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;

PHILIP J. WEISER, in his official capacity as Attorney General of the State of Colorado; and

PATRICIA A. EVACKO, ERIC 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.

DEFENDANT CONWAY'S MOTION TO DISMISS

Pursuant to Fed. R. Civ. P. 12(b)(1) and (6), Defendant Commissioner Michael Conway, through the Colorado Attorney General, moves to dismiss Plaintiff's claim against him.

D.C.COLO.LCivR 7.1(b)(2) CERTIFICATION

In accordance with D.C.COLO.LCivR 7.1(b)(2) and DDD Civ. P.S. III(D)(1), undersigned counsel conferred with Teva before filing this Motion on November 13, 2023. Teva opposes this Motion, "subject to the negotiation of a joint stipulation of dismissal."

INTRODUCTION

To increase access to life-saving epinephrine, Colorado's General Assembly passed

HB 23-1002. *See* HB 23-1002 [Doc. 20-1].[1] Among other things, HB 23-1002 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.

Section 3 of HB 23-1002 ("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).

A manufacturer that fails to comply with the requirements of the Affordability Program may be subject to discipline, including a fine, by the Colorado Board of Pharmacy and potential

[1] The final signed Act for HB 23-1002 was attached as Exhibit 1 to the Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction [Doc 20-1]. The Court may take judicial notice of the signed Act. *Territory of Alaska v. Am. Can Co*., 358 U.S. 224, 226–27 (1959).

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).

Teva, a manufacturer of epinephrine auto-injectors, takes issue with the Affordability Program. It asserts a Fifth Amendment Takings Clause violation [Docs. 1 and 22] and seeks preliminary relief to enjoin the Affordability Program from taking effect [Doc. 3] or from being enforced against it.[2] Teva names as one of the Defendants Michael Conway, the Colorado Commissioner of Insurance. Commissioner Conway is the state official responsible for the Colorado Division of Insurance whose limited role in the Affordability Program is to develop and make available a form that individuals use to access the epinephrine auto-injectors under the Affordability Program. The Commissioner lacks jurisdiction or oversight over the components of the Affordability Program at issue in Teva's Amended Complaint. Nevertheless, Teva asks that Commissioner Conway be enjoined from enforcing the Affordability Program – something the Commissioner has no authority to do in the first place.

The Commissioner is a wholly improper defendant and should be dismissed.

ARGUMENT

Because Commissioner Conway has an immaterial role in the Affordability Program and in no way enforces it, he is immune under the Eleventh Amendment and Plaintiff has not stated a viable claim against him under 42 U.S.C. § 1983. This Court lacks jurisdiction over Teva's claim against Commissioner Conway, and he should be dismissed from this suit under Fed. R. Civ. P. 12(b)(1) and (6).

[2] Teva does not challenge section 2 of HB 23-1002. [Doc. 22 at ¶ 23].

For brevity and pursuant to Fed. R. Civ. P. 10(c), Commissioner Conway also incorporates the legal arguments regarding Teva's failure to show likelihood of success on the merits found in Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction [Doc. 20] to support his arguments that this court lacks subject matter jurisdiction. The Commissioner also incorporates the arguments made pursuant to Fed. R. Civ. P. 12(b)(1) in The Attorney General's Motion to Dismiss [Doc. 29] relating to the lack of subject matter jurisdiction due to Eleventh Amendment immunity, lack of standing, and lack of ripeness, in addition to the arguments relating to Teva's failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6).

I. COMMISSIONER CONWAY IS IMMUNE UNDER THE ELEVENTH AMENMDENT BECAUSE HE HAS NO RESPONSIBILITY FOR ENFORCEMENT OF THE AFFORDABILITY PROGRAM AND HE SHOULD BE DISMISSED.

Fed. R. Civ. P. 12(b)(1) provides for dismissal of a complaint where the court lacks subject-matter jurisdiction. The determination of a court's subject-matter jurisdiction is a threshold question of law for which the party invoking the court's jurisdiction bears the burden of proof. *Safe Sts. All. v. Hickenlooper*, 859 F.3d 865, 878 (10th Cir. 2017). If the opposing party challenges the jurisdiction of the court as a matter of law, the court must accept the factual allegations as true and determine whether those facts state a claim over which the court has jurisdiction. *Amoco Prod. Co. v. Aspen Grp.*, 8 F. Supp. 2d 1249, 1251 (D. Colo. 1998).

The Eleventh Amendment grants states and state entities the legal power to assert sovereign immunity, which then bars the exercise of federal subject matter jurisdiction. *Steadfast Ins. Co. v. Agric. Ins. Co*., 507 F.3d 1250, 1252-53 (10th Cir. 2007). Eleventh Amendment immunity extends to suits against a state official in their official capacity and applies regardless of whether a plaintiff

seeks declaratory or injunctive relief, or monetary damages. *Id.* at 1252; *Hendrickson v. AFSCME Council 18*, 992 F.3d 950, 965 (10th Cir. 2021).

"Eleventh Amendment immunity 'is not absolute.'" *Hendrickson*, 992 F.3d at 965. "Under the *Ex parte Young* exception [to state sovereign immunity], 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*, 992 F.3d at 965 (citing *Ex parte Young*, 209 U.S. 123, 159-60 (1908)). But to satisfy this exception, the named state official must "have a particular duty to 'enforce' the statute in question and a demonstrated willingness to exercise that duty[.]"*Prairie Band Potawatomi Nation v. Wagnon*, 476 F.3d 818, 828 (10th Cir. 2007) (finding that state officials may be sued because they give effect to the law when they manage and supervise the program, determine validity of documents under the law, and are responsible for enforcement). Enforcement is "[t]he act or process of compelling compliance with a law, mandate, command, decree, or agreement." *Enforcement*, BLACK'S LAW DICTIONARY (11th ed. 2019).

Assuming without conceding that Teva may maintain its Fifth Amendment takings claim for equitable relief in this Court, Teva must still establish that Commissioner Conway has a duty to enforce the Affordability Program to satisfy the *Ex parte Young* exception to the Eleventh Amendment. Because it cannot, the Commissioner should be dismissed.

The Affordability Program 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 against these entities. The Commissioner not only lacks a duty to enforce the Affordability Program, he lacks authority to do so.

The Affordability Program contains three discrete tasks that involve the Division of Insurance: (1) develop the application form for eligible individuals to submit to pharmacies to receive auto-injectors (C.R.S. § 12-280-142(4)(a)); (2) make the form available on its website and to pharmacies, providers, and facilities that prescribe or dispense auto-injectors (C.R.S. § 12-280-142(4)(b)); and (3) help promote the availability of the program (C.R.S. § 12-280-142(9)). None of these tasks involves compelling compliance with the Affordability Program's requirements on pharmacies and manufacturers. Neither the Division of Insurance nor the Commissioner verifies eligibility, ensures the pharmacy dispenses the auto-injectors, requires pharmacies to submit a claim to the manufacturer, or monitors whether a manufacturer issues a reimbursement or re-supplies the pharmacy. The Division's role is purely consumer-facing.

Teva alleges that "The bill also directed the Colorado Division of Insurance to establish an 'affordability program' by January 1, 2024." [Doc. 22 at ¶ 24.] But HB 23-1002 does no such thing. HB 23-1002 does not direct the Commissioner to establish the Affordability Program; the statute itself establishes the program. [Doc. 20-1 at § 1(2)]. The bill summary set forth in the Exhibit to Teva's Motion for Preliminary Injunction [Doc. 2] again underscores the Division's limited role — "The bill requires the division of insurance in the department of regulatory agencies (division) to create an application for the program and requires the division and the department of health care policy and financing to make the application available on their websites and to promote the availability of the program." [Doc. 2-2 at 3]. The Division of Insurance does not "establish"

the program; it does not have authority to promulgate rules related to the Affordability Program, verify eligibility, or discipline for non-compliance. Teva's Amended Complaint lacks any allegations as to how Commissioner Conway violates Teva's rights at all.

"[W]hen 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). The State Board of Pharmacy is the state entity with responsibility for enforcing the Affordability Program.[3] Recognizing this, Teva has amended its Complaint to add the Board members as Defendants. [Doc. 22]. But, inexplicably and despite the fatal jurisdictional flaws[4], it has not dismissed the Commissioner.

Additionally, and under the legal arguments set forth more fully in The Attorney General's Motion to Dismiss [Doc. 29] and the Defendants' Response in Opposition to the Motion for Preliminary Injunction [Doc. 20] (as incorporated above), the Commissioner of Insurance is immune under the Eleventh Amendment because Teva cannot bring a takings claim in federal court against any state defendant. It has an adequate remedy under state law and federal jurisdiction, even in equity, is inappropriate.

[3] The Affordability Program is codified at C.R.S. § 12-280-142. The State Board of Pharmacy has the responsibility for enforcing the provisions within title 12, article 280 of the Colorado Revised Statutes. C.R.S. § 12-280-104(1).

[4] Teva acknowledges these jurisdictional flaws stating that "if the Pharmacy Board has the enforcement authority for the affordability program, and the Division of Insurance lacks any, then the Board members are proper defendants, and the Commissioner of Insurance is not." [Doc. 26 at 4].

II. TEVA FAILS TO STATE A CLAIM THAT THE COMISSIONER IS THE "MOVING FORCE" BEHIND THE AFFORDABILITY PROGRAM AS IS NECESSARY TO ESTABLISH LIABILITY UNDER 42 U.S.C. § 1983.

Under Fed. R. Civ. P. 12(b)(6), a court may dismiss a complaint for failure to state a claim upon which relief can be granted. "[T]o withstand a motion to dismiss, a complaint must contain enough allegations of fact 'to state a claim to relief that is plausible on its face.'" *Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) (citation omitted); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "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*, 556 U.S. at 678. "Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007).

For a government entity's official sued in his official capacity to be liable under 42 U.S.C. § 1983, the entity's "policy or custom" must have been the moving force behind the alleged violation of federal law. *Kentucky v. Graham,* 473 U.S. 159, 166 (1985); *Dalcour v. City of Lakewood,* 492 F. App'x 924, 930 (10th Cir. 2012). A plaintiff must demonstrate "(1) the defendant promulgated, created, implemented, or possessed responsibility for the continued operation of a policy that (2) caused the complained of constitutional harm, and (3) acted with the state of mind required to establish the alleged constitutional deprivation." *Dodds v. Richardson*, 614 F.3d 1185, 1199 (10th Cir. 2010) (citing *Summum v. City of Ogden*, 297 F.3d 995, 1000 (10th Cir. 2002)).

The Amended Complaint is facially insufficient because it fails to allege any facts that would establish an affirmative link between Commissioner Conway and the alleged constitutional

violations caused by the Affordability Program (*see Martinez v. Milyard,* 440 F. App'x 637, 638 (10th Cir. 2011), let alone that he "promulgated, created, implemented, or possessed responsibility for the continued operation" of the Affordability Program by operation of a policy or custom (*Dodds*, 614 F.3d at 1199). The Amended Complaint merely concludes: "By seeking to implement and enforce the Act, Defendants, acting under color of state law, have violated and, unless enjoined by this Court, will continue to violate Teva's constitutional rights." Doc 22 at ¶ 38.

Teva fails to allege any facts necessary to establish that Commissioner Conway was the "moving force" behind the alleged constitutional violations associated with the Affordability Program. Nor could it. As set forth above, the Commissioner has no responsibility to enforce or implement the Affordability Program. The Division of Insurance merely develops an application and posts information on its website. Eligible individuals, applicable pharmacies, and potential manufacturers implement the Affordability Program components that Teva objects to in its Amended Complaint. This is wholly inadequate to hold the Commissioner responsible in his official capacity under 42 U.S.C. § 1983.

For these reasons Commissioner Conway requests that he be dismissed for Plaintiff's failure to state a claim against him.

CONCLUSION

Because Commissioner Conway is immune under the Eleventh Amendment and Teva fails to state a claim against him, Teva's claims against him should be dismissed.

DATED: November 15, 2023.

PHILIP J. WEISER

Attorney General

/s/ Abby Chestnut

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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/ Abby Chestnut