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; Patricia A. Evacko, Eric Frazier, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli, in their official capacities as members of the Colorado State Board of Pharmacy,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Colorado

No. 23-cv-2584

PLAINTIFF-APPELLEE'S RESPONSE TO PETITION FOR REHEARING EN BANC

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November 10, 2025

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INTRODUCTION

This appeal arises from a suit by Teva Pharmaceuticals USA, Inc. ("Teva") that seeks to enjoin the enforcement of a Colorado law requiring that, any time an eligible Coloradan purchases one of Teva's generic auto-injectors, Teva must either send the pharmacy a free replacement or reimburse the pharmacy in full. The district court has already held that this law takes Teva's auto-injectors without compensation, in violation of the Takings Clause. On remand, the question will be whether Teva is entitled to the injunction it seeks, or whether Teva has an adequate remedy at law in the form of an endless series of suits for compensation in state court.

The only question on appeal, however, is whether the Eleventh Amendment provides Colorado with immunity from Teva's federal suit. The panel and district court both correctly concluded that Teva's suit "easily satisfies the *Ex parte Young* exception to Eleventh Amendment immunity." Slip Op. 5. The Supreme Court has held that, "[i]n determining whether the doctrine of *Ex parte Young* avoids an Eleventh Amendment bar to suit, a court need only conduct a straightforward inquiry into whether a complaint *alleges* an ongoing violation of federal law and *seeks relief* properly characterized as prospective." *Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002) (emphases added; internal quotation marks omitted).

Here, the State Officials do not even dispute that Teva's suit meets those requirements.

The State Officials nonetheless insist that, when deciding whether Ex parte Young applies, a court must consider whether a plaintiff can obtain prospective relief, not just whether the plaintiff seeks prospective relief. And the State Officials argue that injunctive relief is categorically unavailable in takings cases if a compensation remedy exists in state court. The panel correctly concluded that, even if the State Officials were correct about the ultimate availability of injunctive relief—which they are not—that would be a merits issue and not an Eleventh Amendment problem. The State Officials identify no valid authority for their conflation of the merits and Ex parte Young analyses, and instead rely on the same inapposite decisions that they cited to the panel. The State Officials even acknowledge that they are inviting this Court to create a split with the Eighth Circuit, which held in a materially identical case that the Eleventh Amendment did not bar the plaintiff's suit to enjoin a law authorizing the repeated taking of pharmaceutical products without compensation. See Pharm. Rsch. & Mfrs. of Am. v. Williams, 64 F.4th 932, 950 (8th Cir. 2023) ("*PhRMA*").

The State Officials' warnings about the consequences of the panel's decision also ring hollow. The opinion is not precedential and will not bind other district courts or panels in future litigation. And if courts do adopt the panel's approach (as

they should), there will not be any significant increase in states' exposure to federal litigation. Under the panel's opinion, if a plaintiff has not plausibly alleged an entitlement to prospective relief, then the district court should dismiss the claim on the merits, and not on sovereign immunity grounds. Either way, the claim fails at the outset. Here, Teva's claim went forward because the district court determined Teva *had* plausibly alleged an entitlement to prospective relief, relying on the well-settled principle—applied by the Eighth Circuit in *PhRMA*—that an injunction is warranted when a party would otherwise have to resort to an endless series of retrospective damages suits. The State Officials disagree with that ruling, but it is a merits question that can and should be litigated in federal court.

STATEMENT OF THE CASE

A. Colorado Requires Manufacturers to Provide Pharmacies With Free Epinephrine Auto-Injectors.

On June 7, 2023, Colorado Governor Jared Polis signed a bill directing the Colorado Division of Insurance to establish an epinephrine auto-injector "affordability program" by January 1, 2024. All Coloradans who (a) have a valid prescription for epinephrine auto-injectors, (b) are ineligible for Medicaid or Medicare, and (c) do not have private health insurance that covers the auto-injectors are eligible for the program. Colo. Rev. Stat. § 12-280-142(3). Eligible individuals can fill out an application form created by the Division of Insurance, submit the application and proof of Colorado residence at any pharmacy, and obtain a two-pack

of epinephrine auto-injectors for no more than sixty dollars. *Id.* § 12-280-142(4)— (7).

The constitutional problem is what comes next. The pharmacy can pocket the sixty-dollar payment for the auto-injectors and request full reimbursement or free replacements from the manufacturer. Within thirty days of receiving a reimbursement claim, a manufacturer must either (a) "reimburse the pharmacy in an amount that the pharmacy paid for the number of epinephrine auto-injectors dispensed through the program" or (b) "send the pharmacy a replacement supply of epinephrine auto-injectors in an amount equal to the number of epinephrine autoinjectors dispensed through the program." Id. § 12-280-142(8)(c). Anv manufacturer who fails to comply with the bill is subject to "a fine of ten thousand dollars for each month of noncompliance" and "engages in a deceptive trade practice" under the Colorado Consumer Protection Act, which can be enforced by private plaintiffs as well as the state Attorney General, Colo. Rev. Stat. §§ 6-1-103, 6-1-113 (1), and can result in treble damages. *Id.*, 12-280-142(9)(a).

B. The District Court Denies the State Officials' Motion to Dismiss.

Teva filed suit against the State Officials on October 3, 2023, seeking a permanent injunction against the enforcement of the requirement that Teva reimburse or resupply Colorado pharmacies with epinephrine auto-injectors. Teva also moved for a preliminary injunction to stop the reimburse-or-resupply

requirement from going into effect on January 1, 2024. The State Officials opposed the motion for a preliminary injunction and then moved to dismiss the case on several grounds, including Eleventh Amendment immunity.

The district court denied the State Officials' motion to dismiss, as well as Teva's motion for a preliminary injunction, on December 27, 2023. The court found that Teva had standing to mount a pre-enforcement challenge, that its claim was ripe, and, as relevant here, that the State Officials were not immune from suit under the Eleventh Amendment. "[T]he Eleventh Amendment shields state officials from monetary claims for takings," the court explained, "[b]ut 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." App'x 346 (citing *Hendrickson v. AFSCME Council 18*, 992 F.3d 950, 965 (10th Cir. 2021)). Because "Teva has disclaimed any intent to pursue monetary damages and seeks only prospective injunctive relief," the suit satisfied the *Ex parte Young* exception to Eleventh Amendment immunity. *Id*.

The district court also held that the reimburse-and-resupply requirement would effect an unconstitutional taking of Teva's property, and noted that a "permanent injunction may be appropriate as part of a final judgment" if Teva could prove that it would otherwise "be bound to bring an infinite series of takings suits against the State for the foreseeable future." App'x 353. But the court declined to

grant a preliminary injunction because "[a]ny takings claims that accrue between now and the final resolution of the suit can be compensated for with a finite set of, or possibly even a single, lawsuit." App'x 354.

C. The Panel Unanimously Affirms the District Court.

The State Officials brought an interlocutory appeal of the district court's sovereign-immunity ruling, and a panel of this Court unanimously affirmed in an unpublished decision. The panel held that Teva's suit "easily satisfies the *Ex parte Young* exception to Eleventh Amendment immunity under *Verizon*" because Teva "alleges an ongoing violation of federal law" and "seeks relief properly characterized as prospective." Slip Op. 5-6. The panel rejected the State Officials' argument that the applicability of *Ex parte Young* turns on "whether injunctive relief is ultimately available," *id.* at 6, noting that "our straightforward *Ex parte Young* inquiry under *Verizon* does not extend to an analysis of whether injunctive relief is available in a particular case." *Id.* at 5.

ARGUMENT

- I. THE COMPLAINT SASTISFIES THE *EX PARTE YOUNG* EXCEPTION TO ELEVENTH AMENDMENT IMMUNITY.
 - A. The Complaint Seeks Prospective Relief, and *Ex parte Young* Requires No Analysis of the Merits.

The Supreme Court held in *Verizon* that, in deciding whether a suit satisfies the *Ex parte Young* exception to a state's Eleventh Amendment immunity from suit in federal court, "a court need only conduct a straightforward inquiry into whether a

complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective." 535 U.S. at 645. Under that simple rule, this is an easy case. Teva alleges that Colorado is violating the Takings Clause by requiring Teva to surrender its property without compensation, and Teva seeks an injunction barring the enforcement of that requirement going forward.

The State Officials object, as they did before the panel, that they are nonetheless entitled to Eleventh Amendment because, although Teva *seeks* prospective relief, "there is no viable claim for prospective injunctive relief for a Takings Claim." Pet. 2. But the panel correctly held that this (mistaken) argument is irrelevant to the *Ex parte Young* analysis. *Verizon* made clear that "[t]he inquiry into whether suit lies under *Ex parte Young* does not include an analysis of the merits of a claim," 535 U.S. at 636-37, and whether Teva has a "viable" claim for prospective relief is obviously a merits question. Pet. 2.

The panel's reasoning is consistent with the Eighth Circuit's decision in *PhRMA*, which held that the *Ex parte Young* doctrine applied to a materially identical takings suit. In *PhRMA*, a trade group of pharmaceutical manufacturers sued to enjoin a law that permitted individuals to obtain insulin from Minnesota pharmacies for relatively small co-payments and—like the program at issue here—required manufacturers to either resupply pharmacies "at no charge" or "reimburs[e] the pharmacy in an amount that covers the pharmacy's acquisition cost." 64 F.4th at

937–38. Because the plaintiff "specifically requested declaratory and injunctive relief" against "ongoing" takings, 64 F.4th at 950, and did not seek "compensation for the damage … *already caused*," *id.* (quoting *Ladd v. Marchbanks*, 971 F.3d 574, 581 (6th Cir. 2020)), the Eighth Circuit held that "the *Ex Parte Young* exception is applicable, and sovereign immunity does not bar PhRMA's suit." *Id.*

The Eighth Circuit is not alone in applying the doctrine of Ex parte Young to takings claims. In *PhRMA*, the Eighth Circuit relied on the Sixth Circuit's decision in Laborers' International Union of North America, Local 860 v. Neff, 29 F.4th 325 (6th Cir. 2022), which observed that the defendant's "status as an arm of the State would not prevent us from enjoining [it] from future violations of the Takings Clause." Id. at 334 (citing Ex parte Young, 209 U.S. 123, 159–60 (1908)). Neff's express statement that a federal court could properly enjoin a taking under Ex parte Young belies the State Officials' reliance on the decision, which the panel properly rejected. See Slip Op. 7 n.3. And as the panel noted, this Court itself "considered whether Ex parte Young" applied to a takings claim in Williams v. Utah Department of Corrections, 928 F.3d 1209, 1213 (10th Cir. 2019), and "determined it did not under our 'straightforward inquiry," which "does not consider the availability of a state forum." Id. at 5 n.2 (quoting Williams, 928 F.3d at 1214–15).

The State Officials have not identified any authority holding that—contrary to the conclusions of the panel, the Eighth Circuit, the Sixth Circuit, and this Court

in *Williams—Ex parte Young* is categorically inapplicable in takings cases because injunctive relief is never available. The State Officials emphasize that the *Ex parte Young* analysis goes "beyond pleading labels," Pet. 10, but the cases on which the State Officials rely involved plaintiffs who, although they purported to seek prospective relief, were effectively seeking retrospective damages in the guise of an injunction. As the panel rightly explained, the question in those cases is "whether relief is 'properly characterized as prospective," which "is a separate question from whether injunctive relief is warranted in a given case." Slip Op. 6 (quoting *Hill v. Kemp*, 478 F.3d 1236, 1259 (10th Cir. 2007)). "[A]nd here, no question exists that [Teva] *seeks* injunctive relief to prevent enforcement of an allegedly unconstitutional act." *Id*.

The State Officials also make the new argument that, even though Teva seeks prospective relief, the Eleventh Amendment applies because Teva's suit would have "the practical effect of ensuring an award of damages in a subsequent state court action." Pet. 12. The State Officials point out that, because the district court determined when denying the motion to dismiss that Colorado's reimburse-or-resupply requirement violates the Takings Clause, "Teva can simply take the district

¹ One such case was *EEE Minerals, LLC v. North Dakota*, 81 F.4th 809 (8th Cir. 2023), where the Eighth Circuit declined to apply *Ex parte Young* because the plaintiff had "repackage[d] her claim for monetary relief as a request for an injunction that cures past injuries." *Id.* at 816.

court's takings decision to state court where it would serve as res judicata" and obtain a damages award. Pet. 14. But the State Officials obscure the critical point that Teva would be obtaining compensation for takings that occurred after Teva filed its federal action for injunctive relief, and after the district court ruled those takings would be unconstitutional. This is not a case like Green v. Mansour, 474 U.S. 64 (1985), where there was "no claimed continuing violation of federal law" and the only live dispute concerned "the lawfulness of [the government's] past actions," id. at 73, nor like Edelman v. Jordan, 415 U.S. 651 (1974), where the plaintiffs sought monetary compensation for past injuries under the guise of "equitable restitution," id. at 668. The State Officials are really complaining about the fact that, when a federal court agrees with a plaintiff that an impending government action would violate the Constitution, the government will expose itself to monetary liability if it nonetheless chooses to go forward with the illegal action. That is an unavoidable consequence of the government's own decision, and it does not somehow render the plaintiff's otherwise permissible suit for prospective relief invalid under Ex parte Young.

B. Prospective Relief Is Available When a Statute Authorizes an Endless Series of Takings.

In any event, although it is a merits question irrelevant to this interlocutory appeal, the State Officials are wrong that injunctions are never available in takings cases. The State Officials rely heavily on *Knick v. Township of Scott*, 588 U.S. 180

(2019), which observed that injunctions will "ordinarily" be unavailable in takings cases, *id.* at 202, because an after-the-fact suit for compensation will give the property owner an "adequate remedy at law," *id.* at 200. But *Knick* did not hold, as the Eighth Circuit noted in *PhRMA*, "that *every* state's compensation remedy is adequate *in a particular situation.*" *PhRMA*, 64 F.4th at 941 (emphasis added). When the remedy of retrospective compensation would not be "as complete, practical, and efficient as that which equity could afford," *id.* at 942 (quoting *Terrace v. Thompson*, 263 U.S. 197, 214 (1923)), then the plaintiff is entitled to an injunction. And courts have long recognized that injunctions are warranted when "effective legal relief can be secured only by a multiplicity of actions, as, for example, when the injury is of a continuing nature." *Id.* at 943 (quoting Charles Alan Wright et al., *Federal Practice and Procedure* § 2944 (3d ed. 2013)).

Accordingly, the Eighth Circuit held in *PhRMA* that retrospective suits for compensation are not an adequate remedy when a statute "authorizes a repetitive (and essentially endless) series of new, *per se* takings." *Id.* at 942. The Eighth Circuit rightly observed that "[f]orcing a party to engage in repetitive lawsuits indefinitely seems to be precisely the sort of legal inadequacy that would make equitable relief an available and preferred method of redress." *Id.* The same result should follow here. Because Colorado law authorizes the repeated and indefinite

taking of Teva's property without compensation, the only adequate remedy is an injunction.

II. THE PANEL'S DECISION IS NOT EXCEPTIONALLY IMPORTANT.

Rehearing en banc would be inappropriate not only because the panel's decision is correct and consistent with directly on-point authority from a sister circuit, but also because the decision does not raise "an issue of exceptional public importance." L.R. 40.1(B). As a threshold matter, en banc review cannot be warranted to undo an unpublished decision that will not bind district courts in other litigation or future panels of this Court. The decision can be cited only for its persuasive value, and state governments will have an opportunity to explain to future courts why they should not adopts its reasoning.

Even putting aside the decision's lack of precedential value, it will not "open[] the door for plaintiffs to pursue relief in federal court to which they are not entitled," as the State Officials argue. Pet. 18. If a plaintiff seeks prospective relief to which he is plainly not entitled—as in the case of a typical, one-time taking, where full compensation is available in state court—then the court will dismiss his complaint for failure to state a claim upon which the requested relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). The State Officials would apparently prefer that the dismissal rest on Eleventh Amendment grounds, but the distinction is academic. A state government will be forced to litigate a takings claim in state court only where, as

here, the plaintiff alleges an unusual circumstance where post-taking compensation is not an adequate remedy. Such circumstances do not often arise, but when they do, federal courts have an obligation to hear the plaintiff's case and, if warranted, enjoin the state's unconstitutional actions going forward.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for rehearing en banc.

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