IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, 1800 Concord Pike Wilmington, DE 19803, Plaintiff, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, DC 20201, and CHIQUITA BROOKS-LASURE, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES, 7500 Security Boulevard Baltimore, MD 21244, Defendants.	Civil Action No. _____

COMPLAINT

AstraZeneca Pharmaceuticals LP (AstraZeneca) brings this Complaint challenging certain aspects of the drug pricing negotiation provisions of the Inflation Reduction Act of 2022, Pub. L. 117-169 (IRA), as well as recent guidance issued by the Centers for Medicare & Medicaid Services (CMS) purporting to implement the statute.

PRELIMINARY STATEMENT

1. This case is about a statute and guidance designed to cut costs to the federal government at great cost to innovation and the country's most vulnerable patients. The Inflation Reduction Act enacted sweeping changes to drug pricing under Medicare, jettisoning a market-

based approach in favor of a new scheme of price controls established by the federal government. The IRA's drug pricing provisions, however, run headlong into the goals of the Orphan Drug Act, a federal statute designed to encourage manufacturers to invest in new therapies for rare (or "orphan") diseases.

2. It is not uncommon for an orphan drug to have multiple designations for multiple different rare conditions, as is the case with AstraZeneca's LYNPARZA® (olaparib) and SOLIRIS® (eculizumab), both of which provide important therapeutic options for patients with a variety of rare diseases. The IRA nominally exempts orphan drugs from its drug pricing program – so long as the drug is designated for the treatment of a single orphan condition. 42 U.S.C. § 1320f-1(e)(3)(A). Should a drug be designated for a second orphan condition – as is often the case – the exemption no longer applies, meaning that an orphan-protected drug product could immediately be selected for negotiation and subject to the resulting price controls in as little as two years. The losers in this cost-cutting exercise, in the end, will be the patients who need new therapies for their rare diseases.

3. Innovator pharmaceutical companies take on enormous risks in developing new drug products. It takes vast amounts of time and the support of significant monetary investment to identify, test, and develop any new drug candidate. Even when a drug shows early promise in clinical trials, the United States Food and Drug Administration (FDA)'s rigorous drug approval process means very few of those early drug candidates are ever approved and commercialized. Studies estimate that only *one* out of every 5,000 compounds that enters preclinical testing will achieve FDA approval – a failure rate of 99.98%.[1]

[1] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), *available at* https://bit.ly/2Y2gwEK.

4. The most important constituents depending on that high-risk, low-probability drug development marathon are patients, whose well-being – and sometimes lives – depend on the efficacy and safety of the therapies available to treat them. There is one subset of patients, in particular, for whom drug makers' research and investment choices may spell life or death: individuals with what are called "orphan diseases" – rare illnesses or afflictions shared by a vanishingly small cohort in the United States.

5. Orphan diseases are generally defined as conditions that affect fewer than 200,000 people in the entire country – less than the population of Sussex County, Delaware. They vary in name recognition; cystic fibrosis and Lou Gehrig's disease are orphan illnesses. So are eosinophilic esophagitis and peritoneal cancer. Individually, these diseases are extremely rare. But collectively, they number over seven thousand, affecting about 30 million Americans and 400 million people worldwide. Half of these patients are children.

6. Until the 1980s, individuals with rare diseases had very few options for drug product treatment. The process for pharmaceutical manufacturers to discover, test, and secure approval of a drug was so challenging that very few manufacturers would take that risk for a small patient population. That is why drug products designed to treat rare diseases are called "orphan drugs": There was little incentive for manufacturers to "adopt" and develop them, given the costs associated with research and development and the low odds of crossing the finish line with FDA approval.

7. In 1983, Congress passed the Orphan Drug Act, a law designed to create incentives for manufacturers to discover, sponsor, and market drugs for rare-disease patient populations. The Orphan Drug Act does so by providing, among other things, seven years of marketing exclusivity to sponsors of approved drug products covering orphan indications. Importantly, in this context,

the Orphan Drug Act does not limit the number of orphan designations a drug may receive, or constrain the resulting market exclusivity by the number of orphan indications that are approved. Nor is a product ineligible for orphan exclusivity simply because it is also approved for non-orphan uses.

8. The Orphan Drug Act has been successful. Since 1983, FDA has approved approximately six hundred distinct drug products designed to treat orphan conditions suffered by tens of millions of Americans. NORD, *New Study Investigates the Number of Available Orphan Products, Generics, and Biosimilars* (Mar. 25, 2021), *available at* https://rarediseases.org/new-study-investigates-the-number-of-available-orphan-products-generics-and-biosimilars/. As one FDA historian put it, "the Orphan Drug Act finally provided for many of those orphaned among blockbuster treatments a hope of their own." FDA, *The Story Behind the Orphan Drug Act*, *available at* https://www.fda.gov/industry/fdas-rare-disease-day/story-behind-orphan-drug-act.

9. Upon enactment, patients of rare diseases had reason to be optimistic, because the Orphan Drug Act facilitated market-based incentives to support the development of new therapies for their orphan conditions.

10. Indeed, many cancer medicines in the U.S. launch first in an orphan indication and broaden their use over time to additional populations. One example of this is AstraZeneca's drug LYNPARZA® (olaparib), a small-molecule cancer medicine approved in 2014 in the U.S. for a small group of late-line ovarian cancer patients. Pre-approval, FDA designated LYNPARZA as an orphan drug for that indication. Additional trials added small groups of breast and pancreatic cancer patients, with the most recent indication in prostate cancer approved just this year – nine years later. If the IRA had been in place, significant disincentives would have existed for pursuing the late-line ovarian cancer approval in the U.S., an indication which has benefited patients in great

need of this unique medicine for their rare condition.

11. Another example is Alexion (AstraZeneca Rare Disease)'s SOLIRIS® (eculizumab), which has received approval to treat four rare diseases, including debilitating and potentially life-threatening neuromuscular and hematological diseases. First approved in 2007 in paroxysmal nocturnal haemoglobinuria (PNH), a rare chronic blood disorder, historic dynamics enabled continued research investment to support further innovation, resulting in a U.S. approval more than a decade later in neuromyelitis optica spectrum disorder (NMOSD), a rare autoimmune disease that affects the central nervous system. The IRA would have deterred the continued development of this life-changing medicine for patients with rare diseases beyond its initial indication.

12. The work done by the Orphan Drug Act is far from over. Even with the gains made following its passage, more than 90% of orphan diseases have no treatment options. The Orphan Drug Act encourages manufacturers to research and develop drugs for small patient populations. But the Orphan Drug Act did not – and could not – relieve the risk manufacturers take when they embark on the process of research and discovery. Manufacturers still confront daunting odds for each and every product they attempt to perfect and bring to market. They accept those odds because they understand that *if* they discover a compound, *if* it can be made into a drug that proves safe and efficacious, *if* it obtains regulatory approval, and *if* it reaches patients and fulfills a medical need, the product *might* earn market-based returns.

13. Enter the IRA. Medicare – which covers approximately 20% percent of the entire U.S. population – has long relied on market-driven pricing incentives to control prescription drug costs. The IRA jettisons these market-based solutions in favor of price controls set by the federal government. Specifically, Congress has purported to delegate to CMS the authority to unilaterally

select drugs and biologics lacking generic competition for a purported "negotiation" with their manufacturers after such drugs have been on the market for a specified period, and then to dictate a "maximum fair price" (sometimes referred to as "MFP") for each selected drug product that cannot exceed a statutory ceiling. 42 U.S.C. § 1320f-1.

14. To be clear, there is no actual negotiation involved: A manufacturer may either consent to the agency's dictated price or face an extreme tax penalty of up to 95% of the drug's gross U.S. revenues on the drug – including non-Medicare sales. *Id.* § 1320f-5(a)(6); 26 U.S.C. § 5000D.[2] Manufacturers thus have no real choice but to accede to the agency's unilaterally dictated price or terminate its Medicare Part D agreements and Medicaid rebate agreement – not just for the drug in question, but for *all* of the manufacturer's drugs.

15. Congress paired the scale of this market intervention with a breathtakingly expansive grant of implementation authority to CMS. The IRA authorizes CMS to implement the particulars of this program through guidance, without any notice or opportunity to comment afforded to drug manufacturers – or, for that matter, patients themselves. Pub. L. 117-169, Title I, § 11002(c); 42 U.S.C. § 1320f-1. As if that was not enough, the statute also purports to shield several key aspects of the new drug pricing program from judicial review, including the selection of a particular drug product for negotiation and the determination of a "maximum fair price." 42 U.S.C. § 1320f-7.

16. The IRA is designed to result in steep discounts. Selected products are subject to

[2] The Internal Revenue Service recently issued a notice that it "intend[s] to propose regulations" interpreting this provision, "including how taxpayers would report and pay" this excise tax. *See* IRS Notice 2023-52, "Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax" (Aug. 4, 2023). The IRS notice indicates that the tax penalty *may* be limited to Medicare sales. *See id.* at 3.

statutory price ceilings defined to require deep cuts from the current, market-based prices. For nearly all drugs, there is no floor. The Secretary could decide that Medicare should pay only a penny for a particular drug, and the manufacturer would have to sell at that price or assume massive liabilities.

17. Multiple lawsuits have been filed challenging the constitutionality of the IRA. There is little question that the statute's draconian regime violates a number of constitutional protections, including basic due process principles, as explained later. CMS compounded the injury, however, when it purported to implement the program through guidance.

18. In March and June 2023, CMS issued two Medicare Drug Price Negotiation Program guidance documents detailing how the agency planned to execute these sweeping changes, with the first tranche of selected drugs to be identified no later than September 1. The two guidance documents (collectively referred to as the Guidance Documents) violate the Administrative Procedure Act (APA) for at least two reasons: They override the statutory definition of "Qualifying Single Source Drug," such that the term impermissibly includes two different drugs approved at different times, and they add a new "bona fide marketing" requirement that sweeps drugs into the selection process even when they have generic competition, and keeps them subject to the discounted price longer.

19. These statutory violations only serve to compound the due process problems inherent in the IRA itself. On the front end, the IRA forces manufacturers to engage in purported "negotiations" but affords them no bargaining power, no meaningful opportunity to walk away, and no ability to protect their interests against a so-called "maximum fair price" capped at an amount drastically below actual fair market value. Then, on the back end, it purports to preclude affected manufacturers even from seeking judicial review. 42 U.S.C. § 1320f-7. In sum:

Manufacturers have no meaningful right to participate or be heard from beginning to end. The cumulative effect of these provisions violates the procedural due process guarantees of the Fifth Amendment.

20. The IRA also undermines the Orphan Drug Act by radically reducing the market incentives for pharmaceutical manufacturers to invest in new drug candidates and new indications for existing therapies, like LYNPARZA and SOLIRIS. This is especially the case when it comes to treatments targeting orphan indications: While the IRA exempts orphan drugs from selection for their first orphan designations, it *removes* that exemption once the drug receives any *additional* orphan designations. By reducing manufacturers' ability to recoup their investment on new orphan indications for existing drugs post-approval, the IRA disincentivizes the very research and development the Orphan Drug Act was intended to – and for the last four decades, did – spur. The IRA's stingy approach to orphan products generates real risk that future treatment breakthroughs will be jeopardized, particularly for therapies with the potential to treat multiple orphan conditions, undermining patient access to meaningful treatment options and life-saving therapies.

21. These are not hypothetical harms. They are already happening. *See* Joe Grogan, *The Inflation Reduction Act Is Already Killing Potential Cures*, Wall Street Journal (Nov. 3, 2022), *available at* https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291?ns=prod/accounts-wsj.

22. On or before September 1, 2023, CMS is poised to identify the first ten drugs selected for negotiation. Once that process starts, it moves quickly. The manufacturer then must enter into an agreement to "negotiate" by October 1, 2023. AstraZeneca therefore seeks expedited briefing in this administrative record-based case to allow for an early decision.

PARTIES

23. Plaintiff AstraZeneca is a limited partnership organized in Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines.

24. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services (HHS). Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

25. Defendant Chiquita Brooks-LaSure is the Administrator of CMS and is responsible for administering the guidance and statutory provisions challenged here on behalf of the Secretary. Defendant Brooks-LaSure maintains an office at 7500 Security Boulevard, Baltimore, Maryland, 21244.

JURISDICTION AND VENUE

26. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiff requires a declaration of its rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

27. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is a civil action in which Defendants are officers of the United States acting in their official capacities.

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

A. Medicare and FDA's Drug Approval Process

28. The Medicare program, enacted in 1965, provides health insurance for individuals 65 years of age and older, some individuals with disabilities under age 65, and individuals with certain conditions such as end-stage renal disease. Medicare Part B covers enrolled beneficiaries for, in relevant part, drugs and biologicals administered by physicians and other health care providers. Medicare Part D, which is optional, helps cover enrolled beneficiaries for the cost of non-physician-administered drugs. In totality, approximately 20 percent of all Americans are covered by Medicare.

29. All "new drugs" must be approved by FDA before being introduced or delivered for introduction into interstate commerce. 21 U.S.C. §§ 355(a), 331(d). A "new drug" may be a drug product that has never been approved, or it may be an approved drug product with a change, such as a new intended use or indication, or a different strength or dosage form. 21 U.S.C. § 321(p). Innovator drugs are typically approved under a New Drug Application (NDA) or a Biologics License Application (BLA).

30. Innovator pharmaceutical companies invest tremendous resources into pursuing a new drug candidate in the hopes that it might provide new therapeutic options for patients that can save their lives, or at least make them better. The process is arduous, however, and only a scant few early drug candidates are ever approved and commercialized. For that reason, innovator drugs are often rewarded with periods of marketing exclusivity and patent rights.

31. Historically, innovator manufacturers have been able to sell their products both commercially and under Medicare at prices dictated by market dynamics. That market-driven dynamic has now come to a crashing halt with the passage of the IRA.

B. Congress Passes the IRA

32. In August 2022, President Biden signed the IRA, which made sweeping changes to health care, tax, and climate laws. Relevant here, the IRA provides for a "Drug Price Negotiation Program" that lowers the Medicare Parts B and D prices of certain drugs and biologics that lack generic or biosimilar competition, starting in 2026.

33. Starting September 1, 2023, the Secretary is directed each year to select a specified number of "negotiation-eligible" drugs with the highest total Part B or D expenditures over a specified preceding 12-month period. 42 U.S.C. § 1320f-1(b)(1)(A). CMS must rank these "negotiation-eligible" drugs in order of the highest total Medicare expenditures during that period and must select an increasing number of the highest ranked drugs for the Program each year. *Id.* § 1320f–1(a)-(b). The number of drugs selected for price-setting is cumulative. Once a drug is selected, it remains selected until the first year that begins at least nine months *after* the date on which CMS determines that a generic version of the drug is approved and marketed. *Id.* § 1320f–1(c)(1). Thus, for the first initial price applicability year (aptly known as "IPAY"), 2026, CMS will select up to ten Part D drugs. For 2027, CMS will select up to fifteen more Part D drugs, on top of the ten drugs previously selected. For 2028, CMS will select up to fifteen more Part B or D drugs. And for 2029 and each year thereafter, CMS will select up to twenty more Part B or D drugs. *Id.*

34. To be eligible for selection and negotiation, a drug must be a "Qualifying Single Source Drug." 42 U.S.C. § 1320f-1(d)(1). That term is expressly defined in the statute, and the

definition has several parts. First, for the first IPAY, the drug must be "a covered part D drug (as defined in section 1395w-102(e) of this title [the Medicare statute])." 42 U.S.C. § 1320f-1(e)(1). Second, the drug is required to be a drug approved by FDA, and at least 7 years must have elapsed "since the date of such approval." *Id.* § 1320f-1(e)(1)(A). And third, the drug must not be the reference listed drug for a generic drug that has been "approved and marketed." *Id.* The same is true for biological products, except the applicable time period is 11 years from the date of "such licensure" by FDA, and no biosimilar must have been "licensed and marketed." *Id.* § 1320f-1(e)(1)(B).

35. Orphan drugs are nominally exempt from selection – but only so long as the drug is designated for the treatment of a single orphan condition and all approved indications are limited to the treatment of that one orphan condition. 42 U.S.C. § 1320f-1(e)(3)(A). In other words, orphan drugs are only exempt so long as they have a single orphan designation. Should a drug even be designated for the treatment of a second orphan condition, as is often the case with orphan therapies, the exclusion no longer applies, and the market benefits of the seven years of exclusivity promised by the Orphan Drug Act is effectively a nullity, as the product could be selected for negotiation immediately and subject to the resulting price controls in as little as two years.

36. Once a manufacturer's drug is selected for negotiation, the manufacturer must enter into an agreement to negotiate the price of the drug. 42 U.S.C. § 1320f-3(a). The agency then purportedly "negotiate[s]" with the manufacturer over a "maximum fair price" for the selected drug, with the agency ultimately having the final say with a take-it-or-leave-it offer. *Id.* This is a negotiation in name only. The IRA directs CMS to "develop and use a consistent methodology and process . . . for negotiations . . . that aims to achieve the *lowest* maximum fair price for each selected drug." *Id.* § 1320f–3(b)(1) (emphasis added).

37. The "maximum fair price" contemplated by the IRA, however, is neither maximum nor fair. The price is capped at a fraction of reference prices specified by statute and defined by the Guidance to be as low as possible, and the agency can insist that the "maximum fair price" be set lower than the cap. 42 U.S.C. § 1320f-3(c). The "maximum fair price" will be adjusted each subsequent year by an inflation factor for a specified preceding 12-month period.

38. Once CMS has imposed a maximum fair price for a selected drug, the statute provides that the manufacturer must provide "access to such price" to a wide variety of individuals and entities participating in Medicare. *Id.* § 1320f–2(a)(1). These participants include all eligible Medicare beneficiaries who are dispensed drugs under Medicare Parts B and D; all "pharmacies, mail order services, and other dispensers" that dispense drugs to Medicare beneficiaries; and all "hospitals, physicians, and other providers of services and suppliers" that furnish or administer drugs to Medicare beneficiaries. *Id.* § 1320f–2(a)(1)(A)-(B); *see id.* § 1320f(c)(2).

39. Manufacturers that fail to provide the required access to the maximum fair price are subject to a civil monetary penalty of ten times the difference between the price the manufacturer actually charges and the maximum fair price, multiplied by the total number of units sold. *Id.* § 1320f–6(a).

40. None of this process occurs at arm's length. Any manufacturer that declines to enter into negotiations, or declines to agree with CMS on a "maximum fair price," is subject to penalty in the form of an escalating and punitive "excise tax." 26 U.S.C. § 5000D(b). The statute suggests this tax can be as high as 95% of the *total* U.S. revenues for the drug. *Id.* § 5000D(a). The penalty continues to accrue every day until the manufacturer acquiesces to CMS's demands (or until the drug in question ceases to be a selected drug).

41. The penalty is calculated based on an "applicable percentage," which starts at 65% and increases by 10% for each successive quarter that the manufacturer is out of compliance, to a maximum of 95%. *Id.* § 5000D(d). The statute provides that the penalty is "in an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold [sic]." *Id.* § 5000D(a). The excise-tax penalty thus represents a multiple of the manufacturer's total revenues from the drug in question, not merely its profits.

42. The IRA provides for the "[s]uspension" of the excise-tax penalty, but only if the manufacturer terminates its Medicare Part D agreements and Medicaid rebate agreement – not just for the drug in question, but for *all* of the manufacturer's drugs. 26 U.S.C. § 5000D(c); *see id.* § 5000D(c)(1) (providing that the penalty is suspended only during a period in which "none of the drugs of the manufacturer … are covered by an agreement" under certain programs within Medicare Part D and the manufacturer has terminated "all applicable agreements," including agreements necessary for the manufacturer's drugs to be payable under Medicare and Medicaid). Terminating the Medicaid rebate agreement would also result in all of the manufacturer's products losing Part B coverage. 42 U.S.C. § 1396r–8(a)(1). Thus, in order to suspend application of the tax penalty, a pharmaceutical manufacturer must entirely cease participation in both Medicare and Medicaid, withdrawing the availability of its products to potentially millions of patients. This draconian "alternative" to negotiation is no alternative at all – at least for a manufacturer that hopes to keep its doors open.

43. Manufacturers that disagree with the selection of their drug or with the price dictated by CMS are, according to the IRA, out of luck. Congress included in the statute a provision purporting to preclude judicial review for certain key aspects of the drug price

negotiation program, including the "selection of drugs," the "determination of qualifying single source drugs," and the "determination of a maximum fair price." 42 U.S.C. § 1320f-7.

C. CMS Issues Guidance Implementing The IRA

44. On March 15, 2023, CMS issued an initial guidance document detailing how the agency planned to execute these sweeping changes for the first year of the program. CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* (Mar. 15, 2023) (the Initial Guidance).

45. The foundational policies governing the selection of drugs subject to negotiation for IPAY 2026 are set forth in Section 30 of the Initial Guidance. Leaning into the IRA's power-grab, CMS issued Section 30 in final form, with no opportunity for manufacturers or impacted patients to comment. Initial Guidance at 2, 5.

46. On June 30, 2023, CMS released another guidance document representing the agency's final word on implementation of the Drug Price Negotiation Program before the selection of the first year's list of drugs occurs by September 1, 2023. CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023) (the Final Guidance). The Final Guidance doubled down on the most problematic aspects of Section 30.

47. The Guidance Documents violate the IRA in at least two ways.

48. First, CMS impermissibly overrode the statutory definition of an individual "Qualifying Single Source Drug" (QSSD). The statutory text makes clear that whether a drug constitutes its own Qualifying Single Source Drug depends on whether it has been approved under a separate New Drug Application (NDA) or licensed under a separate Biologics License

Application (BLA). 42 U.S.C. § 1320f-1(e). In its Guidance Documents, however, CMS has defined a Qualifying Single Source Drug to embrace *all* dosage forms and strengths of *any* drug marketed by the manufacturer with the same active moiety or ingredient – greatly expanding the universe of products that are lumped together and treated as a single "drug." Initial Guidance at 8; Final Guidance at 99.

49. The agency's interpretation has material consequences for manufacturers: Two products with the same active moiety – including one approved years after the first – will run on the same selection clock, based on the approval or licensure date of the earlier approved product. Medicare expenditures on both products will be aggregated for purposes of ranking the qualifying single source drug for selection for negotiation. In addition, the negotiated maximum fair price will apply across both products.

50. Second, CMS impermissibly expanded the requirements that must be met before a drug is deemed to have generic competition such that it is ineligible for selection or negotiation. The IRA sets up two alternative pathways for moderating the prices of those drugs with the highest levels of Medicare spending: market-based competition in the form of a generic or biosimilar competitor, or failing that, price controls. The IRA specifies two objective criteria for a generic drug or biosimilar to render a brand name drug ineligible for selection and negotiation: the generic drug must be "approved" (or in the case of biologics, "licensed") and it must be "marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A) and (B). Both of these requirements are a check-the-box, point-in-time determination: A drug is either approved or it is not, and it is either marketed or it is not. A drug is approved when FDA grants an application or licensure for the product, and it is marketed when it has been launched by its manufacturer and enters the commercial marketplace for sale.

51. In its Guidance Documents, however, CMS has created an entirely new and different test: CMS will subjectively assess the generic or biosimilar biological product over time in order to determine whether it has been the subject of "bona fide marketing." Initial Guidance at 62; Final Guidance at 101–102. The agency's subjective "bona fide marketing" test finds no support in the statutory text.

52. The combined effect of these two definitions has vast real-world consequences. The agency's broad definition of Qualifying Single Source Drug benefits the Medicare program at the expense of pharmaceutical manufacturers in several important ways. First, two distinct drugs that were evaluated and approved by FDA under entirely separate drug approval processes will nevertheless have their Medicare sales aggregated for purposes of selection so long as they share the same "active moiety" and have the same NDA-holder, increasing the likelihood that the aggregated products will cross the $200 million sales threshold for eligibility. Second, the agency's approach means that some new drug products could be subject to selection and negotiation *immediately* upon approval, contrary to the prohibition on selecting products until "at least 7 years will have elapsed since the date of [FDA] approval." 42 U.S.C. § 1320f–1(e)(1)(A)(i)-(ii). Under the agency's approach, the clock would begin to run from when FDA approved the *first* product with the same active moiety, rather than the date mandated by statute: the date of approval of a newer, otherwise distinct drug product.

53. The breadth of CMS's Qualifying Single Source Drug definition has one downside for the Government, however, which CMS has grudgingly recognized: It means that a generic for *any* one version of the drug is sufficient to render *all* forms of the drug ineligible for negotiation. Initial Guidance at 10; Final Guidance at 12, 102. In such a scenario, one form of the drug may have its price moderated by competition, while others will not, but the generic entrant nevertheless

disqualifies the drug, as a whole, from negotiation. CMS therefore added the qualitative and subjective "bona fide" overlay to the statutory "marketed" determination to draw out and delay the date by which any generic entrant disqualifies a drug from negotiation. In doing so, CMS crafted bespoke definitions of two key terms that together work to endow CMS with boundless, and extra-statutory, discretion that transcends even Congress's generous grant of authority.

54. Both of these provisions are unlawful.

II. CMS's Guidance Violates The Administrative Procedure Act

55. Agency action violates the APA when it contravenes the text of an agency's governing statute. *See Natural Res. Def. Council v. EPA*, 643 F.3d 311, 323 (D.C. Cir. 2011); *Orion Rsrvs. Ltd. P'ship v. Salazar*, 553 F.3d 697, 703 (D.C. Cir. 2009); *Bennett v. Donovan*, 4 F. Supp. 3d 5, 13 (D.D.C. 2013); *Lone Mountain Processing, Inc. v. Secretary of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013).

56. In addition, agency action is arbitrary and capricious under the APA when the agency fails to adequately explain a deviation from prior policy, *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003), or ignores evidence bearing on the issue, *Butte County v. Hogen*, 613 F.3d 190 (D.C. Cir. 2010). Agency action also is arbitrary and capricious when the agency entirely "fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

57. CMS has violated all of these maxims here.

Qualifying Single Source Drug

58. First, CMS's definition of a "Qualifying Single Source Drug" violates the statute by impermissibly aggregating different drug products approved under different NDAs (or in the case of biologicals, different BLAs).

59. In Section 30 of the Guidance Documents, CMS specified that two drug products with the same active moiety are treated as the same Qualifying Single Source Drug, even if they were approved under distinct NDAs. Initial Guidance at 8; Final Guidance § 30.1 at 99. Similarly, two biological products with the same active ingredient are treated as the same Qualifying Single Source Drug, even if they were licensed under distinct BLAs. *Id.*

60. That has profound implications for drug manufacturers when they have two drugs approved under different applications that share the same active moiety or active ingredient: such products – including one approved years after the first – will run on the same seven- or eleven-year selection clock, based on the approval or licensure date of the *earlier* approved or licensed product. That means that some new products will be subject to selection and negotiation *immediately* upon approval, contrary to the statutory prohibition on selecting products until "at least 7 years will have elapsed since the date of [FDA] approval." 42 U.S.C. § 1320f–1(e)(1)(A)(i)-(ii). Under the agency's approach, the clock will begin to run from when FDA approved the *first* product with the same active moiety, rather than from the date of approval of the newer product, as Congress required. Medicare expenditures on both products will be aggregated for purposes of ranking the qualifying single source drug for selection for negotiation. And the negotiated maximum fair price will apply across both products.

61. None of this is what Congress intended. Under the plain language of the statute, two products are the same Qualifying Single Source Drug *only* where the two products share the same NDA or BLA. This statutory mandate is expressed in several different ways.

62. First, the statute defines the term "Qualifying Single Source Drug" by reference to "a covered part D drug," as that term is defined in the Medicare statute. 42 U.S.C. § 1320f-1(e)(1). The definition of a "covered Part D drug," in turn, cross-references the definition of a "covered outpatient drug" in the Medicaid Drug Rebate Program (MDRP) statute. *Id.* § 1395w-102(e)(1). Under that definition, whether a single source drug is a distinct "covered outpatient drug" is based on whether the product is approved pursuant to a distinct NDA or BLA. *Id.* §§ 1396r–8(k)(2), (k)(7)(A)(iv).

63. The *only* exception to this MDRP standard – that a drug is defined by its NDA or BLA – comes in context of line extensions, which involve new formulations of a drug. Congress specifically amended the MDRP statute to treat line extensions as the same "covered outpatient drug" even if they were approved under different NDAs or BLAs. Patient Protection and Affordable Care Act of 2010, § 2503, Pub. L. No. 111-148, 124 Stat. 119 (codified at 42 U.S.C. § 1396r–8(c)(2)(C)). Congress knew about this "line extension" exception to the one-NDA-one-drug standard when it created the IRA because it included that exception in the new law, but it did so selectively: Congress chose *not* to include this exception in the IRA's drug pricing negotiation program but *did* expressly do so in its Part D inflation rebate provision. 42 U.S.C. § 1395w-114a(b)(5)(B). Congress therefore must be presumed to have specifically chosen *not* to include that exception in connection with the Drug Price Negotiation Program.

64. The IRA further defines a Qualifying Single Source Drug as a drug approved by FDA and for which "at least 7 years will have elapsed since the date of *such approval*." 42 U.S.C.

§ 1320f-1(e)(1)(A) (emphasis added). The definition is the same for a biological product, except the applicable time period is "at least 11 years will have elapsed since the date of *such licensure*." 42 U.S.C. § 1320f-1(e)(1)(B) (emphasis added). This language directs that each Qualifying Single Source Drug be identified by reference to its *individual* approval or licensure, i.e., its distinct NDA or BLA. Any other reading – including the one based on common active moiety or common active ingredient espoused by CMS – contradicts the plain text of the statute.

65. Finally, the statutory definition of "Qualifying Single Source Drug" is grounded in FDA's framework for approving and licensing drugs and biologics, and such framework distinguishes among drugs and biologics via distinct applications. By expressly cross-referencing the FDA framework in the Qualifying Single Source Drug definition, Congress clearly intended that CMS rely on such framework in distinguishing among qualifying single source drugs.

66. In fact, by excluding from selection "the listed drug for any drug that is approved and marketed under section 355(j)" – i.e., the reference drug for an approved and marketed generic – the IRA necessarily uses "drug" in reference to a single, specific NDA. This is because, under the Federal Food, Drug, and Cosmetic Act, sponsors of generics apply for approval by identifying a specific NDA for the reference drug. FDA, in turn, approves generics based on that specific NDA. By excluding listed drugs from the Qualifying Single Source Drug definition, therefore, the IRA confirms that "drug" means "drug marketed pursuant to a specific NDA."

67. CMS's approach will pull drugs into the queue for "negotiation" significantly earlier than the statutorily prescribed approach, based on the approval date of another drug. The Final Guidance also dramatically increases the chance that an individual drug will be among the highest-spend drugs selected for "negotiation" because its Medicare expenditures will be

aggregated with the Medicare expenditures of a distinct – and potentially statutorily ineligible – drug.

68. The agency's definition of this arcane term – Qualifying Single Source Drug – will have real-world consequences for patients as well. It works to discourage pharmaceutical manufacturers from investing time and money to discover whether an active ingredient used in an existing drug could also be used in a new product to address distinct patient populations, especially those with orphan conditions. Even if the new product is approved under a distinct application or licensure, CMS will consolidate any Medicare expenditures for the two products, thereby increasing the likelihood of selection of *both* products for the draconian Drug Price Negotiation Program. Perhaps worse, the new product could be deemed eligible for selection *immediately* upon approval, if it comes more than 7 years after approval of the initial product (11 years for a biological product). The agency's approach thus incentivizes manufacturers not to innovate.

69. This approach was so concerning that stakeholders submitted comments opposing this definition, despite CMS's admonition that the definition was final as issued and that comments should not be submitted. Initial Guidance at 2, 5. The Final Guidance acknowledges that these problems were nevertheless brought to CMS's attention through comments submitted on the Initial Guidance. The agency's response only underscores the absurdity of its statutory interpretation. To justify redefining Qualifying Single Source Drugs, the Final Guidance does not ground its approach in the definition of a Qualifying Single Source Drug itself, but rather invokes the IRA's "Use of Data" provision, and the provision requiring CMS to "compute and apply the [Maximum Fair Price] across different strengths and dosage forms of a selected drug," 42 U.S.C. § 1320f-5(a)(2). Neither provision justifies the agency's approach.

70. CMS reasons in its Guidance Documents that an expansive definition of Qualifying Single Source Drug "aligns with" the IRA's "Use of Data" provision, 42 U.S.C. § 1320f–1(d)(3)(B). *See* Final Guidance § 30.1 at 100. The "Use of Data" provision proves the opposite. That provision specifies that "the Secretary shall use data that is aggregated across dosage forms and strengths" of a Qualifying Single Source 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***" in determining whether a Qualifying Single Source Drug satisfies any of the selection criteria. 42 U.S.C. § 1320f–1(d)(3)(B) (emphases added). The emphasized phrases above are important. The provision only applies when the different dosage forms, strengths, and formulations under consideration involve the ***same*** Qualifying Single Source Drug. The identification of the Qualifying Single Source drug is a predicate determination. If the products are not the same drug, then the Use of Data provision is not triggered.

71. CMS also points toward a statutory provision requiring the agency to "compute and apply the [Maximum Fair Price] across different strengths and dosage forms ***of a selected drug*** and not based on the specific formulation or package size or package type of such drug," *id.* § 1320f-5(a)(2) (emphasis added). Again, the emphasized language is important. To be consolidated, the different strengths and dosage forms must all be "of a selected drug" – that is, they must qualify as the same drug. This provision also would be unnecessary if all products sharing the same active moiety or ingredient were already consolidated into the same Qualifying Single Source Drug.

72. For all of these reasons, CMS's definition of what constitutes a distinct Qualifying Single Source Drug is unlawful.

Bona Fide Marketing

73. The Guidance Documents also purport to overwrite the statutory requirements governing the generic competition that renders a drug ineligible for selection or negotiation.

74. Whether a generic has been "marketed" has far-reaching consequences under the Program. Under the IRA, a drug that is the listed reference product for an approved and "marketed" generic cannot be a Qualifying Single Source Drug, and therefore cannot be selected for "negotiation." *See* 42 U.S.C. § 1320f–1(e)(1). The IRA also requires CMS to remove a selected drug from the selected drug list on January 1 of the first "subsequent year" (i.e., a year after the initial price applicability year) that begins at least 9 months after CMS determines that a generic has been approved and "marketed." *Id.* § 1320e(c)(1). CMS also must cease "negotiations" if, after a drug has been selected but before the end of the "negotiation period," a generic version is approved and "marketed." *Id*. § 1320f–1(c)(2).

75. The statutory test for these off-ramps is simple. The IRA requires that a generic drug be "approved and marketed," or in the case of a biological biosimilar product, "licensed and marketed." 42 U.S.C. §§ 1320f-1(e)(1)(A) and (B).

76. CMS, however, adds both language and substance in the Guidance Documents: it "will consider a generic drug . . . to be market*ed*" only if certain sources of data "reveal[ ] that the manufacturer of that drug or product is engaging in bona fide market*ing* of that drug." Final Guidance § 30.1 at 102 (emphases added). In other words, generic competition will be subjected to CMS's bespoke and ongoing "bona fide marketing" test – a subjective, multi-factor inquiry based on the "totality of the circumstances." Initial Guidance at 62; Final Guidance at 101–102. The agency said that it plans to review data over a 12-month period and make a "holistic inquiry"

based on the "totality of the circumstances" about "whether a generic drug or biosimilar is marketed on a bona fide basis." Initial Guidance at 62; Final Guidance at 101–102.

77. The end result is that even a drug with generic competition on the market may be selected for negotiation, forced to go through negotiation, and then subject to a Maximum Fair Price if CMS concludes that the generic competition is not "bona fide" enough. This expanded qualitative standard enables CMS to slow-walk a drug's disqualification from the Drug Price Negotiation Program. Such delays, dressed up as "bona fide" determinations, become particularly important to CMS in the context of a Qualifying Single Source Drug definition that draws in products subject to multiple NDAs (or BLAs), which can be disqualified from negotiation eligibility when a generic for only one version of the drug is marketed.

78. This problem is compounded by the agency's further decision to monitor, "after such determination is made, whether meaningful competition *continues to exist* in the market by ongoing assessments of whether the manufacturer of the generic drug . . . is engaging in bona fide marketing." Final Guidance § 90.4 at 170 (emphasis added). There is no statutory basis for the agency to conduct ongoing monitoring after a generic competitor is approved and marketed. Yet, the agency threatens to withdraw its prior determinations that a drug is disqualified from selection or price controls based on the agency's unilateral determination at some later time that there is insufficiently "meaningful" competition between the innovative and generic versions of a drug.

79. CMS intends to conduct such monitoring by reviewing a number of factors, including but not limited to "whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug." *Id*. CMS also intends to

"analyze the share of generic drug or biosimilar biological product units identified in [Medicare claims] data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the selected drug as part of their [Average Manufacturer Price (AMP)] reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units." *Id.*

80. As part of this ongoing monitoring process, CMS "reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar." *Id.* If CMS determines through monitoring that a generic drug manufacturer is not engaged in bona fide marketing after a previous determination that there was an approved and marketed generic, "the drug/biologic could be eligible for negotiation in a future price applicability year." *Id.* at 78.

81. None of that is allowed by the statute. CMS cannot supplant the statutory reference point – the date a product is "marketed" – with a wholly extra-statutory standard tied to the agency's subjective and ongoing assessment of adequate utilization. The plain meaning of the statutory phrase "approved . . . and . . . marketed" makes clear that Congress intended this to be a check-the-box inquiry. Marketing is "[t]he act[] . . . of bringing or sending a product or commodity to market." Oxford English Dictionary, Definition of Marketing, *available at* https://www.oed.com/view/Entry/114186?rskey=36dfg4&result=2&isAdvanced=false#eid (last accessed Aug. 23, 2023). Whether a product is "marketed" is an objective point-in-time determination based on when the product enters the commercial marketplace for sale. Once the product has entered the marketplace, it has been "marketed." That is true regardless of its utilization.

82. Indeed, one other section of the *Initial* Guidance – the provision listing the data that manufacturers must submit to CMS – actually defined "marketing" in accordance with the plain meaning of the term: "[T]he introduction or delivery for introduction into interstate commerce of a drug product." Initial Guidance at 82. CMS deleted that definition in the *Final* Guidance without explanation, an implicit acknowledgement of the sharp contrast between the accepted, objective definition and CMS's new, entirely subjective "bona fide marketing" standard.

83. The objective, point-in-time meaning of "marketing" is consistent with the approach CMS has taken with regard to the same statutory term in numerous other contexts, including other provisions of the IRA itself. With respect to the IRA's Part B inflation rebate, CMS has proposed to determine when a product is "marketed" by reference to the "date of first sale" that the manufacturer must report for average sales price (ASP) purposes, which likewise is an objective point-in-time determination. CMS, Medicare Part B Inflation Rebates Paid by Manufacturers: Initial Memorandum, at 13–14 (Feb. 9, 2023). It also is consistent with the meaning of the term "marketing" as used in FDA regulations. *See* 21 C.F.R. § 314.3(b) (defining "commercial marketing" in relevant part as "the introduction or delivery for introduction into interstate commerce of a drug product").

84. For purposes of the IRA's Part D inflation rebates, CMS similarly proposed to determine when a product is "marketed" by reference to its "market date" as reported under the MDRP. CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, at 18–19 (Feb. 9, 2023); FDA, National Drug Code Directory (July 22, 2022). In turn, CMS's longstanding policy under the MDRP has been to define "marketed" by reference to the date on which a product "is available for sale." *Announcement of Medicaid Drug Rebate Program*, 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018) (MDRP National Rebate Agreement); *see*

also 42 C.F.R. § 447.502. That meaning is echoed in the agency's pending proposed MDRP rule, where CMS has proposed to define a drug's "market date" as the "date on which the . . . drug was first sold." *Updates Under the Medicaid Drug Rebate Program*, 88 Fed. Reg. 34,238, 34,292 (May 26, 2023). The Final Guidance reinforced the relevance of these MDRP definitions when it explained that CMS will evaluate "bona fide" marketing using sales volume data reported under the MDRP. Final Guidance at 2, 101–102. In doing so, CMS highlighted the paradox of its bona fide marketing standard: CMS will evaluate whether a drug is "marketed" for purposes of the Drug Price Negotiation Program by reference to MDRP sales volume data – which can be reported to the MDRP only once the drug qualifies as being "marketed" such that its sales volume can be reported in the first place.

85. This same problem plays out in reference to the second data set CMS will rely upon in determining whether a drug is "marketed." In addition to Medicaid data, CMS has stated it will also evaluate Part D program Prescription Drug Event (PDE) data in effectuating its bona fide marketing standard. PDE data is summary claims data generated when a Part D plan sponsor fills a prescription under Medicare Part D. CMS has recognized that the date on which a product is "release[d] onto the market" triggers certain coverage-related obligations on the part of Part D plans. CMS requires that Part D plan sponsor Pharmacy & Therapeutics committees "make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and . . . make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met." Prescription Drug Benefit Manual, ch. 6 § 30.1.5 (rev. Jan. 15, 2016). All of this means that, like with the MDRP data, CMS

will have already recognized that a product has been released onto the market by the time PDE data show product utilization.

86. None of this is authorized by the statute. It is clear that Congress used the phrase "approved and marketed" intentionally, to refer to the first time a generic product enters the marketplace. CMS may not override the bright-line test imposed by the statute in favor of a subjective standard that effectively gives the agency unlimited discretion to determine whether and when a product is sufficiently subjected to "bona fide" generic competition.

87. This is especially so given that Congress has demonstrated that it knows how to establish a subjective "bona fide" standard as well as a standard requiring the availability of a drug broadly in the market and on a nationwide basis. 42 U.S.C. § 1396r–8 (k)(1)(B)(i)(II) (as amended by Pub. L. No. 111–148, § 2503(a)(2) (2010)) (amending the MDRP statute to specify that only "bona fide" service fees are exempt from the calculation of average manufacturer price); § 1396r-8(e)(5) (as amended by Pub. L. No. 111-148 § 2503(a)(1)) (amending the MDRP statute to direct the calculation of a drug's federal upper limit using "pharmaceutically and therapeutically equivalent multiple source drug products . . . available for purchase by retail community pharmacies on a nationwide basis"). Congress did neither here. "[W]here Congress knows how to say something but chooses not to, its silence is controlling." *Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 789 F. 3d 1206, 1217 (11th Cir. 2015).

88. One further note about the Qualifying Single Source Drug and "bona fide marketing" tests. These two provisions do not operate wholly independently. CMS's insistence on combining drugs approved under separate NDAs as a single "Qualifying Single Source Drug" and then evaluating whether a generic product is sufficiently marketed exacerbates the problems created by both unlawful positions. A generic drug is tied to a particular NDA. If FDA approves

a generic drug that references one NDA, the generic will *not* be rated therapeutically equivalent to the other product approved under a different NDA or automatically substitutable for that product under state substitution laws. Thus, one form of the drug may have its price moderated by competition, while others will not, but the generic entrant nevertheless disqualifies the drug as a whole from negotiation. CMS's addition of the qualitative and subjective "bona fide" overlay to the "marketed" determination thus allows the agency to further orchestrate (and delay) the date by which any generic entrant disqualifies a drug from negotiation.

III. The IRA Violates The Due Process Clause

89. The agency's unlawful implementation of the IRA only compounds an already unlawful statutory scheme.

90. Drug manufacturers have at least two property interests implicated by the IRA: their property rights in their drug products and their patent rights. The IRA undermines both, without providing notice or an opportunity to be heard, either before or after the deprivation. Agency action that deprives a person or entity of a property interest, without an opportunity to be heard, is unconstitutional. *See Propert v. District of Columbia*, 948 F.2d 1327, 1333 (D.C. Cir. 1991).

91. The IRA has due process problems from the beginning of its process to its very end. On the front end, the statute contemplates that the first few years of the Drug Price Negotiation Program will be instituted through agency guidance rather than the standard notice-and-comment rulemaking. To compound this problem, CMS dropped the key aspects of the selection and negotiation provisions for the first year of the program (IPAY 2026) on regulated entities through guidance that was finalized as soon as it was announced, with no formal opportunity for comment. The overreach evidenced by CMS's adoption of its Qualifying Single Source Drug and bona fide marketing positions amply demonstrates CMS's embrace of this unbridled authority.

92. Once a drug is selected, the IRA forces manufacturers to engage in purported "negotiations" but affords them no leverage, no meaningful opportunity to walk away, and no ability to protect their interests. It then directs CMS to unilaterally impose a "maximum fair price" for selected drugs that is drastically below the actual fair market value of the product.

93. Manufacturers that disagree with the selection of their product or the fairness of the price proffered by the agency have no leverage to push back. Although the Drug Price Negotiation Program is designed to mimic a negotiation – including use of terms like "offer," "counteroffer," and "negotiation," 42 U.S.C. § 1320f–3 – the statute uses these terms to conceal the true nature of the process. In reality, the Program is designed to coerce manufacturers to submit to government-imposed price controls. The Program is enforced through an "Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods." IRA § 11003 (codified at 26 U.S.C. § 5000D(b)(1)–(4)). A manufacturer who fails to enter into a Program agreement (at the initiation of the "negotiation" period) or who fails to "agree[]" to the ultimate price that CMS sets is subject to a steep and escalating daily penalty, 26 U.S.C. § 5000D(b), which the statute suggests applies to each sale of the subject drug, *id.* § 5000D(a). The penalty continues to accrue every day until the manufacturer acquiesces to CMS's demands (or until the drug in question ceases to be a selected drug). The penalty maxes out at 95% of total U.S. revenues for the product – not just for Medicare sales but for *all* sales. *Id.* § 5000D(d). Moreover, it applies to total *revenues* from the drug in question, not merely its *profits*. *Id.*

94. There is no easy off-ramp for manufacturers who do not wish to negotiate. While the IRA provides for the "[s]uspension" of the punitive excise-tax penalty, that happens only if the manufacturer terminates both its Medicare Part D agreements and Medicaid rebate agreement – not just for the drug in question, but for *all* of the manufacturer's drugs. *Id.* § 5000D(c); *see id.*

§ 5000D(c)(1). That would result in loss of access to important medicines for a significant amount of the U.S. population. It is simply not a choice that any manufacturer can afford to make lightly.

95. On the back end, the statute purports to preclude affected manufacturers from exercising their constitutional right to judicial review of a number of critical inputs, among them the drug selected and the price set. 42 U.S.C. § 1320f-7. While Congress has authority to define the scope of judicial review, that power cannot be exercised to "cut off all review of an allegedly unconstitutional statute" that may result in a property deprivation. *Feinberg v. Fed. Deposit Ins. Corp.*, 522 F.2d 1335, 1341–42 (D.C. Cir. 1975); *see also Marozsan v. United States*, 852 F.2d 1469, 1478 (7th Cir. 1988).

96. The IRA does not just preclude manufacturers from negotiating or challenging the government's price-fixing process. It also hollows out other statutory incentives.

97. The Orphan Drug Act, 21 U.S.C. §§ 360aa-360ee, provides a seven-year period of marketing exclusivity to remedy the lack of pharmaceutical options for rare diseases or conditions. Before the Act, it was difficult to justify the expense involved in pursuing drug candidates intended to treat rare diseases or conditions. *See, e.g.*, HHS, Office of Inspector General, The Orphan Drug Act: Implementation and Impact, Report OEI-09-00-00380 at 7 (May 2001). The incentives provided by the Orphan Drug Act include grants, tax credits, and, most importantly, a seven-year marketing exclusivity period. Those incentives work. Since passage of the Orphan Drug Act, more than 600 products to treat rare disease have been approved by FDA, providing important treatment options for tens of millions of Americans.

98. The IRA excludes orphan drugs from selection – but only so long as the drug is designated for the treatment of a single orphan condition and all approved indications are limited to the treatment of that one orphan condition. 42 U.S.C. § 1320f-1(e)(3)(A). Should a drug be

designated for a second orphan condition, which often happens, the exclusion no longer applies. Final Guidance at 102. This significantly undermines the value of any subsequent orphan designation. By rendering such orphan drugs eligible for selection as soon as they come off their seven-year marketing exclusivity for the first approval, the IRA undermines the very incentive structure that was designed to promote innovation.

99. Take, for example, AstraZeneca's drug LYNPARZA. LYNPARZA is an orphan drug that was first approved in 2014 and designed to treat a rare type of ovarian cancer. Over the next 8 years, AstraZeneca continued to invest in the drug, engaging in research and development efforts that led to additional orphan indications for fallopian tube cancer, peritoneal cancer, and rare pancreas cancer. Each one of these additional approved indications has saved or extended lives. Had the IRA's negotiation eligibility clock been in effect then, only a fraction of current LYNPARZA patients would benefit from the drug now: Investors would not have supported the continued research and development that made possible its additional orphan approvals. This would have had a particular impact on minority communities, who are disproportionately impacted by ovarian, prostate, and breast cancers.

100. Another example is SOLIRIS. SOLIRIS received orphan exclusivity in 2001 for treatment of idiopathic membranous glomerular nephropathy; in 2003 for treatment of paroxysmal nocturnal hemoglobinuria; in 2009 for treatment of atypical hemolytic uremic syndrome; in 2011 for treatment of Shiga-Toxin producing escherichia coli hemolytic uremic syndrome; in 2013 for treatment of neuromyelitis optica; in 2014 for treatment of Myasthenia Gravis; and in 2022 for treatment of Guillain-Barré syndrome. Each new indication was spurred by additional research and development efforts spawned by the incentives provided by the Orphan Drug Act.

101. The IRA's application to drugs with more than one orphan designation will disincentivize companies from investing in follow-on indications in distinct orphan diseases, and prioritize orphan conditions with the largest populations. Neither of these outcomes is good for patients. As several health policy experts recently explained, the IRA "may lead pharmaceutical manufacturers to develop more single-indication orphan drugs (which are not subject to negotiations) rather than follow-on indications. Our analysis suggests that the potential for foregone follow-on indication approvals for serious illness and unmet needs could be nontrivial." Chambers et al., *Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act*, JAMA Network Open (2023). The Rare Disease Company Coalition, for its part, similarly explained that "Unfortunately, by making orphan products with a second designation eligible for drug price negotiation, this provision will disincentivize further investment in rare disease research and development." *Revised Inflation Reduction Act Guidance Increases Risk of Rare Disease Drug Development* (June 30, 2023).

102. Any one of these problems is independently concerning. Collectively, they immobilize manufacturers like AstraZeneca from participating in any meaningful way in a true "negotiation," prevent AstraZeneca from challenging in any meaningful way the IRA's Drug Price Negotiation Program, and sap AstraZeneca of the resources needed to invest in further rare disease research. The overall scheme unlawfully deprives manufacturers of fundamental due process rights under the Fifth Amendment.

IV. CMS's Actions Cause Concrete And Imminent Harm To AstraZeneca and Patients

103. AstraZeneca has been and will continue to be harmed absent preliminary relief, as explained below.

104. Pharmaceutical manufacturers like AstraZeneca discover and develop life-saving and life-enhancing medicines that are distributed, prescribed, and used across the nation and around the world. The cost of developing such groundbreaking drugs is stunning.

105. The unlawful activities complained of herein – the due process problems of the IRA coupled with CMS's unlawful definitions of "Qualifying Single Source Drug" and "marketed" – collectively discourage innovation and punish manufacturers who take risks on small patient populations or unconventional therapies.

106. That in turn harms patients, particularly patients of rare and orphan diseases, because the incentive structure that was designed to encourage innovation is compromised by the IRA's imposition of price controls on therapies that seek to treat more than one orphan condition.

107. AstraZeneca markets FARXIGA® (dapagliflozin) tablets, which was approved by FDA in 2014 to improve glycemic control in adults with type 2 diabetes. Generic entry is expected in the near future. CMS's determination of when generic entry constitutes "bona fide marketing" will directly impact when any maximum fair price sunsets for FARXIGA.

108. AstraZeneca's cancer medication LYNPARZA® (olaparib) was approved in capsule form in 2014. It has since been discontinued. AstraZeneca subsequently invested in developing a formulation that was better tolerated by patients, and a tablet form of the drug was approved by FDA under a separate NDA in 2017. The tablet product allowed patients to reduce the number of pills they must take per day, making it far more convenient for patients and improving adherence to the prescribed treatment, with the goal of improving patient outcomes.

109. CMS's definition of "Qualifying Single Source Drug" would render the LYNPARZA tablet and capsule as *the same* Qualifying Single Source Drug, because the capsule and tablet forms of LYNPARZA contain "the same active moiety." That is so even though the

two products were approved under unique NDAs, and even though the capsule that started the negotiation clock, three years before approval of the tablet, is no longer marketed. Under CMS's test, the tablet form would immediately be eligible for selection on September 1, 2023, even though it has not yet been approved for seven years as contemplated by the statute.

110. AstraZeneca's drug CALQUENCE® (acalabrutinib), a leukemia medicine, was approved in capsule form in 2017 and in 2022 in tablet form under a different NDA. The tablet product expanded the patient population able to benefit from CALQUENCE because, unlike the capsule, it may be taken with gastric acid-reducing agents, including proton pump inhibitors, antacids, and H2-receptor antagonists. FDA viewed the products to be different enough that it warranted unique NDAs, and the IRA accordingly mandates that the products be treated separately. But CMS's definition would treat the two products – approved under separate NDAs – as a single Qualifying Single Source Drug. Under the language of IRA, the tablet form will be ineligible as a Qualifying Single Source Drug until at least February 1, 2030, because that is the first selection date seven years after CALQUENCE was "marketed pursuant to such approval" – i.e., pursuant to its 2022 approval. But under CMS's test, the capsule and tablet forms would *both* be eligible for selection in 2025 for IPAY 2027, even though the tablet will not have been approved for seven years as contemplated by the statute.

111. Because AstraZeneca has developed and markets a number of drug products that are well-represented within the Medicare program, it faces an especially serious risk of injury from the IRA and CMS's unlawful implementation thereof. Compounding this risk, these drugs are some of AstraZeneca's most successful products. AstraZeneca thus has an acute interest in ensuring protection of its rights.

112. Because the IRA eschews any process for meaningful negotiation or challenging selection of a drug or the maximum fair price once set, the IRA's effects are felt even before a company is formally subjected to the law's drug-price controls. Indeed, due to the speed at which CMS is moving to reorder the Medicare drug pricing landscape pursuant to the IRA, AstraZeneca has already been required to take significant steps to fundamentally reposition its business operations and investments in pipeline products in response to CMS's Guidance Documents.

113. Take research and development activities that once seemed like reasonable investments. As a matter of IRA-driven economic necessity, many of those projects must now be abandoned. The average cost of successfully bringing a drug to market now stands at $2.3 billion. *See* Deloitte, *Seize the Digital Momentum: Measuring the Return from Pharmaceutical Innovation 2022* at 12 (Jan. 2023).[3] That *average* figure does not include the costs associated with research and development activities for failed or abandoned drugs – which is far and away the norm in the high-risk enterprise of pharmaceutical innovation.

114. As previously noted, manufacturers developing new drugs face daunting odds. Of the therapies approved for patient use, only one-third manage to cover their cost of development, much less to provide an economic return significant enough to allow for continued investment and innovation. *See* John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three-Factor Model*, 19 J. Health Econ. 1002, 1004 (2009).

115. The improper approach to identifying qualifying single-source drugs set forth in Section 30 drastically undermines AstraZeneca's ability to recoup investments on its existing drugs. In particular, it makes the impending selection of LYNPARZA and CALQUENCE

[3] *Available at* https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf.

significantly more likely, which forces AstraZeneca to make irrevocable resource-allocation decisions now – even prior to selection.

116. The harms wrought by the IRA are already beginning to pile up. AstraZeneca must labor under the assumption – starting now – that its most successful current and future products will be subjected to the IRA's scheme. The IRA's design mandates that its targeted price controls must be trained on the most revolutionary therapies: Those drugs that are not only therapeutically groundbreaking, but are also widely prescribed because of their significant benefit to patients.

117. Those same products fund the bulk of AstraZeneca's research and development capabilities. Like other manufacturers, AstraZeneca is making the painful decision to suspend ongoing research and development activities. The Guidance Documents eliminate incentives for research and development of new treatment applications for existing drugs. Under the improperly broad definition of Qualifying Single Source Drug set forth in Section 30, a manufacturer has no reason to invest years and billions of dollars of resources researching whether an active ingredient or active moiety in an existing drug could also be used to treat a separate disease. If the manufacturer identifies such an application, the new drug's eligibility for negotiation will be tied with the eligibility timeline of the existing drug.

118. The prospects for future innovation are even more dire. Already, AstraZeneca has reckoned with the delayed launch of cancer drugs, and certain other of the company's product development plans have been shelved entirely. *See* Biocentury, AstraZeneca May Defer U.S. Cancer Drug Launches in Response to IRA.[4]

[4] *Available at* https://www.biocentury.com/article/645834/astrazeneca-may-defer-u-s-cancer-drug-launches-in-response-to-ira (Nov. 10, 2022).

119. For example, last year AstraZeneca was forced to begin making preparations to curb its investment in pipeline products in anticipation of the IRA's expected impact. *See* Reuters, "AstraZeneca's Soriot warns new U.S. drug price law will hurt innovation."[5]

120. These harms are bad for AstraZeneca, but they are also bad for patients and for public health. The IRA delivers a death blow to the incentive structure that has encouraged pharmaceutical companies to continue to innovate, looking for new treatment therapies and new improvements on their existing drugs. That in turn means fewer new treatment options for patients, who rely on new therapies to save their lives and improve their lives. Nobody will feel the impact on incentives more than patients of rare and orphan diseases.

121. Absent prompt judicial relief, AstraZeneca will be forced to make even further irreversible cutbacks to its business operations and its level of investment in life-saving and life-extending products.

COUNT I
(Administrative Procedure Act — Qualifying Single Source Drug)

122. AstraZeneca realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

123. The APA prohibits CMS from implementing its statutory mandate in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law. 5 U.S.C. § 706(2)(A).

124. CMS's unlawful definition of a Qualifying Single Source Drug constitutes agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

[5] *Available at* https://www.reuters.com/business/healthcare-pharmaceuticals/astrazenecas-soriot-warns-new-us-drug-price-law-will-hurt-innovation-2022-08-23/ (Aug. 24, 2022).

125. The statute makes clear that two drugs approved under separate NDAs or BLAs count as two separate Qualifying Single Source Drugs. CMS's Guidance Documents, however, purport to lump multiple Qualifying Single Source Drugs together for purposes of selection and assessment of a maximum fair price. That is unlawful.

126. CMS's finalized Guidance documents – undertaken in accordance with its statutory mandate to implement the first year of the program through guidance – constitute final agency action for which AstraZeneca has no other adequate remedy within the meaning of 5 U.S.C. § 704.

127. Both AstraZeneca and the patient population will be irreparably harmed unless the agency's definition of a Qualifying Single Source Drug is set aside.

128. There is no mechanism by which AstraZeneca can be made whole for the injuries described herein. AstraZeneca is without an adequate remedy at law because of the unique nature of the harm it would suffer absent injunctive relief.

129. The intent of Congress will be served by an Order vacating CMS's unlawful definition of Qualifying Single Source Drug. In addition, the public interest will be served by such an Order.

COUNT II
(Administrative Procedure Act — Bona Fide Marketing)

130. AstraZeneca realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

131. The APA prohibits HHS from implementing its statutory mandate in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, or contrary to law. 5 U.S.C. § 706(2)(A).

132. CMS's interpretation of the statutory "approved . . . and . . . marketed" (or in the case of biological products, "licensed . . . and . . . marketed") requirement constitutes agency

action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

133. The statute just says "approved . . . and . . . marketed" or "licensed . . . and . . . marketed." That is a point-in-time inquiry tied to product launch. The statute does not support a backward-looking, "holistic" inquiry into the utilization of the generic drug after entering the market.

134. CMS's "bona fide marketing" standard – implemented in accordance with its statutory mandate that the first year of the program should be implemented through guidance – constitutes final agency action for which AstraZeneca has no other adequate remedy within the meaning of 5 U.S.C. § 704.

135. Both AstraZeneca and the patient population will be irreparably harmed unless the agency's "bona fide marketing" standard is set aside.

136. There is no mechanism by which AstraZeneca can be made whole for the injuries described herein. AstraZeneca is without an adequate remedy at law because of the unique nature of the harm it would suffer absent injunctive relief.

137. The intent of Congress will be served by an Order vacating CMS's unlawful "bona fide marketing" standard. In addition, the public interest will be served by such an Order.

COUNT III
(Fifth Amendment — Due Process)

138. AstraZeneca realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

139. The Fifth Amendment's Due Process Clause prohibits the government from depriving a person or entity of a constitutionally protected property interest without following constitutionally sufficient procedures.

140. At its core, the Due Process Clause requires notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965); *see also Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Due process requires procedural protections to prevent, to the extent possible, an erroneous deprivation of property. *See Gilbert v. Homar*, 520 U.S. 924, 930–932 (1997).

141. The IRA deprives AstraZeneca of two constitutionally protected property interests: its investment-backed patent rights and common-law right to sell its products at market prices free from arbitrary and inadequately disclosed governmental constraints. And the statute works this deprivation upon AstraZeneca involuntarily.

142. The IRA deprives AstraZeneca of those property interests by directing the Secretary to fix prices at the "lowest" level, without affording adequate procedural safeguards.

143. Even the most rudimentary of these procedural safeguards are absent from the statutory scheme. On the front end, the IRA strips manufacturers of any ability to meaningfully negotiate a reasonable price for their products. The IRA also dispenses with traditional hearing and notice-and-comment rulemaking procedures, freeing CMS of any obligation to consider the input of affected drug manufacturers, providers, or patients. On the back end, the statute vests the agency with unchecked authority to finalize its decisions without any process for administrative or judicial review, leaving AstraZeneca without any meaningful opportunity to be heard. 42 U.S.C. § 1320f-7.

144. The statute's lack of ex-ante procedural protections, combined with its refusal to supply any ex-post process for parties affected by its decisions, pushes the agency's scheme beyond the perimeter of constitutionally mandated due-process safeguards.

145. AstraZeneca's purported "option" to avoid the Drug Price Negotiation Program's reach by forgoing all Medicare and Medicaid reimbursement is no option at all. Even if it were possible for a manufacturer to withdraw from the programs in time to avoid the application of the maximum fair price, these programs account for a gargantuan percentage of the pharmaceutical market. It simply is not an economically viable course for manufacturers to withdraw from both programs.

146. The risk of erroneous deprivation resulting from the IRA's lack of process is substantial, and the Government has no legitimate interest in shielding CMS's decisions from public input or judicial review.

147. The IRA's drug price control program is therefore unconstitutional under the Fifth Amendment and should be enjoined.

PRAYER FOR RELIEF

For the foregoing reasons, AstraZeneca prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that CMS's definition of a Qualifying Single Source Drug is unlawful, arbitrary, and capricious under the APA;

B. A declaration pursuant to 28 U.S.C. § 2201 that CMS's "bona fide marketing" standard is unlawful, arbitrary, and capricious under the APA;

C. An order vacating and setting aside the definitions of "Qualifying Single Source Drug" and "Bona Fide Marketing" set forth in the Guidance Documents;

D. A declaration pursuant to 28 U.S.C. § 2201 that the IRA is unconstitutional and

violates the Due Process Clause of the United States Constitution;

E. Preliminary and permanent injunctive relief barring Defendants from applying the drug pricing provisions of the IRA to AstraZeneca;

F. An order awarding AstraZeneca its costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

G. Such other and further relief as the Court deems just and proper.

Dated: August 25, 2023

Respectfully submitted,

MCCARTER & ENGLISH, LLP

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JS 44 (Rev. 09/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

AstraZeneca Pharmaceuticals LP

(b) County of Residence of First Listed Plaintiff New Castle County, DE
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Daniel M. Silver, McCarter & English, LLP, Renaissance Centre,
405 N. King St., 8th Floor, Wilmington, DE 19801
Telephone: (302) 984-6300

DEFENDANTS

Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Chiquita Brooks-LaSure, in her official capacity as Administrator of Centers for Medicare & Medicaid Services

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit (15 USC 1681 or 1692)
- ❒ 485 Telephone Consumer Protection Act
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. § 706(2)

Brief description of cause:
Administrative Procedure Act and constitutional challenge

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ❒ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE N/A DOCKET NUMBER N/A

DATE
08/25/2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Daniel M. Silver (#4758)

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____