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

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

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff,

v.

MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; and
PHILIP J. WEISER, in his official capacity as Attorney General of the State of Colorado,
Defendants.

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**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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Anaphylaxis—a severe allergic reaction—is provoked by a variety of causes, happens suddenly, and is life-threatening. *See* Teva Epinephrine, https://www.tevaepinephrine.com/ ("Teva Website") (last visited Oct. 20, 2023). Epinephrine addresses anaphylaxis by rapidly improving breathing, preventing airways from closing, decreasing shock, and reducing swelling, among other things. *See* HB23-1002, Ex. 1 at 2 (§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* Teva Website.

Unfortunately, recognizing the essential nature of their product and their inherent market power, epinephrine auto-injector manufacturers have driven up the price of epinephrine auto-

injectors for years.[1] 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.*, HB23-1002, Ex. 1 at 2 (§§1(f)-(g)).

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

Unhappy with the policy approach Colorado has taken to address the epinephrine auto-injector affordability crisis, Teva asserts a Fifth Amendment Takings Clause violation [Doc. 1] and seeks preliminary relief to enjoin the Affordability Program from taking effect [Doc. 3]. But seeking such relief based solely on hypothetical future injury—that, even if found to be a taking, is fully compensable through an award of just compensation—flatly contravenes well-established Eleventh Amendment and Takings Clause principles. Simply put, Teva is asking for the wrong relief, in the wrong forum, against the wrong defendants, at the wrong time. Accordingly, its Motion [Doc. 3] should be denied.

[1] For example, between 2010 and 2016, Mylan increased the price of EpiPen® by approximately 400%. *See* https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates. *See* F.R.E. 201; *Lake v. Hobbs,* 623 F.Supp.3d 1015, 1023 n. 5 (D. Ariz. 2022) (taking judicial notice of government websites).

## BACKGROUND

The Affordability Program allows eligible individuals to complete an application form—developed by the Division of Insurance—that they may then take to a pharmacy with other documentation demonstrating eligibility. 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. C.R.S. §§ 12-280-142(6)-(7).

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

Effective January 1, 2024, a manufacturer that fails to comply with the requirements of the Affordability Program may be subject to discipline 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), -142(2) & (11).

## ARGUMENT

"A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *United States ex rel. Citizen Band Potawatomi Indian Tribe of Okla. v. Enter. Mgmt. Consultants, Inc.,* 883 F.2d 886, 888 (10th Cir. 1989). "Because it constitutes drastic relief to be provided with caution, a preliminary injunction should be granted only in cases where the necessity for it is

clearly established." *Id*. at 889. A plaintiff seeking a preliminary injunction must establish each of these factors: that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.,* 555 U.S. 7, 20 (2008); *see also Denver Homeless Out Loud v. Denver*, 32 F.4th 1259, 1279 (10th Cir. 2022) ("movant must show all four factors before a preliminary injunction can issue"). The last two factors—assessing the harm to the opposing party and weighing the public interest—merge when the government is the opposing party. *Denver Homeless Out Loud*, 32 F.4th at 1278 (citation omitted).

## I. TEVA CANNOT ESTABLISH LIKELIHOOD OF SUCCESS ON THE MERITS BECAUSE THIS COURT LACKS SUBJECT MATTER JURISDICTION.

### A. Eleventh Amendment sovereign immunity shields Defendants from suit.

Only one substantive federal right is at-issue in this case—Teva's right to just compensation under the Fifth Amendment Takings Clause if the Affordability Program's reimburse-or-resupply requirement effectuates a taking. *See* Doc. 1 at ¶¶ 8, 24-32. Yet Teva seeks only equitable relief against Defendants, who are named solely in their official capacities. *See* Doc. 1 at ¶¶ 6, 24-32, A-B; *see also* Doc. 3. To be sure, awarding any injunctive relief to Teva is improper because it is beyond well-settled that "[e]quitable relief is not available to enjoin an alleged taking of private property for a public use[.]" *Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1016 (1984); *see also* Section II, *infra*. Indeed, the U.S. Supreme Court more recently reiterated that a takings claim cannot support a request for injunctive relief. *See Knick v. Twp. Of Scott,* 139 S. Ct. 2162, 2176 (2019) ("As long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking."). This is because the Takings Clause "is designed not to limit the governmental interference with property rights *per se*, but

rather to secure *compensation* in the event of otherwise proper interference amounting to a taking." *First English Evangelical Lutheran Church of Glendale v. Cnty. Of Los Angeles*, 482 U.S. 304, 315 (1987) (emphasis in original). But even if Teva reframes its claim as one for just compensation and proves a taking,[2] Eleventh Amendment sovereign immunity bars such a claim because it would "impose a liability which must be paid from public funds in the state treasury[.]" *Edelman v. Jordan*, 415 U.S. 651, 663 (1974). "Because the State's assertion of Eleventh Amendment immunity challenges the subject matter jurisdiction of the district court, the issue must be resolved before a court may address the merits of the underlying claim." *Joseph A. ex rel. Wolfe v. Ingram*, 275 F.3d 1253, 1259 (10th Cir. 2002) (citation omitted).

It is well established that the Eleventh Amendment prohibits unconsented lawsuits against a State or its agencies, which constitute "arms" of the State, brought in federal court for any type of relief, unless the State has waived its sovereign immunity. *See, e.g.*, *Steadfast Ins. Co. v. Agric. Ins. Co.*, 507 F.3d 1250, 1252-53 (10th Cir. 2007). "It is also well established that even though a State is not named a party to the action, the suit may nonetheless be barred by the Eleventh Amendment." *Edelman*, 415 U.S. at 663. "[W]hen the action is in essence one for the recovery of money from the state, the state is the real, substantial party in interest and is entitled to invoke its sovereign immunity from suit even though individual officials are nominal defendants." *Id.*

[2] Defendants hereby reserve the right to later argue that the Affordability Program will not effectuate a taking, but this response focuses solely on the jurisdictional and other obstacles to Teva's request for preliminary relief.

(quotations omitted). And while the *Ex Parte Young* doctrine[3] provides an exception to Eleventh Amendment immunity, 209 U.S. 123, 148 (1908), it does not follow "that any form of relief may be awarded against a state officer, no matter how closely it may in practice resemble a money judgment payable out of the state treasury, so long as the relief may be labeled 'equitable' in nature." *Edelman*, 415 U.S. at 666. Rather, "the 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." *Id.* at 663.

Consistent with the holding in *Edelman*, appellate courts in this and other Circuits have held that the Eleventh Amendment bars Fifth Amendment takings claims against State officials in federal court provided that the plaintiff has a remedy available in state court. *See Williams v. Utah Dep't of Corr.*, 928 F.3d 1209, 1212-14 (10th Cir. 2019) (takings claim against Utah prison officials for failure to pay interest on prison accounts barred); *see accord 74 Pinehurst LLC v. New York*, 59 F.4th 557, 570 (2d Cir. 2023); *EEE Mins., LLC v. North Dakota*, 81 F.4th 809, 816 (8th Cir. 2023); *Zito v. N. Carolina Coastal Res. Comm'n,* 8 F.4th 281, 288, 290 (4th Cir. 2021); *Ladd v. Marchbanks*, 971 F.3d 574, 578-80 (6th Cir. 2020); *Bay Point Props., Inc. v. Miss. Transp. Comm'n*, 937 F.3d 454, 455-57 (5th Cir. 2019).[4] Accordingly, the Eleventh Amendment bars Teva's Fifth Amendment Takings Clause claim for just compensation against any Colorado

[3] Namely, "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).

[4] Each of these cases post-dates the 2019 *Knick* decision. As the Tenth Circuit explained in *Williams*, "*Knick* did not involve Eleventh Amendment immunity, which is the basis of our holding in this case." 928 F.3d at 1214. Thus, the critical issue here is immunity from suit, not exhaustion of remedies.

official in federal court regardless of the fact that it is couched as one for only equitable relief. *See Williams*, 928 F.3d at 1214-15; *see also Los Molinos Mut. Water Co. v. Ekdahl*, No. 2021-cv-01961-DAD-DMC, 2023 WL 6386898, at *8 & n.7 (E.D. Cal. Sept. 29, 2023) (takings claim for past diversion of water mandated by their emergency orders barred and prospective relief unavailable).

Here, Teva has an available state court remedy to obtain just compensation under the Takings Clause in Colorado's Constitution. *See* Colo. Const. Art. II, § 15. For alleged regulatory takings of personal property, a plaintiff is not required to file a state court inverse condemnation proceeding. Rather, a claim for just compensation may be brought directly under Colo. Const. Art. II, § 15 in state court. *Cf. Colo. Dep't of Health v. The Mill*, 809 P.2d 434, 440-41 (Colo. 1991) (noting that "[u]nder Colorado law, inverse condemnation is not the exclusive remedy for a taking" and discussing alternative state law remedies available); *see also Callopy v. Wildlife Comm'n*, 625 P.2d 994, 997, 1005-06 (Colo. 1981) (considering regulatory takings claims brought directly under Colo. Const. Art. II, § 15); *Game and Fish Comm'n v. Farmers Irr. Co.*, 426 P.2d 562, 565-66 (Colo. 1967) (same).

Teva does not allege that it has sought just compensation in state court under Colo. Const. Art. II, § 15, and does not assert any constitutional challenge to the adequacy of Colo. Const. Art. II, § 15. *See* Doc. 1. And because the reimburse-or-resupply requirement does not take effect until January 1, 2024, Colorado has not yet actually taken anything from Teva pursuant to the Affordability Program. If Teva ever provides anything to Colorado pharmacies pursuant to the Affordability Program, it may seek compensation from the correct Colorado entity in Colorado state court using the just compensation remedies available under Colorado law. Accordingly,

*Edelman* and *Williams* foreclose Teva's ability to maintain a Fifth Amendment takings claim against any Colorado official in this Court.

**B. Teva has named the wrong Colorado officials as defendants.**

Assuming without conceding that Teva may maintain its Fifth Amendment takings claim for equitable relief in this Court, another aspect of the *Ex Parte Young* exception to Eleventh Amendment sovereign immunity must be met. Specifically, the named State official must "have a particular duty to 'enforce' the statute in question *and* a demonstrated willingness to exercise that duty[.]" *Hendrickson*, 992 F.3d at 965 (emphasis added). The Defendants have neither.

Michael Conway, who is the Colorado Commissioner of Insurance (the "Commissioner") and oversees the Colorado Division of Insurance, *see* C.R.S. § 10-1-104(1), is entitled to sovereign immunity from suit because he has no particular duty to enforce the Affordability Program's penalties against Teva if it flouts the reimburse-or-resupply requirement.[5] Rather, in such event, the Pharmacy Board members are the Colorado officials directly responsible for enforcing that requirement because it resides in Article 280 of Title 12, C.R.S. *See* C.R.S. §§ 12-280-104(1) ("[t]he responsibility for enforcement of this article 280 is vested in the state board of pharmacy"); -126(1)(c)(I) (grounds for discipline by the Pharmacy Board include a violation of "[a]ny of the provisions of this article 280"); -303(1) (a wholesaler who does not reside in Colorado must be registered prior to engaging in wholesale distribution); *see also* C.R.S. § 12-280-103(54)(a), (55)

[5] The Affordability Program also does not fall under the purview of the Commissioner's core duty to "supervise the business of insurance in this state." C.R.S. § 10-1-108(7)(a). Manufacturers and pharmacies acting in accordance with the requirements of the Affordability Program are not engaged in the business of insurance in Colorado and the Commissioner is without jurisdiction to enforce its requirements.

(defining wholesaler to include a person engaged in the distribution of prescription drugs to persons other than consumers or patients). This responsibility includes imposing the monthly fine required by C.R.S. § 12-280-142(11)(a). In contrast, the Commissioner's role in the Affordability Program is limited to developing a form that individuals can use to obtain the epinephrine auto-injectors, making that form available, and promoting the Affordability Program. *See* C.R.S. §§ 12-280-142(4)(a)-(b) & (9). But these are not enforcement activities and, "when a state law explicitly empowers one set of officials to enforce its terms, a plaintiff cannot sue a different official absent some evidence that the defendant is connected to the *enforcement* of the challenged law." *Peterson v. Martinez*, 707 F.3d 1197, 1207 (10th Cir. 2013) (emphasis added).

And while the Affordability Program provides that "[a] manufacturer that fails to comply with the requirements of this section . . . [e]ngages in a deceptive trade practice under section 6-1-105(1)(zzz)," *see* C.R.S. § 12-280-142(11)(b), bringing such a civil law enforcement action under those provision is wholly discretionary on the part of Defendant Philip J. Weiser, who is the Colorado Attorney General. *See* C.R.S. §§ 6-1-103, 6-1-113(1) ("The provisions of this article shall be *available* in a civil action for any claim against any person who has engaged in or caused another to engage in any deceptive trade practice listed in this article." (emphasis added)). A general duty to enforce a separate law that is not even challenged in this Court is insufficient to place the Attorney General within *Ex parte Young*'s ambit as it relates to the Affordability Program. *Cf. Sgaggio v. Weiser*, No. 22-CV-01791-PAB, 2022 WL 3700723, at *4 (D. Colo. Aug. 26, 2022). Additionally, the Complaint does not allege that the Attorney General has either threatened Teva with a civil law enforcement action, much less actually initiated such an action. *See* Doc. 1. As a result, even if the Court agrees that the Attorney General has "a particular duty

to enforce" C.R.S. § 12-280-142(11)(b), Teva has not satisfied its burden of showing that the Attorney General also has "a demonstrated willingness to exercise that duty." *Peterson*, 707 F.3d at 1205 (quotation omitted). For these reasons, the Attorney General likewise is entitled to sovereign immunity from suit.

**C. Teva cannot establish standing or that its claim is ripe.**

Teva also cannot establish likelihood of success on the merits because it has sued at the wrong time: it does not yet have standing to assert its claims and its claims are not ripe. These are additional jurisdictional bases to deny Teva's motion for preliminary relief.

**i. Teva has not established standing because it presents only a hypothetical injury.**

To establish standing, a plaintiff must show that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo v. Robins,* 136 S. Ct. 1540, 1547 (2016). A plaintiff has the burden to show that they have suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical. *Id*. at 1548. "A claimed injury that is contingent upon speculation or conjecture is beyond the bounds of a federal court's jurisdiction." *Tandy v. City of Wichita*, 380 F.3d 1277, 1283-84 (10th Cir. 2004). Teva asks this court to make countless assumptions to create hypothetical standing that Teva may have in the future. This is insufficient to establish subject-matter jurisdiction.

As of this date, no one has taken anything from Teva pursuant to the Affordability Program. In attempting to allege an injury, Teva asks this court to assume a slew of events that may never occur in the future and may never impact its property rights. A court cannot have Article III standing based on hypothetical jurisdiction. *Initiative & Referendum Inst. v. Walker*, 450 F.3d

1082, 1087 (10th Cir. 2006). "Where an injury is threatened rather than actual, '[a]llegations of *possible* future injury are not sufficient' to establish standing." *Tennille v. Western Union Co.,* 809 F.3d 555, 560 (10th Cir. 2015) (citation omitted).

To the extent Teva asserts it will be injured by the uncompensated "taking" of its epinephrine auto-injectors in the future under the Affordability Program, its Complaint is insufficient. To imagine such an injury, one must make a number of assumptions about the operation of the Affordability Program that have not yet obtained, such as: the number of people who may be eligible for the Affordability Program because they are not covered for epinephrine auto-injectors under Medicare, Medicaid, or their insurance plan; whether those individuals will apply for auto-injectors using this program; whether they will be dispensed an auto-injector at a pharmacy; whether a pharmacy will actually make a claim of a manufacturer;[6] and how much, if any, economic harm a manufacturer will suffer. These are all matters of pure conjecture.

Further, Teva invites this court to assume that to the extent the Affordability Program is used by eligible Coloradans, it will necessarily impact *Teva's* products. Based on past estimated sales,[7] Teva speculates that it "will be forced to supply tens of thousands of generic epinephrine

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

[7] Teva provides no evidence of how many of its past products sold in Colorado were distributed to individuals who might be eligible under the Affordability Program. Instead, it alleges it distributed approximately 14,000 epinephrine auto-injectors in Colorado during a one-year period and then argues it will be forced to supply "tens of thousands" of its products under the Affordability Program. Doc. 1 at ¶¶ 20, 23. But Teva's past business activities do not shed light on how many of its products may ultimately end up dispensed to the narrow group of eligible individuals—those not eligible for Medicare or Medicaid and that do not have prescription drug coverage with a co-pay cap—who actually go through the process of completing the application and meeting the requirements.

auto-injectors *for free* to Colorado citizens." Doc. 1 at ¶ 23. But this presumption brushes over a critical fact necessary to establish an actual injury: whether Teva's epinephrine auto-injectors will ultimately be dispensed through the Affordability Program in 2024. This is insufficient to establish that Teva has suffered an actual injury in fact necessary to establish standing.

**ii. Teva cannot demonstrate that its claims are ripe.**

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

As discussed above, it is unclear if Teva's products will ever be involved in the Affordability Program. The possibility that the Affordability Program could involve Teva's products at some point in the future does not render its claims currently ripe. *See Knick*, 139 S. Ct. at 2172 ("a property owner has a claim for a violation of the Takings Clause as soon as a

government takes his property for public use without paying for it."); *cf. MacDonald, Sommer, & Frates v. Yolo Cnty.*, 477 U.S. 340, 348 (1986) ("A court cannot determine whether a regulation has gone "too far" unless it knows how far the regulation goes.").

Teva must also establish finality of a decision effecting a taking for a claim to be prudentially ripe. The finality requirement "ensures that a plaintiff has actually 'been injured by the Government's action' and is not prematurely suing over a hypothetical harm." *Pakdel v. City and Cnty. of San Francisco,* 141 S. Ct. 2226, 2230 (2021) (citation omitted). A takings claim is final once there is no question about how the regulations at issue apply to the property in question. *Id.* at 2230 (city requirement that two property owners execute a lifetime lease for their multiunit residential building satisfied finality); *cf. N. Mill St., LLC v. City of Aspen*, 6 F.4th 1216 (10th Cir. 2021) (lack of final decision with respect to a property because the city retained discretion to approve a use variation from zoning regulations).

Here, Teva has not satisfied the finality requirement because the Complaint failed to allege that the challenged provisions of the Affordability Program have been specifically applied to its property. *See* Doc. 1. It is premature to assume that Teva's epinephrine auto-injectors will be impacted by the Affordability Program. *Pakdel,* 141 S. Ct. at 2230. Unless and until there is an actual claim directed to Teva for a re-supply or reimbursement for auto-injectors, there is no finality. Teva's claims are prudentially unripe.

## II. TEVA CANNOT DEMONSTRATE IRREPARABLE HARM BECAUSE A TAKING IS INHERENTLY COMPENSABLE.

Teva's motion for a preliminary injunction should be denied because Teva will not suffer irreparable harm in the absence of preliminary relief. "The party seeking that extraordinary remedy faces a high bar—it must make a clear and unequivocal showing it will likely suffer irreparable

harm absent preliminary relief." *Colorado v. U.S. Env't Prot. Agency*, 989 F.3d 874, 886 (10th Cir. 2021). "[A] showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction." *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.,* 356 F.3d 1256, 1260 (10th Cir. 2004) (citations omitted). "[T]o constitute irreparable harm, an injury must be imminent, certain, actual and not speculative." *Colorado,* 989 F.3d at 886. "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.,* 555 U.S. at 22. "[P]urely speculative harm does not amount to irreparable injury." *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003).

To establish irreparable harm that entitles a plaintiff to injunctive relief, a plaintiff must show "a *significant risk* that he or she will experience harm that cannot be compensated after the fact by monetary damages." *Greater Yellowstone Coal.*, 321 F.3d at 1258 (citations omitted). It is "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. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003)

Claims under the Takings Clause are inherently compensable by money damages. Takings proceedings exist for the specific purpose of identifying the property rights at issue, determining the extent of the taking, and ordering just monetary compensation. Indeed, a takings proceeding "is a remedy for a taking that violated the Constitution." *Knick*, 139 S. Ct. at 2177. "Accordingly, equitable relief is not available to enjoin a lawful taking when a property owner can subsequently sue the government for compensation." *Gordon v. Norton*, 322 F.3d 1213, 1216 (10th Cir. 2003).

"As long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Knick*, 139 S. Ct. at 2176.

Teva's epinephrine auto-injectors are discrete physical products with a value that can be easily determined. For example, Teva alleges that in 2023, it sold its epinephrine auto-injectors at a wholesale acquisition cost of $300 per two-pack.[8] Doc 1. ¶ 21. If any of its epinephrine auto-injectors are ever taken, Teva's purported economic loss could be fully remediated through a just compensation proceeding in Colorado state court.[9] Since all harm Teva would suffer under the Affordability Program could be compensable through monetary damages, Teva cannot demonstrate irreparable harm.

Teva tries to avoid this fact by claiming that it would need to institute "a continuous series of repetitive damages actions seeking compensation for each epinephrine auto-injector commandeered by the program," and therefore lacks an adequate remedy at law. *See* Doc. 3 at 10 (relying on *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932 (8th Cir. 2023)). But this is incorrect. There is nothing that would require Teva to institute a separate action for each individual epinephrine auto-injector that it would provide under the Affordability Program. The Colorado Rules of Civil Procedure, like their federal counterpart, allow for broad joinder of claims and parties to prevent multiple lawsuits. *See, e.g.*, C.R.C.P. 18(a); C.R.C.P. 20(a); § 18:2 Joinder of

[8] The appropriate amount of compensation would be determined through a state court action under Colo. Const. Art. II, §15, if Teva proves that the Affordability Program effectuates a taking. Defendants do not concede that Teva would be entitled to any specific amount at this time.

[9] As explained above in Section I.A., Colorado law provides avenues for Teva to obtain just compensation for any taking that it proves, and the Eleventh Amendment bars Teva from bringing a Fifth Amendment Takings Clause claim against any Colorado agency or official in federal court to obtain such compensation.

claims, 11 Colo. Prac., Civil Procedure Forms & Commentary § 18:2 (3d ed.). The Rules provide mechanisms for consolidating actions that involve common questions of law or fact. *See, e.g.,* C.R.C.P. 42(a). Indeed, by their very nature, the "rules of civil procedure are designed to avoid extensive seasons of fractured litigation" and "promote expeditious resolution of all disputes arising out of the same transaction in a single lawsuit." *CLPF-Parkridge One, L.P. v. Harwell Invs., Inc.*, 105 P.3d 658, 662 (Colo. 2005).

Further, the statute of limitations for a takings claim in Colorado is two years. *See, e.g.*, C.R.S. § 13-80-102(1)(h); *Bad Boys of Cripple Creek Mining Co. v. City of Cripple Creek*, 996 P.2d 792, 795 (Colo. App. 2000). Teva could simply wait, track the number of epinephrine auto-injectors it provides under the Affordability Program, and then bring a single action for just compensation in Colorado state court for all alleged takings occurring within the limitations period. Teva may consider this inconvenient, but that does not render its available state court remedy at law inadequate. *See Williams*, 928 F.3d at 1213-14 (concluding that Utah state court proceedings were adequate to adjudicate takings claim alleging that state officials improperly retained interest on prisoner bank account funds).

Any purported harm that Teva would suffer, if proven, would be easily redressed with just compensation obtained through a state court proceeding. Accepting Teva's claim that it would suffer irreparable harm by following well-established just compensation procedures in an takings case would turn Fifth Amendment jurisprudence and the concept of irreparable harm on their heads. *See Knick*, 139 S. Ct. at 2177. This Court should decline Teva's invitation to carve out a "pharmaceutical company exception" to the irreparable harm requirement, as this would be

contrary to established precedent (such as *Knick* and *Williams*) and based on Teva's unsupported allegations of harm that are purely speculative at this time.

## III. THE PUBLIC INTEREST WEIGHS STRONGLY IN FAVOR OF ALLOWING THE AFFORDABILITY PROGRAM TO TAKE EFFECT.

Finally, the balance of the equities weighs in favor of denying Teva's motion for preliminary injunction. "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter*, 555 U.S. at 24. Courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Id.* (citation omitted). "In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id.* (citation omitted).

Colorado is home to approximately 565,824 individuals with life-threatening food allergies – and of those, 101,848 are children – for whom epinephrine auto-injectors can be the difference between life and death. *See* HB 23-1002, Ex. 1 at 2 (§1(d)). Many individuals are unable to afford epinephrine auto-injectors and "risk their lives every day by not having access to this life-saving medicine." *Id.* (§1(f)). The epinephrine auto-injector affordability crisis is a pressing issue that Colorado has a duty to address. The Affordability Program provides eligible individuals with an opportunity to access life-saving epinephrine auto-injectors at a lower cost to them. Granting Teva's motion would prevent some people in need from accessing a life-saving medical device. Therefore, there is a strong public interest in allowing the Affordability Program to become effective.

Teva does not appear to dispute Colorado's ability to regulate epinephrine auto-injectors, and even offers potential policy alternatives. *See, e.g.*, Doc. 3 at 10 ("Colorado could impose a

similar sixty-dollar price control on all retail sales of epinephrine auto-injectors"). But Teva's preference for a different approach does not outweigh the public's interest, especially given the remedies available to Teva if a taking occurs. Teva asks this Court to find that the mere future possibility that Teva's products may be dispensed through the Affordability Program—an entirely compensable action—outweighs the potential to increase access of life-saving medication to eligible individuals. Speculative and compensable harm never outweighs the value of a life. The Affordability Program objectively serves the public interest.

Since there is a strong public interest providing a means for people to obtain affordable epinephrine auto-injectors, and takings proceedings are available to Teva in Colorado state court, the balance of the equities tips in favor of allowing the Affordability Program to take effect. Accordingly, Teva's motion for preliminary injunction should be denied.

**CONCLUSION**

Because Teva cannot establish likelihood of success on the merits, irreparable harm, or that its interest outweighs the public interest, Defendants respectfully request that the Court deny Teva's Motion for Preliminary Injunction.

DATED: October 25, 2023.

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**STATEMENT OF COMPLIANCE**

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

*/s/ Pawan Nelson*

**CERTIFICATE OF SERVICE**

I hereby certify that on October 25, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system and additionally electronically served the attorneys listed below who are not registered with CM/ECF:

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