



## TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES .....	ii
ARGUMENT .....	1
I.    ASTRAZENECA HAS CONSTITUTIONAL STANDING.....	2
A.  Injury-In-Fact .....	2
B.  Traceability.....	6
C.  Redressability .....	7
II.   ASTRAZENECA SATISFIES ANY OTHER STANDING CONSIDERATIONS, TO THE EXTENT APPLICABLE .....	7
CONCLUSION.....	9

**TABLE OF AUTHORITIES**

	<u>Page(s)</u>
<b>CASES:</b>	
<i>California v. Texas</i> , 593 U.S. 659 (2021).....	7
<i>Carey v. Phipus</i> , 435 U.S. 247 (1978).....	5
<i>Cella v. Togum Constructeur Ensembleier en Industrie Alimentaire</i> , 173 F.3d 909 (3d Cir. 1999).....	4
<i>Center for Biological Diversity v. EPA</i> , 861 F.3d 174 (D.C. Cir. 2017).....	7
<i>City of Los Angeles v. Lyons</i> , 461 U.S. 95 (1983).....	2
<i>Clapper v. Amnesty Int’l USA</i> , 568 U.S. 398 (2013).....	6
<i>Cottrell v. Alcon Laby’s</i> , 874 F.3d 154 (3d Cir. 2017).....	5
<i>Craig v. Boren</i> , 429 U.S. 190 (1976).....	8
<i>Elkin v. Fauver</i> , 969 F.2d 48 (3d Cir. 1992).....	8
<i>Exhaustless Inc. v. FAA</i> , 931 F.3d 1209 (D.C. Cir. 2019).....	6
<i>Free Speech Coal., Inc. v. Attorney Gen. United States</i> , 974 F.3d 408 (3d Cir. 2020).....	8
<i>Freeman v. Corzine</i> , 629 F.3d 146 (3d Cir. 2010).....	6
<i>Hassan v. City of New York</i> , 804 F.3d 277 (3d Cir. 2015).....	5
<i>Holland v. Rosen</i> , 895 F.3d 272 (3d Cir. 2018).....	3
<i>Kowalski v. Tesmer</i> ,	

543 U.S. 125 (2004)..... 8

*Lexmark Int’l, Inc. v. Static Control Components, Inc.*,  
572 U.S. 118 (2014)..... 8

*Long v. Southeastern Pa. Transp. Auth.*,  
903 F.3d 312 (3d Cir. 2018)..... 3

*Lujan v. Defenders of Wildlife*,  
504 U.S. 555 (1992)..... 2, 4, 7

*McNair v. Synapse Grp. Inc.*,  
672 F.3d 213 (3d Cir. 2012)..... 2

*Multistar Indus., Inc. v. U.S. Dep’t of Transp.*,  
707 F.3d 1045 (9th Cir. 2013)..... 5

*New Jersey Physicians, Inc. v. President of U.S.*,  
653 F.3d 234 (3d Cir. 2011)..... 6

*Oxford Assocs. v. Waste Sys. Auth. of E. Montgomery Cnty.*,  
271 F.3d 140 (3d Cir. 2001)..... 7

*Plains All Am. Pipeline L.P. v. Cook*,  
866 F.3d 534 (3d Cir. 2017)..... 3

*Protect Our Parks, Inc. v. Chicago Park Dist.*,  
971 F.3d 722 (7th Cir. 2020)..... 3

*Reed v. Goertz*,  
598 U.S. 230 (2023)..... 7

*Sierra Club v. Morton*,  
405 U.S. 727 (1972)..... 5

*Stehney v. Perry*,  
101 F.3d 925 (3d Cir. 1996)..... 7

*Town Court Nursing Ctr., Inc. v. Beal*,  
586 F.2d 266 (3d Cir. 1978)..... 3

*TransUnion LLC v. Ramirez*,  
594 U.S. 413 (2021)..... 1, 3, 5

*Trump v. Hawaii*,  
138 S. Ct. 2392 (2018) ..... 3

*Yaw v. Delaware River Basin Comm’n*,  
49 F.4th 302 (3d Cir. 2022)..... 2

**STATUTES:**

26 U.S.C. § 5000D .....	5
42 U.S.C. § 1320f-2(a)(1) .....	4
42 U.S.C. § 1320f-3(b)(1) .....	4

## ARGUMENT

AstraZeneca has both constitutional and prudential standing to bring its due process claim. AstraZeneca meets all the elements of Article III standing: It faces concrete and imminent injuries that directly result from the unconstitutional aspects of the Drug Price Negotiation Program, and they are redressable by this Court. AstraZeneca also satisfies all of the requirements of prudential standing: It does not assert generalized grievances or seek to protect the rights of a third party, and it is squarely within the zone of interests of the statute and the Constitution.

With one of its products chosen for “negotiation,” AstraZeneca is in the thick of a process that denies selected manufacturers meaningful opportunity to be heard at every critical turn. On the front end, AstraZeneca was denied an opportunity to submit comments before CMS’s Guidance issued and the program commenced; on the back end, it will not have a meaningful opportunity for judicial review of the “Maximum Fair Price.” By the Government’s own telling, even a blatant violation of the statutory terms is not subject to judicial review. The Program also deprives AstraZeneca of its interest in a valuable economic benefit by reducing the price on a large swath of sales of its drug product FARXIGA. That certain and imminent harm supplies another independent injury for standing purposes.

Standing is not dispensed in gross; it must be evaluated on a claim-by-claim basis. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). It is telling, then,

that despite challenging AstraZeneca’s standing to bring its two APA claims, the Government did not challenge AstraZeneca’s standing to bring its due process claim—just as it did not contest standing for any other manufacturer bringing constitutional claims. The Government’s silence is understandable; a manufacturer whose drug product is selected for negotiation and funneled through the Drug Price Negotiation Program has standing to challenge the constitutionality of that program.

### **I. ASTRAZENECA HAS CONSTITUTIONAL STANDING.**

Constitutional standing requires a plaintiff to demonstrate “(1) an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely redressed by a favorable judicial decision.” *Yaw v. Delaware River Basin Comm’n*, 49 F.4th 302, 310 (3d Cir. 2022). When seeking prospective relief, a plaintiff must show that it is “‘likely to suffer future injury’ from the defendant’s conduct.” *McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983)). AstraZeneca readily satisfies the “constitutional minimum of standing.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

#### **A. Injury-In-Fact**

An injury-in-fact is “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent.” *Id.* at 560. The injury requirement for standing is “very generous, requiring only that claimant allege some

specific, identifiable trifle of injury.” *Long v. Southeastern Pa. Transp. Auth.*, 903 F.3d 312, 322 (3d Cir. 2018). From an injury perspective, traditional harms include those “specified by the Constitution itself” as well as “monetary harms.” *TransUnion*, 594 U.S. at 425. AstraZeneca suffers both.<sup>1</sup>

First, the company faces ongoing procedural injuries from the Program’s unconstitutional process. *See, e.g., Plains All Am. Pipeline L.P. v. Cook*, 866 F.3d 534, 545 (3d Cir. 2017) (“Submission to a fatally biased decisionmaking process is in itself a constitutional injury.”); *Holland v. Rosen*, 895 F.3d 272, 278 (3d Cir. 2018) (plaintiffs’ injury for a procedural due process claim was being subjected to an “unconstitutional process”). Having been selected, AstraZeneca now faces all of the procedural harms it challenges in its Complaint. *See* D.I. 16 (Amended Complaint) ¶¶ 19, 90–103; 112–122; D.I. 60 (Declaration of Jim Ader (Ader Decl.)) ¶¶ 9–11; *see also, e.g., Town Court Nursing Center, Inc. v. Beal*, 586 F.2d 266, 275 (3d Cir. 1978) (provider had standing to assert a due-process challenge against procedures used to terminate Medicare agreement).

---

<sup>1</sup> The injury-in-fact analysis is distinct from the merits question of whether the plaintiff can establish a protected property interest. *See Trump v. Hawaii*, 138 S. Ct. 2392, 2416 (2018) (rejecting argument that plaintiffs failed to establish standing without “a legally protected interest” because the argument “concerns the merits rather than the justiciability” of a claim); *see also Protect Our Parks, Inc. v. Chicago Park Dist.*, 971 F.3d 722, 736 (7th Cir. 2020) (“deciding whether [a protected property interest] exists virtually always goes to the merits rather than standing”).



AstraZeneca did not volunteer for price negotiation; FARXIGA was selected unilaterally by the Government. AstraZeneca lacks any meaningful leverage in the negotiations given the extensive penalties associated with a refusal to agree on a maximum fair price, including the loss of access to Medicare and Medicaid for all of AstraZeneca's drug products. And in the Government's view, AstraZeneca will have no opportunity to be heard on any of its APA claims, either before or after the negotiations conclude. In fact, the Government goes so far as to argue that drug manufacturers lack any right to judicial review for even clear violations of the agency's statutory mandate. *See* D.I. 21-1 at 30–35; *see also* D.I. 64 (Tr. at 97–101). These procedural harms satisfy the injury-in-fact requirement. *See Cella v. Togum Constructeur Ensembleier en Industrie Alimentaire*, 173 F.3d 909, 911 (3d Cir. 1999) (deprivation of a party's "legitimate expectation of being able to litigate in a particular forum . . . can be sufficient to render" that party aggrieved for due process purposes).

AstraZeneca also faces imminent economic harm. Its ongoing procedural injuries are closely tied to its economic interest in the revenue from its patented drug, FARXIGA. *See Lujan*, 504 U.S. at 573 n.8. AstraZeneca will lose profits on its patented drug, FARXIGA, because it will be forced to sell its drug at a discounted price to a vast portion of the market. *See* 42 U.S.C. § 1320f-3(b)(1); *id.* § 1320f-2(a)(1); Ader Decl. ¶¶ 5, 28. The Government acknowledges that the Program would

place “downward pressure on future pharmaceutical profits.” D.I. 21-1 at 41. Significant economic loss also would occur if AstraZeneca *left* the Program: It either would be forced to pay an excise tax or suffer drastic economic consequences from having to withdraw its entire drug portfolio from Medicare and Medicaid. *See* 26 U.S.C. § 5000D; Ader Decl. ¶¶ 9, 11–14.

AstraZeneca’s economic harms “readily qualify as concrete injuries under Article III.” *TransUnion*, 594 U.S. at 425; *see Sierra Club v. Morton*, 405 U.S. 727, 733 (1972) (“[P]alpable economic injuries have long been recognized as sufficient to lay the basis for standing.”). The amount of harm does not matter; “an identifiable trifle” will do. *Hassan v. City of New York*, 804 F.3d 277, 289 (3d Cir. 2015), *as amended* (Feb. 2, 2016); *Cottrell v. Alcon Laby’s*, 874 F.3d 154, 163 (3d Cir. 2017) (“Any monetary loss suffered by the plaintiff satisfies [the injury-in-fact] element.”); *see also Carey v. Piphus*, 435 U.S. 247, 266 (1978) (“[T]he denial of procedural due process should be actionable for nominal damages without proof of actual injury.”). The Program thus “threaten[s] [AstraZeneca]’s economic interests.” *Multistar Indus., Inc. v. U.S. Dep’t of Transp.*, 707 F.3d 1045, 1054 (9th Cir. 2013).

These injuries also are sufficiently particularized. FARXIGA has already been selected for the Program and will soon receive a government-imposed price ceiling for its drug. The Program thus affects AstraZeneca directly and particularly.

*See New Jersey Physicians, Inc. v. President of U.S.*, 653 F.3d 234, 238 (3d Cir. 2011).

AstraZeneca’s injuries also are actual and imminent, not speculative. FARXIGA has been selected; AstraZeneca has been funneled into an unconstitutional regime and is in the thick of “negotiations” now. The penalties for withdrawing from the program are looming, and the “Maximum Fair Price” will be finalized imminently. AstraZeneca’s entitlement to a meaningful hearing has already been curtailed, and the threat of economic harm to FARXIGA’s revenue is “certainly impending.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 410 (2013).

## **B. Traceability**

Traceability requires showing an “indirect causal relationship” between the agency’s challenged actions and AstraZeneca’s injuries. *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010). “[T]here usually is little doubt of causation” when a plaintiff—like AstraZeneca—“itself is the object of the challenged agency action.” *Exhaustless Inc. v. FAA*, 931 F.3d 1209, 1212 (D.C. Cir. 2019). AstraZeneca’s ongoing procedural injuries and future economic harms flow directly from the Program.

These harms are not self-inflicted. AstraZeneca was given no choice before its drug was selected for the Program, and it cannot decline to participate or leave the Program without facing dire consequences: disproportional and severe penalties

from the excise tax on the one hand, or the threatened ouster of its entire drug portfolio from Medicare and Medicaid on the other. *Cf. California v. Texas*, 593 U.S. 659, 669 (2021) (insurance purchases not traceable to ACA individual mandate provision where statute no longer penalized failure to buy health insurance).

### **C. Redressability**

A finding that the Program violates due process would remedy AstraZeneca’s procedural and economic injuries because such a finding precludes the Government from enforcing an unconstitutional statute. *See, e.g., Reed v. Goertz*, 598 U.S. 230, 234 (2023) (petitioner likely “would obtain relief that directly redresse[d] the injury suffered” if court concluded that state’s procedures “violate[d] due process”). This is so even where a plaintiff cannot predict for certain what the outcome would be of adding the necessary procedure. *See Lujan*, 504 U.S. at 572 n.7; *Stehney v. Perry*, 101 F.3d 925, 931 (3d Cir. 1996) (plaintiff’s injury was “likely to be redressed” by order directing agency to conduct new review); *Center for Biological Diversity v. EPA*, 861 F.3d 174, 182 (D.C. Cir. 2017) (“relax[ing] the redressability” requirement of standing for a procedural injury).

## **II. ASTRAZENECA SATISFIES ANY OTHER STANDING CONSIDERATIONS, TO THE EXTENT APPLICABLE.**

AstraZeneca also satisfies prudential standing. *See Oxford Assocs. v. Waste Sys. Auth. of E. Montgomery Cnty.*, 271 F.3d 140, 145–146 (3d Cir. 2001)

(describing the various strands of prudential standing). It does not seek to vindicate the rights of a third party, *see Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004). It does not assert claims on behalf of an organization or association. *See Free Speech Coal., Inc. v. Attorney Gen. United States*, 974 F.3d 408, 421 (3d Cir. 2020). Nor is AstraZeneca’s due-process claim precluded by the bar on generalized grievances or the zone-of-interests test; AstraZeneca is one of just ten manufacturers suffering imminent injury after being swept directly into the negotiation net.

In any event, to the extent prudential standing doctrines apply to AstraZeneca’s constitutional claim in the first place, *see Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 & n.3 (2014), they are non-jurisdictional. *Elkin v. Fauver*, 969 F.2d 48, 52 n.1 (3d Cir. 1992) (construing *Craig v. Boren*, 429 U.S. 190, 193–194 (1976) to mean that “prudential standing [is] not jurisdictional”). The Government accordingly has waived those arguments.

## CONCLUSION

For the foregoing reasons, AstraZeneca has standing to raise its due process claim.

Dated: February 12, 2024

Catherine E. Stetson\*  
Susan M. Cook\*  
Marlan Golden\*  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, NW  
Washington, D.C. 20004  
Tel: (202) 637-5600  
cate.stetson@hoganlovells.com  
susan.cook@hoganlovells.com  
marlan.golden@hoganlovells.com

\*admitted pro hac vice

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver  
Daniel M. Silver (#4758)  
Alexandra M. Joyce (#6423)  
Renaissance Centre  
405 North King Street, 8th Floor  
Wilmington, DE 19801  
(302) 984-6300  
dsilver@mccarter.com  
ajoyce@mccarter.com

*Attorneys for Plaintiffs*