and served them with its motion for a preliminary injunction. The parties are negotiating a stipulation regarding the respective enforcement authorities of the Pharmacy Board and Division of Insurance that, once entered, will permit Teva to dismiss the Commissioner of Insurance from this case.

Attorney General Weiser, however, is a proper defendant under *Ex parte Young*. HB 23-1002 designates the failure to comply with the reimburse-or-resupply

requirement a "deceptive trade practice" under the CCPA. § 4, 6-1-105. By statute, the Attorney General is "responsible for the enforcement" of that Act. Colo. Rev. Stat. §§ 6-1-103, 6-1-113 (1). The Attorney General does not shirk that responsibility. *See, e.g.*, *State ex rel. Weiser v. Ctr. for Excellence in Higher Educ.*, 529 P.3d 599 (Colo. 2023) (civil enforcement action initiated by Attorney General Weiser under the CCPA); *State ex rel. Weiser v. JUUL Labs, Inc.*, 517 P.3d 682 (Colo. 2022) (same); *State ex rel. Weiser v. Castle Law Grp.*, 457 P.3d 699 (Colo. App. 2019) (same). The Attorney General thus has "a particular duty to 'enforce' the statute in question and a demonstrated willingness to exercise that duty." *Hendrickson*, 992 F.3d at 965 (quoting *Prairie*, 476 F.3d at 828). Indeed, just weeks ago, this Court enjoined the Attorney General from enforcing a statute that, like HB 23-1002, codified a new "deceptive trade practice" under the CCPA. *See Bella Health & Wellness v. Weiser*, 2023 WL 6996860, at *4 (D. Colo. Oct. 21, 2023).[1]

The Attorney General protests that "[a] general duty to enforce a separate law that is not even challenged in this Court is insufficient" under *Ex parte Young*, Opp. 9, but his objection is unfounded. The CCPA and the reimburse-or-resupply

[1] In *Bella Health*, the Attorney General did not even argue that the plaintiff's request for an injunction against enforcement of the new "deceptive trade practice" provision did not satisfy *Ex parte Young*. The Attorney General raised an Eleventh Amendment only against a distinct amendment to Colorado's medical-licensing laws. *See* 2023 WL 6996860, at *14.

requirement are not "separate law[s]." HB 23-1002 inserts *into the CCPA itself* a provision stating that the failure to comply with the reimburse-or-resupply requirement is a "deceptive trade practice." § 4, 6-1-105. This is not, therefore, a case where the Attorney General's authority "only derive[s] from a 'general enforcement power.'" *Bella Health*, 2023 WL 6996860, at *14 (quoting *Hendrickson*, 992 F.3d at 967). The Attorney General has a direct, specific statutory responsibility to bring enforcement actions against companies that do not comply with the reimburse-or-resupply requirement.

The Attorney General also argues that he has not demonstrated his willingness to enforce the provision because he has not "threatened Teva with a civil law enforcement action." Opp. 9. But *Ex parte Young* does not require that a state official actually threaten to enforce the statute at issue against the plaintiff—a rule that would foreclose any effort to enjoin an unconstitutional statute before it goes into effect. There was no record of threats or past enforcement for the new law at issue in *Bella Health*, yet this Court issued an injunction against the Attorney General nonetheless. *See* 2023 WL 6996860, at *11.

C. Teva Has Standing.

Teva has standing to mount a pre-enforcement challenge to the reimburse-or-resupply requirement. "[A] plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a

constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). In the absence of the reimburse-or-resupply requirement, Teva obviously would not provide Colorado pharmacies with free replacement auto-injectors or reimburse the pharmacies for the auto-injectors' cost. And there is a "credible threat" of prosecution for noncompliance because the statute authorizes the Pharmacy Board to impose monthly $10,000 fines and authorizes both private plaintiffs and the Attorney General to bring CCPA suits for treble damages.

Defendants do not even mention the "credible threat" standard for a pre-enforcement challenge, and instead simply assert that Teva asks this Court "to assume a slew of events that may never occur[.]" Opp. 10. But Teva makes only three, eminently reasonable assumptions: (1) some eligible Coloradans will actually make use of the affordability program; (2) one or more of those Coloradans will purchase one of Teva's auto-injectors; and (3) the pharmacies where those purchases take place will submit requests for reimbursement or replacement.

The Attorney General only really contests the second assumption, disputing that the affordability program "will necessarily impact *Teva's* products." Opp. 11. But it is a virtual certainty that, at some point during the life of the affordability program, an eligible Coloradan will purchase one of the thousands of auto-injectors

that Teva ships to Colorado each year. Colorado law permits pharmacists, when filling a prescription for a brand-name product, to "substitute an equivalent drug product if … in the pharmacist's professional judgment, the substituted drug product is therapeutically equivalent." Colo. Rev. Stat. § 12-280-125(1)(a). And according to the FDA's "Orange Book," Teva's auto-injectors are one of only *two* generic epinephrine auto-injectors with an "AB" rating, denoting that they have been determined to be bioequivalent to the brand-name product. *See Approved Drug Products with Therapeutic Equivalents* (43d ed. 2023), p. 3-170. Given the number of Teva auto-injectors shipped to Colorado, state law encouraging the use of generic products, and Teva's position in the generic market, it is nothing short of impossible that no eligible Coloradan will *ever* purchase a Teva auto-injector under the affordability program.

D. Teva's Claim Is Ripe.

Defendants also argue that Teva's claim is not ripe because no taking has yet occurred. *See* Opp. 12. But this simply restates Defendants' standing argument, and as Teva explained above, it has already suffered an injury-in-fact because it faces a "credible threat" of prosecution for failing to acquiesce in the imminent taking of its property without compensation. For the same reasons that Teva has standing, its pre-enforcement challenge is ripe. *See 303 Creative LLC v. Elenis*, 6 F.4th 1160, 1176 (10th Cir. 2021) (noting that "in pre-enforcement challenges, standing and

ripeness often 'boil down to the same question'" (quoting *SBA List*, 573 U.S. at 157 n.5)).

Defendants also invoke "prudential" ripeness, but the Tenth Circuit has made clear that "prudential considerations" should "not prevent [a federal court] from exercising [its] 'virtually unflagging' obligation to hear cases within [its] jurisdiction." *Id*. (quoting *SBA List*, 573 U.S. at 167). In any event, there is no prudential reason to delay review until Teva is forced to either relinquish its property without compensation or face an enforcement action for refusing to do so. Teva's challenge to the reimburse-or-resupply requirement "presents an issue that is 'purely legal, and will not be clarified by further factual development.'" *SBA List*, 573 U.S. at 167 (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985)). The constitutionality of the reimburse-or-resupply provision can be resolved now—indeed, the issue is not even contested.

Nor does the "finality requirement" present an obstacle to this Court's jurisdiction. Opp. 13. The "finality requirement" is a "hurdle[ ] to a *regulatory* takings claim," not to claims alleging *per se* takings like the state-authorized seizure of Teva's epinephrine auto-injectors. *N. Mill St., LLC v. City of Aspen*, 6 F.4th 1216, 1225 (10th Cir. 2021) (quoting *Suitum v. Tahoe Reg'l Plan. Agency*, 520 U.S. 725, 734 (1997) (emphasis added)). All that this "relatively modest" rule—which almost always arises in challenges to land-use regulations, where individual landowners

have the opportunity to seek variances—requires is that "there [is] no question … about how the 'regulations at issue apply to the particular land in question.'" *Pakdel v. City and Cty. of S.F.*, 141 S. Ct. 2226, 2230 (2021) (quoting *Suitum*, 520 U.S. at 739). The finality requirement has no application here, where it is undisputed that the reimburse-or-resupply requirement will take the property of manufacturers like Teva without compensation.

II. INJUNCTIVE RELIEF IS WARRANTED BECAUSE TEVA LACKS AN ADEQUATE REMEDY AT LAW.

Teva explained in its opening brief that injunctive relief is appropriate because, as the Eighth Circuit recently held when considering a challenge to a materially identical law, "the legal remedy of damages is not 'complete, practical, and efficient'" when a statute authorizes an indefinite series of takings. *PhRMA*, 64 F.4th at 945 (quoting *Terrace*, 263 U.S. at 214)). Defendants do not attempt to distinguish *PhRMA*, nor do they even engage its reasoning. Instead, Defendants argue that Teva would not need to "institute a separate action for each individual epinephrine auto-injector" because it could join together multiple claims for compensation, or even wait until the eve of the expiration of the two-year statute of limitations and file a single suit seeking compensation for all auto-injectors it provided during those two years. Opp. 15–16.

The procedural maneuvers Defendants suggest are surely possible, but they would not be as "complete, practical, and efficient" as simply enjoining Defendants

from carrying out an indisputably illegal series of takings in the first place. Adding a new claim for compensation through joinder every time Teva is forced to provide a free replacement is nearly as inefficient as filing an entirely new suit. And filing an omnibus suit every two years would require Teva to wait many months for its constitutionally required compensation, and would still involve repeated litigation.

Settled principles of equity hold that a legal remedy is not adequate unless it provides "as complete, practical, and efficient as that which equity could afford." *Id*. at 942 (quoting *Terrace*, 263 U.S. at 214). Accordingly, courts have long held that "[a]voidance of the burden of numerous suits at law between the same or different parties, where the issues are substantially the same, is a recognized ground for equitable relief[.]" *Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935). Defendants cannot escape the fact that, without an injunction, Teva will be forced to bring a series of identical just-compensation claims in the Colorado courts. The far more "complete, practical, and efficient" remedy is for this Court to enjoin Defendants from enforcing the statute that authorizes an indefinite series of unconstitutional seizures of Teva's property.

III. AN INJUNCTION IS IN THE PUBLIC INTEREST.

Teva does not question the public interest in improving access to its potentially life-saving epinephrine auto-injectors. But it is also "always in the public interest to prevent the violation of a party's constitutional rights," *Awad v. Ziriax*,

670 F.3d 1111, 1132 (10th Cir. 2012), and Defendants do not even contest that the reimburse-or-resupply requirement violates the Takings Clause. The Court should not permit an indisputably unconstitutional program to take effect, thereby inducing uninsured Coloradans to rely on a program that will inevitably be struck down.

CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court enter a preliminary injunction barring Defendants from enforcing the requirements of the epinephrine auto-injector affordability program established by HB 23-1002.

Dated: November 8, 2023

Respectfully submitted,

/s/ Alexandra I. Russell

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STATEMENT OF COMPLIANCE

I hereby certify that the foregoing pleading complies with the type-volume limitation set forth in Judge Domenico's Practice Standard III(A)(1).

/s/ Alexandra I. Russell

CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2023, I caused a copy of the foregoing to be filed through the Court's CM/ECF system.

/s/ Alexandra I. Russell