

CASE NO. 24-1035

**IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT**

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff – Appellee,

v.

PHILIP J. WEISER, in his official capacity as,
Attorney General of the State of Colorado, and
PATRICIA A. EVACKO, ERIN 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– Appellants.

On Appeal from the United States District Court
For the District of Colorado
The Honorable Daniel D. Domenico
District Court Case No. 23-cv-02584-DDD-JPO

ATTACHMENT 1 TO APPELLANTS' OPENING BRIEF

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Daniel D. Domenico**

Civil Action No. 1:23-cv-02584-DDD-SKC

TEVA PHARMACEUTICALS, USA, INC.,

Plaintiffs,

v.

PHIL WEISER, in his official capacity as Attorney General of the State of Colorado;

PATRICIA A. EVACKO,

ERIC FRAZER,

RYAN LEYLAND,

AVANI SONI,

JAYANT PATEL,

KRISTEN WOLF, and

ALEXANDRA ZUCCARELLI, in their official capacity as members of the Colorado State Board of Pharmacy,

Defendants.

**ORDER DENYING PLAINTIFF’S MOTION FOR PRELIMINARY INJUNCTION
AND DEFENDANTS’ MOTION TO DISMISS**

Colorado’s recently enacted Epinephrine Affordability Program goes into effect January 1, 2024. Plaintiff Teva Pharmaceuticals brought this case alleging that the Affordability Program will require it to provide autoinjectors to pharmacies at no cost in violation of the Fifth Amendment’s prohibition against taking private property without just compensation. Doc. 1. It has also moved for a preliminary injunction to prevent the law from going into effect. Doc. 2. The Defendants oppose that motion and have moved to Dismiss Plaintiff’s case in its entirety. Docs. 29, 35. Both motions are denied.

BACKGROUND

I. Epinephrine Autoinjectors and Colorado Generic-Drug Laws

Epinephrine autoinjectors, commonly known as EpiPens,¹ are frequently used medical devices. The epinephrine injected by an autoinjector is a reliable countermeasure to allergy-induced anaphylactic shock. For people with severe allergies, having quick access to an EpiPen can literally be a matter of life and death.

Plaintiff Teva Pharmaceuticals manufactures a “bioequivalent” generic-alternative autoinjector. Doc. 26 at 12. In Colorado, pharmacists may substitute specified generic alternatives, like Teva’s autoinjectors, for brand name drug products. Colo. Rev. Stat. § 12-280-125(1)(a). And generic alternatives are typically less expensive than brand name drugs. This encourages pharmacists to provide consumers with generic drugs instead of brand names. For example, if a consumer was given a prescription by a doctor for a brand-name EpiPen, a pharmacist, under Colo. Rev. Stat. § 12-280-125(1)(a), could fill that prescription with a Teva-manufactured autoinjector as a cheaper, but medically equivalent, alternative. Teva does not directly market its autoinjectors to Colorado consumers. Instead, Teva sells two-packs of its autoinjectors in bulk to distributors and wholesalers for \$300 per pack. *See* Deposition of Kevin Galownia, December 15, 2023, at 12–13. Those distributors and wholesalers then sell to individual pharmacies at a markup for their own profit. *Id.* According to Teva, more than 14,000 of its autoinjectors (or

¹ Much like Kleenex, Frisbee, or, in some parts of the country at least, Coke, “EpiPen” is a brand-name eponym for an Epinephrine Auto-Injector. Brand-name EpiPens are a product of Pfizer. *See* Deposition of Kevin Galownia, December 15, 2023 at 10.

7,000 two-packs) were sold to pharmacies in Colorado in a single year. Doc. 1 at 9.

II. Colorado's Affordability Program

Autoinjector prices have increased substantially over the years. See Doc. 29 at 2, n.1. To address these rising costs, the Colorado legislature enacted HB23-1002. The law established an affordability program aimed at improving the affordability of autoinjectors. *Id.* Most prominently, this involves limiting the costs to consumers for autoinjectors to \$60 per two-pack. To accomplish that, the law identifies two different types of purchasers: insured consumers, who may be charged no more than a \$60 copayment (with the insurance company covering the rest); and qualifying uninsured consumers, who are simply charged no more than a flat \$60.

Teva is concerned with what comes next. When a pharmacist dispenses an autoinjector to an uninsured consumer, it receives only \$60 for a product when it likely paid more than five times that amount. To offset this loss, the law provides that a pharmacist or pharmacy may submit a form to the manufacturer of the autoinjector, which then has the choice to: “(I) Reimburse the pharmacy in an amount that the pharmacy paid for the number of epinephrine auto-injectors dispensed through the program; or (II) Send the pharmacy a replacement supply of epinephrine auto-injectors in an amount equal to the number of epinephrine auto-injectors dispensed.” Colo. Rev. Stat. § 12-280-142(8)(c)(I–II). Failure to comply with this “reimburse or resupply” requirement results in a \$10,000 fine. *Id.* Non-compliance is also considered a “deceptive trade practice” under Colo. Rev. Stat. § 6-1-105(1)(zzz), which can carry substantial penalties. The affordability program goes into effect January 1, 2024.

Teva has sued the attorney general of Colorado and each member of the State's board of pharmacy, all in their official capacities. The Defendants are referred to as the "State Defendants" or the "State" throughout this Order.² Teva claims that the reimburse or resupply requirement would violate the Fifth Amendment Takings Clause, and seeks permanent and preliminary injunctive and declaratory relief. Docs. 1, 3. The Attorney General filed a Motion to Dismiss Teva's claim, joined by the members of the board of pharmacy. Docs. 29, 35.

LEGAL STANDARDS

"A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *Mrs. Fields Franchising, LLC v. MFGPC*, 941 F.3d 1221, 1232 (10th Cir. 2019). Such relief may be granted "only when the movant's right to relief is clear and unequivocal." *McDonnell v. City & Cty. of Denver*, 878 F.3d 1247, 1257 (10th Cir. 2018). To succeed on a motion for preliminary injunction, the moving party must show: (1) that it is "substantially likely to succeed on the merits"; (2) that it will "suffer irreparable injury" if the court denies the injunction; (3) that its "threatened injury" without the injunction outweighs the opposing party's under the injunction; and (4) that the injunction is not "adverse to the public interest." *Mrs. Fields*, 941 F.3d at 1232; accord *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The third and fourth preliminary-injunction factors "merge" when the government is the party opposing the injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

When presented with a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), a court "must accept all

² Teva originally sued Michael Conway in his official capacity as Commissioner of the Colorado Division of Insurance. See Doc. 1. Teva later dismissed its claims against Mr. Conway after the instant motions were filed. See Docs. 31, 32. Mr. Conway's dismissal did not effect the motions at issue.

the well-pleaded allegations of the complaint as true and must construe them in the light most favorable to the plaintiff.” *Alvarado v. KOB-TV, L.L.C.*, 493 F.3d 1210, 1215 (10th Cir. 2007). But “mere ‘labels and conclusions’ and ‘a formulaic recitation of the elements of a cause of action’ will not suffice” to state a plausible claim for relief. *Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). So a court should “disregard conclusory statements and look only to whether the remaining, factual allegations plausibly suggest the defendant is liable.” *Id.* “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).

Under Rule 12(b)(1), a party may move to dismiss for lack of subject-matter jurisdiction, “mounting either a facial or factual attack.” *Baker v. USD 229 Blue Valley*, 979 F.3d 866, 872 (10th Cir. 2020). Factual attacks go “beyond the allegations in the complaint and adduce[] evidence to contest jurisdiction.” *Id.* In such cases, the court has “wide discretion to allow affidavits, other documents, and a limited evidentiary hearing to resolve disputed jurisdictional facts.” *Id.* (internal quotation marks and citation omitted). Reliance on such evidence does not necessarily convert the motion to one for summary judgment. *Id.*

DISCUSSION

I. Defendants’ Motion to Dismiss

The Defendants seek to dismiss the case on the grounds that Teva does not have standing, that its claim is not ripe, that the affordability program would not cause a taking, and that the Defendants have immunity. *See* Doc. 29. Because these overlapping issues implicate this court’s

jurisdiction, I address this motion first before turning to the remaining obstacles to Plaintiff's motion for a preliminary injunction.

a. Standing and Ripeness

Defendants argue that Teva lacks standing to bring its takings claim and that the claim is not ripe for adjudication. In both the motion to dismiss and in response to Teva's motion for a preliminary injunction, Defendants' ripeness and standing concerns boil down to essentially the same argument: Teva won't be injured until a physical taking actually occurs, and the claim "is not ripe until the taking has happened." Doc. 20 at 10–12.

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. As Defendants argue, the usual rule is that "when it comes to per se takings, which Teva alleges is at issue here, a Fifth Amendment claim becomes justiciable when the physical property is actually taken or when the government attempts to assess a fine." Doc. 45. at 6. In contrast to other constitutional violations, Defendants argue that in a takings case, "there is no constitutional right to vindicate until an uncompensated taking actually occurs." *Id.*

Although courts routinely grant pre-enforcement injunctive relief for many types of constitutional challenges to state laws, they historically have not granted prospective injunctive relief to prevent a physical taking before it occurs—or to prevent a regulatory taking before it becomes "final." As the Supreme Court recently recounted, by the 1870s, "as state courts began to recognize implied rights of action for damages under the state equivalents of the Takings Clause, they declined to grant injunctions because property owners had an adequate remedy at law." *Knick v. Twp. of Scott, Pennsylvania*, 139 S. Ct. 2162, 2176 (2019). Shortly thereafter, the United States passed the Tucker Act, and the Supreme

Court “subsequently joined the state courts in holding that the compensation remedy is required by the Takings Clause itself.” *Id.* Even “[t]oday, because the federal and nearly all state governments provide just compensation remedies to property owners who have suffered a taking, equitable relief is generally unavailable. 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.*

Prior to *Knick*, there were two requirements for takings claims to be ready for review in federal court: (1) a “final decision” from the relevant state actor; and (2) the plaintiff's completion of all state court procedures available to receive just compensation. *Wireman v. City of Orange Beach*, No. CV 20-00005-KD-B, 2020 WL 5523403, at *6 (S.D. Ala. May 7, 2020) (summarizing rule stated in *Williamson Cnty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 176 (1985)). *Knick* expressly did not disturb the first “finality” prong, but it jettisoned the second “state-litigation” requirement. *Compare* 139 S. Ct. at 2169 and 139 S. Ct. at 2178-79.

In so doing, the Court held that “a property owner may bring a takings claim under § 1983 upon the taking of his property without just compensation by a local government.” *Id.* at 2179. And as to the remaining “finality” requirement, the Supreme Court has subsequently stated that only “de facto finality is necessary,” at least in the context of regulatory takings. *Pakdel v. City & Cnty. of San Francisco*, 141 S. Ct. 2226, 2230 (2021). For physical takings, prior to *Knick* and *Pakdel*, courts typically viewed the first “finality” prong as being satisfied once the physical taking occurs. *See Wireman*, 2020 WL 5523403, at *6 n. 9 (collecting cases); *see also Hensley v. City of Columbus*, 557 F.3d 693, 696 (6th Cir. 2009) (holding that for “a ‘physical taking,’ the taking itself is viewed as a final action”).

Given this, it is perhaps unsurprising that Teva has cited no cases directly addressing standing and ripeness in a physical takings case before such a taking occurs. If equitable relief, including prospective injunctive relief, remains “generally unavailable” for takings plaintiffs, “pre-enforcement” standing and ripeness doctrines would have little, if any, application to such claims. As the Sixth Circuit recently put it, the *Knick* court “expressed skepticism that a takings claim for injunctive relief would ever be ripe.” *Barber v. Charter Twp. of Springfield, Michigan*, 31 F.4th 382, 388 (6th Cir. 2022) (citing *Knick*, 139 S. Ct. at 2175, 2179).

But the story did not end with *Knick*. Two years after *Knick* was decided, the Supreme Court decided *Cedar Point Nursery v. Hassid*. 141 S. Ct. 2063 (2021). In that case, the plaintiff sought a preliminary injunction to prevent a physical taking, and the defendants moved to dismiss. *Id.* at 2070. The lower courts denied the preliminary injunction motion and granted the motion to dismiss, but the Court reversed the court of appeals’ judgment and remanded. The Supreme Court did not explicitly address whether a preliminary injunction was appropriate or even available to the plaintiff in *Cedar Point*. But at least one circuit court has viewed the *Cedar Point* ruling as a tacit endorsement of the principle that a plaintiff may have a ripe takings claim even prior to the actual physical taking occurring. *Barber*, 31 F. 4th at 388-89. Given this, and other guidance from the Supreme Court, the Sixth Circuit concluded that “a claim for injunctive relief is ripe if the government has reached a final decision that will enable a future physical taking.” *Id.* (citing *Pakdel*, 141 S. Ct. at 2230).

The Sixth Circuit’s approach to physical takings—that is, allowing for the possibility that claims can ripen before a physical taking actually occurs—makes good sense in light of *Knick*, *Cedar Point*, and *Pakdel*.

And for similar reasons, an imminent, future taking can confer standing prior to the physical taking occurring. *See Barber*, 31 F.4th at 389-91 (reversing district court and finding that potential future injury conferred standing even prior to physical taking occurring).

The ripeness and standing analysis, however, should not be conflated with the merits issue of whether Plaintiff can obtain injunctive relief—either preliminary or permanent:

While the ripeness inquiry addresses unique issues in takings cases, courts must not use the ripeness doctrine as an opportunity to prematurely reach thorny merits questions. For example, Defendants focus heavily on other questions that go to the merits: whether Barber can sue for injunctive relief to prevent a taking; whether she is limited to seeking just compensation as a remedy after a taking But these are not *ripeness* questions.

Id. at 389 n.4 (emphasis in original). “For purposes of standing, the question cannot be whether the Constitution, properly interpreted, extends protection to the plaintiff’s asserted right or interest. If that were the test, every losing claim would be dismissed for want of standing.” *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1092 (10th Cir. 2006).

b. Teva Has Standing to Bring Its Takings Claim

Article III of the Constitution limits the jurisdiction of federal courts to “Cases” and “Controversies.” U.S. Const., Art. III, § 2. “The doctrine of standing gives meaning to these constitutional limits by identifying those disputes which are appropriately resolved through the judicial process.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014). To establish standing, a plaintiff must show (1) an injury in fact, (2) a causal connection between the injury and the alleged conduct, and (3) redressability. *Id.* An “injury in fact” must be “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Id.*

(internal quotation marks omitted). “That does not mean that she must have already suffered an injury.” *Barber*, 31 F. 4th at 390. “Rather, ‘a person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring, at least so long as the risk of harm is sufficiently imminent and substantial.’” *Id.* (quoting (*Transunion LLC v. Ramirez*, 594 U.S. 413, 435 (2021)); see also *Peck v. McCann*, 43 F.4th 1116, 1129-30 (10th Cir. 2022)).

Applied here, Teva’s alleged harm is sufficiently “imminent and substantial” to confer standing. Teva faces several impending harms under the new law. First, if Teva complies with the law—and a pharmacy seeks reimbursement for an uninsured customer’s receipt of an autoinjector—Teva will either have to transfer some of its autoinjectors for free or reimburse the pharmacy for previous products that it sold to the pharmacy. Either way, Teva argues, this will amount to an unlawful taking. And if Teva refuses, as it indicated it would when questioned at the hearing, it is subject to a monthly \$10,000 fine, among other potential enforcement actions. See *Consumer Data Industry Ass’n v. King*, 678 F.3d 898 (10th Cir. 2012) (“[T]he existence of a statute implies the threat of its enforcement, and the [plaintiff] was entitled to bring a pre-enforcement challenge based on the probability of future injury.”).

Defendants argue that any risk is too attenuated to confer standing. The argument goes that Teva’s harm depends on a chain of events not guaranteed to happen, including that (1) someone who is uninsured (or underinsured) applies for an autoinjector under the program; (2) a pharmacist will dispense one of Teva’s products to such a person; (3) the pharmacist will make a claim to Teva; and (4) in light of that claim, Teva will suffer some economic harm. According to Defendants, “[t]hese are all matters of pure conjecture.” Doc. 20 at 11.

That is just not so. As Teva has alleged, and the State has not disputed, Teva sold thousands of autoinjectors in Colorado last year and is likely to do so going forward. Teva has represented that its share of the autoinjector market nationally is nearly forty percent, and there is no reason to think it is significantly different in Colorado. And as Teva argues, multiple factors will drive pharmacists to dispense Teva's products, including state law's encouragement of the use of generic products, the limited competition among manufacturers for such products, and the volume of products Teva shipped last year. Doc. 37 at 15. Finally, products that Teva has already shipped to Colorado pharmacies are likely to become subject to the affordability program if dispensed once the program becomes active. So Teva is already in the position of having to decide whether to continue shipping its products and risk facing either an alleged taking or fines for refusing to comply. Far from "pure conjecture," it appears imminent and inevitable that the law will impact Teva in the way they allege is a constitutional violation. This is sufficient to confer standing.

c. Teva's Claim Is Ripe

To the extent there is a difference between constitutional standing and ripeness, it does not alter the analysis here. "Standing and ripeness are closely related in that each focuses on whether the harm asserted has matured sufficiently to warrant judicial intervention." *Peck*, 43 F.4th at 1133 (internal quotation marks and citation omitted). In pre-enforcement challenges, moreover, standing and ripeness often "boil down to the same question." *See SBA List*, 573 U.S. at 157 n.5. It may be possible that a case which is not ripe could satisfy standing, but Defendants have not shown that is the case here.

As touched on above, in light of *Knick*, *Cedar Point*, and *Pakdel*, "a claim for injunctive relief is ripe if the government has reached a final

decision that will enable a future physical taking.” *Barber*, 31 F.4th at 388-89. Here, there’s no question what Teva has to give up should a pharmacy seek reimbursement—autoinjectors or money. *See MacDonald, Sommer, & Frates v. Yolo Cty.*, 477 U.S. 340, 348 (1986). Nor is there uncertainty about how the affordability program works—if Teva refuses to reimburse a pharmacy with its personal property or money, it faces a monetary sanction. This is not a land use case where there is some mechanism for the government to grant a variance that has not yet been finalized. The law here, and how it will apply to Teva, is set. Teva has therefore shown “de facto finality” sufficient for its claim to ripen. *Pakdel*, 141 S. Ct. at 2230. The ripeness analysis therefore aligns with the standing analysis, and this case is ready for adjudication. *See Peck*, 43 F.4th at 1133.

d. Eleventh Amendment Immunity

Defendants also argue that Teva’s claim must be dismissed because they are immune to suit under the Eleventh Amendment. They argue that “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 Federal Court. Doc. 29 at 5.

True, the Eleventh Amendment shields state officials from monetary claims for takings. *See Williams v. Utah Dep’t of Corr.*, 928 F.3d 1209, 1212-14 (10th Cir. 2019). But under the *Ex Parte Young* doctrine, “a plaintiff may sue individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law and the plaintiff seeks only prospective relief.” *Hendrickson v. AFSCME Council 18*, 992 F.3d 950, 965 (10th Cir. 2021) (citation omitted). Teva has disclaimed any intent to pursue monetary damages and seeks only prospective injunctive relief.

But the attorney general also argues that there is no prospective action to enjoin, because “enforcement action under [the affordability program] is wholly discretionary,” and that he is therefore immune from suit. Doc. 20 at 9. That the attorney general’s enforcement is discretionary is no defense to prospective injunctive relief when there has been no disavowal of intent to enforce. *See Mink v. Suthers*, 482 F.3d 1244, 1254 (10th 2007); *Darren Patterson Christian Academy v. Roy*, No. 1:23-cv-01557-DDD-STV, 2023 WL 7270874 at *9 (D. Colo. Oct. 20, 2023).³ The mere “existence of a statute *implies* the threat of its enforcement,” and Teva may seek prospective injunctive relief on that ground. *King*, 678 F.3d at 902 (emphasis added). This falls squarely within the *Ex Parte Young* exception to Eleventh Amendment immunity and provides no grounds for dismissal. *See Hendrickson*, 992 F.3d at 965.

e. The Reimburse and Resupply Requirement Would Effect a Taking

A physical taking of property under the Fifth Amendment occurs if “government has physically taken property for itself or someone else—by whatever means. . . . Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred.” *Cedar Point Nursery*, 141 S.Ct. at 2072 (internal citations omitted).

Defendants argue in their motion to dismiss that even triggering the reimburse-or-resupply requirement would not inflict a taking on Teva at all. Instead, the State contends that when acting pursuant to its police power, no taking can occur. Doc. 29 at 11. The State relies on *Lech v. Jackson*, 791 F. App’x 711, 718 (10th Cir. 2019), a case in which police damaged a private home while attempting to apprehend a criminal

³ While the Board of Pharmacy defendants joined the attorney general’s motion in full, (Doc. 46), it was not argued that their duty to enforce the statute was discretionary, and they have provided no disavowal of enforcement.

barricaded inside. The Tenth Circuit found that “the damage caused in the course of arresting a fugitive on plaintiffs’ property was not a taking for public use, but rather it was an exercise of the police power.” *Id.*

Lech is an unpublished decision and therefore not binding authority, but even accepting its holding, there is a world of difference between that case and this one. While *Lech* involved a very literal exercise of the police power—enforcing criminal law—this case involves “physical appropriation of property,” therefore, it is a “*per se* taking.” *Cedar Point Nursery*, 141 S. Ct. at 2072. *Lech*, and the primary case that it cites, are not only specific to “the most traditional function of the police power: entering property to effectuate an arrest or a seizure,” but also to damage or destruction of property. *Id.*; *Bachmann v. United States*, 134 Fed. Cl. 694, 696 (Fed. Cl. 2017) (law enforcement causing property damage in pursuit of a fugitive); *AmeriSource Corp. v. United States*, 525 F.3d 1149, 1150 (Fed. Cir. 2008) (law enforcement seizing and “render[ing] worthless” property in a criminal investigation).

That is not the effect of the affordability program’s reimburse or re-supply requirement. The State in this case does not damage, destroy or devalue Teva’s property. It requires that possession of property be transferred from its owner to another. That is all that is required to trigger the Taking Clause. *Cedar Point Nursery*, 141 S. Ct. at 2072 (“The essential question is . . . whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner’s ability to use his own property.”); *Horne v. Dep’t of Ag.*, 576 U.S. 350, 360 (2015) (affirming “the rule that a physical appropriation of property gave rise to a *per se* taking, without regard to other factors”). The affordability program would enact a taking of Teva’s autoinjectors, and the Fifth Amendment renders that taking unconstitutional unless just compensation is provided.

II. Teva's Motion for a Preliminary Injunction

Teva's complaint seeks a permanent injunction and a declaration that the affordability program is unconstitutional. Doc. 26. In addition, Teva has moved for a preliminary injunction to block the reimburse or resupply requirement during the pendency of this suit. Docs. 2, 3. Many of the State's arguments against the preliminary injunction mirror the arguments in its Motion to Dismiss. *See generally*, Doc. 20. Those arguments, already addressed above, will not be repeated here. The only remaining argument is whether injunctive relief is available for the harm that Teva alleges it would incur.

Equitable relief in the form of a preliminary injunction is only justified if a plaintiff will suffer "irreparable injury" during the pendency of the case without an injunction. *Beltronics USA, Inc. v. Midwest Inventory Distrib.*, 562 F.3d 1067, 1070 (10th Cir. 2009); *Schrier v. University of Co.*, 427 F.3d 1253, 1267 (10th Cir. 2005) ("The purpose of a preliminary injunction is not to remedy past harm but to protect plaintiffs from irreparable injury that will surely result without their issuance."). "What makes an injury 'irreparable' is the inadequacy of, and the difficulty of calculating, a monetary remedy after a full trial." *Free the Nipple v. City of Fort Collins*, 916 F.3d 792, 806 (10th Cir. 2019) (quoting *Awad v. Ziriak*, 670 F.3d 1111, 1131 (10th Cir. 2012)).

This presents an incongruity in the law. Teva seeks to enjoin the taking of its property without compensation. Such a taking would violate Teva's constitutional rights, and that alone is usually an irreparable injury. *Id.* ("Most courts consider the infringement of a constitutional right enough and require no further showing of irreparable injury."). But "[i]t is also well settled that simple economic loss usually does not, in and of itself, constitute irreparable harm; such losses are compensable by monetary damages." *Heideman v. South Salt Lake City*, 148 F.3d 1182, 1189

(10th Cir. 2003). To resolve this incongruity, courts typically treat takings claims as compensable, rather than irreparable, making even permanent injunctive relief unavailable in most cases. *See Knick*, 139 S. Ct. at 2198; *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016 (1984) (“Equitable relief is not available to enjoin an alleged taking of private property for a public use.”). “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.

As Teva points out, however, the property owner’s means of obtaining compensation must be “adequate” to preclude injunctive relief. *See Regional Rail Reorganization Act Cases*, 419 U.S. 102, 107, 149, (1974) (reversing an injunction because “the availability of the Tucker Act guarantees an *adequate remedy at law* for any taking which might occur” (emphasis added)); *Hurley v. Kincaid*, 285 U.S. 95, 99, 105, (1932) (declining to “enjoin the carrying out of any work” because the Tucker Act provided “a plain, *adequate*, and complete remedy at law”) (emphasis added); *Cherokee Nation v. Southern Kan. Ry. Co.*, 135 U.S. 641, 659 (1890) (denying injunctive relief where compensation was “sufficiently reasonable, certain, and *adequate*”) (emphasis added). Adequacy of a legal remedy, for these purposes, is considered under the hundred-year-old test from *Terrace v. Thompson*, 263 U.S. 197 (1923). While weighing whether to issue injunctive relief in that case, the Supreme Court was clear “[t]hat a suit in equity does not lie where there is a plain adequate and complete remedy at law is so well understood as not to require the citation of authorities. *But the legal remedy must be as complete, practical and efficient as that which equity could afford.*” *Id.* at 214 (emphasis added).

Teva argues that it has no legal remedy as complete, practical and efficient as injunctive relief. According to Teva, the only legal remedy

that could compensate for the reimburse or resupply taking would be an endless series of state suits for monetary damages. The affordability act has no sunset clause, and the applicable statute of limitations is two years. And as discussed above, the number of autoinjectors that Teva will have to resupply is nowhere near certain. Teva believes that to get just compensation in the form of monetary damages, it would be required to keep track of every autoinjector it resupplies, determine its fair market value, and then bring biannual suits against the State of Colorado to compensate for two years' worth of taken autoinjectors. That process, Teva argues, would be neither practical nor efficient.

The argument has some force. A repetitive multiplicity of suits can render a legal remedy inadequate. *Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935) (“Avoidance 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 in the federal courts.”); *Hale v. Allinson*, 188 U.S. 56, 72–78 (collecting cases). But the possibility of multiplicity does not *ensure* equity is available. *Di Giovanni*, 296 U.S. at 71 (“The single fact that a multiplicity of suits may be prevented by this assumption of jurisdiction is not in all cases enough to sustain it.”); *Hale*, 188 U.S. at 77 (“Cases in sufficient number have been cited to show how divergent are the decisions on the question of jurisdiction. It is easy to say it rests upon the prevention of a multiplicity of suits, but to say whether a particular case comes within the principle is sometimes a much more difficult task.”).

In the context of a takings claim, however, the longstanding recognition that compensation is an adequate remedy makes this harder to apply. Teva relies on *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998). *Apfel* is useful, but not dispositive. First, it did not turn on the “multiplicity of suits” theory Teva relies on, but rather on the observation that

compensation for a taking purely of money “would entail an utterly pointless set of activities” (i.e., the plaintiffs there paying money into a fund only to be reimbursed by the government). *Id.* at 521. Second, that view was adopted by only four justices in a plurality opinion. The fifth vote, which came from Justice Kennedy, was based on Due Process rather than the Takings Clause. *Id.* at 539. The Tenth Circuit has declined to apply *Apfel* because the non-plurality majority of the Court, consisting of four dissenters and concurring Justice Kennedy, found that the case did not implicate the Fifth Amendment Takings Clause. *See Gordon v. Norton*, 322 F.3d 1213, 1217 (10th Cir. 2003). It also distinguished continuous physical takings from “the statutory taking of monetary assets” that occurred in that case. *Id.* at 1218.

More on point is *Pharmaceutical Research and Manufacturers of America v. Williams*, 64 F.4th 932 (8th Cir. 2023) (“*PhRMA*”). In that case, Minnesota enacted a law very much like Colorado’s Affordability Program. It required pharmacies to dispense insulin to qualifying individuals, while charging no more than a \$35 co-pay. *Id.* at 938. The pharmacies could then demand that the manufacturer of the insulin either “reimburse the pharmacy in an amount that covers the pharmacy’s acquisition cost” or “send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed.” Minn. Stat. § 151.74(3)(d). After that law went into effect, a trade group of pharmaceutical companies sought to have it enjoined and declared an unconstitutional taking.

The district court dismissed the case, but the Eighth Circuit reversed, holding that *PhRMA*’s only legal remedy was inadequate “because *PhRMA*’s members would be ‘bound to litigate a multiplicity of suits’ to be compensated.” *PhRMA*, 64 F.4th at 945 (quoting *Equitable Life Assur. Soc. v. Wert*, 102 F.2d 10 (8th Cir. 1939)). The Eighth Circuit

acknowledged that *Knick* repeatedly warned against enjoining government takings. *Id.* at 941 (citing *Knick*, 139 S.Ct. at 2176). But it reasoned that “*Knick* does not hold that every state’s compensation remedy is adequate in a particular situation; implicit in *Knick* is the requirement that just compensation must be available to petitioners seeking a remedy.” *Id.* The panel concluded that repetitive suits for damages were not “complete practical and efficient,” and injunctive relief was appropriate. *Id.* (quoting *Terrace*, 263 U.S. at 214).

PhRMA is not binding, and Teva points to no similar decision that is. The Tenth Circuit, for its part, has never recognized that a multiplicity of suits renders legal remedies inadequate in the takings context. *See Gordon*, 322 F.3d at 1216. And while *PhRMA* is nearly on all fours with this case, a key difference remains. *PhRMA* did not seek *preliminary* injunctive relief. In fact, not a *single* case cited by Teva granted preliminary relief to enjoin a taking.

Teva’s case is based on the proposition that it would be bound to bring an infinite series of takings suits against the State for the foreseeable future. That may end up being true, in which case a declaratory judgment or permanent injunction may be appropriate as part of a final judgment. But it does not warrant extraordinary preliminary relief. “[T]he limited purpose of a preliminary injunction ‘is merely to preserve the relative positions of the parties until a trial on the merits can be held.’” *Schrier*, 427 F.3d at 1258 (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). Preliminary relief is not appropriate unless the harm “during the time it will take to litigate this case” would make it “impossible to . . . restore the status quo ante in the event they prevail.” *Heideman*, 348 F.3d at 1189. That is why “[a] preliminary injunction is an extraordinary remedy, the exception rather than the rule.” *Mrs. Fields Franchising, LLC v. MFGPC*, 941 F.3d 1221, 1232 (10th

Cir. 2019). “District courts have discretion over whether to grant preliminary injunctions.” *FTN*, 916 F.3d at 796. And one may be granted “only when the movant’s right to relief is clear and unequivocal.” *McDonnell v. City & Cty. of Denver*, 878 F.3d 1247, 1257 (10th Cir. 2018).

Even if Teva is right that it would be required to indefinitely bring multiple, repetitive, complicated suits under this law, and that that renders any compensation constitutionally inadequate, that is not true of the time during the pendency of this case. Teva would not have an incalculable or infinite number of takings claims occur in the limited timeframe between now and the conclusion of this suit. Any takings claims that accrue between now and the final resolution of this suit can be compensated for with a finite set of, or possibly even a single, lawsuit.⁴ The possible redundancy and inefficiency of future suits for monetary relief may eventually require injunctive relief. But it does not apply during the pendency of this suit, so preliminary relief must be denied.

⁴ Teva argues that valuation alone would be extremely difficult, as the wholesalers’ and distributors’ prices vary and the amount of “just compensation” due for each set of autoinjectors would too. The State disputes this. The hearing did not clarify the answer to this dispute over the operation of the law, and that uncertainty further undermines the propriety of a preliminary injunction at this early stage of the litigation.


CONCLUSION

It is **ORDERED** that:

Plaintiff's Motion for a Preliminary Injunction, **Doc. 2**, and Defendants' Motion to Dismiss, **Doc. 29**, are both **DENIED**.

DATED: December 27, 2023

BY THE COURT:

A handwritten signature in black ink, appearing to read 'Daniel D. Domenico', is written over a horizontal line.

Daniel D. Domenico
United States District Judge