IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

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.

Case No.: 23-cv-2584

PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), the Fifth Amendment of the United States Constitution, and the Local Rules of the District of Colorado, Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") seeks a preliminary injunction enjoining Michael Conway, in his official capacity as Commissioner of the Colorado Division of Insurance, and Philip J. Weiser, in his official capacity as the Attorney General of Colorado, from implementing and enforcing the epinephrine auto-injector "affordability program" created by section 3 of House Bill 23-1002 ("HB 23-1002"). The requested relief would avert irreparable injury to Teva and the public interest during the pendency of this litigation. Because HB 23-1002 is

scheduled to go into effect on January 1, 2024, Teva respectfully requests that this Court enter the requested injunction no later than December 31, 2023.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules

Other Authorities

INTRODUCTION

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") seeks a preliminary injunction barring the implementation of the epinephrine auto-injector "affordability program" established by HB 23-1002 because it will compel unconstitutional *per se* takings of Teva's products. Under the program, any time an eligible uninsured Coloradan acquires an epinephrine auto-injector from a Colorado pharmacy, Teva must send the pharmacy a *free* replacement. Teva's only alternative is to reimburse the pharmacy the full price it paid for the auto-injector—an amount that will almost always be *more* than what Teva could make (and did make) selling the product to a wholesaler. In other words, Teva can either give its product away for free, or make a cash payment that equals or exceeds the product's market value to Teva.

Neither of those options complies with the Takings Clause of the Fifth Amendment, which provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const. amend. V. Colorado has many constitutional means at its disposal to enhance its citizens' access to epinephrine auto-injectors—including HB 23-1002's cap on insurance copayments, which is not at issue here. But if the Takings Clause forbids anything, it forbids Colorado from seizing products from their manufacturers without any compensation.

If the affordability program is permitted to go into effect, Teva will be forced to provide Colorado pharmacies with free epinephrine auto-injectors, or else risk

tens of thousands of dollars in fines and an action for treble damages under the Colorado Consumer Protection Act. And Teva cannot effectively recover compensation for its products in an after-the-fact suit for compensation because, without an injunction, there will always be more demands for free auto-injectors during the pendency of any suit. The only alternative to an injunction is an unending series of lawsuits seeking compensation for unlawful takings, which is hardly an adequate remedy. Teva will thus be irreparably injured unless this Court enters a preliminary injunction to preserve the status quo.

A preliminary injunction also serves the public interest. Preventing constitutional violations is always in the public interest, and there is no doubt that, without an injunction, Teva will suffer repeated violations of its constitutional rights. Denying a preliminary injunction would only induce uninsured Coloradans to rely on an affordability program that will inevitably be struck down because of its obvious constitutional defects. The best course is for this Court to preserve the status quo by issuing a preliminary injunction and for the state of Colorado to consider alternative, constitutionally sound means of enhancing its uninsured citizens' access to epinephrine auto-injectors.

STATEMENT OF FACTS

A. Teva Sells Life-Saving Epinephrine Auto-Injectors at Competitive Prices.

Epinephrine auto-injectors are single-use, spring-loaded syringes that can deliver a dose of the hormone epinephrine (also known as adrenaline) to individuals experiencing anaphylaxis—a potentially fatal allergic reaction that can involve swelling of the throat and tongue, vomiting, and medical shock. FDA first approved the epinephrine auto-injector in 1987. More than thirty years later, in 2018, FDA granted Teva's application to sell the first generic epinephrine auto-injector in the United States.

Teva sells 0.3-milligram and 0.15-milligram epinephrine auto-injectors at a "wholesale acquisition cost" ("WAC") of $300, minus any applicable discounts or price concessions. *See* Ex. A, Decl. of Kevin Galownia ("Galownia Decl.") ¶¶ 3, 5. The WAC for Teva's auto-injectors is approximately half that for branded epinephrine auto-injectors. *Id.* ¶ 6. Teva sells its products to distributors and wholesalers, who then sell the auto-injectors to pharmacies. *Id.* ¶ 4. According to the sales data available to Teva, between June 30, 2022 and June 30, 2023, at least 14,000 of its epinephrine auto-injectors were shipped to pharmacies in Colorado. *Id.* ¶ 7.

B. Colorado's Epinephrine Auto-Injector Affordability Program

On June 7, 2023, Governor Jared Polis signed HB 23-1002, a bill "concerning the affordability of epinephrine auto-injectors." The bill began by declaring that "[e]pinephrine auto-injectors are essential because they are the easiest and most efficient way to potentially save the life of an individual exhibiting symptoms of or experiencing anaphylactic shock" and that "[m]any individuals are unable to afford an epinephrine auto-injector because they cannot pay the copayment amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector[.]" §§ 1(e)-(f). The bill addressed this affordability problem through two distinct measures. First, the bill provided that "[f]or health coverage plans issued or renewed on or after January 1, 2024, if a carrier provides coverage for prescription epinephrine auto-injectors, the carrier shall cap the total amount that a covered person is required to pay for all covered prescription epinephrine auto-injectors at an amount not to exceed sixty dollars for a two-pack of epinephrine auto-injectors[.]" § 2, 10-16-160 (2). Teva does not challenge the constitutional validity of this sixty-dollar cap on copayments.

Second, the bill directed the Colorado Division of Insurance to establish the "affordability program" at issue here 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. § 3, 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 initial application remains valid for one year, and there are no limits on the number of epinephrine auto-injectors an individual can obtain under the program. *Id.*

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. The bill requires all manufacturers of epinephrine auto-injectors sold in Colorado to "develop a process for a pharmacy to submit an electronic claim for reimbursement" by January 1, 2024. *Id*. 12-280-141 (8)(b). Within thirty days of receiving a reimbursement claim, a manufacturer must either (a) "[r]eimburse the pharmacy in an amount that the pharmacy paid for the number of epinephrine auto-injectors dispensed through the program" or (b) "[s]end the pharmacy a replacement supply of epinephrine auto-injectors in an amount equal to the number of epinephrine auto-injectors dispensed through the program[.]" *Id.* 12-280-142 (8)(c).[1] Any manufacturer who fails to comply with the bill is subject

[1] As originally drafted, subsection 8(d) exempted manufacturers from the reimburse-or-resupply requirement if they sold epinephrine auto-injectors at a "wholesale acquisition cost" of twenty dollars or less. *See* Ex. B at § 3, 12-280-141(8)(II)(d). That exemption was removed from the final version. Due to an apparent drafting oversight, the final bill still provides that pharmacies may submit claims for

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 (2019), 6-1-113 (1) (2022), and can result in treble damages. *Id*. 6-1-113 (2)(a)(III).

C. This Lawsuit

On October 3, 2023, concurrently with the filing of this motion, Teva filed suit in this Court against Michael Conway—who, as Commissioner of the Colorado Division of Insurance, is tasked with establishing and administering the epinephrine-injector affordability program—and Philip Weiser—who, as Colorado Attorney General, has the authority to file a Colorado Consumer Protection action against any manufacturer that does not comply with the program's requirements—in their official capacities. Teva's complaint seeks a permanent injunction barring Defendants from enforcing HB 23-1002's requirement that Teva reimburse or resupply Colorado pharmacies who dispense Teva's epinephrine auto-injectors to individuals participating in the affordability program, as well as a declaratory judgment that the reimburse-or-resupply requirement violates the Takings Clause of the Fifth Amendment of the Constitution of the United States.

---

reimbursement "except as provided in subsection (8)(d)," even though there is no subsection (8)(d) in the bill.

ARGUMENT

To prevail on a motion for a preliminary injunction, a plaintiff must establish that: (1) it is substantially likely to succeed on the merits; (2) it will suffer irreparable injury if the injunction is denied; (3) its threatened injury outweighs the injury the opposing party will suffer under the injunction; and (4) the injunction would not be adverse to the public interest. *See Beltronics USA, Inc. v. Midwest Inventory Distrib.*, 562 F.3d 1067, 1070 (10th Cir. 2009). The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). All the factors are readily met here.

I. TEVA IS HIGHLY LIKELY TO SUCCEED ON THE MERITS.

To establish a substantial likelihood of success on the merits, a plaintiff "must present a prima facie case but need not show a certainty of winning." *Coal. of Concerned Citizens to Make Art Smart v. Fed. Transit Admin.*, 843 F.3d 886, 901 (10th Cir. 2016) (quoting 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure*, § 2948.3, at 201 (2013)). Teva is highly likely to succeed on its challenge to the epinephrine-auto-injector affordability program, which indisputably takes Teva's property without any compensation.

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. There cannot be any serious dispute that, by requiring Teva to either replace the

epinephrine auto-injectors that pharmacies dispense or reimburse the pharmacies for their cost—which reimbursement will inevitably equal or (more likely) exceed the money Teva makes in selling these products to its wholesaler distributors—the affordability program effects an uncompensated taking of Teva's property.

"When the government physically acquires private property for a public use, the Takings Clause imposes a clear and categorical obligation to provide the owner with just compensation." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021). That obligation to compensate applies with the same force to acquisitions of personal property, including items a business produces for sale, as to acquisitions of real property. *See Horne v. Dept. of Agric.*, 576 U.S. 350, 359 (2015) (rejecting the contention that "personal property [i]s any less protected against physical appropriation than real property"). The affordability program's requirement that Teva provide replacement auto-injectors to Colorado pharmacies for free is clearly a "*per se* physical taking" of Teva's personal property that triggers a "simple, *per se* rule: The government must pay for what it takes." *Cedar Point Nursery*, 141 S. Ct. at 2071–72.

It makes no difference that the affordability program requires Teva to deliver free auto-injectors to Colorado pharmacies, rather than the government itself. What matters is that the taking is "government-*authorized*," not who physically acquires the property. *Id*. at 2073 (emphasis added). Accordingly, the Supreme Court has

repeatedly held that a physical appropriation "authorized by state law is a taking without regard to whether the State, or instead a party authorized by the State" receives the property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 432 n.9 (1982); *see id*. at 438 (holding that statute authorizing a cable television company to install cables and boxes on private property effected a taking); *Cedar Point Nursery*, 141 S. Ct. at 2072 (holding that law granting "union organizers a right to physically enter and occupy the growers' land" effected a *per se* taking).

Nor does it matter that the affordability program gives Teva the option of reimbursing pharmacies for the epinephrine auto-injectors, rather than replacing them. The Supreme Court has made clear that a government may not "simply give the owner a choice of either surrendering [the property] or making a payment equal to [the property's] value." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013). Moreover, because the price pharmacies pay wholesalers for auto-injectors will almost always be higher than the price that Teva can charge those same wholesalers, the choice between replacement and reimbursement is really no choice at all. Sending free auto-injectors will be cheaper for Teva than paying pharmacies *more* than Teva could earn if it were to keep the auto-injectors and sell them.

Colorado has other, constitutional means of increasing low-income Coloradans' access to epinephrine auto-injectors. The other section of HB 23-1002 imposes a sixty-dollar cap on insurance copayments for auto-injectors, which is

indisputably within the State's regulatory authority. Colorado could impose a similar sixty-dollar price control on all retail sales of epinephrine auto-injectors, which would allow uninsured Coloradans to purchase auto-injectors at the same price they would pay under HB 23-1002's affordability program. What Colorado cannot do is force manufacturers like Teva to bear the entire cost of the program by requiring them to surrender their property without any compensation.

Colorado's epinephrine auto-injector affordability program will, quite clearly, take Teva's epinephrine auto-injectors without compensation and distribute them to eligible members of the public. Because the program presents a straightforward violation of the Takings Clause, Teva is highly likely to succeed on the merits of its challenge.

II. TEVA WILL SUFFER IRREPARABLE INJURY ABSENT AN INJUNCTION.

If the epinephrine auto-injector affordability program goes into effect, Teva will face repeated takings of its epinephrine auto-injectors without any effective means of obtaining compensation. Without an injunction, Teva's only recourse would be a continuous series of repetitive damages actions seeking compensation for each epinephrine auto-injector commandeered by the program. That is not an adequate remedy at law, as the Eighth Circuit recently concluded in a suit to enjoin a materially identical Minnesota law. *See Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932 (8th Cir. 2023) (hereinafter *PhRMA*).

PhRMA concerned Minnesota's Alec Smith Insulin Affordability Act, which allowed eligible 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. A trade association of manufacturers sued for injunctive and declaratory relief on the ground that the statute took their insulin products without compensation, in violation of the Takings Clause. The district court dismissed on the ground that injunctive relief was unavailable because the manufacturers could pursue claims for compensation after surrendering their property. *See Pharm. Rsch. & Mfrs. Of Am. v. Williams*, 525 F. Supp. 3d 946, 951 (D. Minn. 2021). The district court relied heavily on the Supreme Court's decision in *Knick v. Township of Scott*, 139 S. Ct. 2162 (2019), which held that a property owner can bring a federal takings claim the moment the government takes his property without compensation. *Knick* explained that, although a government commits a constitutional violation when it takes property without paying for it, "[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*. at 2176.

The Eighth Circuit reversed, holding that a post-taking suit for compensation was "an inadequate legal remedy because PhRMA's members would be 'bound to

litigate a multiplicity of suits' to be compensated." 64 F.4th at 945 (quoting *Equitable Life Assur. Soc. of U.S. v. Wert*, 102 F.2d 10, 14 (8th Cir. 1939)). The Eighth Circuit noted that the Supreme Court's general statements about injunctions in *Knick* followed from the traditional rule that equitable relief is unavailable where a plaintiff has an "adequate remedy at law." *Knick*, 139 S. Ct. at 2176; *see also id*. at 2180 (Thomas, J., concurring) ("Injunctive relief is not available when an adequate remedy exists at law."). Injunctive relief is "ordinarily" unavailable in takings cases because, where the government seizes a single piece of property or enacts a law that deprives the owner of the property's value, an after-the-fact suit for compensation will make the owner whole. *Id*. at 2177. "But *Knick* does not hold," the Eighth Circuit explained, "that *every* state's compensation remedy is adequate *in a particular situation*." *PhRMA*, 64 F.4th at 941 (emphasis added). A court must instead consider any unique circumstances of the case before it and determine whether "the legal remedy" of post-taking compensation would 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)); *see also United States v. Union Pac. Ry. Co.*, 160 U.S. 1, 51 (1895) ("'It is not enough that there is a remedy at law. It must be paid and adequate, or, in other words, as practical and efficient to the ends of justice and its prompt administration as the remedy in equity.' The circumstances

of each case must determine the application of the rule.") (quoting *Boyce Ex'rs v. Grundy*, 3 Pet. 210, 215 (1830)).

The Eighth Circuit correctly concluded that "the legal remedy of damages is not 'complete, practical, and efficient'" when a statute authorizes an indefinite series of takings. *PhRMA*, 64 F.4th at 945 (quoting *Terrace*, 263 U.S. at 214). Because a suit for retrospective damages will be "incapable of compensating the manufacturers for the repetitive, future takings that will occur under the [statute's] requirements," the property owners would be forced to bring "a repetitive succession of inverse condemnation suits," with each new action trying to recover for the takings not covered by the previous suit. *Id*. The Eighth Circuit noted that courts have long held "equitable relief will be deemed appropriate" where "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)); *see also 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."). Accordingly, the Eighth Circuit held that the insulin manufacturers could seek an injunction against all future takings authorized by Minnesota's insulin affordability program.

The same result should follow here. Colorado's epinephrine auto-injector affordability program authorizes repeated, uncompensated takings of Teva's property. Absent an injunction, Teva can only obtain compensation through an endless series of damages actions. Because "the legal remedy of damages is not 'complete, practical, and efficient'" in those circumstances, injunctive relief is appropriate. *PhRMA*, 64 F.4th at 945 (quoting *Terrace*, 263 U.S. at 214)).

III. A PRELIMINARY INJUNCTION IS IN THE PUBLIC INTEREST.

The public interest is best served by enjoining the plainly unconstitutional takings authorized by HB 23-1002. "[I]t is always in the public interest to prevent the violation of a party's constitutional rights," and there cannot be any dispute that the epinephrine auto-injector affordability program will violate Teva's rights under the Takings Clause. *Awad v. Ziriax*, 670 F.3d 1111, 1132 (10th Cir. 2012) (quoting *Awad v. Ziriax*, 754 F. Supp.2d 1298 (W.D. Okla. 2010)). There is, of course, a significant public interest in increasing access to potentially life-saving medical devices. But "a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change." *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922). Allowing the affordability program to go into effect would only induce uninsured Coloradans to rely on a program that will, inevitably, be struck down because of its obvious constitutional defects.

CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court enter a preliminary injunction barring Defendants from enforcing the requirements of the epinephrine auto-injector affordability program established by HB 23-1002.

Dated: October 3, 2023

Respectfully submitted,

/s/ Alexandra I. Russell

Alexandra I. Russell
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-5258
alexandra.russell@kirkland.com

Jay P. Lefkowitz, P.C. (*Admission Pending*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4970
lefkowitz@kirkland.com

Cole Carter (*Admission Pending*)
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-1951
cole.carter@kirkland.com

Counsel for Plaintiff Teva Pharmaceuticals USA, Inc.