

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA
PHARMACEUTICALS LP, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official
capacity as SECRETARY OF THE
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Civ. No. 1:23-cv-931-CFC

**DEFENDANTS' SUPPLEMENTAL FILING ON STANDING IN
RESPONSE TO THE COURT'S ORDER OF FEBRUARY 6, 2024**

As the parties seeking to invoke this Court's jurisdiction, it is Plaintiffs alone who bear the burden of demonstrating each of the elements for Article III standing. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). In addition, "standing is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021).

The elements of Article III standing "are not mere pleading requirements but rather an indispensable part of the plaintiff's case," so "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Accordingly, "in response to a summary judgment motion, . . . the plaintiff can no longer rest on . . . mere

allegations, but must set forth by affidavit or other evidence specific facts” that support Article III standing for each claim. *Id.* (citation omitted).

Despite that burden, Plaintiffs’ summary-judgment motion (ECF Nos. 18-20) did not attach declarations or other evidence that would support standing. In response, Defendants argued in their summary-judgment brief that Plaintiffs lacked standing to assert Counts I and II, their challenges to portions of the agency’s Revised Guidance. *See* ECF No. 21-1 at 14-21. Defendants supported that argument with a Declaration from the Deputy Director of the Centers for Medicare & Medicaid Services, Cheri Rice, who explained that “[a]dopting either of Plaintiffs’ interpretations of the statute . . . would have had no effect on Farxiga’s selection by the Secretary as one of the 10 selected drugs for initial price applicability year 2026.” ECF No. 21-2 ¶ 8.

In their opposition-reply brief, Plaintiffs submitted a declaration from Jim Ader, Vice President of U.S. Market Access at AstraZeneca, ECF No. 60, which largely seeks to address Plaintiffs’ standing to assert Counts I and II, in response to the arguments raised in Defendants’ motion. But for the reasons explained in Defendants’ reply and at oral argument, the Ader Declaration falls far short of Plaintiffs’ burden to show standing on Counts I and II. *See, e.g.*, Ader Decl. ¶ 23 (conceding that AstraZeneca’s “clinical trials are currently focused on ‘combination product’ therapies that would not be impacted by the agency’s definition of Qualifying Single Source Drug”).

Plaintiffs have not devoted the same attention to their burden to show standing for Count III. Nevertheless, under the facts and circumstances of this case, Defendants have not argued (and do not now argue) that Plaintiffs lack standing to bring Count III.

Dated: February 12, 2024

Respectfully submitted,

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