



**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**
717 MADISON PLACE, N.W.
WASHINGTON, D.C. 20439

JARRETT B. PERLOW
CLERK OF COURT

CLERK'S OFFICE
202-275-8000

August 4, 2026

NOTICE OF DOCKETING

Federal Circuit Docket No.: 2026-2111

Federal Circuit Short Caption: Amgen Inc. v. Mizner

Date of Docketing: August 4, 2026

Originating Tribunal: United States District Court for the District of Colorado

Originating Case No.: 1:25-cv-03452-DDD-STV

Appellants: Gail Mizner, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, James Justin VandenBerg, Michael Conway, Philip Weiser

A notice of appeal has been filed and assigned the above Federal Circuit case number. The court's official caption is included as an attachment to this notice. Unless otherwise noted in the court's rules, the assigned docket number and official caption or short caption must be included on all documents filed with this Court. It is the responsibility of all parties to review the Rules for critical due dates. The assigned deputy clerk is noted below and all case questions should be directed to the Case Management section at (202) 275-8055.

FEE PAYMENT: The filing fee has been paid or in forma pauperis status has been granted.

The following filings are due within 14 days of this notice:

- [Entry of Appearance](#) or [Notice of Unrepresented Person](#). (Fed. Cir. R. 47.3.)
- [Certificate of Interest](#). (Fed. Cir. R. 47.4; not required for unrepresented and federal government parties unless disclosing information under Fed. Cir. R. 47.4(a)(6))
- [Docketing Statement](#). (Fed. Cir. R. 47.6 and the [Mediation Guidelines](#); no docketing statement is required in cases with an unrepresented party)
- [Statement Concerning Discrimination](#) in MSPB or arbitrator cases. (Fed. Cir. R. 15(c); completed by petitioner only)

- Fee payment or appropriate fee waiver request, if the docketing fee was not prepaid.

FILING DOCUMENTS: Each counsel representing a party must be a member of the court's bar and registered for the court's electronic filing system. Parties represented by counsel must make all filings through the court's electronic filing system.

Unrepresented parties may choose to submit case filings to the court either in paper or through the court's electronic filing system; electronic filing will only be permitted for unrepresented parties after successful registration for the court's electronic filing system and submission of a completed Notice of Unrepresented Person Appearance. Fed. Cir. R. 25(a). The court's Electronic Filing Procedures may be accessed at www.cafc.uscourts.gov/contact/clerks-office/filing-resources.

CONTACT INFORMATION: Electronic filers, or unrepresented parties registered to receive electronic service, must update their contact information in their PACER service center profile whenever their contact information changes. Counsel must file an amended Entry of Appearance and unrepresented parties must file an amended Notice of Unrepresented Person Appearance whenever contact information changes. Fed. Cir. R. 25(a)(5).

OFFICIAL CAPTION: The court's official caption is attached and reflects the lower tribunal's caption pursuant to Fed. R. App. P. 12(a), 15(a), and 21(a). Please review the caption carefully and promptly advise this court in writing of any improper or inaccurate designations.



Jarrett B. Perlow
Clerk of Court

By: I. Hammer, Deputy Clerk

Attachments:

- Official caption
- Paper Copies of Forms (to unrepresented parties only):
 - [Notice of Unrepresented Person Appearance](#)
 - [Motion and Affidavit for Leave to Proceed in Forma Pauperis](#) (only to filers owing the docketing fee)
 - [Supplemental in Forma Pauperis Form for Prisoners](#) (only to filers in a correctional institution)

cc: United States District Court for the District of Colorado

Official Caption

**AMGEN INC., IMMUNEX CORPORATION, AMGEN MANUFACTURING
LTD. LLC,**

Plaintiffs-Appellees

v.

**GAIL MIZNER, SAMI DIAB, AMARYLIS GUTIERREZ, CATHERINE
HARSHBARGER, JAMES J. VANDENBERG, MICHAEL CONWAY, PHILIP
WEISER,**

Defendants-Appellants

Short Caption

Amgen Inc. v. Mizner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-3452-DDD-STV

AMGEN INC., et al.,

Plaintiffs,

v.

GAIL MIZNER MD, in her official capacity
as Chair of the Colorado Prescription Drug
Affordability Review Board, et al.,

Defendants.

DEFENDANTS' NOTICE OF APPEAL FROM AN APPEALABLE ORDER

Pursuant to 28 U.S.C. §§ 1292(a)(1) & (c)(1), Defendants Gail Mizner, M.D., Sami Diab, M.D., Amarylis Gutierrez, Pharm.D., Catherine Harshbarger, and James Justin Vandenberg, Pharm.D., in their official capacities as Board members of the Colorado Prescription Drug Affordability Review Board; Michael Conway, in his official capacity as Commissioner of Insurance; and Philip J. Weiser, in his official capacity as Attorney General of the State of Colorado hereby appeal to the United States Court of Appeals for the Federal Circuit from the Court's Order Granting Motion for Preliminary Injunction (Doc. 66) dated July 1, 2026, and for all interlocutory or other orders and rulings subsidiary or related thereto.

Dated: July 30, 2026

Respectfully submitted,

PHILIP J. WEISER
Attorney General

s/ Pawan Nelson

SARA STULTZ, 54357*
PAWAN NELSON, 49462*
Senior Assistant Attorneys General
REBECCA WALKER, 55290*
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** Counsel of Record for Defendants*

ALLMTN,FEDAPP,JD3

U.S. District Court – District of Colorado
District of Colorado (Denver)
CIVIL DOCKET FOR CASE #: 1:25-cv-03452-DDD-STV

Amgen Inc. et al v. Mizner et al
Assigned to: Chief Judge Daniel D. Domenico
Referred to: Magistrate Judge Scott T. Varholak
Cause: 28:2201 Declaratory Judgment

Date Filed: 10/30/2025
Jury Demand: None
Nature of Suit: 950 Constitutionality of
State Statutes
Jurisdiction: Federal Question

Plaintiff

Amgen Inc.

represented by **Alexander Kazam**
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Plaintiff

Immunex Corporation

represented by **Alexander Kazam**
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ATTORNEY TO BE NOTICED

Ashley Charles Parrish
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ATTORNEY TO BE NOTICED

Cliff Stricklin
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ATTORNEY TO BE NOTICED

Jared Michael Lax
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ATTORNEY TO BE NOTICED

Kelly Nicole Reeves
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ATTORNEY TO BE NOTICED

Nicholas A. Meccas-Faxon
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Paul Alessio Mezzina
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ATTORNEY TO BE NOTICED

Plaintiff

Amgen Manufacturing Limited LLC

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Cliff Stricklin
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Nicholas A. Meccas-Faxon
(See above for address)
ATTORNEY TO BE NOTICED

Paul Alessio Mezzina
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

Gail Mizner

*MD, in her official capacity as Chair of
the Colorado Prescription Drug
Affordability Review Board*

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ATTORNEY TO BE NOTICED

Defendant

Sami Diab

*MD, in his official capacity as a
member of the Colorado Prescription
Drug Affordability Review Board*

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ATTORNEY TO BE NOTICED

Pawan Nelson

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ATTORNEY TO BE NOTICED

Rebecca Walker

(See above for address)
ATTORNEY TO BE NOTICED

Sara Louise Stultz

(See above for address)
ATTORNEY TO BE NOTICED

Defendant

Amarylis Gutierrez

*PharmD, in her official capacity as a
member of the Colorado Prescription
Drug Affordability Review Board*

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ATTORNEY TO BE NOTICED

Rebecca Walker

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ATTORNEY TO BE NOTICED

Sara Louise Stultz

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ATTORNEY TO BE NOTICED

Defendant

Catherine Harshbarger
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the Colorado Prescription Drug
Affordability Review Board*

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Pawan Nelson
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ATTORNEY TO BE NOTICED

Rebecca Walker
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Sara Louise Stultz
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Defendant

James Justin VandenBerg
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member of the Colorado Prescription
Drug Affordability Review Board*

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ATTORNEY TO BE NOTICED

Sara Louise Stultz
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ATTORNEY TO BE NOTICED

Defendant

Michael Conway
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of the Colorado Division of Insurance*

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Defendant

Philip Weiser
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Amicus

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Amicus

**The Chamber of Commerce of the
United States of America**

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Amicus

**The Biotechnology Innovation
Organization**

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V.

Movant

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Movant

Colorado Consumer Health Initiative

represented by **Annamarie Martinez**
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Email All Attorneys

Email All Attorneys and Additional Recipients

Date Filed	#	Docket Text
10/30/2025	<u>1</u>	COMPLAINT against Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser (Filing fee \$ 405, Receipt Number ACODC-10637849) Attorney Paul Alessio Mezzina added to party Amgen Inc.(pty:pla), Attorney Paul Alessio Mezzina added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Paul Alessio Mezzina added to party Immunex Corporation(pty:pla), filed by Amgen Manufacturing Limited LLC, Immunex Corporation, Amgen Inc.. (Attachments: # <u>1</u> Exhibit A, # <u>2</u> Exhibit B, # <u>3</u> Exhibit C, # <u>4</u> Exhibit D, # <u>5</u> Exhibit E, # <u>6</u> Exhibit F, # <u>7</u> Exhibit G, # <u>8</u> Exhibit H, # <u>9</u> Exhibit I, # <u>10</u> Exhibit J, # <u>11</u> Summons, # <u>12</u> Civil Cover Sheet)(Mezzina, Paul) (Entered: 10/30/2025)
10/30/2025	<u>2</u>	CORPORATE DISCLOSURE STATEMENT identifying Corporate Parent Amgen Inc. for Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 10/30/2025)
10/30/2025	3	Case assigned to Judge Daniel D. Domenico and drawn to Magistrate Judge Scott T. Varholak. Text Only Entry. (echa,) (Entered: 10/30/2025)
10/30/2025	<u>4</u>	SUMMONS issued by Clerk. (Attachments: # <u>1</u> Summons, # <u>2</u> Summons, # <u>3</u> Summons, # <u>4</u> Summons, # <u>5</u> Summons, # <u>6</u> Summons, # <u>7</u> Magistrate Judge Consent

		Form) (echa,) (Entered: 10/30/2025)
10/30/2025	<u>5</u>	ORDER REFERRING CASE to Magistrate Judge Scott T. Varholak. Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B) and Fed. R. Civ. P. 72(a) and (b), this case is referred to the assigned United States Magistrate Judge to (1) convene a scheduling conference under Fed. R. Civ. P. 16(b) and enter a scheduling order meeting the requirements of Local Civ. R. 16.2, (2) conduct such status conferences and issue such orders necessary for compliance with the scheduling order, including amendments or modifications of the scheduling order upon a showing of good cause, (3) hear and determine pretrial matters, including discovery and other non-dispositive motions, (4) conduct hearings, including evidentiary hearings, and submit proposed findings of fact and recommendations for rulings on dispositive motions, and (5) pursuant to Local Civ. R. 16.6 and at the discretion of the Magistrate Judge, convene such early neutral evaluation and/or settlement conferences and direct related procedures as may facilitate resolution of this case without the necessity of a motion or prior authorization of the undersigned. SO ORDERED by Judge Daniel D. Domenico on 10/30/2025. Text Only Entry. (rkeec) (Entered: 10/30/2025)
10/30/2025	<u>6</u>	ORDER SETTING SCHEDULING CONFERENCE by Magistrate Judge Scott T. Varholak on 10/30/2025. IT IS ORDERED: Pursuant to Fed. R. Civ. P. 16(b) and Local Civil Rule 16.1, the Court shall hold a scheduling conference on: January 6, 2026 at 11:45 AM in Courtroom A-402, Alfred A. Arraj United States Courthouse, 901 19th Street, Denver, Colorado. On or before December 30, 2025, the parties shall file a joint proposed scheduling order in the form required pursuant to D.C.COLO.LCivR 16.2. (jrobe,) (Entered: 10/30/2025)
11/03/2025	<u>7</u>	NOTICE of Entry of Appearance by Ashley Charles Parrish on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Ashley Charles Parrish added to party Amgen Inc.(pty:pla), Attorney Ashley Charles Parrish added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Ashley Charles Parrish added to party Immunex Corporation(pty:pla) (Parrish, Ashley) (Entered: 11/03/2025)
11/03/2025	<u>8</u>	NOTICE of Entry of Appearance by Alexander Kazam on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Alexander Kazam added to party Amgen Inc.(pty:pla), Attorney Alexander Kazam added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Alexander Kazam added to party Immunex Corporation(pty:pla) (Kazam, Alexander) (Entered: 11/03/2025)
11/03/2025	<u>9</u>	NOTICE of Entry of Appearance by Nicholas A. Mecsas-Faxon on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Nicholas A. Mecsas-Faxon added to party Amgen Inc.(pty:pla), Attorney Nicholas A. Mecsas-Faxon added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Nicholas A. Mecsas-Faxon added to party Immunex Corporation(pty:pla) (Mecsas-Faxon, Nicholas) (Entered: 11/03/2025)
11/03/2025	<u>10</u>	NOTICE of Entry of Appearance by Kelly Nicole Reeves on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Kelly Nicole Reeves added to party Amgen Inc.(pty:pla), Attorney Kelly Nicole Reeves added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Kelly Nicole Reeves added to party Immunex Corporation(pty:pla) (Reeves, Kelly) (Entered: 11/03/2025)
11/03/2025	<u>11</u>	NOTICE of Entry of Appearance by Cliff Stricklin on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Cliff Stricklin added to party Amgen Inc.(pty:pla), Attorney Cliff Stricklin added to party Amgen

		Manufacturing Limited LLC(pty:pla), Attorney Cliff Stricklin added to party Immunex Corporation(pty:pla) (Stricklin, Cliff) (Entered: 11/03/2025)
11/06/2025	<u>12</u>	WAIVER OF SERVICE Returned Executed by Amgen Manufacturing Limited LLC, Immunex Corporation, Amgen Inc.. Michael Conway waiver sent on 10/30/2025, answer due 12/29/2025; Sami Diab waiver sent on 10/30/2025, answer due 12/29/2025; Amarylis Gutierrez waiver sent on 10/30/2025, answer due 12/29/2025; Catherine Harshbarger waiver sent on 10/30/2025, answer due 12/29/2025; Gail Mizner waiver sent on 10/30/2025, answer due 12/29/2025; James Justin VandenBerg waiver sent on 10/30/2025, answer due 12/29/2025; Philip Weiser waiver sent on 10/30/2025, answer due 12/29/2025. (Mezzina, Paul) (Entered: 11/06/2025)
11/06/2025	<u>13</u>	NOTICE of Entry of Appearance by Sara Louise Stultz on behalf of All Defendants Attorney Sara Louise Stultz added to party Michael Conway(pty:dft), Attorney Sara Louise Stultz added to party Sami Diab(pty:dft), Attorney Sara Louise Stultz added to party Amarylis Gutierrez(pty:dft), Attorney Sara Louise Stultz added to party Catherine Harshbarger(pty:dft), Attorney Sara Louise Stultz added to party Gail Mizner(pty:dft), Attorney Sara Louise Stultz added to party James Justin VandenBerg(pty:dft), Attorney Sara Louise Stultz added to party Philip Weiser(pty:dft) (Stultz, Sara) (Entered: 11/06/2025)
11/06/2025	<u>14</u>	NOTICE of Entry of Appearance by Nicholas Andrew DePetro on behalf of All Defendants Attorney Nicholas Andrew DePetro added to party Michael Conway(pty:dft), Attorney Nicholas Andrew DePetro added to party Sami Diab(pty:dft), Attorney Nicholas Andrew DePetro added to party Amarylis Gutierrez(pty:dft), Attorney Nicholas Andrew DePetro added to party Catherine Harshbarger(pty:dft), Attorney Nicholas Andrew DePetro added to party Gail Mizner(pty:dft), Attorney Nicholas Andrew DePetro added to party James Justin VandenBerg(pty:dft), Attorney Nicholas Andrew DePetro added to party Philip Weiser(pty:dft) (DePetro, Nicholas) (Entered: 11/06/2025)
11/06/2025	<u>15</u>	NOTICE of Entry of Appearance by Pawan Nelson on behalf of All Defendants Attorney Pawan Nelson added to party Michael Conway(pty:dft), Attorney Pawan Nelson added to party Sami Diab(pty:dft), Attorney Pawan Nelson added to party Amarylis Gutierrez(pty:dft), Attorney Pawan Nelson added to party Catherine Harshbarger(pty:dft), Attorney Pawan Nelson added to party Gail Mizner(pty:dft), Attorney Pawan Nelson added to party James Justin VandenBerg(pty:dft), Attorney Pawan Nelson added to party Philip Weiser(pty:dft) (Nelson, Pawan) (Entered: 11/06/2025)
11/06/2025	<u>16</u>	NOTICE OF CASE ASSOCIATION by Sara Louise Stultz on behalf of All Defendants (Stultz, Sara) (Entered: 11/06/2025)
11/21/2025	<u>17</u>	MOTION for Leave to File Excess Pages in <i>Plaintiffs' Motion for Preliminary Injunction</i> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>18</u>	MOTION for Preliminary Injunction by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>19</u>	DECLARATION of <i>Patrick Costello</i> regarding MOTION for Preliminary Injunction <u>18</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>20</u>	

		DECLARATION of <i>Natalie Adams</i> regarding MOTION for Preliminary Injunction <u>18</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>21</u>	DECLARATION of <i>Christopher Reed</i> regarding MOTION for Preliminary Injunction <u>18</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>22</u>	DECLARATION of <i>Jeanine Singer</i> regarding MOTION for Preliminary Injunction <u>18</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>23</u>	DECLARATION of <i>Adam Grennan [redacted]</i> regarding MOTION for Preliminary Injunction <u>18</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>24</u>	Unopposed MOTION for Leave to Restrict by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 11/21/2025)
11/21/2025	<u>25</u>	RESTRICTED DOCUMENT – Level 1: Unredacted <u>23</u> Declaration of <i>Adam Grennan</i> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) Modified on 12/4/2025 to add linkage (agarc,). (Entered: 11/21/2025)
11/21/2025	<u>26</u>	NOTICE of Entry of Appearance by Rebecca Walker on behalf of All Defendants Attorney Rebecca Walker added to party Michael Conway(pty:dft), Attorney Rebecca Walker added to party Sami Diab(pty:dft), Attorney Rebecca Walker added to party Amarylis Gutierrez(pty:dft), Attorney Rebecca Walker added to party Catherine Harshbarger(pty:dft), Attorney Rebecca Walker added to party Gail Mizner(pty:dft), Attorney Rebecca Walker added to party James Justin VandenBerg(pty:dft), Attorney Rebecca Walker added to party Philip Weiser(pty:dft) (Walker, Rebecca) (Entered: 11/21/2025)
11/26/2025	<u>27</u>	NOTICE of Entry of Appearance by Jeffrey L. Handwerker on behalf of Pharmaceutical Research and Manufacturers of America, The Chamber of Commerce of the United States of AmericaAttorney Jeffrey L. Handwerker added to party Pharmaceutical Research and Manufacturers of America(pty:am), Attorney Jeffrey L. Handwerker added to party The Chamber of Commerce of the United States of America(pty:am) (Handwerker, Jeffrey) (Entered: 11/26/2025)
11/26/2025	<u>28</u>	MOTION for Leave to <i>file Brief as Amici Curiae</i> by Amicus Parties Pharmaceutical Research and Manufacturers of America, The Chamber of Commerce of the United States of America. (Attachments: # <u>1</u> Proposed Amicus Brief, # <u>2</u> Proposed Order (PDF Only))(Handwerker, Jeffrey) (Entered: 11/26/2025)
11/28/2025	<u>29</u>	NOTICE of Entry of Appearance by Douglas H. Hallward–Driemeier on behalf of The Biotechnology Innovation OrganizationAttorney Douglas H. Hallward–Driemeier added to party The Biotechnology Innovation Organization(pty:am) (Hallward–Driemeier, Douglas) (Entered: 11/28/2025)
11/28/2025	<u>30</u>	NOTICE of Entry of Appearance by Andrew J. O'Connor on behalf of The Biotechnology Innovation OrganizationAttorney Andrew J. O'Connor added to party The Biotechnology Innovation Organization(pty:am) (O'Connor, Andrew) (Entered: 11/28/2025)

11/28/2025	<u>31</u>	NOTICE of Entry of Appearance by Phillip Z. Yao on behalf of The Biotechnology Innovation Organization Attorney Phillip Z. Yao added to party The Biotechnology Innovation Organization(pty:am) (Yao, Phillip) (Entered: 11/28/2025)
11/28/2025	<u>32</u>	MOTION to File Amicus Brief by Amicus The Biotechnology Innovation Organization. (Attachments: # <u>1</u> Brief of Amicus Curiae, # <u>2</u> Proposed Order)(Hallward-Driemeier, Douglas) (Entered: 11/28/2025)
12/01/2025	<u>33</u>	ORDER re: <u>18</u> Plaintiffs' Motion for Preliminary Injunction. <u>17</u> Plaintiffs' Motion to Exceed Word Limitation is GRANTED, and the motion for preliminary injunction is accepted for filing. The defendants must respond on or before 12/19/2025, and the plaintiffs may reply on or before 1/16/2026. The defendants' response(s) must not exceed 10,000 words, and the plaintiffs' reply, if any, must not exceed 5,500 words. The parties must submit all pertinent exhibits and direct witness testimony (by affidavit or declaration) as attachments to their briefs. After reviewing the defendants' response(s) and the plaintiffs' reply, if any, the Court will determine whether to (a) hold a preliminary-injunction hearing, (b) request supplemental briefing from the parties on specific legal or factual questions, or (c) decide the motion on the papers submitted. Live testimony at the preliminary-injunction hearing, if one is held, will be limited to cross-examination and redirect examination. The parties are directed to reserve 1/29/2026 at 1:30 PM on their calendars for a potential preliminary-injunction hearing. <u>28</u> Motion of Pharmaceutical Research and Manufacturers of America and the Chamber of Commerce of the United States of America for Leave to File Brief as Amici Curiae and <u>32</u> Motion of Biotechnology Innovation Organization for Leave to File Brief as Amicus Curiae are GRANTED, and Docs. 28-1 and 32-1 are accepted for filing. <u>24</u> Plaintiffs' Unopposed Motion to Restrict is GRANTED, and the Clerk of Court is directed to maintain Doc. <u>25</u> at Level 1 restriction. SO ORDERED by Judge Daniel D. Domenico on 12/1/2025. Text Only Entry (dddlc1,) (Entered: 12/01/2025)
12/05/2025	<u>34</u>	MOTION for Discovery by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Attachments: # <u>1</u> Exhibit Ex 1 – Email Correspondence, # <u>2</u> Exhibit Ex 2 – Defendants First Set of Requests for Production of Documents, # <u>3</u> Exhibit Ex 3 – Defendants First Set of Interrogatories and Requests for Admission)(Stultz, Sara) (Entered: 12/05/2025)
12/05/2025	<u>35</u>	MOTION for Extension of Time to File Response/Reply as to <u>18</u> MOTION for Preliminary Injunction by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Attachments: # <u>1</u> Exhibit Ex 1 – Email Correspondence)(Stultz, Sara) (Entered: 12/05/2025)

12/05/2025	<u>36</u>	ORDER REFERRING MOTION: <u>34</u> Motion for Discovery filed by James Justin VandenBerg, Sami Diab, Philip Weiser, Amarylis Gutierrez, Catherine Harshbarger, Michael Conway, Gail Mizner. Motion referred to Magistrate Judge Scott T. Varholak by Judge Daniel D. Domenico on 12/5/2025. Text Only Entry (dddlc1,) (Entered: 12/05/2025)
12/05/2025	<u>37</u>	ORDER GRANTING <u>35</u> Motion for Extension of Time to Respond to Plaintiffs' Motion for Preliminary Injunction. The defendants' response deadline is extended to four weeks after the completion of any expedited discovery granted by Magistrate Judge Varholak, or three weeks after Judge Varholak's denial of the motion for expedited discovery. The plaintiffs' reply, if any, is due three weeks after the defendants' response(s). The parties need no longer reserve 1/29/2026 on their calendars for a potential hearing. The Court will determine a new hearing date if necessary after briefing on the preliminary-injunction motion is complete. SO ORDERED by Judge Daniel D. Domenico on 12/4/2025. Text Only Entry (dddlc1,) (Entered: 12/05/2025)
12/05/2025	<u>38</u>	MINUTE ORDER This matter is before the Court on Defendants' <u>34</u> Motion for Limited Expedited Discovery (the "Motion"). The Court sets the following expedited briefing schedule: Plaintiffs shall file a Response to the Motion on or before 12/19/25, and Defendants may then file a reply on or before 12/26/25. This Motion will be taken up at a Hearing set for 1/7/26 at 11:30 AM in Courtroom A 402 before Magistrate Judge Scott T. Varholak. SO ORDERED, by Magistrate Judge Scott T. Varholak on 12/5/2025. Text Only Entry (stvlc7,) Modified to correct text on 12/5/2025 (jrobe,). (Entered: 12/05/2025)
12/08/2025	<u>39</u>	STIPULATION for Extension of Time to Answer or Respond to the Complaint by Defendants Amarylis Gutierrez, Catherine Harshbarger, Michael Conway, James Justin VandenBerg, Gail Mizner, Philip Weiser, Sami Diab. All Defendants. (Stultz, Sara) (Entered: 12/08/2025)
12/08/2025	<u>40</u>	MINUTE ORDER The Scheduling Conference set for 1/6/2026 and all associated deadlines are VACATED given the pending <u>18</u> Motion for Preliminary Injunction. SO ORDERED, by Magistrate Judge Scott T. Varholak on 12/8/2025. Text Only Entry (stvlc7,) (Entered: 12/08/2025)
12/19/2025	<u>41</u>	RESPONSE to <u>34</u> MOTION for Discovery filed by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 12/19/2025)
12/24/2025	<u>42</u>	REPLY to Response to <u>34</u> MOTION for Discovery filed by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Stultz, Sara) (Entered: 12/24/2025)
01/07/2026	<u>43</u>	MINUTE ENTRY for Motion Hearing held on 1/7/2026 before Magistrate Judge Scott T. Varholak: ORDERED: <u>34</u> Defendants Motion for Limited Expedited Discovery is GRANTED IN PART as stated on the record. FTR: A402. (msmot,) (Entered: 01/07/2026)
01/15/2026	<u>44</u>	

		TRANSCRIPT of MOTION HEARING held on 01/07/2026 before Magistrate Judge Varholak. Pages: 1–32. Prepared by: AB LITIGATION SERVICES (cboone@ablitservices.com or bpritchard@ablitservices.com). NOTICE – REDACTION OF TRANSCRIPTS: Within seven calendar days of this filing, each party shall inform the Court, by filing a Notice of Intent to Redact, of the party's intent to redact personal identifiers from the electronic transcript of the court proceeding. If a Notice of Intent to Redact is not filed within the allotted time, this transcript will be made electronically available after 90 days. Please see the Notice of Electronic Availability of Transcripts document at www.cod.uscourts.gov. Transcript may only be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber prior to the 90 day deadline for electronic posting on PACER. (AB Court Reporting & Video, Inc.,) (Entered: 01/15/2026)
01/16/2026	<u>45</u>	ANSWER to <u>1</u> Complaint,, by Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser.(Stultz, Sara) (Entered: 01/16/2026)
02/04/2026	<u>46</u>	Joint MOTION for Protective Order by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Attachments: # <u>1</u> Exhibit 1 – Joint Protective Order)(Mezzina, Paul) (Entered: 02/04/2026)
02/05/2026	47	ORDER REFERRING MOTION: <u>46</u> Joint Motion for Protective Order filed by Amgen Manufacturing Limited LLC, Amgen Inc., Immunex Corporation. Motion referred to Magistrate Judge Scott T. Varholak by Judge Daniel D. Domenico on 2/5/2026. Text Only Entry (ddd1c1,) (Entered: 02/05/2026)
02/05/2026	<u>48</u>	NOTICE of Entry of Appearance by Jared Michael Lax on behalf of Amgen Inc., Amgen Manufacturing Limited LLC, Immunex CorporationAttorney Jared Michael Lax added to party Amgen Inc.(pty:pla), Attorney Jared Michael Lax added to party Amgen Manufacturing Limited LLC(pty:pla), Attorney Jared Michael Lax added to party Immunex Corporation(pty:pla) (Lax, Jared) (Entered: 02/05/2026)
02/05/2026	49	ORDER granting <u>46</u> Joint Motion for Entry of Protective Order. The Court will enter the protective order proposed by the parties. SO ORDERED, by Magistrate Judge Scott T. Varholak on 2/5/2026. Text Only Entry(stvlc7,) (Entered: 02/05/2026)
02/05/2026	<u>50</u>	JOINT PROTECTIVE ORDER by Magistrate Judge Scott T. Varholak on 2/5/2026. (sphl,) (Entered: 02/05/2026)
03/10/2026	51	MINUTE ORDER Pursuant to parties' request, a Discovery Hearing is set for 3/11/2026 at 11:00 AM in Courtroom A 402 before Magistrate Judge Scott T. Varholak. Today, 3/10/2026, the parties shall submit via email to Varholak_Chambers@cod.uscourts.gov brief statement(s) setting forth the issues to be resolved by the Court and the parties' respective positions on each issue. All parties that wish to participate in the hearing by telephone may do so by calling 571–353–2301 at the scheduled time and using Meeting ID: 252821415#. The participants may hear the conclusion of a prior hearing at the time they call in and are instructed to simply wait until their case is called. SO ORDERED, by Magistrate Judge Scott T. Varholak on 3/10/2026. Text Only Entry (stvlc7,) (Entered: 03/10/2026)
03/11/2026	<u>52</u>	COURTROOM MINUTES for Discovery Hearing held on 3/11/2026 before Magistrate Judge Scott T. Varholak. ORDERED: Defendants' deadline for production

		of documents is extended to March 27, 2026. The discovery cut-off is set for March 31, 2026, with the exception to allow the deposition of Dr. Mizner, as stated on the record. The deposition shall be conducted between March 31, 2026 and April 28, 2026 in Aspen, CO or virtually, as discussed. Defendants' response to Plaintiffs' Motion for Preliminary Injunction <u>18</u> shall be filed on or before April 28, 2026. Plaintiffs reply to the motion shall be filed on or before May 19, 2026, as stated on the record. FTR: STV A402. (sgrim) (Entered: 03/11/2026)
04/28/2026	<u>53</u>	Unopposed MOTION for Leave to Restrict re <u>54</u> by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Stultz, Sara) Modified on 4/28/2026 to add linkage (echa,). (Entered: 04/28/2026)
04/28/2026	<u>54</u>	RESTRICTED DOCUMENT – Level 1: <i>Response in Opposition to Plaintiffs' Motion for Preliminary Injunction</i> by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser.. (Attachments: # <u>1</u> Exhibit 21 – Twenty-Third Amendment to the Preferred Savings Grid Rebate Program Agreement between Express Scripts and Amgen Inc., # <u>2</u> Exhibit 24 – Fourteenth Amendment to the Rebate Agreement between Optum Rx and Amgen Inc., # <u>3</u> Exhibit 25 – Plaintiffs' Responses and Objections to Defendants' First Set of Interrogatories and Requests for Admission, # <u>4</u> Exhibit 26 – Section 1194(e)(1) Data Factors, # <u>5</u> Exhibit 29 – Rule 30(b)(6) Deposition of Amgen Inc., through Patrick Costello (March 31, 2026), # <u>6</u> Exhibit 30 – Rule 30(b)(6) Deposition of McKesson Corporation Representative Jeanine Singer (March 20, 2026), # <u>7</u> Exhibit 47 – Pages J23–49 – 2023 Affordability Review Summary Report: Enbrel)(Stultz, Sara) (Entered: 04/28/2026)
04/28/2026	<u>55</u>	Exhibits in Support of <u>54</u> Restricted Document – Level 1,,, <i>Exhibit 12</i> by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (Attachments: # <u>1</u> Exhibit 14 – United States Securities and Exchange Commission, Form 10-K, Amgen Inc., # <u>2</u> Exhibit 31 – PhRMA, Follow the Dollar (2017), # <u>3</u> Exhibit 32 – 2023 Affordability Review Summary Report: Enbrel (with Addendum), # <u>4</u> Exhibit 33 – Testimony of Mr. Robert Bradway, Chairman and Chief Executive Officer, Amgen Inc., Hearing before the Committee on Oversight and Reform, House of Representatives, 116th Congress (October 1, 2020), # <u>5</u> Exhibit 34 – International Prescription Drug Price Comparisons: Estimates Using 2022 Data, Assistant Secretary for Planning and Evaluation, U.S. Dept. of Health & Human Services (2024), # <u>6</u> Exhibit 35 – NHE Fact Sheet, Centers for Medicare & Medicaid Services (last modified January 14, 2026), # <u>7</u> Exhibit 36 – Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026, Centers for Medicare & Medicaid Services (August 2024), # <u>8</u> Exhibit 37 – The White House, Fact Sheet: President Donald J. Trump Launches TrumpRx.gov to Bring Lower Drug Prices to American Patients (February 5, 2026), # <u>9</u> Exhibit 38 – Colorado Senate Bill 21–175, Concerning the Colorado Prescription Drug Affordability Review Board, # <u>10</u> Exhibit 39 – Prescription Drug Affordability Board Policies and Procedures, Policy Numbers 01–05, # <u>11</u> Exhibit 40 – Declaration of Nathan Blake, # <u>12</u> Exhibit 42 – Testimony of Robert A. Bradway, Chairmain and Chief Executive Officer, Amgen Inc., Before the U.S. House Committee on Oversight and Reform (October 1, 2020), # <u>13</u> Exhibit 43 – Maximum Fair Price (MFP) Explanation for Enbrel, Centers for Medicare & Medicaid Services, # <u>14</u> Exhibit 44 – Prescription Drug Affordability Board Meeting Minutes (December 8, 2023), # <u>15</u> Exhibit 45 – Prescription Drug Affordability Board Meeting Minutes (February 16, 2024), # <u>16</u> Exhibit 46 – Prescription Drug

		Affordability Board Meeting Minutes (February 23, 2024), # <u>17</u> Exhibit 48 – Amgen Inc. Comment Letter to PDAB (December 5, 2023), # <u>18</u> Exhibit 49 – Amgen Inc. Comment Letter to PDAB (February 1, 2024), # <u>19</u> Exhibit 50 – Cost-Benefit Analysis for Part 4.3: Concerning an Upper Payment Limit for Enbrel, Division of Insurance (April 1, 2025), # <u>20</u> Exhibit 51 – Regulatory Analysis – Proposed Rule # 3 CCR 702-9 Part 4.3 Upper Payment Limit for Enbrel, # <u>21</u> Exhibit 52 – Amgen Inc. Comment Letter to PDAB (July 9, 2025), # <u>22</u> Exhibit 53 – Amgen Inc. Comment Letter to PDAB (August 20, 2025), # <u>23</u> Exhibit 54 – Amgen Inc. Comment Letter to PDAB (October 1, 2025), # <u>24</u> Exhibit 55 – Upper Payment Limit Data Submission Guide, Colorado Prescription Drug Affordability Board, # <u>25</u> Exhibit 56 – Upper Payment Limit (UPL) Benchmarks – Enbrel Cost and Price Metrics)(Stultz, Sara) (Entered: 04/28/2026)
05/05/2026	<u>56</u>	NOTICE of Entry of Appearance <i>on behalf of AC CCLP and CCHI</i> by Annamarie Martinez on behalf of Colorado Center on Law and Policy, Colorado Consumer Health InitiativeAttorney Annamarie Martinez added to party Colorado Center on Law and Policy(pty:am), Attorney Annamarie Martinez added to party Colorado Consumer Health Initiative(pty:am) (Attachments: # <u>1</u> Motion For Leave to File Amicus Brief, # <u>2</u> BRIEF OF AMICI CURIAE COLORADO CENTER ON LAW AND POLICY AND COLORADO CONSUMER HEALTH INITIATIVE IN SUPPORT OF DEFENDANTS RESPONSE IN OPPOSITION TO PLAINTIFFS MOTION FOR PRELIMINARY INJUNCTION)(Martinez, Annamarie) (Entered: 05/05/2026)
05/06/2026	<u>57</u>	UNOPPOSED MOTION of Colorado Center on Law and Policy and Colorado Consumer Health Initiative for Leave to File Brief as Amici Curiae in Support of Defendants' Response in Opposition to Plaintiffs' Motion for Preliminary Injunction by Amicus Parties Colorado Center on Law and Policy, Colorado Consumer Health Initiative. [Originally attached in error to <u>56</u> Notice of Entry of Appearance] (Attachments: # <u>1</u> Brief of Amici Curiae)(agryan) (Entered: 05/06/2026)
05/07/2026	58	ORDER: The Court will hold a three hour hearing on <u>18</u> Plaintiff's Motion for Preliminary Injunction on June 4, 2026 at 9:30 am in Courtroom A1002 before Judge Daniel D. Domenico. SO ORDERED by Judge Daniel D. Domenico on 5/7/2026. Text Only Entry. (agryan) (Entered: 05/07/2026)
05/19/2026	<u>59</u>	REPLY to Response to <u>18</u> MOTION for Preliminary Injunction filed by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Attachments: # <u>1</u> Exhibit 3 (redacted), # <u>2</u> Exhibit 15 (redacted), # <u>3</u> Exhibit 16 (redacted), # <u>4</u> Exhibit 27, # <u>5</u> Exhibit 57 (redacted), # <u>6</u> Exhibit 58, # <u>7</u> Exhibit 102, # <u>8</u> Exhibit 106)(Mezzina, Paul) (Entered: 05/19/2026)
05/19/2026	<u>60</u>	Unopposed MOTION for Leave to Restrict by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Mezzina, Paul) (Entered: 05/19/2026)
05/19/2026	<u>61</u>	RESTRICTED DOCUMENT – Level 1: <i>Unredacted <u>59</u> Reply in Support of Plaintiffs' Motion for Preliminary Injunction and restricted exhibits</i> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation.. (Attachments: # <u>1</u> Exhibit 3, # <u>2</u> Exhibit 15, # <u>3</u> Exhibit 16, # <u>4</u> Exhibit 57)(Mezzina, Paul) Modified on 5/21/2026 to add link (ccuen,). (Entered: 05/19/2026)
06/02/2026	<u>62</u>	Amended MOTION for Leave to Restrict re: <u>61</u> by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Attachments: # <u>1</u> Exhibit A – Modified Redacted Reply, # <u>2</u> Exhibit B – Public Transcript)(Mezzina, Paul) Modified

		on 6/3/2026 to add linkage (ggill,). (Entered: 06/02/2026)
06/04/2026	<u>63</u>	MINUTE ENTRY for proceedings held before Chief Judge Daniel D. Domenico: Motion Hearing held on 6/4/2026. Granting <u>57</u> Motion to File Amicus Brief. Granting <u>60</u> Motion for Leave to Restrict. Granting <u>62</u> Motion for Leave to Restrict. Taking under advisement <u>18</u> Motion for Preliminary Injunction. Court Reporter: Tammy Hoffschildt. (rkeec) (Entered: 06/04/2026)
06/06/2026	<u>64</u>	TRANSCRIPT of Motion Hearing held on June 4, 2026 before Chief Judge Domenico. Pages: 1–58. NOTICE – REDACTION OF TRANSCRIPTS: Within seven calendar days of this filing, each party shall inform the Court, by filing a Notice of Intent to Redact, of the party's intent to redact personal identifiers from the electronic transcript of the court proceeding. If a Notice of Intent to Redact is not filed within the allotted time, this transcript will be made electronically available after 90 days. Please see the Notice of Electronic Availability of Transcripts document at www.cod.uscourts.gov. Transcript may only be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber prior to the 90 day deadline for electronic posting on PACER. (thoff,) (Entered: 06/06/2026)
06/16/2026	<u>65</u>	Unopposed MOTION to Withdraw as Attorney by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser. (DePetro, Nicholas) (Entered: 06/16/2026)
07/01/2026	<u>66</u>	ORDER Granting Motion for Preliminary Injunction. It is ORDERED that the MOTION FOR PRELIMINARY INJUNCTION (Doc. <u>18</u>) is GRANTED. Defendants are enjoined from enforcing the upper payment limit for Enbrel. SO ORDERED by Chief Judge Daniel D. Domenico on 07/01/2026.(agryan) (Entered: 07/01/2026)
07/09/2026	<u>67</u>	Unopposed MOTION to Withdraw as Attorney by Plaintiffs Amgen Inc., Amgen Manufacturing Limited LLC, Immunex Corporation. (Kazam, Alexander) (Entered: 07/09/2026)
07/30/2026	<u>68</u>	NOTICE OF APPEAL to FEDERAL CIRCUIT as to <u>66</u> Order on Motion for Preliminary Injunction, by Defendants Michael Conway, Sami Diab, Amarylis Gutierrez, Catherine Harshbarger, Gail Mizner, James Justin VandenBerg, Philip Weiser (Filing fee \$ 605, Receipt Number ACODC–11178097) (Nelson, Pawan) (Entered: 07/30/2026)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Daniel D. Domenico**

Civil Action No. 1:25-cv-03452-DDD-STV

AMGEN INC.;
IMMUNEX CORPORATION; and
AMGEN MANUFACTURING LIMITED LLC,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board;
SAMI DIAB, MD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
AMARYLIS GUTIERREZ, PharmD, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
CATHERINE HARSHBARGER, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
JAMES JUSTIN VANDENBERG, PharmD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; and
PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,

Defendants.

**ORDER GRANTING MOTION
FOR PRELIMINARY
INJUNCTION**

The Colorado Prescription Drug Affordability Review Board was created to control the price of certain drugs for Colorado consumers. Doc.

45 at 4.¹ Amgen is a pharmaceutical company that makes Enbrel, a drug of substantial value to Colorado patients suffering from rheumatoid arthritis. Doc. 1 at 3. The Board seeks to cap its price. *Id.* at 28. Amgen objects.² Amgen argues that Colorado’s price cap is preempted by federal patent law, violates its due process rights, and violates the commerce clause. *Id.* at 6-7. Amgen has moved for a preliminary injunction. Doc. 18. For the reasons below, the motion is granted.

BACKGROUND

The pharmaceutical pricing structure is, as the Board argues, rather opaque. Amgen sets a wholesale acquisition cost price at which it sells Enbrel to its wholesalers and distributors. Doc. 18 at 17. Rather than add a markup to this price, the wholesalers and distributors sell to pharmacies at this wholesale rate or below and receive reimbursement from Amgen for sales under the wholesale rate, known as a chargeback. *Id.* Though there are additional wrinkles to the pricing system, it suffices for our purposes to say that this wholesale rate is also the basis for whether a drug is subject to Colorado’s regulatory regime. 3 Colo. Code Regs. § 702-9:3.1(C). Once a drug is determined to be eligible for board regulation, the Board determines whether it is “unaffordable” and if so, it can set a price cap. Colo. Rev. Stat. § 10-16-1407(1). The Board is given a non-exhaustive list of factors to consider in their determination of

¹ Defendants are sued in their official capacity as members of the Board, Commissioner of the Colorado Division of Insurance, and Attorney General of Colorado. The latter two roles involve statutory requirements involving written notice for withdrawing distribution of a drug from the Colorado market and legal enforcement on behalf the board.

² This is the second time Amgen brings this objection to this Court. Its first case was dismissed for lack of standing as the Board had not yet set a price cap. *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. Mar. 28, 2025), ECF 49. The Board issued a cap and gave Amgen standing for this suit.

whether to cap a drug's price and has issued regulations with additional factors it considers. Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). The statutory factors include cost, availability of alternatives, and effects on consumer access to a drug. *Id.* The additional regulatory factors include evaluation of the wholesale cost and rebate system along with health equity factors. 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). Most of these factors are laid out as overarching categories for consideration.

The Board determined that Enbrel qualified for a price cap and set the cap approximately 70% below Amgen's wholesale price. Doc. 18 at 22. Amgen sued, alleging the Board's determination is preempted by federal patent law, violative of its Due Process rights, and contrary to the dormant Commerce Clause. It moves for a preliminary injunction on the first two claims.

LEGAL STANDARD

The standard for assessing a motion for a preliminary injunction is governed by Tenth Circuit law. "A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *Mrs. Fields Franchising, LLC v. MFGPC*, 941 F.3d 1221, 1232 (10th Cir. 2019). One may be granted "only when the movant's right to relief is clear and unequivocal." *McDonnell v. City & Cnty. of Denver*, 878 F.3d 1247, 1257 (10th Cir. 2018). To succeed on a motion for preliminary injunction, the moving party must show: (1) that it is "substantially likely to succeed on the merits" ; (2) that it will "suffer irreparable injury" if the court denies the injunction; (3) that its "threatened injury" without the injunction outweighs the opposing party's under the injunction; and (4) that the injunction is not "adverse to the public interest." *Mrs. Fields*, 941 F.3d at 1232; accord *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

On the other hand, while federal district courts have jurisdiction to hear claims arising from patents under 28 U.S.C. § 1338, including preemption claims, precedent from the Federal Circuit controls the substance of the inquiry. *Biotech. Indus. Org. v. District of Columbia (BIO D)*, 496 F.3d 1362, 1369 (Fed. Cir. 2007).

DISCUSSION

Both parties make important, and persuasive, policy arguments: Colorado is undoubtedly correct that the price of many beneficial medications is difficult, if not impossible, for many citizens to afford. Amgen is correct that the development of the new medications many of us benefit from requires that profits from the few successful ones be large enough to cover not only their own development, but that of dozens of failed experiments. Ultimately, however, those policy issues are not relevant to the legal decision here. Since under binding Federal Circuit precedent, caps on the price of patented drugs like Enbrel are preempted by federal law, Amgen's motion must be granted.³

The Board's main argument is that Amgen has not shown that it will actually be harmed by the price cap given the convoluted way Enbrel is paid for at various levels of the supply chain. And they are right that the system is convoluted, confusing, and often counterintuitive. But it is not necessary to unravel the entire system to understand that, as a result of Colorado's cap, Amgen will receive less money from its wholesalers and will fare more poorly in negotiations with other purchasers in Colorado and elsewhere. The Board attempts to minimize these losses, pointing out that the cap does not apply to sales made by Amgen itself, and that some sales, such as to ERISA plans, are not controlled by Colorado law.

³ It is therefore not necessary to reach Amgen's alternative Due Process argument.

Doc. 54 at 8. While possibly true, this is an argument about the scope of damages, not their existence. As a matter of basic economic logic, Amgen is likely to be significantly harmed by a cap on the price of its product, even if the cap applies unevenly and down the chain. That is sufficient to satisfy its burden.

I. Likelihood of success on the merits

The Federal Circuit’s decision in *Biotech Industry Organization* controls the outcome here. *Bio I*, 496 F.3d 1362. In that case, the plaintiff challenged the District of Columbia’s Prescription Drug Excessive Pricing Act, which banned pharmaceutical pricing it deemed excessive. *Id.* at 1365. Excessive pricing was established relative to drug pricing in other countries. *Id.* The Federal Circuit held that the District’s price caps were preempted by federal patent laws. *Id.* at 1374.

In doing so, the court explained that Congress recognizes that enhanced profits are central to the statutory incentives involved in patents. *Id.* These enhanced profits are only enjoyed by pharmaceutical companies during the period of patent exclusivity before competition brings the price down.⁴ The Federal Circuit recognized that this is in tension with the desire to keep prices low, but balancing these two competing interests, “to reward innovators with higher profits and to keep prices reasonable for consumers,” was the responsibility of Congress. *Id.* And it held that the “underlying determination about the proper balance

⁴ The Board argues that the Patent Act guaranties no particular price, citing *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 581 U.S. 360, 380 (2017). Doc. 54 at 31. True, but the question is whether state law “must yield to congressional enactments if it ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Bio I*, 496 U.S. at 1372 (citing *Leatherman Tool Group, Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed.Cir.1997)). The Federal Circuit’s answer is that it must.

between innovators' profit and consumer access to medications, thought, is exclusively one for Congress to make." *Id.* The District's efforts to alter that balance in one direction was therefore preempted. *Id.* at 1374.

The District of Columbia's petition for rehearing en banc was denied with a concurrence and dissent. *Biotech. Indus. Org. v. District of Columbia (BIO II)*, 505 F.3d 1343 (Fed. Cir. 2007). The concurrence noted that "there is a particularly acute tension in the pharmaceutical context between promoting innovation by increasing the profit reward of patents and the public interest in affordable drugs," which was the precise subject of the Hatch-Waxman Act, which extended the patent term for pharmaceuticals and simplified the generic drug approval process. 505 F.3d at 1347 (Gajarsa, J., concurring in denial of rehearing en banc). The dissent thought that the decision in *Bio I* was errant because it found "a conflict between the D.C. Act and a supposed polity of the patents law to allow patent holders to reap maximum profits during the term of the limited monopoly on the use of the invention." *Id.* at 1350 (Dyk, J., dissenting from denial of rehearing en banc). Each opinion confirms the appropriate read of the Federal Circuit's controlling precedent: that Colorado's attempt to rebalance Congress's patent system is preempted by federal law.

The Board concedes that these precedents are binding but attempts to distinguish the situation. It argues that Amgen is not the real object of its regulation. It claims that the doctrine of patent exhaustion puts Amgen outside the scope of the regulation. Doc. 54 at 35-36. But this distinction does not make a difference. Just as in this case, the District of Columbia's law did "not directly regulate manufacturers' wholesale prices." *Id.* at 1371. Once a patent holder has sold an item, it has no more rights secured by the patent monopoly. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 371 (2017). But that case dealt with

whether a patentee could control purchaser behavior beyond the first sale. *Id.* at 372. The Court pointed to the common law's refusal to permit restraints on the alienation of chattels. *Id.* at 371. And were Amgen suing its wholesalers, that would be apt. The question here is whether a state may, by capping downstream prices, change the bargain struck by Congress. *See Bio I*, 496 F.3d at 1373. The Federal Circuit held that federal patent law means it cannot. Amgen is substantially likely to succeed on the merits of its preemption claim.

II. Irreparable harm

The puzzling opacity of the pharmaceutical pricing system also bears on whether Amgen will suffer irreparable harm if I do not grant issue a preliminary injunction. Amgen must demonstrate that there is a significant risk that it cannot be compensated after the fact by monetary damages. *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003). More than the possibility of some remote future injury is required. *Winter, Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2009) (quoting 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948.1).

The Board argues that Amgen's has not provided empirical evidence that it will actually be harmed by the price cap. First, there is significant evidence on that point in the record. *See, e.g.*, Doc. 25 at 3. Even if there weren't, basic economic logic confirms Amgen's core contention. The point of the Board's price cap, of course, is to lower the price that can be charged for Enbrel, and the Board expects it to have that effect. And if the end price is capped below what the market will bear, at least some of the reduced income will come out of Amgen's pocket. Such an economic injury caused by governmental action that changes market conditions is sufficient to establish injury. *Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319 (Fed. Cir. 2009) (*citing Clinton v. City of*

New York, 524 U.S. 417, 433 (1998)). Caselaw confirms the commonsense proposition that a law can be “aimed directly at” a plaintiff as a targeted object, *American Booksellers Ass’n*, 484 U.S. at 392, even if it does not directly regulate his actions. *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (Kavanaugh, J.). As the Supreme Court has explained, “when the government regulates (or under-regulates) a business, the regulation (or lack thereof) may cause downstream or upstream economic injuries to others in the chain, such as certain manufacturers, retailers, suppliers, competitors, or customers.” *FDA v. Alliance for Hippocratic Medicine*, 602 U. S. 367, 384 (2024).

Amgen also argues that negotiations with its wholesalers and distributors have already begun for 2027 contracts for Enbrel. Doc. 18 at 43. These negotiations, it alleges, ordinarily conclude around May. *Id.* It takes no great imaginative leap to conclude that the people sitting across the table from Amgen will conclude that a capped price for a substantial portion of Colorado’s insured patients will drive down Amgen’s negotiating position and the negotiated price of Enbrel with it. Amgen also argues that it has existing contracts that run into 2027 that cannot be easily renegotiated. *Id.* at 44. Add to this that Colorado law requires Amgen to decide whether to withdraw from the Colorado market by July 5, 2026 or sell Enbrel at the capped price. *Id.*

Amgen will already spend part of 2027 operating under a contract negotiated before Colorado’s price cap was contemplated. And it will need to finalize the rest of its contracts without knowing how severely its wholesale prices will be affected. Each is certain enough to qualify as irreparable harm. These damages will prove quite difficult to calculate. The Board characterizes Amgen’s damages as too speculative to warrant an injunction when they are actually too speculative to calculate after

the fact. See *Southwest Stainless, LP v. Sappington*, 582 F.3d 1176 (10th Cir. 2009).

The Board suggests that any harms could be redressed by suits after the fact for a regulatory taking. Doc. 54 at 29. Amgen points out, however, that the Board possesses sovereign immunity against suits for damages. If Amgen prevails, the Board may well assert this immunity to avoid paying the judgment as it indicated at oral argument. And at the hearing on this motion, Colorado, for obvious reasons, would not concede Amgen's likelihood of success in state court on such a claim, even if Amgen prevailed in this Court. The theoretical possibility of a separate lawsuit that all parties recognize would be quite unlikely to prevail does not make Amgen's harm redressable.

III. Balance of Equities and Public Interest

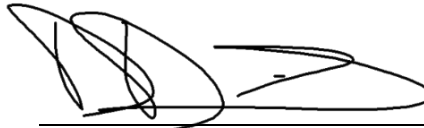
As to the balance of equities and the public interest, these factors "merge" when the government is the party opposing the injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009). But where a law is likely unconstitutional, the interests of the government "do not outweigh" the plaintiff's interest in having its constitutional rights protected. *Awad v. Ziriax*, 670 F.3d 1111, 1131 (10th Cir. 2012). This principle applies where the alleged constitutional infirmity is preemption. *Chamber of Com. v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010). The state's interest in helping citizens afford Enbrel is legitimate, and it has a number of ways to try to do so, including subsidization, using its market power to negotiate lower prices as the federal government has done, or perhaps by finding ways to encourage simplification of the puzzling supply chain. But one way it cannot do so under the binding precedent of the Federal Circuit, is by capping the price of a patented drug.

CONCLUSION

It is ORDERED that:

The MOTION FOR PRELIMINARY INJUNCTION (Doc. 18) is GRANTED. Defendants are enjoined from enforcing the upper payment limit for Enbrel.

DATED: July 1, 2026 BY THE COURT:

A handwritten signature in black ink, appearing to read 'Daniel D. Domenico', is written over a horizontal line.

Daniel D. Domenico
Chief United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-3452-DDD-STV

AMGEN INC., et al.,

Plaintiffs,

v.

GAIL MIZNER MD, in her official capacity
as Chair of the Colorado Prescription Drug
Affordability Review Board, et al.,

Defendants.

DEFENDANTS' NOTICE OF APPEAL FROM AN APPEALABLE ORDER

Pursuant to 28 U.S.C. §§ 1292(a)(1) & (c)(1), Defendants Gail Mizner, M.D., Sami Diab, M.D., Amarylis Gutierrez, Pharm.D., Catherine Harshbarger, and James Justin Vandenberg, Pharm.D., in their official capacities as Board members of the Colorado Prescription Drug Affordability Review Board; Michael Conway, in his official capacity as Commissioner of Insurance; and Philip J. Weiser, in his official capacity as Attorney General of the State of Colorado hereby appeal to the United States Court of Appeals for the Federal Circuit from the Court's Order Granting Motion for Preliminary Injunction (Doc. 66) dated July 1, 2026, and for all interlocutory or other orders and rulings subsidiary or related thereto.

Dated: July 30, 2026

Respectfully submitted,

PHILIP J. WEISER
Attorney General

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Form 7

FORM 7. Appeal Information Sheet

FEDERAL CIRCUIT APPEAL INFORMATION SHEET

- ☒ United States District Court for the District of Colorado
- ☐ United States Court of International Trade
- ☐ United States Court of Federal Claims
- ☐ United States Court of Appeals for Veterans Claims

Type of case: 28:2201 Declaratory Judgment

Amgen Inc. et al v. Mizner et al

(List all parties. Use an asterisk to indicate dismissed or withdrawn parties. Use a separate sheet if needed. Explain any discrepancy with the caption used on the judgment, order, or opinion.)

Docket No. 25-cv-03452-DDD-STV Date of Judgment or Order 07/01/2026

Cross or related appeal? _____ Date of Notice of Appeal 07/30/2026

Appellant is: ☐ Plaintiff ☒ Defendant ☐ Other (explain) _____

FEES: Court of Appeals docket fee paid? ☒ Yes ☐ No

U.S. Appeal? ☐ Yes ☐ No

In forma pauperis? ☐ Yes ☐ No

Is this matter under seal? ☐ Yes ☒ No

COUNSEL: (List name, firm, address, and telephone of lead counsel for each party. Indicate party represented. Use separate sheet if needed.)

Please see attached Docket
Sheet

COURT REPORTER: (Name and telephone): Nick Richards 303-335-2180

IMPORTANT: Attach a copy of the judgment or order appealed from and any supporting opinion or memorandum. Forward together with a copy of the notice of appeal and certified docket entries.

Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439