

**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.

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.

**BOARD MEMBER DEFENDANTS' ANSWER TO PLAINTIFF'S FIRST
AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Defendants Patricia A. Evacko, Eric Frazer, Ryan Leyland, Jayant Patel, Avani Soni, Kristen Wolf, and Alexandra Zuccarelli, in their official capacities as members of the Colorado State Board of Pharmacy (collectively, "Board Defendants"), hereby submit their Answer to Plaintiff Teva Pharmaceutical USA, Inc.'s ("Teva") First Amended Complaint for Declaratory and Injunctive Relief [Doc. #22] ("Amended Complaint").

PRELIMINARY STATEMENT

1. Board Defendants are without knowledge or information sufficient to admit or deny the allegations contained in paragraph 1 of the Amended Complaint and, therefore, deny the same.

2-3. Board Defendants deny the allegations contained in paragraphs 2 and 3 of the Amended Complaint.

4. The allegations contained in paragraph 4 of the Amended Complaint do not appear to be directed to the Board Defendants and do not require an answer from Board Defendants, but to the extent that such allegations require an answer, they are denied.

PARTIES

5. With respect to the allegations contained in paragraph 5 of the Amended Complaint, Board Defendants admit that Teva currently manufactures generic epinephrine auto-injectors in two sizes: 0.3 milligrams and 0.15 milligrams for children. Board Defendants are without knowledge or information sufficient to admit or deny the remaining allegations contained in paragraph 5 of the Amended Complaint and, therefore, deny the same.

6. With respect to the allegations contained in paragraph 6 of the Amended Complaint, Board Defendants admit that Michael Conway is the Commissioner of the Colorado Division of Insurance. Board Defendants deny, however, that Michael Conway is a Defendant in this case. Board Defendants admit the remaining allegations in paragraph 6 of the Amended Complaint.

7-13. Board Defendants admit the allegations contained in paragraphs 7, 8, 9, 10, 11, 12, and 13 of the Amended Complaint.

14. With respect to the allegations contained in paragraph 14 of the Amended Complaint, Board Defendants admit that to the extent the Board of Pharmacy asserts its statutory authority to enforce the relevant provisions of the program, it would be acting under the color of state law. Board Defendants are without knowledge or information sufficient to admit or deny the remaining allegations of paragraph 14 and, therefore deny the same.

15. With respect to the allegations contained in paragraph 15 of the Amended Complaint, Board Defendants admit that HB 23-1002 includes language empowering the State Board of Pharmacy to exercise its discretion in enforcing certain provisions of HB 23-1002. Board Defendants deny that HB 23-1002 will be enforced by each defendant as only the Board of Pharmacy as a whole, not the individual members, has enforcement authority. Board Defendants are without knowledge or information sufficient to admit or deny the remaining allegations of paragraph 15 of the Amended Complaint.

JURISDICTION AND VENUE

16. Board Defendants deny the allegations contained in paragraph 16 of the Amended Complaint.

17. As to paragraph 17, Board Defendants admit that venue lies in this District but deny that HB 23-1002 will be enforced by each defendant in this district as only the Board of Pharmacy as a whole, not the individual members, has

enforcement authority, and state that the Board of Pharmacy has not yet taken an enforcement action under the program since it became effective.

18-21. Board Defendants deny the allegations contained in paragraphs 18, 19, 20, and 21 of the Amended Complaint.

FACTUAL BACKGROUND

Teva's Work to Bring Low-Cost Epinephrine Auto-Injectors to Consumers

22. With respect to the allegations contained in paragraph 22 of the Amended Complaint, Board Defendants admit that 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. Board Defendants further admit that Teva's generic auto-injectors are available in Colorado. Board Defendants are without sufficient knowledge or information to admit or deny the remaining allegations contained in paragraph 22 of the Amended Complaint and, therefore, deny the same.

Colorado's Epinephrine Auto-Injector Affordability Program

23. Board Defendants admit the allegations contained in paragraph 23 of the Amended Complaint.

24. With respect to the allegations contained in paragraph 24 of the Amended Complaint, Board Defendants deny that a Colorado resident must not have private health insurance to be eligible for the program. Board Defendants also deny

the implication that applicants may only be required to provide proof of residency in Colorado to qualify for the program. Board Defendants admit the remaining allegations contained in paragraph 24 of the Amended Complaint.

25. Board Defendants admit the allegations contained in paragraph 25 of the Amended Complaint.

26. With respect to the allegations contained in paragraph 25 of the Amended Complaint, Board Defendants deny Plaintiff's description of the penalties for noncompliance as "significant." Board Defendants admit the remaining allegations of paragraph 26 of the Amended Complaint.

27. With respect to the allegations contained in paragraph 26 of the Amended Complaint, Board Defendants admit that HB 23-1002's imposition of a sixty-dollar cap on insurance copayments for auto-injectors falls within the State's regulatory authority. Board Defendants are without sufficient knowledge or information to admit or deny whether Colorado could impose a similar sixty-dollar price control on all retail sales of epinephrine auto-injectors at the same price they would pay under HB 23-1002's affordability program and, therefore, deny the same. Board Defendants deny the remaining allegations contained in paragraph 27 of the Amended Complaint.

Teva's Sale of Generic Auto-Injectors

28-31. Board Defendants are without knowledge or information sufficient to admit or deny the allegation contained in paragraphs 28, 29, 30 and 31 of the Amended Complaint and, therefore, deny the same.

CLAIMS FOR RELIEF

**FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief – Violation of the Takings Clause of the Fifth Amendment)**

32. Board Defendants restate their answers to paragraphs 1-31 of the Amended Complaint as though fully set out herein.

33-36. Board Defendants deny the allegations contained in paragraphs 33, 34, 35, and 36 of the Amended Complaint.

**SECOND CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)**

37. Board Defendants restate their answers to paragraphs 1-36 of the Amended Complaint as though fully set out herein.

38-40. Board Defendants deny the allegations contained in paragraphs 38, 39, and 40 of the Amended Complaint.

GENERAL DENIAL

Board Defendants deny each and every allegation contained in the Amended Complaint not expressly admitted, and deny all averments contained in Plaintiff's "Prayer for Relief" in paragraphs A-D of the Amended Complaint, including that Plaintiff is entitled to the requested relief.

DEFENSES

1. The Amended Complaint fails, in whole or in part, to state a claim upon which relief may be granted.
2. This Court lacks subject matter jurisdiction over Plaintiff's claims.
3. Plaintiff's claims are not ripe.
4. Plaintiff lacks standing to bring this action.
5. Board Defendants are immune from this lawsuit.
6. To the extent any harm is alleged, Plaintiff failed to mitigate it.

Board Defendants reserve the right to supplement or amend their defenses as the action progresses.

WHEREFORE, the Board Defendants ask this Court to dismiss Plaintiff's Amended Complaint and the causes of action therein, enter judgment in the Board Defendants' favor, and award the Board Defendants their costs and disbursements incurred in connection with the Amended Complaint, including reasonable attorney fees, and for such other and further relief as the Court may deem just and proper.

Dated this 10th day of January 2024.

Respectfully submitted by:

PHILIP J. WEISER
Attorney General

s/ Jennifer Johnson

JENNIFER JOHNSON, #46982*

Assistant Attorney General

Ralph L. Carr Colorado Judicial Center

1300 Broadway, 8th Floor

Denver, CO 80203

Phone: (720) 508-6379

Email: jennifer.johnson@coag.gov