IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 23-cv-2584-DDD-SKC

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, and

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.

THE ATTORNEY GENERAL'S MOTION TO DISMISS

Pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6), Defendant Philip J. Weiser, in his official capacity as Colorado Attorney General (the "Attorney General"), respectfully moves to dismiss Plaintiff's First Amended Complaint ("Amended Complaint") [Doc. 22].

D.C.COLO.LCivR 7.1(b)(2) CERTIFICATION

In accordance with D.C.COLO.LCivR 7.1(b)(2) and Civ. Practice Standard 7.1B., undersigned counsel conferred with Plaintiff before filing this Motion on November 15, 2023. Plaintiff opposes the relief requested.

INTRODUCTION

Anaphylaxis is a severe allergic reaction that is life threatening. *See* HB23-1002, Doc. 20-1 at 2 (§1(b)). Epinephrine quickly addresses anaphylaxis. *See Id.* at 2 (§1(b)). Therefore, for more than 500,000 Coloradans, an epinephrine auto-injector is an essential medical device because it is the best way to administer life-saving epinephrine when facing anaphylactic shock. *See id.* (§§1(d)-(e)).

Unfortunately, epinephrine auto-injector manufacturers have driven up the prices of these essential medical devices for years.[1] To increase access to life-saving epinephrine, Colorado's General Assembly passed HB23-1002. *See* Doc. 20-1. Among other things, HB23-1002 created a program for Coloradans with an epinephrine prescription, who are ineligible for Medicaid or Medicare and who do not have prescription drug insurance coverage that limits the co-pay for epinephrine auto-injectors, to obtain a two-pack of epinephrine auto-injectors for $60 (the "Affordability Program"). The Program is codified at C.R.S. § 12-280-142, and takes effect on January 1, 2024.

Unhappy with the policy approach Colorado has taken to address the epinephrine auto-injector affordability crisis, Teva asserts a Fifth Amendment Takings Clause claim and seeks to enjoin the Affordability Program from ever taking effect. But, Teva's legal theory runs afoul of

[1] For example, between 2010 and 2016, Mylan increased the price of EpiPen® by approximately 400%. *See* https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates. Recently, certain manufacturers have agreed to pay large settlements to resolve claims against them. *See* https://ksd.uscourts.gov/content/epipen-epinephrine-injection-usp-marketing-sales-practices-and-antitrust-litigation-17-md (memorandum and orders approving settlements); *see also* F.R.E. 201; *Lake v. Hobbs*, 623 F.Supp.3d 1015, 1023 n. 5 (D. Ariz. 2022) (taking judicial notice of government websites).

well-established Eleventh Amendment and Takings Clause principles. Accordingly, its Amended Complaint [Doc. 22] should be dismissed.

BACKGROUND

The Affordability Program allows eligible individuals to obtain two epinephrine auto-injectors for no more than $60 from pharmacies in Colorado. *See* C.R.S. §§ 12-280-142(4)-(7).

After dispensing the epinephrine auto-injectors, the pharmacy may make a claim for payment from the manufacturer for the amount the pharmacy paid for the auto-injectors dispensed through the Affordability Program. C.R.S. § 12-280-142(8). Alternatively, the pharmacy may ask the manufacturer to send the pharmacy a replacement supply of epinephrine auto-injectors equal to the number of auto-injectors dispensed through the Program. C.R.S. § 12-280-142(8)(c)(II).

Effective January 1, 2024, a manufacturer that fails to comply with the requirements of the Affordability Program may be subject to discipline, including a fine, and engages in a deceptive trade practice under C.R.S. § 6-1-105(1)(zzz). *See* C.R.S. §§ 12-280-126(1)(c)(I), -142(2) & (11).

On October 31, 2023, Teva filed its Amended Complaint. It asserted a Fifth Amendment Takings Clause claim against the Attorney General, the Commissioner of Insurance, and the Pharmacy Board in their official capacities, alleging that "[b]y 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." Doc. 22 at ¶ 33. Teva seeks a declaration that the Affordability Program "violates the Takings Clause of the Fifth Amendment of the Constitution of the United States and is therefore void and unenforceable" and preliminary and permanent injunctive relief barring Defendants from enforcing "the requirement

that Teva reimburse or resupply Colorado pharmacies that dispense Teva's epinephrine auto-injectors to individuals participating in the affordability program." Doc. 22 at ¶¶ A-B.

For the sake of brevity and pursuant to Fed.R.Civ.P. Rule 10(c), the Attorney General incorporates the legal arguments from Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction [Doc. 20] into this Motion. As further discussed below, Teva's Amended Complaint lacks merit and should be dismissed.

ARGUMENT

I. THIS COURT LACKS SUBJECT MATTER JURISDICTION OVER TEVA'S CLAIM.

A. Eleventh Amendment sovereign immunity shields the Attorney General from suit in federal court.

First, the Amended Complaint should be dismissed because the Eleventh Amendment bars Teva from maintaining its takings claim against the Attorney General in federal court. Eleventh Amendment immunity extends to state officials who are sued in their official capacities for alleged Takings Clause violations and, once effectively asserted, constitutes a bar to the exercise of federal subject matter jurisdiction. *See Williams v. Utah Dep't of Corrs.*, 928 F.3d 1209, 1212-13 (10th Cir. 2019). For example, in *Williams*, the Tenth Circuit dismissed a Takings Claim against state officials based on the Eleventh Amendment because the plaintiff had a remedy in state court. *See id.* at 1213-14; *see accord 74 Pinehurst LLC v. New York*, 59 F.4th 557, 570 (2d Cir. 2023); *EEE Mins., LLC v. North Dakota*, 81 F.4th 809, 816 (8th Cir. 2023); *Zito v. N. Carolina Coastal Res. Comm'n,* 8 F.4th 281, 288, 290 (4th Cir. 2021); *Ladd v. Marchbanks*, 971 F.3d 574, 580 (6th Cir. 2020); *Bay Point Props., Inc. v. Miss. Transp. Comm'n*, 937 F.3d 454, 455-57 (5th Cir. 2019).

Here, Teva has alleged that the Affordability Program's reimburse-or-resupply requirement effectuates a taking, and seeks a declaration and injunction preventing the Attorney General and the other Defendants from enforcing it. *See* Doc. 22 at ¶¶ 32-36. But, the Takings Clause "is designed not to limit the governmental interference with property rights *per se*, but rather to secure *compensation* in the event of otherwise proper interference amounting to a taking." *First English Evangelical Lutheran Church of Glendale v. Cnty. of Los Angeles*, 482 U.S. 304, 315 (1987) (emphasis in original). Accordingly, it is well-settled that "[e]quitable relief is not available to enjoin an alleged taking of private property for a public use." *Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1016 (1984). Indeed, the U.S. Supreme Court more recently reiterated, "As long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *See Knick v. Twp. of Scott,* 139 S. Ct. 2162, 2176 (2019). And even if Teva properly reframes its claim as one for just compensation and proves a taking has occurred, Eleventh Amendment sovereign immunity still bars such a claim from being brought against any state official in this Court because it would "impose a liability which must be paid from public funds in the state treasury[.]" *Edelman v. Jordan*, 415 U.S. 651, 663 (1974).

Teva has not provided anything to anyone pursuant to the Affordability Program. Teva's objective is to prevent the Affordability Program from ever going into effect. However, a "property owner has an actionable Fifth Amendment takings claim when the government takes his property without paying for it." *Knick*, 139 S. Ct. at 2167. Since Colorado has not taken any property from Teva, there has been no Takings Clause violation and there is no ongoing violation of federal law

sufficient to overcome the Eleventh Amendment bar.[2] But, if Teva provides its products in the future, Teva has an available state court remedy to obtain just compensation. For alleged takings of personal property, Teva can bring a claim for just compensation in Colorado state court under the Fifth Amendment and Colo. Const. Art. II, § 15. *See Colo. Dep't of Health v. The Mill*, 809 P.2d 434, 440-41 (Colo. 1991); *Callopy v. Wildlife Comm'n*, 625 P.2d 994, 1005-06 (Colo. 1981); *Game and Fish Comm'n v. Farmers Irr. Co.*, 426 P.2d 562, 565-66 (Colo. 1967). Accordingly, Teva cannot maintain a Fifth Amendment takings claim against any Colorado official in this Court. *See Williams*, 928 F.3d at 1213-14.

The fact that Teva has asked for injunctive relief does not salvage their claim since injunctive relief is not available in this context. Teva does not dispute that there is an available state court remedy to obtain just compensation. *See* Doc. 26 at 10-11. Nevertheless, relying entirely on the Eighth Circuit's decision in *Pharm. Rsch. & Manufacturers of Am. V. Williams*, 64 F.4th 932 (8th Cir. 2023) ("*PhRMA*"), Teva argues that the state remedy is inadequate as a matter of law it would allegedly have to bring multiple takings claims. *See* Doc. 26 at 10-11. To be sure, the Attorney General disagrees with this legal assertion. *See* Doc. 20 at 15-17. But, even if it were correct, the Eighth Circuit's holding in *PhRMA* is based on an incorrect reading of *Knick*, and applying it as a categorical rule is inappropriate. *See Sanders v. Mountain Am. Fed. Credit Union*, 689 F.3d 1138, 1143-44 (10th Cir. 2012) ("categorical relief is beyond the reach of the courts' equitable powers").

[2] "Under *Ex parte Young*, a plaintiff may bring suit against individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law and the plaintiff seeks prospective relief." *Williams*, 928 F.3d at 1214 (quotations, alterations, and citations omitted). Since there has been no violation of the Fifth Amendment, an ongoing violation of federal law does not exist, and *Ex parte Young* does not apply.

In *Knick*, the Supreme Court made clear that the Takings Clause does not prohibit regulation "in the absence of contemporaneous compensation." *Knick*, 139 S. Ct. at 2177. Rather, a takings proceeding itself "is a remedy for a taking that violated the Constitution," and so as long as "an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Id.* at 2176. Put differently, so long as "the property owner has *some way* to obtain compensation after the fact, governments need not fear that courts will enjoin their activities." *Id.* at 2168 (emphasis added). Under *Knick*, therefore, the focus of the just compensation inquiry in the Takings Clause context is whether a property owner has "some way" to obtain compensation "after the fact." If they do, then injunctive relief is not available. Indeed, consistent with *Knick*, the Tenth Circuit has dismissed Takings Claims involving potential repeated future takings on the basis that alternative just compensation procedures were available. *See Gordon v. Norton*, 322 F.3d 1213, 1218 (10th Cir. 2003) (no declaratory or injunctive relief in case involving alleged takings of livestock due to reintroduced wolves because Tucker Act remedy available); *Williams*, 928 F.3d at 1213-14 (Eleventh Amendment barred claim that state's failure to pay interest on prison bank accounts amounted to a taking since state law remedies available). The Eighth Circuit erred by grafting a "no multiplicity of suit" requirement onto this straightforward rule from *Knick*.

Here, it is undisputed that just compensation remedies exist under Colorado law. If Teva can prove an uncompensated taking has occurred sometime in the future, then it can obtain such compensation for that taking using those state court remedies. It may not be Teva's preferred approach, but Teva cannot escape the fact that, without an injunction, it can obtain *full and complete* just compensation with the available state court remedies. That is all that is required

under the Fifth Amendment. *See Knick*, 139 S. Ct. at 2177. Since just compensation remedies exist under Colorado law, Teva's Fifth Amendment claim against the Attorney General (and any other state official) must be dismissed. *Williams*, 928 F.3d at 1213-14.

B. Teva cannot establish standing or that its claim is ripe.

The Amended Complaint should be dismissed because Teva does not yet have standing to assert its claim and its claim are not ripe. This Court therefore lacks subject matter jurisdiction.

To establish standing, 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,* 136 S. Ct. 1540, 1547 (2016). A plaintiff has the burden to show that they have suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical. *Id*. at 1548. "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).

To date, Colorado has not taken anything from Teva pursuant to the Affordability Program. A plaintiff cannot have Article III standing based on hypothetical future injury. *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1087 (10th Cir. 2006). "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).

To the extent Teva asserts it will be injured by the uncompensated "taking" of its epinephrine auto-injectors in the future under the Affordability Program, its Amended Complaint is speculative and insufficient. To imagine such an injury, one must make a number of assumptions about the operation of the Affordability Program that have not yet obtained, such as: the number

of people who may be eligible for the Program because they are not covered for epinephrine auto-injectors under Medicare, Medicaid, or their insurance plan; whether those individuals will apply for auto-injectors; whether they will be dispensed an auto-injector at a pharmacy; whether a pharmacy will actually make a claim of a manufacturer;[3] and how much, if any, actual economic harm a manufacturer will suffer. These are all matters of pure conjecture.

Further, Teva invites this court to assume that to the extent the Affordability Program is used by eligible Coloradans, it will necessarily impact *Teva's* products. Based on past estimated sales,[4] Teva speculates that it "will be forced to supply tens of thousands of generic epinephrine auto-injectors *for free* to Colorado citizens." Doc. 22 at ¶ 31. But to establish an actual, concrete injury, Teva's epinephrine auto-injectors must, in fact, be dispensed through the Affordability Program in 2024 and beyond. The allegations of harm in the Amended Complaint are wholly speculative, which is insufficient to establish that Teva has suffered an actual injury in fact necessary to establish standing.

As for ripeness, a takings claim is not ripe until the taking has happened. "[W]hether a claim is ripe for review bears on a court's subject matter jurisdiction." *New Mexicans for Bill*

[3] The electronic claims process between the pharmacy and the manufacturer is neither automatic, nor required by the Affordability Program. C.R.S. § 12-280-142(8).

[4] Teva provides no evidence of how many of its past products sold in Colorado were distributed to individuals who might be eligible under the Affordability Program. Instead, it alleges it distributed approximately 14,000 epinephrine auto-injectors in Colorado during a one-year period and then argues it will be forced to supply "tens of thousands" of its products under the Affordability Program. Doc. 22 at ¶¶ 28, 31. But Teva's past business activities do not shed light on how many of its products may ultimately end up dispensed to the narrow group of eligible individuals—those not eligible for Medicare or Medicaid and that do not have prescription drug coverage with a co-pay cap—who actually go through the process of completing the application and meeting the requirements.

*Richardson v. Gonzale*s, 64 F.3d 1495, 1498 (10th Cir. 1995). For ripeness, "the central focus is on whether the case involves uncertain or contingent future events that may not occur as anticipated, or indeed may not occur at all." *Id.* at 1499 (quotation omitted). "[B]ecause a taking without compensation violates the self-executing Fifth Amendment *at the time of the taking*, the property owner can bring a federal suit *at that time*." *Knick*, 139 S. Ct. at 2172 (emphasis added). Any injury is speculative on a complaint filed when a taking has not occurred and "no just compensation [is] due to any particular individual for a yet-to-occur taking." *Sante Fe All. for Pub. Health and Safety v. City of Sante Fe,* 993 F.3d 802, 814 (10th Cir. 2021) (finding that a plaintiff seeking redress for alleged *future* losses of homes and businesses did not present claim ripe for review because the taking had not occurred at the time of the amended complaint).

As discussed above, it is unclear if Teva's products will ever be involved in the Affordability Program and so its claim is currently unripe. *See Knick*, 139 S. Ct. at 2172 ("a property owner has a claim for a violation of the Takings Clause as soon as a government takes his property for public use without paying for it."); *cf. MacDonald, Sommer, & Frates v. Yolo Cnty.*, 477 U.S. 340, 348 (1986) ("A court cannot determine whether a regulation has gone "too far" unless it knows how far the regulation goes.").

II. TEVA'S COMPLAINT SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM BECAUSE THE STATE ENACTED THE AFFORDABILITY PROGRAM PURSUANT TO ITS POLICE POWER

Under Fed. R. Civ. P. 12(b)(6), a court may dismiss a complaint for failure to state a claim upon which relief can be granted. "[T]o withstand a motion to dismiss, a complaint must contain enough allegations of fact 'to state a claim to relief that is plausible on its face.'" *Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) (citation omitted). "A claim has facial plausibility

when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) "Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). The Amended Complaint should be dismissed under Fed. R. Civ. P. 12(b)(6) because the Affordability Program is a valid exercise of the state's police power to regulate pharmaceuticals and is, therefore, not a takings for the purposes of the Takings Clause.

A state's "police power encompasses the authority to provide for the public health, safety, and morals," and "controls the use of property by the owner for the public good." *Lech v. Jackson*, 791 F. App'x 711, 718 (10th Cir. 2019) (quotations and citations omitted). When a "state acts pursuant to its police power, rather than the power of eminent domain, its actions do not constitute a taking for purposes of the Takings Clause," a distinction that "remains dispositive" even in cases involving "the direct physical appropriation or invasion of private property." *Id*. at 717; *see also Zitter v. Petruccelli*, 744 F. App'x 90, 96 (3d Cir. 2018); *Johnson v. Manitowoc Cnty.*, 635 F.3d 331, 336 (7th Cir. 2011).

It is a "universally recognized" principle 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* C.R.S. § 12-280-101 (noting that the "practice of pharmacy" affects "the public health, safety, and welfare and is subject to regulation and control in the public interest"); C.R.S. § 12-280-303 (regulating wholesalers that engage in the wholesale distribution of prescription drugs in

Colorado). Indeed, Teva concedes that the state has the authority to regulate epinephrine auto-injectors. *See* Doc. 3 at 9-10.

Here, the state enacted the Affordability Program—a specific program for a discrete number of eligible individuals—pursuant to its police power to regulate the sale of drugs. The General Assembly found that epinephrine auto-injectors are essential medical devices because "they are the easiest and most efficient way to potentially save the life of an individual exhibiting symptoms of or experiencing anaphylactic shock," but that "[r]ising costs of epinephrine auto-injectors make this life saving medication difficult or impossible to obtain for many people." HB 23-1002, §§ 1(1)(e), (g). The Affordability Program's intent is to address this public health crisis and "ensure Colorado residents have greater access to epinephrine." *Id*. § 1(2). The Affordability Program accomplishes this by creating a mechanism for a narrow group of individuals to obtain epinephrine auto-injectors at a reasonable price. The Affordability Program was enacted to protect public health and to promote the public good.

Price gouging by certain epinephrine auto-injector manufacturers should not prevent certain at-risk Coloradans from obtaining access to this life saving medication. As part of a highly regulated industry, epinephrine auto-injector manufacturers know that they will be subject to a certain degree of regulation as part of doing business. *See, e.g., Ruckelshaus v. Monsanto Co.*, 467 U.S. at 1007 (regulations are "the burdens we all must bear in exchange for the advantage of living and doing business in a civilized community." (quotations omitted)). They also know that that regulations can adjust "the benefits and burdens of economic life to promote the common good." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978). As a matter of fundamental

fairness and justice, manufacturers may be forced to play their part in alleviating the affordability crisis of their own making.

As discussed above, the Affordability Program is not yet in effect and Teva has not provided any epinephrine auto-injectors to anyone pursuant to the Affordability Program. If Teva ever does provide replacement auto-injectors or reimbursements pursuant to the Affordability Program, it will be doing so pursuant to a state regulation that "controls the use of property by the owner for the public good" and that was enacted under the state's police power to regulate the sale of drugs. That would not constitute a taking under the Takings Clause. *See Lech*, 791 F. App'x at 719. Indeed, it would be inconsistent that the Takings Clause would tolerate the destruction of private property pursuant to the state's power to protect the safety of its citizens (as in *Lech*), but prohibit regulations broadening access to a life-saving drugs, as the Affordability Program will do, enacted pursuant to the state's power to protect the health and welfare of its citizens.

Simply put, the Affordability Program is a regulation that regulates the sale of life-saving prescription drugs and was enacted pursuant to the state's police power. Accordingly, the Affordability Program will not subject Teva to a taking under the Takings Clause, and Teva's Amended Complaint must be dismissed. *See Carrasco v. City of Udall*, No. 20-1322-EFM, 2022 WL 522959, at *3 (D. Kan. Feb. 22, 2022) (applying *Lech* to conclude that removal of trees was not a taking under the Fifth Amendment); *Britton v. Keller*, No. 119CV01113KWRJHR, 2020 WL 1889017, at *4 (D.N.M. Apr. 16, 2020), aff'd, 851 F. App'x 821 (10th Cir. 2021) (applying *Lech* to conclude that program involving stray feral cats fell within police powers and Takings Claim failed as a matter of law); *David v. Midway City*, No. 2:20-CV-00066-DBP, 2021 WL 6927739,

at *7 (D. Utah Dec. 14, 2021), appeal dismissed, No. 22-4009, 2022 WL 3350513 (10th Cir. Aug. 3, 2022) (applying *Lech* to conclude that invasions due to snowplowing was not a taking).

CONCLUSION

Because this court lacks subject matter jurisdiction and Teva has failed to state a claim, the Attorney General requests that the Court dismiss the Amended Complaint.

DATED: November 15, 2023.

PHILIP J. WEISER

Attorney General

s/Pawan Nelson

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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)(II).

s/ Pawan Nelson