UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-1819

ASTRAZENECA PHARMACEUTICALS, LP; ASTRAZENECA AB,
Appellants

v.

SECRETARY UNITED STATED DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES

On Appeal from the United States District Court
for the District of Delaware
(D.C. Civil No. 1:23-cv-00931)
District Judge: Honorable Colm F. Connolly

Argued on October 30, 2024

Before: HARDIMAN, PHIPPS, and FREEMAN, *Circuit Judges*

JUDGMENT

This cause came to be considered on the record from the United States District Court for the District of Delaware and was argued on October 30, 2024.

On consideration whereof, it is hereby **ORDERED and ADJUDGED** that the order of the District Court entered on March 1, 2024, be and is hereby **AFFIRMED**. Costs are taxed against Appellants. All of the above in accordance with the opinion of this Court.

ATTEST:

s/ Patricia S. Dodszuweit
Clerk

Dated: May 8, 2025

Certified as a true copy and issued in lieu of a formal mandate on May 30, 2025

Teste: Patricia A Dodszuweit

Clerk, U.S. Court of Appeals for the Third Circuit

OFFICE OF THE CLERK

PATRICIA S. DODSZUWEIT

CLERK

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May 30, 2025

Randall C. Lohan
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N King Street
Wilmington, DE 19801

RE: AstraZeneca Pharmaceuticals LP, et al v. Secretary United States Department of Health and H, et al
Case Number: 24-1819
District Court Case Number: 1:23-cv-00931

Dear District Clerk

Enclosed herewith is the certified judgment together with copy of the opinion or certified copy of the order in the above-captioned case(s). The certified judgment or order is issued in lieu of a formal mandate and is to be treated in all respects as a mandate.

Counsel are advised of the issuance of the mandate by copy of this letter. The certified judgment or order shows costs taxed, if any.

For the Court,

s/ Patricia S. Dodszuweit
Clerk

Date: May 30, 2025

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PRECEDENTIAL

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(Opinion filed: May 8, 2025)

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OPINION OF THE COURT

FREEMAN, *Circuit Judge*.

The Inflation Reduction Act of 2022 ("IRA") created the Drug Price Negotiation Program ("Negotiation Program"). The Negotiation Program directs the Centers for Medicare & Medicaid Services ("CMS") to negotiate prices for certain

drugs that have resulted in high expenditures to Medicare. To implement that statutory directive, CMS issued guidance explaining how it would select the qualifying drugs for 2026—the first year of the Negotiation Program. CMS then selected the drugs that are subject to negotiation. One of the selected drugs is Farxiga, which is manufactured by AstraZeneca.[1]

AstraZeneca sued the Secretary of the Department of Health and Human Services and CMS's Administrator (collectively, "the government") to challenge the Negotiation Program and portions of CMS's guidance. AstraZeneca claims that the Negotiation Program deprives it of procedural due process and that two provisions of CMS's guidance violate the Administrative Procedure Act ("APA").

The District Court determined that AstraZeneca failed to state a due process violation to challenge the Negotiation Program and lacks standing to pursue its APA claims. Accordingly, the District Court entered judgment in favor of the government. For the following reasons, we will affirm the District Court's judgment.

I

Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities. *See* 42 U.S.C. § 1395 *et seq.* Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes. *See id.* § 1396 *et seq*. "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide

[1] We refer to AstraZeneca Pharmaceuticals LP, and AstraZeneca AB collectively as "AstraZeneca."

spending on prescription drugs." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023) (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)).

Medicare is divided into Parts, two of which (Parts B and D) are relevant here. Part B is a voluntary supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician. *See* 42 C.F.R. § 410.28. Part D "is a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). Part D works through prescription drug plans operated by private insurance companies that it calls "sponsors." Sponsors then work with subcontractors, including pharmacy benefit managers, who handle administrative tasks and process claims. *See id.* Those subcontractors in turn contract with the pharmacies that dispense prescription drugs to Medicare beneficiaries. *See id.*

When Congress enacted Medicare Part D in 2003, it included a "non-interference" provision. That provision states that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and "may not institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Nineteen years later, when Congress enacted the IRA, it created an exception to the non-interference provision: the Negotiation Program directs CMS to "negotiate . . . maximum fair prices" for certain drugs, *id.* § 1320f(a)(3), subject to price ceilings derived from the price on the private market, *id.* § 1320f-3(c). Each selected drug's "maximum fair price"

applies beginning in a given drug-pricing period (a period of one calendar year), the first of which is 2026, until the drug is no longer eligible for negotiation or the price is renegotiated. *Id.* §§ 1320f(b)(1)–(2), 1320f-1(c), and 1320f-3(f).

The Negotiation Program sets out a two-phase process for each drug-pricing period. First, CMS identifies the drugs subject to negotiation. Second, CMS negotiates with the manufacturer of each identified drug. We will refer to these as the Identification Phase and the Negotiation Phase.

During the Identification Phase for any given drug-pricing period, CMS first identifies "qualifying single source drugs," which are drugs approved by the FDA for at least seven years and not subject to competition from a generic "that is approved and marketed." *Id.* § 1320f-1(e)(1)(A)(i)–(iii). CMS then rank-orders the qualifying single source drugs according to highest associated expenditures under Medicare Part B or Part D over a recent twelve-month period. To determine the total spending on a drug, CMS looks to "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." *Id.* § 1320f-1(d)(3)(B). The fifty drugs that represent the highest total spending under each respective Part are "negotiation-eligible drugs." *Id.* § 1320f-1(d)(1).[2]

[2] The Negotiation Program applies to drugs covered by Medicare Part D for the 2026 and 2027 drug-pricing periods. 42 U.S.C. § 1320f-1(a)(1)–(2), (d)(1). The Negotiation

Next, CMS selects and publishes a list of the negotiation-eligible drugs that will be subject to negotiation for the relevant drug-pricing period, *id.* § 1320f-1(a), prioritizing negotiation for the drugs that represent the largest expenditures to Medicare, *see id.* § 1320f-1(b)(1)(B). It selected ten drugs for drug-pricing period 2026, and the number of selected drugs will increase for subsequent drug-pricing periods. *Id.* § 1320f-1(a).

Once CMS publishes the list of drugs selected for negotiation, the Negotiation Phase begins. When negotiating, CMS "shall . . . aim[] to achieve the lowest maximum fair price for each selected drug," *id.* § 1320f-3(b)(1), and is barred from offering or agreeing to a price that is more than 75 percent of the private market price for the drug, *see id.* § 1320f-3(c). Lower price ceilings (65 percent or 40 percent) apply to drugs that have been approved or licensed for a longer time (at least 12 years or at least 16 years, respectively). *Id.*

CMS must consider several factors during negotiations, including the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities, FDA product approvals, sales data, and alternative treatments. *See id.* § 1320f-3(e). Manufacturers supply information about these factors to CMS. *See id.* § 1320f-3(b)(2)(A). Based on the enumerated factors and the price ceilings, CMS makes an initial offer. *Id.* § 1320f-

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Program first applies to drugs covered by Medicare Part B during the 2028 drug-pricing period. *Id.* § 1320f-1(a)(3)–(4), (d)(1).

3(b)(2)(B). The manufacturer then has an opportunity to make a counteroffer, to which CMS will respond. *Id.* §§ 1320f-3(b)(2)(C)–(D). Negotiations must end by November 1 of the year two years prior to when the pricing will take effect, *id.* § 1320f-3(b)(2)(E), and CMS must publish the maximum fair price by November 30, *id.* § 1320f-4(a)(1). CMS then has until March 1 of the following year (i.e., ten months before the price goes into effect) to publish an explanation of how the maximum fair price comports with the statutory factors. *Id.* § 1320f-4(a)(2).

Congress directed CMS to implement the Negotiation Program for drug-pricing periods 2026 through 2028 "by program instruction or other forms of program guidance." *Id.* § 1320f note. Accordingly, in March 2023 CMS issued an initial program guidance. After receiving more than 7,500 public comments, it made revisions and issued revised guidance ("the Guidance") in June 2023. By its terms, the Guidance applies only for drug-pricing period 2026, though CMS has stated that it may incorporate the comments it received when promulgating the Guidance into its program guidance for drug-pricing periods 2027 and 2028.

AstraZeneca challenges two aspects of the Guidance. The first is the Guidance's grouping of variations of the same drug. As noted above, the Negotiation Program requires CMS to determine total Medicare expenditures for negotiation-eligible drugs by using "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended-release formulation, and not based on the specific formulation or package size or package type of the drug." *Id.* § 1320f-1(d)(3)(B). Relying on this language, the Guidance states that CMS "will identify a potential qualifying single source drug using . . . all dosage

forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs."[3] App. 217 (footnotes omitted).

The second challenge is to the Guidance's test for generic competition. Recall that the Negotiation Program states that drugs qualify for negotiation if they lack a generic competitor that "is approved and *marketed*." 42 U.S.C. § 1320f-1(e)(1)(A)(iii) (emphasis added). The Guidance states that CMS will consider an approved generic "to be marketed when the totality of the circumstances . . . reveals that the manufacturer of the generic drug . . . is engaging in bona fide marketing of that drug." App. 124. It explains that the statutory term "is marketed" contemplates "that a generic . . . must have a continuing presence on the market." App. 190. It also explains that "manufacturers' past behavior warrants CMS review on an ongoing basis as to whether a generic drug . . . is being bona fide marketed." *Id.* It reasons that, without that review, a generic-drug manufacturer "could launch into the market a token or de minimis amount of a generic drug" and the manufacturer of a drug selected for negotiation could "claim that the [maximum fair price] should no longer apply." *Id.* Accordingly, to determine whether a manufacturer is engaging in bona fide marketing, the Guidance says CMS will

[3] As defined by FDA regulations, a drug's active moiety is the core "molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3. An NDA is the FDA's approval of a pharmaceutical for sale and marketing; a drug can have multiple approved uses under one NDA and multiple NDAs for different uses. *See generally* 21 U.S.C. § 355.

review data on prescriptions being filled and the average price a manufacturer offers to direct purchasers.

In August 2023, after CMS published the Guidance, AstraZeneca filed this lawsuit challenging the Guidance and the Negotiation Program. Four days after AstraZeneca filed suit, CMS published a list of the ten drugs it selected for negotiation for drug-pricing period 2026. AstraZeneca then amended its complaint to allege that CMS had selected one of the drugs AstraZeneca manufactures: Farxiga, which is used to treat diabetes, heart disease, and kidney disease. While this case proceeded, AstraZeneca and CMS undertook the steps set out in the Negotiation Program's Negotiation Phase, and the parties agreed to a "maximum fair price" for Farxiga during drug-pricing period 2026.[4]

Meanwhile, the parties cross-moved for summary judgment, agreeing that their motions presented purely legal issues. In March 2024, the District Court denied AstraZeneca's motion and granted the government's motion. It determined that AstraZeneca lacked standing to challenge the Guidance under the APA and failed to state a procedural-due-process claim that could lead to relief from the Negotiation Program. AstraZeneca timely appealed.

[4] The Negotiation Program defines the term "maximum fair price" to mean, with respect to a selected drug and a given drug-pricing period, "the price negotiated pursuant to [the Negotiation Program], . . . as applicable, for such drug and year." 42 U.S.C. § 1320f(c)(3).

II[5]

We exercise plenary review of summary-judgment orders, applying the same standard used by district courts. *Auto-Owners Ins. Co. v. Stevens & Ricci Inc.*, 835 F.3d 388, 402 (3d Cir. 2016). Under that standard, summary judgment is only appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

A

In its APA claims, AstraZeneca challenges how the Guidance defines a qualifying single source drug and how it instructs CMS to determine whether a drug is subject to generic competition. It asserts that these Guidance provisions conflict with or exceed the terms of the Negotiation Program and must be set aside. But before we can address the merits of these claims, AstraZeneca must demonstrate that it has Article III standing. *Nat'l Shooting Sports Found. v. Att'y Gen. of N.J.*, 80 F.4th 215, 218 (3d Cir. 2023); *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) ("[A] plaintiff must demonstrate standing for each claim he seeks to press.").

"To establish standing, a plaintiff must show an injury in fact caused by the defendant and redressable by a court order." *United States v. Texas*, 599 U.S. 670, 676 (2023). The injury-in-fact must be "concrete, particularized, and actual or imminent." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). "A concrete injury is real rather than abstract, and a particularized injury is one that affects the plaintiff in a

[5] The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1346, and 1361. We have jurisdiction under 28 U.S.C. § 1291.

personal and individual way." *Ellison v. Am. Bd. of Orthopaedic Surgery*, 11 F.4th 200, 205 (3d Cir. 2021). A plaintiff bears the burden of establishing standing "as of the time [it] brought [its] lawsuit," *Carney v. Adams*, 592 U.S. 53, 59 (2020), and it must do so "for each claim [it] seeks to press." *DaimlerChrysler Corp.*, 547 U.S. at 335.

AstraZeneca articulates two theories of injury stemming from both challenged aspects of the Guidance: (1) the impact on AstraZeneca's decision-making about research, development, and marketing, and (2) the company's difficulty valuing Farxiga in negotiations with CMS. Neither theory of injury is concrete or particularized.

1

We begin with AstraZeneca's asserted injury to its business decision-making. According to the company, the Guidance's grouping of related drugs has caused or will cause AstraZeneca to make research, development, and marketing choices that account for the risk that its new drug products will be subject to price negotiation. Similarly, AstraZeneca contends that the Guidance's bona-fide-marketing requirement forces it to account for the risk that its drugs could be simultaneously subject to generic competition and negotiated pricing.

At summary judgment, a plaintiff cannot rely on mere allegations to demonstrate standing. It "must set forth by affidavit or other evidence specific facts demonstrating that [standing] requirements have been met." *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010) (internal quotation marks and citation omitted). Seeking to satisfy this requirement, AstraZeneca submitted an affidavit from its Vice President of

U.S. Market Access, Jim Ader. Ader stated that the grouping of different drug products "diminishes incentives for AstraZeneca to invest in future therapies and treatments for the active moiety of a selected drug product." App. 101. He continued:

> While clinical trials are currently focused on "combination product" therapies that would not be impacted by the agency's definition of Qualifying Single Source Drug, there are other ongoing drug development efforts involving the same active moiety as FARXIGA where one development pathway could result in the product being treated as the same QSSD as FARXIGA under CMS's position.

App. 103. He asserted that the Guidance "dramatically alters manufacturers' incentives to invest in . . . follow-on therapies using a previously approved active moiety" and that "AstraZeneca would have no incentive to spend years and a steep financial investment researching alternative treatment uses for the active moiety of a selected product." App. 104–05.

Ader's affidavit—the only evidence AstraZeneca submitted to support its theory of injury-in-fact—does not establish a concrete and particularized injury to AstraZeneca. Ader did not identify any actual decision about drug development or marketing that AstraZeneca has made or will make to avoid different drugs being grouped together. While he hypothesized that some unspecified "pathway" of AstraZeneca's ongoing drug-development efforts involving Farxiga's active moiety *could* result in a product that would be grouped with Farxiga in the future, he provided no evidence

about how the company has been (or imminently will be) injured. *See Sherwin-Williams Co. v. Cnty. of Delaware, Pa.*, 968 F.3d 264, 269 (3d Cir. 2020) ("Allegations of possible future injury do not satisfy the requirements of Art. III." (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990))). Ader merely suggested a hypothetical scenario. But "[u]nder Article III, federal courts do not adjudicate hypothetical . . . disputes." *TransUnion*, 594 U.S. at 423; *accord Trump v. New York*, 592 U.S. 125, 131 (2020) (recounting that standing requires "an injury that is concrete, particularized, and imminent rather than conjectural or hypothetical" (citation omitted)).[6] And Ader's statements about "broad-based market effects stemming from regulatory uncertainty are quintessentially conjectural," *New Eng. Power Generators Ass'n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013), and thus insufficient to establish standing.[7]

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[6] In his affidavit, Ader describes Calquence—a leukemia medicine approved under two different NDAs—and avers it is "a potential candidate for selection" for negotiation in pricing period 2027. App. 106. Ader states that the Guidance's definition "dramatically alters manufacturers' incentives to invest in such follow-on therapies," App. 104, but he provides no detail about how "AstraZeneca has to make investment decisions now on research development" related to Calquence, App. 106. Nor does the fact that CMS later selected Calquence for the 2027 pricing period demonstrate that AstraZeneca had a concrete and particularized injury at the time it sued.

[7] While this appeal was pending, the Fifth Circuit held in *National Infusion Center Association v. Becerra*, 116 F.4th 488

AstraZeneca's asserted injury to its ability to value Farxiga in negotiations with CMS is not concrete or particularized either. AstraZeneca filed Ader's affidavit before CMS made an initial offer for Farxiga's "maximum fair price" for drug-pricing period 2026. It argues that it had to assume the Guidance applied, so the Guidance injured its business decisions even before any offers were made. But the only evidence presented is Ader's statement that "AstraZeneca . . . is forced to make a number of decisions now about its willingness to go forward with its participation in the program." App. 99. This "general factual allegation[] of injury resulting from the defendant's conduct" is insufficient to

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(5th Cir. 2024) ("*NICA*"), that a medical trade organization had standing to bring constitutional challenges to the Negotiation Program. AstraZeneca asserts that *NICA* supports standing here. Not so. AstraZeneca's standing to challenge the Negotiation Program is not in dispute, and *NICA* says nothing about standing to challenge the Guidance provisions at issue here. And, of course, courts assess standing based on the record before them. In *NICA*, the plaintiff demonstrated how the Negotiation Program caused it both present and future injury. *See id.* at 502 ("NICA has specifically described the ways in which the [Negotiation] Program limits its members' ability to obtain necessary debt and equity capital."); *id.* at 501 ("NICA has shown that at least one of its members' drugs will be subject to the [Negotiation] Program, that the [Negotiation] Program will lower the price for that drug, and that the lower price will lead to lower revenue for the member."). Here, AstraZeneca has failed to demonstrate either actual or imminent injury caused by the Guidance.

establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). AstraZeneca has introduced no "specific facts" about how the Guidance shaped its behavior before or during those negotiations.[8] *Id.*

Absent an injury-in-fact, AstraZeneca lacks Article III standing to challenge the Guidance. We will therefore affirm the District Court's order granting summary judgment in favor of the government with respect to AstraZeneca's APA claims.

III

In its due process claim, AstraZeneca argues that the Negotiation Program itself (not the Guidance) deprives the company of its property interests in drugs subject to negotiation and does not provide adequate procedural safeguards.

To state a procedural due process claim, "a plaintiff must allege that (1) he was deprived of an individual interest that is encompassed within the Fourteenth Amendment's protection of life, liberty, or property, and (2) the procedures available to him did not provide due process of law." *Hill v. Borough of Kutztown*, 455 F.3d 225, 233–34 (3d Cir. 2006) (internal quotation marks and citation omitted). "For a property interest to be protected, a plaintiff must show a legitimate claim of entitlement to it." *Coon v. Cnty. of Lebanon*, 111 F.4th 273, 275 (3d Cir. 2024) (internal quotation

[8] AstraZeneca, of course, could have sought to file any confidential evidence under seal. *See, e.g.*, *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1118 (D.C. Cir. 2005) (describing evidence of confidential marketing plans filed under seal that established injury-in-fact).

marks and citation omitted). The Due Process Clause protects property interests that are created and defined outside of the Constitution, such as by federal statute or state law. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972).

AstraZeneca argues that the Negotiation Program limits its ability to sell its drugs at a market rate, thereby infringing on its property rights. It contends that those property rights derive from its patents and regulatory exclusivity periods. *See* Opening Br. 43 (asserting a deprivation of its "core property interests in its patented drugs and the right to determine the revenue it derives therefrom"); *id.* at 43–44 (suggesting regulatory exclusivity periods enhance its right to exclude); *accord id.* at 23 (describing the deprivation of "some of the rights conferred by Farxiga's patent").

AstraZeneca is correct that patent rights exist to permit greater profits during a product's exclusivity period to incentivize innovation. *See Eldred v. Ashcroft*, 537 U.S. 186, 215–16 (2003). But "the federal patent laws do not create any affirmative right to make, use, or sell anything." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (citation omitted). And where federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price. (No other applicable provision of property law confers a right to sell goods at a particular price either.)

There is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs. AstraZeneca's asserted interest does not "resemble any traditional conception of property," *Town of Castle Rock, Colorado v. Gonzales*, 545

U.S. 748, 766 (2005),[9] and AstraZeneca has no more than "a unilateral expectation" of that interest, *Roth*, 408 U.S. at 577.

AstraZeneca also contends that the Negotiation Program violates the Due Process Clause by imposing price controls on private market transactions while barring judicial review of CMS's price-setting decisions. For support, it relies on *Bowles v. Willingham*, 321 U.S. 503, 517–21 (1944). *Bowles* involved a wartime rent-control statute governing certain private housing transactions. The Supreme Court upheld the statute, noting that it provided for judicial review of the agency's price-setting decisions. *Id.* at 520–21. According to AstraZeneca, its drug sales to Medicare plan sponsors are private market transactions, so any price controls on those transactions must get judicial review as in *Bowles*. But the Negotiation Program only sets prices for drugs *that CMS pays*

[9] In *Burns v. Pennsylvania Department of Corrections*, we looked to A. M. Honoré's eleven "standard incidents" of property ownership to determine whether a claimed interest qualified as property under the Due Process Clause. 544 F.3d 279, 287 (3d Cir. 2008) (citation omitted). Honoré's list of "standard incidents" of property ownership are "the right to possess, the right to use, the right to manage, the right to the income of the thing, the right to the capital, the right to security, the rights or incidents of transmissibility and absence of term, the prohibition of harmful use, liability to execution, and the incident of residuarity." *Id.* (quoting A. M. Honoré, *Ownership*, *in* Oxford Essays in Jurisprudence 107 (A.G. Guest, ed. 1961), *reprinted in* Tony Honoré, Making Law Bind: Essays Legal and Philosophical (1987) (emphasis omitted)). AstraZeneca's claimed interest does not align with any of these incidents of ownership.

for when it reimburses sponsors. *See* 42 U.S.C. §§ 1395w-111–1395w-112 (establishing a scheme in which sponsors bid to be accepted into Medicare Part D and enter contracts with CMS for reimbursement); *see also* 42 C.F.R. § 423.301 *et seq.* (setting forth rules for reimbursing sponsors). These are not private market transactions, regardless of the private hands through which CMS's funds pass. *See Spay*, 875 F.3d at 749 (describing the public-private structure of Medicare Part D).

Because AstraZeneca does not articulate a protected property interest, we will affirm the District Court's grant of summary judgment in favor of the government on AstraZeneca's due process claim.

* * *

For the foregoing reasons, we will affirm the District Court's judgment.