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

APPELLANTS' OPENING BRIEF

ORAL ARGUMENT IS REQUESTED

Respectfully submitted,

PHILIP J. WEISER
Attorney General

PAWAN NELSON*
Assistant Attorney General

JENNIFER JOHNSON**
Assistant Attorney General

1300 Broadway, 10th Floor
Denver, Colorado 80203
Telephone: 720-508-6628
Email: pawan.nelson@coag.gov;
Jennifer.johnson@coag.gov

* Counsel of Record for AG Weiser

** Counsel of Record for Patricia A. Evacko, Erick Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli

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The Defendants-Appellants Colorado Attorney General Philip J. Weiser and Colorado State Board of Pharmacy members Patricia A. Evacko, Eric Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli (collectively, "State Officials") respectfully submit the following Opening Brief:

STATEMENT OF RELATED CASES

There are no related district court or appellate cases.

JURISDICTIONAL STATEMENT

Plaintiff-Appellee Teva Pharmaceuticals USA, Inc. ("Teva") alleged that the district court had jurisdiction over the claims in its complaint pursuant to 28 U.S.C. § 1331. (App. Vol. I at 15, 119).[1] In their Motion to Dismiss, the State Officials argued that they had Eleventh Amendment immunity, and therefore the district court lacked subject matter jurisdiction. (*See* App. Vol. I at 152-56, 197-201). The district court denied

[1] Consistent with 10th Cir. R. 28.1(A)(1), references to the appendix in this brief use the convention of appendix volume followed by page number. References to transcripts in the appendix will use the convention of appendix volume, followed by page number and line number. For example, "App. Vol. II at 233:22-234:20" refers to the text starting on page 233, line 22 in Appendix Volume 2 and ending on page 234, line 20 in Appendix Volume 2.

the State Officials' Motion to Dismiss and retained jurisdiction over this case on December 27, 2023. (*See* App. Vol. II at 335-347).

The district court's denial of the State Official's Motion to Dismiss, specifically, its finding that Eleventh Amendment sovereign immunity does not deprive it of subject matter jurisdiction over Teva's claims, is immediately appealable under the collateral order doctrine. *See Puerto Rico Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993) ("'arms of the state' may take advantage of the collateral order doctrine to appeal a district court order denying a claim of Eleventh Amendment immunity"); *Opala v. Watt*, 454 F.3d 1154, 1157 (10th Cir. 2006) ("28 U.S.C. § 1291 … provides for interlocutory appeal of orders denying motions to dismiss brought on the basis of Eleventh Amendment immunity). The State Officials timely filed their notice of appeal on January 26, 2024. (App. Vol. II at 371-72).

STATEMENT OF THE ISSUE

Whether the Eleventh Amendment bars Teva from bringing a Fifth Amendment Takings Clause claim against the State Officials in federal

court when just compensation remedies are available in Colorado state court.

STATEMENT OF THE CASE

The Epinephrine Affordability Crisis.

Anaphylaxis—a severe allergic reaction—is provoked by a variety of causes, happens suddenly, and is life-threatening. (*See* App. Vol. I at 67 (citing to Teva Epinephrine, https://www.tevaepinephrine.com/)). Epinephrine addresses anaphylaxis by rapidly improving breathing, preventing airways from closing, decreasing shock, and reducing swelling, among other things. (*See* App. Vol. I at 88 (§1(b))). For more than 500,000 Coloradans, an epinephrine auto-injector (colloquially referred to as "EpiPen®") 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))). Indeed, Teva counsels patients to "always carry your Epinephrine Injection (Auto-Injector) with you because you may not know when anaphylaxis may happen." (*See* App. Vol. I at 67 (quoting Teva Epinephrine, https://www.tevaepinephrine.com/)).

Unfortunately, wielding their inherent market power, epinephrine auto-injector manufacturers have driven up the price of epinephrine auto-injectors for years. (*See* App. Vol. I at 67-68 & n.1, 150 & n.1).[2] The price increases have been so steep that Colorado is now facing an affordability crisis, forcing those with serious health conditions to make the life and death choice between purchasing or forgoing an epinephrine auto-injector. (*See, e.g.*, App. Vol. I at 88 (§§1(f)-(g))).

The Affordability Program.

To increase access to life-saving epinephrine auto-injectors, Colorado's General Assembly passed HB23-1002. (*See* App. Vol. I at 87-

[2] The rising price of epinephrine auto-injectors has attracted scrutiny from Congress. *See, e.g., Reviewing the Rising Prices of EpiPens*, Hearing Before the House Committee on Oversight and Government Reform, 114th Cong. 114-124 (2016), available at https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/pdf/CHRG-114hhrg24914.pdf. Epinephrine auto-injector pricing has also spawned extensive litigation, some of which has been consolidated in the District of Kansas for pretrial proceedings. *See, e.g.*, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 979-80 (10th Cir. 2022).

96). Among other things,[3] 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 autoinjectors, to obtain a two-pack of epinephrine auto-injectors for $60 (the "Affordability Program"). (App. Vol. I at 89-94 (§ 3)). The Affordability Program is codified at C.R.S. § 12-280-142 and took effect on January 1, 2024. (App. Vol. I at 89, 91 (§ 3(2))).

The Affordability Program allows eligible individuals to complete an application form that they may then take to a pharmacy with other documentation demonstrating eligibility. *See* C.R.S. §§ 12-280-142(4)-(5). If the individual satisfies the requirements, a pharmacy must dispense the epinephrine auto-injectors and charge the individual no more than $60 for a two-pack of epinephrine auto-injectors. *See* C.R.S. §§ 12-280-142(6)-(7).

[3] HB23-1002 also set a $60 price cap on insurance copayments for epinephrine auto injectors. (App. Vol. I at 88-89 (§ 2)). Teva does not challenge the $60 price cap, conceding that it "is indisputably within the State's regulatory authority." (*Id.* at 59-60; *see also* App. Vol. II at 274:12-22).

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. *See* C.R.S. § 12-280-142(8). Alternatively, the manufacturer may agree to send the pharmacy a replacement supply of epinephrine auto-injectors equal to the number of auto-injectors dispensed through the Program. *See* C.R.S. § 12-280-142(8)(c)(II).

A manufacturer that fails to comply with the requirements of the Affordability Program may be subject to discipline by the Colorado Board of Pharmacy ("Pharmacy Board"), a fine imposed by the Pharmacy Board, and potential civil liability through a consumer protection enforcement action brought under C.R.S. § 6-1-105(1)(zzz). *See* C.R.S. §§ 12-280-126(1)(c)(I), 12-280-142(11).

Teva's Lawsuit and Motion for Preliminary Injunction.

Unhappy with the policy approach the Colorado legislature took to address the epinephrine auto-injector affordability crisis, Teva filed suit in the district court and moved for a preliminary injunction on October 3,

2023, three months before the Affordability Program became effective. (*See* App. Vol. I at 12-25, 26-42, 46-66).

Teva is one of five manufacturers of epinephrine auto-injectors for the U.S. market. (*See* App. Vol. II at 233:22-234:20). Along with pharmaceutical companies Viatris, Amneal, and Kaleo, Teva produces generic epinephrine auto-injectors. (*See id.*) Teva currently manufactures generic epinephrine auto-injectors in two sizes: .3 mg and .15 mg for children. (App. Vol. I at 29 (¶ 2), 118 (¶ 5)).[4]

Teva does not sell its epinephrine auto-injectors directly to pharmacies in Colorado. (*See* App. Vol. I at 29 (¶ 4); App. Vol. II at 235:10-22). Rather, Teva sells its product to wholesalers or distributors, who in turn sell the epinephrine auto-injectors to pharmacies. (*Id.*)[5] Teva sells a

[4] The circumstances surrounding the development of Teva's generic epinephrine auto-injector – and its alleged connection to inflated prices in the market – is currently the subject of a putative class action pending in the District of Kansas. *See Edgar et al. v. Teva Pharmaceutical Indus. Ltd. et al.*, No. 22-2501-DDC-TJJ, 2024 WL 1282436, at *1 (D. Kan. Mar. 26, 2024) (denying Teva's motion to dismiss in part).

[5] For further background on the distribution and pricing for epinephrine auto-injectors, please see this Court's discussion in *In re EpiPen*, 44 F.4th at 964-68.

two-pack of its epinephrine auto-injectors to wholesalers at a wholesale acquisition cost of $300. (App. Vol. I at 29 (¶ 3); App. Vol. II at 235:23-236:17).

Teva estimates that approximately 14,000 of its epinephrine auto-injectors were shipped to Colorado from June 30, 2022 through June 30, 2023, but is unable to say, or provide any data as to, how many of those 14,000 epinephrine auto-injectors were sold to individuals who would have qualified for the Affordability Program. (App. Vol. I at 30 (¶ 7); App. Vol. II at 239:3-240:12, 246:6-248:12).

In its Amended Complaint,[6] Teva alleged that the (not yet in effect) Affordability Program violated the Fifth Amendment's Takings Clause and sought: (1) a declaration that the Affordability Program violates the Takings Clause and (2) preliminary and permanent injunctive relief barring the State Officials from enforcing the Affordability Program. (*See* Vol. I at 126-29). In its Motion for Preliminary Injunction, Teva argued

[6] On October 31, 2023, Teva amended its Complaint and added the Pharmacy Board Members as defendants. (App. Vol. I at 116-130). Teva then voluntarily dismissed Michael Conway, the Commissioner of the Colorado Division of Insurance, as a defendant. (*Id.* at 164-67).

that it was likely to succeed on the merits because the (not yet in effect) Affordability Program would effect an uncompensated taking of Teva's property. (*See* App. Vol. I at 57-60). Relying on the Eighth Circuit's decision in *Pharm. Rsch. & Mfrs. Of Am. v. Williams*, 64 F.4th 932 (8th Cir. 2023) ("*PhRMA*"), Teva argued that it would suffer irreparable injury because it would allegedly need to file "a continuous series of repetitive damages actions seeking compensation for each epinephrine auto-injector commandeered by the program." (App. Vol. I at 60; *see also id.* at 61-64).

The State Officials opposed Teva's Motion for Preliminary Injunction (*see* App. Vol. I at 67-86, 169-73) and filed a Motion to Dismiss (*see id.* at 149-63, 174-76). Pointing to this Court's decision in *Williams v. Utah Dep't of Corrs.*, 928 F.3d 1209 (10th Cir. 2019), the State Officials argued that the Eleventh Amendment bars Fifth Amendment takings claims against state officials in federal court provided that the plaintiff has a remedy in state court. (*See* App. Vol. I at 70-73, 152-53; App. Vol. II at 312:20-313:11, 314:15-24). Because Colorado provides Teva with a state court just compensation remedy, the State Officials argued that the

district court lacked subject matter jurisdiction under the Eleventh Amendment. (*See* App. Vol. I at 73-74, 81-83, 152-56, 197-201; App. Vol. II at 311:23-312:7, 315:20-316:20, 323:4-12, 325:23-326:9).

The District Court's Order.

The district court held a hearing on Teva's Motion for Preliminary Injunction and the State Officials' Motion to Dismiss on December 18, 2023. (App. Vol. II at 270-334). On December 27, 2023, the district court issued its Order Denying Plaintiff's Motion for Preliminary Injunction and Defendants' Motion to Dismiss. (*See* App. Vol. II at 335-355). The district court found that Teva had failed to demonstrate irreparable harm since it would not suffer an "incalculable or infinite number of takings claims" in the "limited timeframe between now and the final resolution of this suit," and that any takings that accrued before final resolution could be "compensated with a finite set, or even single lawsuit." (*Id.* at 354). The district court properly denied Teva's Motion for Preliminary Injunction.[7] (*See id.*)

[7] Neither Teva nor the State Officials are appealing this aspect of the district court's Order.

However, the district court improperly denied the Defendants' Motion to Dismiss. After rejecting the Defendants' justiciability arguments, *(id.* at 339-46), the district court concluded that because Teva only requested prospective injunctive relief, Teva's claims fell within the *Ex parte Young* exception to the Eleventh Amendment. (*Id.* at 346-47). The district court noted that the "Tenth Circuit, for its part, has never recognized that a multiplicity of suits renders legal remedies inadequate in the takings context." (*Id.* at 353 (citing *Gordon v. Norton*, 322 F.3d 1213, 1216 (10th Cir. 2003))). Nevertheless, the district reasoned that Teva might have to bring "an infinite series of takings suits against the State for the foreseeable future," in which "case a declaratory judgment or permanent injunction may be appropriate as part of a final judgment." (App. Vol. II at 353). The district court did not explicitly address the State Officials' argument that the availability of Colorado state court remedies provided them with Eleventh Amendment immunity under *Williams*.

The State Officials timely filed their Notice of Appeal on January 26, 2024. (*Id.* at 371-72).

SUMMARY OF THE ARGUMENT

The district court's order denying the State Officials' Motion to Dismiss should be reversed and Teva's case should be dismissed. The Eleventh Amendment bars Fifth Amendment Takings Clause claims against state officials when a remedy is available in state court. *See Williams v. Utah Dep't of Corr.*, 928 F.3d 1209, 1213-14 (10th Cir. 2019). Here, compensation remedies are available to Teva in Colorado's state courts for any alleged takings of its epinephrine auto-injectors. Accordingly, the Eleventh Amendment bars Teva's Takings Clause claims against the State Officials.

The *Ex parte Young* exception does not allow Teva to remain in federal court. Compensation–not injunctive relief–is the remedy for a Takings Clause violation. As a result, for over a century (and most recently in *Knick v. Twp. Of Scott*, 588 U.S. 180 (2019)), the Supreme Court has repeatedly instructed courts that equitable relief is not available to enjoin an alleged taking when a suit for compensation can be brought after the taking. Because compensation remedies are available

to Teva in Colorado state court, the district court erred in relying on *Ex parte Young* to retain jurisdiction over the State Officials.

The district court's fear that Teva could, theoretically, be required to bring multiple suits against Colorado for its epinephrine auto-injectors dispensed under the Affordability Program does not mean injunctive relief is available to Teva for its Takings Clause claim. This "multiplicity of suit" rationale has no basis in the Takings Clause, has never been recognized by this Court, and is incorrect as a practical matter given well-established preclusion principles. Federal courts have repeatedly held that Colorado's just compensation remedies are adequate for Taking Clause purposes. The district court erred by adopting the "multiplicity of suit" rationale to reason that Teva may be entitled to permanent injunctive relief as part of a final judgment and retaining jurisdiction over the State Officials.

States have a special status and an important policymaking role in our federal system. Sovereign immunity prevents states and state officials from being involuntarily dragged into federal court at the behest of private parties. In this case, Colorado's legislature adopted the

Affordability Program to address a pressing public health issue. Teva may disagree with Colorado's approach, but it cannot use the Takings Clause and the federal courts to completely block the Affordability Program simply because the Affordability Program may have an economic effect on Teva in the future. By retaining jurisdiction, the district court has provided an opening for private parties to use the coercive injunctive power of the federal courts to attack state economic regulations simply because those regulations may impose future economic costs. To uphold important principles of sovereign immunity and federalism, the district court's denial of the State Officials' Motion to Dismiss should be reversed and this case should be dismissed.

ARGUMENT

It is well-settled that the Fifth Amendment's Takings Clause "does not prohibit the taking of private property, but instead places a condition on the exercise of that power." *First Eng. Evangelical Lutheran Church of Glendale v. Los Angeles Cnty.*, 482 U.S. 304, 314 (1987) (citations omitted). For over 130 years, that condition has simply been that a plaintiff must have some way to secure compensation after a taking has

occurred. *See, e.g.*, *Cherokee Nation v. S. Kan. Ry. Co.*, 135 U.S. 641, 658-59 (1890); *Knick*, 588 U.S. at 198-99. Because obtaining compensation is the remedy for a taking, "[a]s long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Knick*, 588 U.S. at 201.

In this case, Teva has requested injunctive relief, but it can obtain *complete* compensation for any purported taking that occurs in the future through well-established compensation remedies available in Colorado state court. Nevertheless, the district court retained jurisdiction over the State Officials by applying the *Ex parte Young* doctrine and using a "multiplicity of suit" theory that has no basis in the Takings Clause. Since the district court's novel approach will transform the Takings Clause and subvert important principles of sovereign immunity and federalism, the district court's denial of the State Officials' Motion to Dismiss should be reversed and this case should be dismissed.

Standard of Review

The denial of a motion to dismiss based on Eleventh Amendment immunity is reviewed de novo. *Couser v. Gay*, 959 F.3d 1018, 1026 (10th

Cir. 2020) (citation omitted); *Crumpacker v. Kansas Dep't of Hum. Res.*, 338 F.3d 1163, 1168 (10th Cir. 2003).

I. The Eleventh Amendment bars Teva's Takings Clause claims against the State Officials because state compensation remedies are available.

States have sovereign immunity from suits brought in federal court by its own citizens or citizens of other states. *See Alden v. Maine*, 527 U.S. 706, 712 (1999); *Williams*, 928 F.3d at 1212. Sovereign immunity serves the important function of preserving the "dignity" to which states are entitled "as residuary sovereigns and joint participants in the governance of the Nation." *Alden*, 527 U.S. at 713-14, 748-49. It does so by preventing states from being involuntarily "dragged" into any court—a prerogative of sovereigns well established at the time of the founding. *See id.* at 715-18.

"The Eleventh Amendment confirmed, rather than established, sovereign immunity as a constitutional principle[.]" *Id.* at 728-29. "'The very object and purpose of the 11th Amendment were to prevent the indignity of subjecting a State to the coercive process of judicial tribunals at the instance of private parties.'" *Puerto Rico Aqueduct*, 506 U.S. at 146

(quoting *In re Ayers,* 123 U.S. 443, 505 (1887)). "Once effectively asserted, Eleventh Amendment immunity constitutes a bar to the exercise of federal subject matter jurisdiction." *Williams*, 928 F.3d at 1212 (alterations, quotation marks, and citation omitted).

"[T]he rule has evolved that a suit by private parties seeking to impose a liability which must be paid from public funds in the state treasury is barred by the Eleventh Amendment." *Edelman v. Jordan*, 415 U.S. 651, 663 (1974) (citations omitted). Therefore, the Eleventh Amendment bars damages actions in federal court against states, state agencies, and state officials acting in their official capacity—like the State Officials. *See Williams*, 928 F.3d at 1212.

The remedy for a Takings Clause violation is compensation. *See Knick*, 588 U.S. at 193, 201 (citing *First Eng.*, 482 U.S. at 316). Accordingly, the Eleventh Amendment also bars Takings Clause claims against state officials in federal court when state compensation remedies are available. The Tenth Circuit applied this principle in *Williams v. Utah Dep't of Corr.*, 928 F.3d 1209 (10th Cir. 2019). In *Williams*, the plaintiff brought takings claims against a state agency and several state

officials alleging that they improperly retained the interest earned on inmate bank accounts. *Id.* at 1211-12. The plaintiff sought monetary damages and injunctive relief. *See id.* at 1211-15. Although the district court in *Williams* did not address the defendants' Eleventh Amendment immunity arguments, the *Williams* court deemed the issue important enough to consider sua sponte. *Id.* at 1212. The *Williams* court noted that other courts "that have considered whether a claim under the Fifth Amendment Takings Clause is barred by Eleventh Amendment immunity have held that it is barred, as long as a remedy is available in state court." *Id.* at 1213. After concluding that the plaintiff's "takings claim may be brought in Utah state court," the court held that the plaintiff's takings claims "must be dismissed based on Eleventh Amendment immunity" and remanded to the district court with instructions to dismiss. *Id.* at 1214.

Multiple circuits have adopted the rule discussed in *Williams* and have recognized that takings claims against a state, state agency, or state official are barred in federal court when the plaintiff can obtain adequate compensatory relief through the state's courts. *See 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, 580-82 (6th Cir. 2020); *Bay Point Props., Inc. v. Miss. Transp. Comm'n*, 937 F.3d 454, 455-57 (5th Cir. 2019); *Maine Educ. Ass'n Benefits Trust v. Cioppa*, 695 F.3d 145, 152 n.3 (1st Cir. 2012); *Seven Up Pete Venture v. Schweitzer*, 523 F.3d 948, 955-56 (9th Cir. 2008); *Harbert Intern., Inc. v. James*, 157 F.3d 1271, 1277-79 (11th Cir. 1998).

Therefore, if Teva has an available remedy in Colorado state court, then its Takings Clause claims against the State Officials are barred by the Eleventh Amendment. Here, it is undisputed Colorado provides means for obtaining compensation after a taking. Colorado provides a cause of action in Colorado state court for just compensation directly under the Colorado Constitution. *See* Colo. Const. Art. II, § 15; *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).

These just compensation procedures would provide Teva with full and complete compensation, including compensation for the products, attorneys' fees, and interest from the time of the taking. *See, e.g.*, Colo. Jury Instr., Civil 36:3 (noting that "value of property actually taken" is its "reasonable market value"); C.R.S. § 38-1-116 (prejudgment interest available); C.R.S. § 38-1-122 (attorneys' fees available); *see also Game and Fish Comm'n*, 426 P.2d at 565-66 (plaintiff bringing takings claim against agency without eminent domain power not limited to measure of damages usually applicable in condemnation case).

Teva's epinephrine auto-injectors are identical physical products with a value that can be easily determined. Any economic loss Teva experiences because of the Affordability Program can be fully remediated through a just compensation proceeding in Colorado state court. Teva has never disputed that these proceedings are available. It may not be Teva's preferred approach, but the fact of the matter is Teva can obtain full and complete just compensation with available state court remedies. That is all that is required under the Fifth Amendment. Since Teva's claim may be brought in Colorado state court, Teva's Takings Clause claims against

the State Officials must be dismissed under the Eleventh Amendment. *See Williams*, 928 F.3d at 1214.

II. The district court erred by concluding that it had jurisdiction under *Ex Parte Young* since injunctive relief is not available for this Takings Clause claim.

In its Order, the district court did not address *Williams* or consider Colorado's available state court remedies. Rather, the district court concluded that it had jurisdiction over the State Officials under *Ex parte Young* because Teva requested prospective injunctive and declaratory relief for an alleged ongoing constitutional violation. (App. Vol. II at 346-47). However, because that conclusion conflicts with the well-settled principles governing the remedies that are available in the Takings Clause context, the district court's order should be reversed.

The *Ex parte Young* doctrine allows certain suits for declaratory or injunctive relief against state officers acting in their official capacities to proceed in federal court. *See, e.g., Ex parte Young*, 209 U.S. 123, 155-56 (1908). Under that doctrine, suits seeking prospective injunctive relief for ongoing constitutional violations are allowed while suits seeking retroactive relief, such as monetary payments for past violations, are not.

See, e.g., Edelman, 415 U.S. at 677. Application of the *Ex parte Young* exception should be "tailored to conform as precisely as possible to those specific situations in which it is necessary to permit the federal courts to vindicate federal rights." *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 277 (1997) (internal quotation marks and citations omitted).

The problem with applying *Ex parte Young* in the Takings Clause context is that injunctive relief is not the way courts vindicate a plaintiff's rights under the Takings Clause. The Takings Clause states that no private property shall "be taken for public use, without just compensation." U.S. Const. amend V. As its language indicates, the Takings Clause "does not prohibit the taking of private property, but instead places a condition on the exercise of that power." *First Eng.*, 482 U.S. at 314 (citations omitted). The Takings Clause was designed not "to limit governmental interference with property rights *per se*, but rather to secure *compensation* in the event of otherwise proper interference amounting to a taking." *Id.* at 315 (emphasis in original). Compensation need not precede the taking nor be contemporaneous with a taking. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016 (1984). All that is

required is "reasonable, certain and adequate provision for obtaining compensation after a taking." *Knick*, 588 U.S. at 198 (internal quotation marks and citation omitted); *see also, e.g., Zito*, 8 F.4th at 288. This law has been well-settled for nearly 130 years. *See Cherokee Nation*, 135 U.S. at 658-59; *Knick*, 588 U.S. at 199-201.

Since compensation is all that is required under the Takings Clause, the Supreme Court has repeatedly emphasized that injunctive relief is not available for takings claims where a plaintiff can obtain just compensation. In 1932, the Supreme Court held that the Takings Clause "affords no basis for an injunction if [ ] compensation may be procured in an action at law." *Hurley v. Kincaid*, 285 U.S 95, 104 (1932). Over fifty years later, the Supreme Court confirmed this principle stating, "[e]quitable relief is not available to enjoin an alleged taking of private property for a public use, duly authorized by law, when a suit for compensation can be brought against the sovereign subsequent to the taking." *Ruckelshaus* 467 U.S. at 1016 (citation omitted). Twenty-five years after *Ruckelshaus*, the Supreme Court, *once again*, stated, "[a]s

long as just compensation remedies are available . . . injunctive relief will be foreclosed." *Knick*, 588 U.S. at 205.

In *Knick*, the Supreme Court described how this rule developed. Initially, injunctive relief was available for takings claims because plaintiffs had no means of redressing a violation of the Takings Clause. *Id.* at 199-200. "But in 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." *Id.* at 200. "Today, 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." *Id.* at 201. That is, "[a]s long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Id.*

Unsurprisingly, several circuits have held that *Ex parte Young* does not apply to a Takings Claim where—like here—there is an adequate remedy at law. *See, e.g.*, *EEE Minerals*, 81 F.4th at 816 (even if plaintiff was seeking prospective injunctive relief for his takings claims, *Ex parte*

Young would not apply because, "equitable relief is unavailable to enjoin an alleged taking of private property where, as here, a remedy at law is available through a suit for just compensation in state court.") (citations omitted); *Laborers' International Union of North America, Local 860 v. Neff*, 29 F.4th 325, 334 (6th Cir. 2022) (noting that plaintiff could file action in state court and concluding that the "availability of a legal remedy does not on its own bar the damages claims. But it does preclude an injunction."); *Long v. Area Manager Bureau of Reclamation*, 236 F.3d 910, 917 (8th Cir. 2001) ("Even if we were to find that a taking occurred in Mr. Long's case, however, we could not grant an injunction against the state official. 'Equitable relief is not available to enjoin an alleged taking of private property ... when a suit for compensation can be brought against the sovereign subsequent to the taking'" (quoting *Ruckelshaus*, 467 U.S. at 1016)).

Multiple district courts have followed suit and have also held that *Ex parte Young* does not apply to takings claims where the plaintiff has an adequate remedy at law. *See Los Molinos Mutual Water Company v. Ekdahl*, --- F.Supp.3d ---, 2023 WL 6386898, *7-8 (E.D. Cal. Sept. 29,

2023) ("When viewed from this remedial perspective, plaintiffs' [complaint] does not satisfy the *Ex parte Young* exception because prospective injunctive relief is not available to them based on the allegations in their [complaint]."); *Virginia Hospital & Healthcare Ass'n v. Roberts*, 671 F.Supp.3d 633, 668-69 (E.D. Va. 2023) (rejecting plaintiff's *Ex parte Young* argument: "because Plaintiffs seek to enforce their Takings Clause claim through injunctive relief and a suit can be brought against DMAS in state court to seek just compensation, Plaintiffs' claim against DMAS is barred by Eleventh Amendment immunity."); *Culinary Studios, Inc. v. Newsom*, 517 F.Supp.3d 1042, 1064-65 (E.D. Cal. 2021) (holding that court's conclusion that just compensation can be had by the plaintiffs "forecloses operation of *Ex parte Young* with respect to the State officials.").

Teva has brought a Takings Clause claim, contending that the State Officials' enforcement of the Affordability Program will violate its Fifth Amendment rights. (*See* App. Vol. I at 126-28). The remedy for any alleged taking of Teva's property pursuant to the Affordability Program is compensation. But, Teva has requested injunctive and declaratory

relief. (*Id.* at 128-29). As established above, there are just compensation remedies available in Colorado state court that could provide Teva with complete compensation should a taking ever occur. Since Teva has an adequate remedy at law, injunctive relief is not available, and *Ex parte Young* does not apply. Thus, the district court erred in applying *Ex parte Young*, and should be reversed.

III. The district court erred by concluding that a theoretical multiplicity of suits could justify permanent injunctive relief in this Takings Clause case.

Teva does not dispute that just compensation remedies are available to it in Colorado state court. (App. Vol. I at 183-188). Teva also does not aver that monetary damages would fail to make them whole for any alleged taking conducted pursuant to the Affordability Program. (*Id.*) Rather, Teva contends that its state court remedies are inadequate because it will be subject to a multiplicity of suits for as long as the Affordability Program is in place. (*Id.* at 187-88). The district court recognized that "courts typically treat takings claims as compensable, rather than irreparable, making even permanent injunctive relief unavailable in most cases." (App. Vol. II at 350 (citing *Knick*, 139 S. Ct.

at 2198 and *Ruckelshaus*, 467 U.S. at 1016)). But the district court concluded that it may be true that Teva "would be bound to bring an infinite series of takings suits against the State for the foreseeable future," so "a declaratory judgment or permanent injunction may be appropriate as part of a final judgment." (App. Vol. II at 353). Because this multiplicity of suit rationale is incorrect both legally and practically, the district court should be reversed.

This multiplicity of suit theory is incorrect as a legal matter because it has no basis in the Takings Clause. Teva's multiplicity of suit argument is based entirely on the Eighth Circuit's decision in *PhRMA*, 64 F.4th 932. (*See, e.g.,* App. Vol. I at 183-88). But, as discussed above, the Takings Clause only requires "reasonable, certain, and adequate provision for obtaining compensation," *Cherokee Nation*, 135 U.S. at 659, which means that a property owner has "some way to obtain compensation after the fact." *Knick*, 588 U.S. at 185; *see also id.* at 201; *Williams v. Parker*, 188 U.S. 491, 502-04 (1903); *Hurley*, 285 U.S. at 103-04. The Takings Clause does not confer a right to be free from takings. The Takings Clause does not prohibit the government from multiple takings. It simply requires the

government to provide compensation for a taking after the taking has occurred.

As noted by the district court, this Court has never held that the potential for multiple of lawsuits is a valid justification to give a plaintiff an injunction in takings case. (*See* App. Vol. II at 353). For example, in *Gordon v. Norton*, 322 F.3d 1213 (10th Cir. 2003), this Court affirmed the district court's holding that equitable relief was not available to the plaintiffs under the Takings Clause. *Id.* at 1216-19. The plaintiffs were ranchers whose cattle, horses, and dogs were continuously being killed by wolves reintroduced into the area through a federal program. *Id.* at 1218. The *Gordon* court found that, given the nature of the property at issue, compensatory relief under the Tucker Act was an adequate remedy even though there were continuous physical takings of personal property. *Id.* at 1218-19. Similarly, in *Williams*, the plaintiff alleged that a state agency and state officials were improperly withholding interest on inmate bank accounts. *See Williams*, 928 F.3d at 1211. Interest accrues daily, so these alleged takings happened repeatedly, yet this Court did

not hesitate to dismiss the claim since state compensation remedies were available. *See id*. 1213-14.

Like *Gordon* and *Williams,* numerous other federal courts have also declined to grant equitable relief in cases where the alleged takings at issue could theoretically result in a multiplicity of suits. *See, e.g., Virginia Hosp. & Healthcare Ass'n*, 671 F.Supp.3d at 668 (state law capping hospital reimbursement rates); *Pakdel v. City & Cnty. of San Francisco*, 636 F.Supp.3d 1065, 1077-78 (N.D. Cal. 2022) (requirement to provide lifetime tenancy); *Exotic Smoke & Vape v. Cox*, No. 2:22-CV-408, 2022 WL 2316323, at *1 (D. Utah June 28, 2022) (law restricting tobacco retailers); *Farhoud v. Brown*, No. 3:20-CV-2226-JR, 2022 WL 326092, *11 (D. Or. Feb. 3, 2022) (eviction moratoriums). The district court's conclusion that theoretical multiplicity of suit potentially justifies injunctive relief runs counter to the overwhelming weight of Fifth Amendment Takings Clause precedent.

The multiplicity of suit theory is also incorrect as a practical matter. According to Teva, Teva will opt to deliver the physical epinephrine auto-injectors to the pharmacies in response to the Affordability Program.

(App. Vol. I at 127-26 (¶ 36); App. Vol. II at 275:9-23). Teva would not be "bound to bring an infinite series of takings suits against the State for the foreseeable future" by doing so. (*See* App. Vol. II at 353-54). Colorado's Rules of Civil Procedure allow for a broad joinder of claims and consolidations of actions. Colo. R. Civ. P. 18 ("A party asserting a claim to relief . . . may join . . . as many claims, legal or equitable, as he has against an opposing party."). Teva's claims for alleged takings are subject to a two-year statute of limitations. *See Blake v. Dickason,* 997 F.2d 749, 750–51 (10th Cir.1993) (applying Colorado's two-year residual statute of limitations to a section 1983 claim); *Bad Boys of Cripple Creek Mining Co. v. City of Cripple Creek,* 996 P.2d 792, 795–96 (Colo. App. 2000) (holding that a two-year statute of limitations applies to inverse condemnation claims). As a result, Teva could bring a single lawsuit covering an approximately two-year period of alleged takings. In that single lawsuit, Teva could ask the state court to determine whether the Affordability Act effects a taking and, if so, to determine the amount of just compensation owed to Teva for each taking. Since Teva's products are identical, that single lawsuit would have preclusive effect in future

disputes between these parties. *See, e.g., Knick*, 588 U.S. at 184 (noting preclusion principles apply in Takings Clause context and citing *San Remo Hotel v. San Francisco*, 545 U.S. 323 (2005)); *Gallegos v. Colorado Ground Water Comm'n*, 147 P.3d 20, 32 (Colo. 2006) (discussing elements of claim preclusion under Colorado law); *Sunny Acres Villa, Inc. v. Cooper*, 25 P.3d 44, 47 (Colo. 2001) (discussing elements of issue preclusion under Colorado law). Thus, a single suit properly brought in Colorado state court at the appropriate time would fully resolve the dispute between the parties. The district court's fear that there would be an "infinite" number of suits is not accurate.

Simply put, courts within this circuit have repeatedly held that Colorado's just compensation remedies are adequate for purpose of the Fifth Amendment's Takings Clause. *See, e.g.*, *Nat'l Advert. Co. v. City & Cnty. of Denver*, 912 F.2d 405, 413–14 (10th Cir. 1990); *SK Fin. SA v. La Plata Cnty., Bd. of Cnty. Comm'rs*, 126 F.3d 1272, 1276 (10th Cir. 1997); *Lech v. Jackson*, No. 16-CV-01956-PAB-MJW, 2018 WL 10215862, *4 (D. Colo. Jan. 8, 2018), *aff'd* 791 F. App'x 711 (10th Cir. 2019); *see also 211 Eighth, LLC v. Town of Carbondale*, 922 F.Supp.2d 1174, 1185–86 (D.

Colo. 2013); *Grace Church of Roaring Fork Valley v. Bd. of Cnty. Comm'rs of Pitkin Cnty., Colorado*, 742 F.Supp.2d 1156, 1167 (D. Colo. 2010); *Atchison v. Saddleback Metro. Dist.*, No. 08-cv-00564-PAB-KLM, 2009 WL 306701, *2–3 (D. Colo. Feb. 5, 2009). There is no basis legally or practically for the multiplicity of suit theory in this Takings Clause context. Therefore, Teva has an adequate remedy for any alleged taking caused by the Affordability Program, even if it may hypothetically need to avail itself of such remedy more than once. As a result, the State Officials maintain their sovereign immunity from being sued in federal court.

IV. The district court should be reversed because its conclusion improperly turns the Takings Clause into a weapon to block state policies.

Finally, the district court should be reversed because its determination that permanent injunctive relief could be available in this Takings Clause case will improperly transform the Takings Clause into a tool for private parties to use the coercive power of the federal courts to hamstring state economic regulations that they dislike.

The Constitution "specifically recognizes the States as sovereign entities," and preserves this sovereignty in two ways. *Alden*, 527 U.S. at 713-14 (internal quotation marks and citations omitted). "First, it reserves to them a substantial portion of the Nation's primary sovereignty, together with the dignity and essential attributes inhering in that status." *Id.* at 714. Second, it created "a system in which the State and Federal Governments would exercise concurrent authority over the people[.]" *Id.* (internal quotation marks and citations omitted). In our constitutional framework, the state governments have a fundamental role in policymaking and state courts have a fundamental role in adjudicating disputes.

Our system of federalism recognizes the States' power to govern within their borders through legislation and regulation, including legislation that may affect property interests. The Supreme Court recognized that there are a "nearly infinite variety of ways" for state policies to "affect property interests." *Arkansas Game and Fish Comm'n v. United States*, 568 U.S. 23, 31 (2012). But "[g]overnment hardly could go on if to some extent values incident to property could not be

diminished without paying for every such change in the general law," so the law has recognized that the "government may execute laws or programs that adversely affect recognized economic values." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978) (internal quotation marks and citation omitted).

Colorado used its power to enact the Affordability Program to address a pressing public health issue, specifically the exorbitant cost of life-saving epinephrine auto-injectors. (*See* App. Vol. I at 88 (§§ 1(1)(e), (g)); *see also Moore v. Dist. Ct. In & For City & Cnty. Of Denver*, 518 P.2d 948, 952 (Colo. 1974) (it is a "universally recognized" principle "that the state has authority . . . to regulate the practice of pharmacy and the sale of drugs."); C.R.S. § 12-280-101 ("practice of pharmacy" affects "the public health, safety, and welfare and is subject to regulation and control in the public interest"). The Affordability Program's intent is to address this public health crisis and "ensure Colorado residents have greater access to epinephrine." (App. Vol. I at 88 (§ 1(2)). The Affordability Program was enacted to protect public health and to combat price gouging.

Teva dislikes the approach taken by the Affordability Program. Teva dislikes that the Affordability Program may cost it some money. The district court seems concerned that more than one of Teva's epinephrine auto-injectors may be affected by the Affordability Program. But regulations are "the burdens we all must bear in exchange for the advantage of living and doing business in a civilized community." *Ruckelshaus*, 467 U.S. at 1007 (internal quotation marks and citation omitted). And crucially, as it relates to this case, the Fifth Amendment does not require state governments to "provide compensation in advance of a taking or risk having its action invalidated." *Knick*, 588 U.S. at 185. Rather, as the Supreme Court repeatedly emphasized in *Knick*, "[s]o 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.* "Given the availability of post-taking compensation, barring the government from acting will ordinarily not be appropriate." *Id.* at 202. Just because a state regulation may theoretically have a repeated economic effect on a private party does not mean that federal courts should intervene under the Takings Clause to block state policies

especially where, as here, a state forum and compensation remedies are available to provide that party complete relief.

By concluding that Teva might be entitled to a permanent injunction because Teva might allegedly have to bring "an infinite series of takings suits" and applying *Ex parte Young* to retain jurisdiction over Teva's Takings Clause claims (*see* App. Vol. II at 346-47, 353), the district court undermined that principle and provided an opening for private parties to use the coercive injunctive power of the federal courts to attack regulations whose only "flaw" is that may impose some future economic costs. Since the district court's novel approach will improperly turn the Takings Clause into a weapon and subvert important principles of sovereign immunity and judicial federalism, the district court's denial of the State Officials' Motion to Dismiss should be reversed and this case should be dismissed.

CONCLUSION

The district court failed to properly apply Fifth Amendment Takings Clause jurisprudence when it determined that Teva could move forward on its claims seeking prospective equitable relief against the

State Officials. The Fifth Amendment does not prohibit a government's taking of private property for public use—it simply requires that the owner of the private property be compensated. As a result, equitable relief is not available for takings claims where the plaintiff has an adequate remedy at law. Colorado law provides Teva with an adequate remedy for any alleged taking of its epinephrine auto-injectors effected by the Affordability Act. Further, the district court erred in applying the *Ex parte Young* legal fiction to allow Teva to proceed with claims that seek forms of relief that are otherwise be unavailable for its claims. For all of these reasons, the State Officials respectfully request that the Court reverse the district court's denial of their motion to dismiss, find that *Ex Parte Young* does not apply to Teva's claims, and remand with instructions to dismiss Teva's amended complaint because it is barred by sovereign immunity.

STATEMENT REGARDING ORAL ARGUMENT

Oral argument is warranted in this case because this appeal involves important issues surrounding Eleventh Amendment immunity, which has not been recently and authoritatively resolved in this Circuit.

The argument of counsel may materially assist the Court in its determination of this appeal.

Dated: April 1, 2024.

Respectfully Submitted,

PHILIP J. WEISER
Attorney General

s/Pawan Nelson

PAWAN NELSON*,
Assistant Attorney General
Telephone: 720-508-6578
Email: pawan.nelson@coag.gov

Ralph L. Carr Colorado Judicial Center
1300 Broadway, 10th Floor
Denver, CO 80203

*Counsel of Record for Weiser

s/Jennifer Johnson

JENNIFER JOHNSON**,
Assistant Attorney General
Telephone: 720-508-6379
Email: jennifer.johnson@coag.gov

Ralph L. Carr Colorado Judicial Center
1300 Broadway, 8th Floor
Denver, CO 80203

**Counsel of Record for Patricia A. Evacko, Erick Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli

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Date: April 1, 2024

s/Pawan Nelson

PAWAN NELSON*
Assistant Attorney General
1300 Broadway, 10th Floor
Denver, Colorado 80203
Telephone: 720-508-6628
Email: pawan.nelson@coag.gov

CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2024, I electronically filed the foregoing **APPELLANTS' OPENING BRIEF** with the Clerk of the Tenth Circuit Court of Appeals using the CM/ECF system and was served via the Tenth Circuit CM/ECF on all counsel of record for the parties in this case.

s/Sarah Bomgardner

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.

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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.

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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.

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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.

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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

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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

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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").

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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*.

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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.*

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(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.

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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

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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.

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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.

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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 resupply 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.

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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. Ziriax*, 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

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(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

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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

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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

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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

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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.

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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:

~~Daniel D.~~ Domenico
United States District Judge

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