IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.,
800 Scudders Mill Road,
Plainsboro, NJ 08536

NOVO NORDISK PHARMA, INC.,
800 Scudders Mill Road, Suite 1A-108
Plainsboro, NJ 08536

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244;

CENTERS FOR MEDICARE AND MEDICAID SERVICES
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

No. 3:23-cv-20814

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo"), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), and the heads of those agencies in their official capacities (collectively, "Defendants"), alleging as follows:

PRELIMINARY STATEMENT

1. This lawsuit challenges the prescription drug price control program established by the "Inflation Reduction Act of 2022" ("IRA"), 42 U.S.C. § 1320f *et seq.*, and the guidance and other final agency actions that CMS has taken purporting to implement the statute.

2. The statute violates the Constitution because it eliminates essential procedural and substantive safeguards required to (a) hold Congress accountable for the legislative policy decisions it makes, (b) protect the important public and private interests at stake when price controls are imposed on a major sector of the economy, and (c) ensure that CMS acts within the proper scope of any lawfully delegated authority.

3. The statute's serious constitutional infirmities have been exacerbated by CMS's unlawful and ultra vires actions. CMS has violated multiple express statutory mandates, failed to comply with necessary procedures, and sought to impose new substantive obligations that far exceed the lawful bounds of any authority granted by Congress. CMS has also unlawfully deemed six different Novo products a single "biologic product" and subjected all of them to price controls, even though the products do not satisfy the statutory criteria. Imposing price controls on these different products violates multiple specific and unambiguous statutory commands.

The IRA Is Unconstitutional

4. In recent decades, the federal government has taken control over large segments of the nation's healthcare markets, regulating the sale of drugs to the millions of patients who participate in federal healthcare programs, including Medicare. But Congress has historically prohibited government officials from interfering with the prices of manufacturers' drugs. Congress has instead recognized that government price setting undermines the productive and predictable regulatory environment that is essential to fostering the massive investments necessary to bring to

market new and innovative drugs (and improvements to existing drugs), while also avoiding drug shortages and ensuring that patients have access to the medications they need.

5. The IRA ignores that reality and, for the first time ever, seeks to compel manufacturers to sell their products to federal healthcare beneficiaries at whatever price CMS unilaterally imposes. The statute's unprecedented price-setting provisions, which are structured to impact pricing in both the federal and private commercial markets, depart from more than a century of precedent governing the imposition of price controls on other regulated industries.

6. When erecting a government-run price-control regime, particularly one that delegates significant power to an executive agency, Congress is required to take account of the important public interests and private rights at stake by establishing procedures sufficient to ensure accountability and to protect against unreasonable and confiscatory prices. It also must provide clear instructions to guide the agency's price-setting decisions, allow meaningful opportunities for public input, and provide for judicial review to ensure that the agency acts in accordance with Congress's instructions and within the scope of its delegated authority.

7. Instead of complying with these essential requirements, Congress in the IRA eliminated multiple layers of constitutional safeguards. The statute provides a sweeping delegation of power to CMS with no intelligible principle to guide the agency's price-setting decisions. The statute directs the agency to impose nearly any price it chooses for any reason it chooses, with no mechanism to ensure that CMS acts predictably and consistently, or that the prices it sets are not confiscatory or unduly discriminatory. The statute provides no meaningful opportunity for public input. And, most astonishingly, it contains sweeping judicial review bars designed to insulate many of CMS's most important decisions from any judicial scrutiny or oversight.

8. The constitutional concerns raised by these unprecedented provisions are reinforced by the statute's other features. Although labeled a "drug price negotiation program," the statute does not allow for anything that could be remotely characterized as an actual negotiation between pharmaceutical manufacturers and CMS; instead, the statute permits CMS to act by fiat and impose any below-market prices CMS unilaterally dictates. The statute also threatens manufacturers with astronomical penalties—or being barred from selling *any* of their products in federal healthcare programs (not only the products subject to CMS's price controls)—if they do not accept the unilaterally imposed prices. Moreover, in a clear violation of the First Amendment, the statute compels speech, forcing manufacturers to agree with the government and express the view that the unilaterally imposed prices are "maximum *fair* prices."

9. Through these provisions, the statute is intended to have spillover effects that influence the prices paid in the nation's commercial markets. The terms "fair" and "negotiation" are intended to suggest that manufacturers have had a meaningful say in determining what prices should be charged for their drugs when, in reality, manufacturers have no say at all. CMS's unilaterally imposed price is an offer that manufacturers cannot refuse. There is no realistic opportunity for manufacturers to avoid the "negotiation" process, and the government-imposed prices apply no matter how unfair or misguided the process and prices might be. Commercial purchasers and payors will leverage the "negotiated" prices to extract discounts in the non-Medicare markets. *See* Press Release, White House, Fact Sheet: President Biden Calls on Congress to Lower Prescription Drug Prices (Aug. 12, 2021) ("And it's not just Medicare beneficiaries that would benefit. If Medicare makes the prices it negotiates available to commercial payors, too, costs for employer health insurance would fall ….").

10. No court has ever upheld a price-control regime comparable to the IRA's extreme and unprecedented provisions.

CMS's Actions Implementing the Statute Are Unlawful and Ultra Vires

11. CMS's actions have compounded the IRA's grave constitutional problems.

12. CMS has violated clear and mandatory statutory requirements, and it has exceeded its lawful authority, extending the IRA's already unprecedented price controls far beyond what Congress authorized. CMS has taken advantage of the IRA's open-ended and improper provisions to impose new and onerous substantive obligations that have no basis in the statute.

13. Given the consequences that price controls will have on the nation's drug markets and patients' ability to access the medications they need, CMS should have followed the statute's clear and express mandates. In particular, CMS was duty bound to follow Congress's explicit direction to select *only* 10 products for price controls at first, and then gradually expand the number over time. CMS was also required to heed Congress's clear direction that price controls are *not* to be imposed on any drug or biological product until *that product* has been approved and marketed for the requisite 7- or 11-year period. That timing is critical for manufacturers to have any hope of recovering fair compensation for their investments, and thereby continue innovation, research, and development of novel drug therapies.

14. CMS was also obligated to adhere to administrative law requirements and honor the constitutional principles they protect. Congress directed the agency to proceed by guidance for the program's first three years; Congress did not grant the agency any authority to impose new substantive and coercive obligations during that three-year period. Nor did it exempt CMS from the essential rulemaking requirements of the Administrative Procedure Act and the Medicare Act. Disregarding Congress's directives, CMS has rewritten the law to seize more powers than

Congress authorized, violating the statute's plain language and refusing to comply with proper notice-and-comment rulemaking procedures.

15. In an extreme departure from and violation of the statute's plain text and structure, CMS has substantially increased the number of drug and biological products subject to price controls, including products that do not satisfy the selection criteria dictated by Congress. In particular, CMS has ignored the IRA's definitions of "drug product" and "biological product," changing how those terms of art are used in the IRA and how they have long been interpreted under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA"). CMS has rewritten "drug product" to mean any aggregated grouping of products with the same "active moiety." And it has rewritten "biological product" to mean any aggregated grouping of products with the same "active ingredient." Neither the explicit IRA definitions nor longstanding interpretations of those terms can be read to permit the aggregation imposed by CMS in its guidance. *See* 42 U.S.C. § 1320f-1(e)(1).

16. These statutory rewrites violate the statute's plain text and are at odds with Congress's intent, as they subject more products to price controls than the statute permits, and they impermissibly reorder which products are appropriately subject to price controls in the first place. Instead of setting prices on a limited number of *identifiable drugs* and *biological products*, as Congress directed, CMS has imposed price controls on entire groupings of products with the same *active moieties* or *ingredients*, with no regard to where, when, and how those active moieties or ingredients may be used in current or future clinical development or for what uses they might be approved (or even which products will be identified as containing the same active moieties or ingredients).

17. As a result, while Congress expressly limited CMS to imposing price controls on no more than 10 drug or biological products in the first year of the program, CMS has substantially increased the number of drug and biological products swept into its price-control regime. Moreover, while Congress forbade CMS from imposing price controls on drug and biological products that were approved for less than 7 or 11 years, CMS has violated that clear command, subjecting numerous products to price controls that have been approved for far less than the minimum time period required by the statute.

18. In addition, CMS has imposed arbitrary and extra-statutory limits on the information that the agency will consider when setting prices, restricting what information manufacturers may provide as part of the "negotiation" process and refusing to consider categories of costs that manufacturers have incurred when researching and developing their products. Manufacturers spend massive amounts each year on research and development to discover new life-saving and life-improving drug and biologic products, including incurring substantial costs developing products that are ultimately unsuccessful. Most research and development efforts fail and, even when they are successful, many drugs will not be approved by regulators. The revenues generated by the few drug and biological products that make it to market are essential to being able to fund research and development for new products, but CMS has decided that it will take none of these important considerations into account.

19. CMS has also ensured that the new substantive requirements it has adopted through mere guidance—and others it may seek to impose in the future—will be binding on Novo and other manufacturers. The statute requires that all manufacturers whose drugs are selected for price controls sign an "agreement" under threat of massive penalties—or lose access to federal programs for their entire product portfolio and deprive the millions of patients who depend on accessing

manufacturers' products through those programs from critical treatments. Abusing and exceeding this statutory mandate, CMS's template agreement compels manufacturers to agree that they will comply with and be bound by the requirements of any "guidance" that CMS might issue now or in the future. But neither CMS's guidance nor the agreement was promulgated through proper notice-and-comment procedures, as the law requires. CMS has thus used the statute's contracting process to grant itself new rulemaking powers that Congress has never authorized and without complying with its basic obligations under the Administrative Procedure Act and Medicare Act.

20. Novo and the patients who rely on its medicines and its efforts to innovate face substantial harm as a result of the IRA and CMS's unlawful and extra-statutory actions. As set forth below, no fewer than *six* of Novo's different insulin products have been aggregated together and selected *as a group* by CMS for "negotiation." These six products will be subject to CMS-imposed price controls merely because they contain the same active ingredient, even though many of these biological products have not been marketed for the requisite 11-year period. Moreover, on their own, none of the products would have been selected for price controls under the IRA (because their cost to Medicare is among the top 10 only if they are improperly aggregated).

21. Novo objects to being directly regulated by an unconstitutional statute and being the target of CMS's unlawful, ultra vires actions. Novo should not be required to participate in CMS's one-sided "negotiation" process and objects to being required to submit highly sensitive and confidential data to the government, which is causing and will continue to cause Novo irreparable harm. Novo likewise should not be required to sign an "agreement" that permits CMS to make any unilateral changes it desires and to provide notice of such changes only when it deems such notice to be appropriate.

22. Novo is concerned that, unless this Court grants relief, it will be prevented from challenging CMS's price-setting decision and will be deprived of any reasonable opportunity to be heard. In addition, Novo is concerned that CMS will impose a "maximum fair price" on an aggregated grouping of Novo's products that causes competitive harm and deprives Novo of a reasonable return on its investments, including because CMS has decided—in the teeth of the statute's plain language—to subject multiple of Novo's biological products to price controls. That will make it more difficult for Novo to continue to invest in new and innovative drug research and development efforts, harming both Novo and patients.

23. This Court should declare that the IRA's drug price control program is unconstitutional and strike down CMS's unlawful and ultra vires actions.

JURISDICTION AND VENUE

24. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1346 because this action arises under the laws of the United States, including the Constitution.

25. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201–2202 and 5 U.S.C. §§ 703–706.

26. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this action is brought against officers and agencies of the United States, at least one plaintiff resides in this district, and no real property is involved in this action.

THE PARTIES

27. Novo Nordisk Inc. is the U.S.-based affiliate of a global healthcare company, founded in 1923, with the purpose to drive change to defeat diabetes and other serious chronic diseases, such as obesity, and rare blood and rare endocrine diseases. Novo Nordisk Inc.'s headquarters are located in Plainsboro, New Jersey.

28. Novo Nordisk Pharma, Inc. supplies unbranded biologic versions of Novo Nordisk insulin products. Novo Nordisk Pharma, Inc.'s headquarters are located in Plainsboro, New Jersey.

29. Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. are part of a global health care company committed to improving the lives of people living with serious chronic conditions, including diabetes, bleeding disorders, growth disorders, and obesity. The Novo Nordisk Foundation, Novo Nordisk's majority stakeholder, is among the top five largest charitable foundations in the world. The company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and sustainability of society.

30. Xavier Becerra is the Secretary of the Department of Health and Human Services ("the Secretary"). He oversees the Medicare program and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity only.

31. HHS is an executive department of the United States government headquartered in Washington, D.C. HHS is responsible for administering the Medicare program and the statutory provisions challenged here.

32. CMS is an administrative agency within HHS headquartered in Baltimore, MD, and that administers the Medicare program and the statutory provisions challenged here.

33. Chiquita Brooks-LaSure is the CMS Administrator. She administers the Medicare program and the statutory provisions challenged here on behalf of the Secretary. She is sued in her official capacity only.

STANDING

34. Novo holds multiple New Drug Applications ("NDAs") and Biologics License Applications ("BLAs"). The company manufactures several different products that CMS included together as a single product in the agency's List of Selected Drugs for Initial Price Applicability

Year 2026: NovoLog®, NovoLog® FlexPen®, NovoLog® PenFill® (insulin aspart, BLA 020986) (collectively, the aggregated "NovoLog® Products"), FIASP®, FIASP® Flextouch®, and FIASP® Penfill® (insulin aspart, BLA 208751) (collectively, the aggregated "FIASP® Products"). A copy of CMS's selected drugs list is attached as Exhibit A to this Complaint. (Significantly, CMS has aggregated together some, but not all, of the various insulin aspart products that Novo manufacturers and targeted them for price controls, but it has provided no reasoned explanation why it has chosen to include some insulin aspart products and to exclude others from the aggregated grouping.)

35. The NovoLog® Products are some of Novo's most used products. NovoLog® is a rapid-acting insulin that helps lower mealtime blood sugar spikes in people with diabetes. NovoLog® helps with glycemic control in people with diabetes mellitus. It is typically used in conjunction with a long-acting insulin, and numerous Medicare and Medicaid beneficiaries rely on it to treat their chronic battle against diabetes. It is administered via subcutaneous injection, pump, pen, or intravenous infusion, 5–10 minutes before a meal. Dosage must be individualized, and the duration of action will vary according to dose, injection site, blood flow, temperature, and level of physical activity.

36. The Food and Drug Administration ("FDA") first approved NovoLog® and NovoLog® PenFill® in 2000 in New Drug Application ("NDA") 020986 to treat adult patients with diabetes mellitus, for the control of hyperglycemia. NovoLog® FlexPen® was approved the following year. The active ingredient in the NovoLog® Products is "insulin aspart," a rapid-acting human insulin analog.

37. Because NovoLog® is a biological product, the NDA for the NovoLog® Products was subsequently "deemed" to be a biologics license application ("BLA") in 2020 by operation of

section 7002(e)(4) of the Biologics Price Competition and Innovation Act, which provided that "[a]n approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act." Accordingly, the NovoLog® Products were never licensed under the Public Health Services Act; instead, they were approved in an NDA and transitioned to a biologics license as a result of the Biologics Price Competition and Innovation Act.

38. Novo also manufactures other, different insulin aspart products, including the FIASP® Products. FIASP® is an ultra-fast-acting insulin that controls blood sugar around mealtimes for patients with diabetes mellitus; it can be administered via subcutaneous injection, pump, pen, or intravenous infusion, at first bite or within 20 minutes after starting a meal. FIASP® and FIASP® Flextouch® were approved in 2017 in NDA 208751; FIASP® Penfill® was approved in 2018.

39. Because FIASP® is a biological product, the FIASP® Products were deemed to be licensed under BLA 208751 on March 23, 2020. FIASP® Pumpcart® Cartridge, a unique 1.6 mL strength, was approved just this year, in June 2023. It does not appear by name on CMS's selected drugs list, but CMS has required Novo to submit confidential business information regarding this product and may attempt to sweep this new product into its price control regime.

40. FIASP® is not the same drug as NovoLog®; the FIASP® Products are not the same drugs as the NovoLog® Products. The FIASP® Products contain vitamin B3 and L arginine, in addition to insulin aspart, which results in a faster-acting insulin aspart with a more rapid onset than NovoLog®. FIASP® appears in the bloodstream faster than NovoLog®; while NovoLog® is approved for use within 5-10 minutes immediately before a meal, FIASP® is approved for use

within 20 minutes after starting a meal. Failure to follow each product's specific dosing instructions can increase the risk of hypoglycemia. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454–55 (1983) (explaining the importance of excipients in determining that the term "drug" is "broader" than just the active ingredient, including because "[e]xcipients may affect the rate at which the active ingredient is delivered" and "[i]f delivery is too fast, the patient may be harmed just as if he received an overdose; if delivery is too slow, the treatment of the disease may be ineffective.").

41. None of these biological products, standing alone, would have been among the most widely reimbursed drugs for Medicare Part D patients. Nor would the NovoLog® Products or FIASP® Products separately have been. Accordingly, none of them would have been subject to or eligible for price controls under the requirements set by Congress in the IRA.

42. On August 29, 2023, CMS aggregated these six different insulin aspart products, including both the NovoLog® Products and the FIASP® Products, and deemed them to be a single "selected drug" merely because they share the same active ingredient. Underscoring that CMS is improperly imposing price controls on more products than Congress authorized, CMS listed each of the NovoLog® Products and the FIASP® Products—six distinct biological products—as a single entry on its selected drugs list.

43. As a result of CMS's ultra vires conduct, Novo will be forced to enter "negotiations" with CMS; reveal competitively sensitive proprietary information about the NovoLog® Products, the FIASP® Products, and other insulin products to CMS; and "agree" to CMS's unilaterally imposed "maximum fair price," which is statutorily guaranteed to be substantially lower than different current market prices for any of the different NovoLog® or FIASP® products. CMS's unlawful and ultra vires actions are also diverting resources that Novo

would otherwise deploy differently, and they are causing immediate and ongoing financial and competitive harm to Novo.

44. Novo objects to being the target of regulation under the IRA and CMS's ultra vires actions. Novo's products should not be subject to price controls, and Novo objects to having CMS dictate the prices at which Novo is permitted to sell its products. Novo also objects to disclosing proprietary and confidential information to CMS. CMS should not be permitted to use or retain that proprietary and confidential information.

45. Novo also should not be forced to sign an agreement with CMS (which CMS claims it can unilaterally change) as a condition of selling its products to patients who participate in the federal Medicare program or to patients who participate in the federal/state Medicaid program. Novo also should not be forced to participate in a misnamed "negotiation" process, which is diverting essential resources and employees that Novo would otherwise be using to run its business, develop new medications, and help patients. Nor should Novo be compelled to agree and state that whatever price CMS unilaterally imposes on Novo's six different drugs qualifies as a "maximum fair price."

46. Novo is suffering and will continue to suffer concrete injury and irreparable harm as a result of the IRA and CMS's unlawful actions. That irreparable harm includes being subject to an unconstitutional statute and ultra vires regulation; being forced to sign an agreement as a condition of selling its products to two of the largest segments of the nation's healthcare markets; being forced to engage in compelled speech at the government's direction; being forced to collect, aggregate, and disclose propriety and confidential information that Novo would not otherwise share; being coerced into participating in an unlawful "negotiation" process; and having the

government unilaterally dictate the prices at which Novo is entitled to sell its products, which will make it more difficult for Novo to continue to invest in new and cutting-edge medications.

GENERAL ALLEGATIONS

A. The Constitution and the Proper Exercise of Administrative Powers

47. The Constitution divides power between the three branches of government and vests all legislative powers in the Congress of the United States.

48. Congress is prohibited from transferring its powers to any other branch of government, which ensures that Congress remains accountable for the legislative policies it enacts.

49. Although Congress may delegate *rulemaking* powers to officials within the executive branch, the Constitution imposes limits and requirements to ensure that any exercise of such powers follows constitutional demands for lawful and accountable government. Congress is thus required to make the legislative *policy decisions* in the first instance and to legislate *intelligible principles* that guide the actions of executive agencies. In turn, Congress may authorize an executive agency to promulgate substantive rules that implement, interpret, or prescribe law or policy, but only if the agency complies with notice-and-comment rulemaking procedures, and only if the agency's exercise of rulemaking authority is subject to judicial review. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92 (2015).

50. These procedures and safeguards are essential parts of the compromise—under both the Constitution and the Administrative Procedure Act—that has allowed executive agencies to wield rulemaking powers while taking account of the significant separation-of-powers concerns that arise when Congress delegates such authority to executive branch officials. While there are narrow exceptions to notice-and-comment rulemaking that apply in limited circumstances, those exceptions do not apply here and must be "narrowly construed and only reluctantly countenanced." *New Jersey, Dep't of Env't Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980).

51. Complying with proper procedures and safeguards is of particular importance when the government seeks to impose price controls on products manufactured by a targeted group of regulated parties (as opposed to on an industry as a whole). Price controls raise heightened constitutional concerns because of the risks they pose both to the broader public interest and to private rights, and because of the risk that they will be applied unfairly. When prices are imposed, they not only risk denying regulated parties their rights to obtain a reasonable return on their investments, they can also undermine innovation, inhibit capacity building, cause competitive harms, and create shortages that deprive consumers of the products and services they need. The risk that government will overstep its lawful authority is amplified when executive agencies are not only purchasing products for the government itself (exercising procurement authority), but also regulating prices for the benefit of consumers or other third parties (exercising regulatory authority).

52. Courts have long held that a government agency cannot dictate prices on goods and services unless there are adequate procedures in place to ensure that the prices imposed are set at reasonable and non-confiscatory levels that allow a reasonable return on investment. Moreover, unless Congress specifically dictates the prices to be imposed or the formula to be used when calculating a price, an agency must follow exacting rulemaking procedures to develop such prices or formulas, and its price-setting decisions must be subject to meaningful judicial review.

53. The Supreme Court has made clear that while Congress may occasionally exempt its programs from one or another of these protections, Congress may not *simultaneously* remove *multiple* layers of constitutional safeguards necessary to ensure lawful and accountable government. *See Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183 (2020); *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477 (2010). Those safeguards are necessary

to protect separation of powers, to ensure that agencies act within the proper scope of their delegated authority, and to protect public interests and private rights, including essential due process rights.

54. Moreover, while Congress is permitted to shield certain agency actions from judicial review, statutory review bars must be interpreted narrowly. Statutory bars on judicial review do not apply to constitutional claims, absent particularly clear language that is not present in the IRA. They also do not apply where, as here, an agency has violated clear and express statutory mandates, disregarded unambiguous congressional commands, or otherwise acted in ultra vires fashion. Because an agency's powers to act and how it acts are authoritatively prescribed by Congress, *see City of Arlington v. FCC*, 569 U.S. 290 (2013), agency action that is outside the scope of the agency's delegated authority remains subject to judicial review.

55. A judicial review bar is not an invitation for an agency to go off the rails and, ignoring Congress's express directives, extend its regulatory powers far beyond the scope of any lawfully delegated authority. *See Leedom v. Kyne,* 358 U.S. 184, 188 (1958) (judicial review proper despite statutory preclusion of judicial review, where an agency acts "in excess of its delegated powers and contrary to a specific prohibition" in the statute). Courts remain available to enforce the rule of law, to serve as a check against administrative tyranny through executive fiat, and to reestablish the limits on an agency's authority. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (noting that despite statutory review bar, "judicial review remains available" when an agency has "engaged in 'shenanigans' by exceeding its statutory bounds").

56. As described in more detail below, the IRA's unprecedented provisions, and CMS's attempts to rewrite the statute through mere guidance and to exercise rulemaking powers that Congress never delegated, violate numerous constitutional requirements and are contrary to the

basic requirements of lawful and accountable government. Any one of them (let alone the multiple concurrent violations that have occurred here) provides a sufficient basis on which to declare the IRA invalid and to strike down CMS's extra-statutory price control program, including CMS's unlawful and improper actions with respect to Novo's six insulin aspart products.

B. The Inflation Reduction Act

57. Medicare and Medicaid have historically reimbursed providers for manufacturers' drugs, including biologics, using formulae tied to market prices.

58. Medicare Part B covers various types of outpatient healthcare for beneficiaries, including physician-administered drugs. *See* 42 U.S.C. § 1395k(a)(1); *id*. § 1395x(s)(2)(A). Since 2005, Medicare Part B has reimbursed providers 106% of a drug's Average Sales Price ("ASP")—the average price paid by U.S. commercial purchasers inclusive of rebates and other discounts.

59. Medicare Part D provides coverage for self-administered prescription drugs. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Under the pre-IRA legal framework, CMS would contract with private insurance plans to provide Part D prescription drug benefits, and those private plans (acting under contract with the government), would negotiate drug prices with manufacturers.

60. Under that framework, the Secretary could "not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," nor "require a particular formulary" or "institute a price structure for the reimbursement of covered part D drugs." CMS was precluded from setting drug prices directly or interfering in the market-based negotiations between plan sponsors and pharmaceutical manufacturers. 42 U.S.C. § 1395w-111(i).

61. That longstanding prohibition recognized the government's significant market power—namely, that Medicare, Medicaid, and other federal healthcare programs account for

nearly half of the nation's total healthcare expenditures. It also recognized the unique risk-taking and up-front costs entailed in the drug development and approval process.

62. Congress enacted the IRA in August 2022 through a rushed budget reconciliation process without debate and on a party-line vote. The statute is a novel and unprecedented attempt to impose price controls on the drug manufacturing industry while simultaneously avoiding accountability for the reductions in access, innovation, and supply that will inevitably occur, and indeed have already occurred, as a predictable consequence of those controls.

63. The statute eliminates the Medicare Part D "non-interference clause" and delegates unprecedented authority to CMS to erect a misleadingly named "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). More specifically, the statute authorizes CMS to impose "maximum fair prices" on certain drugs available through Medicare, setting the price that a manufacturer may charge for the selected drug. *Id.* § 1320f-2(a). Through this open-ended delegation to CMS, the statute unfairly and arbitrarily targets certain products for price controls—many of which have been developed to treat costly and burdensome chronic diseases—and upends market competition within classes of drugs, with detrimental consequences for patient access and treatment.

64. This year, the first year of the program, CMS was required to identify the "50 qualifying single source drugs with the highest total expenditures under [Medicare] [P]art D" and to identify the 10 most costly from among that list to subject to price controls. *Id.* § 1320f-1(a)(1), (d)(1)(A). Because total expenditures reflects both volume and price, the statute directs CMS to include in its ranking many of the most widely used drugs in the country, without considering whether those drugs are actually "overpriced" and despite the potential impacts on patients and their ability to access essential medications.

65. CMS announced the 10 "negotiation eligible" "drugs" it selected on August 29, 2023. *Id.* § 1320f-1(d)(1).

66. Now that CMS has selected these products, the statute requires that each drug's manufacturer "shall enter into [an] agreemen[t]" with CMS by October 1, 2023, to "negotiat[e]" a "maximum fair price" for the drug. *Id.* §§ 1320f(d)(2)(A), 1320f-2(a)(1).

67. As part of the "negotiation" process, manufacturers of selected drugs must submit highly sensitive and confidential trade secret and commercial information to CMS by October 2, 2023. *Id*. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A). That information includes (among other things) certain aspects of drug research and development costs, current unit costs of production and distribution of selected drugs, patent and regulatory exclusivity information, and market data and sales volume data for the selected drugs. *See id.* § 1320f-3(e).

68. The agency will make an initial "offer" of a "maximum fair price" for the drug (below a statutory ceiling), and the manufacturer may make a "counteroffer" within 30 days. *Id.* § 1320f-3(b)(2)(B)–(D). Under the statute, however, CMS is free to disregard the manufacturer's counteroffer and unilaterally impose *any* price it chooses (below the price ceiling) with no lower limit. *See id.* §§ 1320f-3(b)(2)(E), 1320f-4(a). The statute directs CMS to "ai[m] to achieve the lowest maximum fair price for each selected drug." *Id*. § 1320f-3(b)(1).

69. The statutory ceiling price is the lowest number yielded by calculations set by the IRA. The IRA sets the ceiling for "negotiation" at the lower of (a) the plan-specific enrollment weighted amount, and (b) between just 40% and 75% of a drug's Non-Federal Average Manufacturer Price (Non-FAMP). 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). Non-FAMP measures a drug's average net sales price to commercial purchasers, including any price concessions obtained through wholesalers. 38 U.S.C. § 8126(h)(5). Because it is a *net* price—the amount a

manufacturer realizes after most discounts—40% to 75% of the Non-FAMP is far below any reasonable price that would be set through market forces.

70. Although the statute directs CMS to "consider" certain factors when "negotiating" the "maximum fair price," *id.* § 1320f-3(e), the statute does not require CMS to base the price it imposes on any specific factor or set of factors; nor does it direct the agency as to how it should consider any particular factors. Although the statute sets a ceiling price, it includes no standards to govern CMS's ultimate price-setting decisions. The statute authorizes CMS to unilaterally select the drug and biological products that will be subject to price controls and to dictate the price that will apply to each of those "selected drugs." *See id.* § 1320f-4(a).

71. Nor is the "maximum fair price" established through proceedings before a neutral adjudicator. Because CMS pays for drug and biological products through Medicare and has a statutory duty to seek the lowest permissible price, the statute creates an obvious conflict of interest, with CMS serving as a market participant, the purchaser of selected drugs, and as the market regulator.

72. By September 1, 2024, CMS will publish its chosen "maximum fair price" for each selected drug for the 2026 initial price applicability year ("IPAY"). *Id.* §§ 1320f(d)(6), 1320f-4.

73. The "maximum fair price[s]" imposed by CMS for the first IPAY will take effect on January 1, 2026. *Id.* §§ 1320f(d)(1), 1320f-2(a)(1), 1320f-3(g). Beginning on that date, the manufacturer must "provide" hospitals, physicians, and other service providers who treat Medicare beneficiaries "access" to the drug at the "maximum fair price." *Id.* § 1320f-2(a).

74. Manufacturers that violate the statute face civil monetary penalties equal to *ten times* the difference between the market price and the "maximum fair price." As described in more detail below, manufacturers' only option to avoid price controls is to exit *all* of their products (not

just those subject to price controls) from federal healthcare programs and to deny access to those products to the millions of patients who depend on those programs to access their medications. *Id.* § 1320f-6(a). But that is not a meaningful choice—both because it is almost impossible as a practical matter to exit the program and because the statute's extreme penalties would be imposed before any manufacturer could exit the program under the statute's plain terms.

75. The "negotiation" process established by the statute is not a fair or meaningful "negotiation" because manufacturers of selected drugs have no alternative but to participate in the one-sided "negotiation" and to accept the prices and other terms and conditions unilaterally imposed by CMS. Nor is there any reasonable possibility that the regime of unilaterally imposed prices will lead to the establishment of a "fair" price.

76. When two contracting parties engage in genuine negotiations, they can walk away and end negotiations if they cannot reach mutually agreeable terms and pricing. In contrast, Congress designed the IRA's price control program to be coercive and mandatory—it leaves manufacturers with no choice but to accept the prices that CMS unilaterally imposes.

77. The IRA levies a debilitating penalty—mislabeled an "excise tax"—on manufacturers that do not (a) "agree" to enter into "negotiation," (b) submit the information demanded by the Secretary, or (c) "agree" to a "maximum fair price" set by the Secretary within the timeframe set by the statute. 26 U.S.C. § 5000D(b)(1)–(4).

78. The "excise tax" penalty is calculated based on total sales revenues. *Id.* § 5000D(d). If a manufacturer refuses to "agree" to the government's demands, the government assesses penalties up to *19 times* the drug's total sales revenue. *See* Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022). Even the lowest possible excise tax penalty fines a manufacturer nearly double its daily

sales revenue from the drug. *See id.* ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance.").

79. Those penalties accrue every day until the manufacturer enters into the "agreement" with CMS, the manufacturer's drug is no longer eligible for "negotiation," or the manufacturer successfully withdraws *all* of its drugs from Medicare Part D and Medicaid. 26 U.S.C. § 5000D(c); *see id*. § 5000D(c)(1); 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii).

80. In addition to imposing excessive penalties on manufacturers that do not wish to have their drugs subject to price controls, Congress also took extreme measures to insulate CMS's price control program from judicial review. Section 1320f-7 provides that there shall be "no administrative or judicial review" of the agency's key determinations regarding which products will be swept into the price control program or of the prices set by the agency.

81. The judicial review bars purport to prohibit a court from reviewing (a) "[t]he determination of a unit, with respect to a drug or biological product," (b) "[t]he selection of drugs under section 1320f-1(b)," (c) "the determination of negotiation-eligible drugs under section 1320f-1(d)," (d) "the determination of qualifying single source drugs under section 1320f-1(e)," (e) "[t]he determination of a maximum fair price under subsection (b) or (f) of section 1320f-3," (f) "[t]he determination of renegotiation-eligible drugs under section 1320f-3(f)(2)," and (g) "the selection of renegotiation-eligible drugs under section 1320f-3(f)(3)." 42 U.S.C. § 1320f-7.

C. CMS's Final Guidance

82. Congress directed CMS to implement the IRA through guidance for the first three years of implementation. That statutory mandate is a clear and express indication that Congress did not authorize the agency during the first three years of the program exercise rulemaking powers, which are necessary if an agency wants to impose new substantive obligations not

expressly articulated in the statute. The statute also includes no indication that Congress exempted CMS or the IRA's drug pricing program from the ordinary requirements of the Administrative Procedure Act.

83. On March 15, 2023, CMS issued its initial guidance describing how the agency intends to implement sections 11001 and 11002 of the IRA. *See* CMS, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (Mar. 15, 2023) ("Initial Guidance"). In this initial guidance, CMS went far beyond the statute, rewriting express statutory provisions to sweep in as many products as possible, while providing virtually no guidance as to CMS's actual price-setting process.

84. Although CMS provided a short, 30-day window for comment on some aspects of its initial guidance, CMS stated that it would not accept comments on certain critical sections of its guidance, including section 30, which addressed the selection of products for "negotiation" and assignment of price controls for IPAY 2026 (with one exception not relevant here).

85. Numerous stakeholders, including Novo, expressed their concerns to CMS. Novo urged CMS to undertake proper rulemaking proceedings, including allowing public comment and responding to those comments. CMS cannot pick and choose when it will comply with the required notice-and-comment rule making process, and when it will abandon such requirements in favor of its own unilateral and substantive decision-making.

86. CMS issued a final, revised guidance on June 30, 2023. *See generally* 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) ("Final

Guidance"). The final guidance doubled down on many of the initial guidance's most problematic provisions and rejected commenters' requests for proper procedures.

87. With its guidance, CMS issued its Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA), expanding the amount of information that manufacturers must collect and share with the agency as part of the "negotiation" process. The Information Collection Request imposed new substantive obligations on manufacturers but was not promulgated using proper notice-and-comment rulemaking procedures.

88. With its guidance, CMS also issued a template "agreement" that each affected manufacturer is required to sign. The template agreement states that the manufacturer "shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations." CMS, Medicare Drug Price Negotiation Program Agreement Template ("Template Agreement"), at 3.

89. The template agreement also ties the terms used in the agreement, including "Selected Drug," to its guidance, and it states that "CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance"—whether or not any notice of such amendments is provided. *See* Template Agreement at 4.

1. CMS's Redefinition of Drug and Biological Products

90. Under the IRA, Congress directed CMS to select and impose price controls on a total of "10" "drug products" or "biological products" for IPAY 2026, each of which is "a covered part D drug" that has been approved or licensed for at least 7 years (in the case of a drug product) or 11 years (in the case of a biologic product) and is not subject to any marketed competition. *See* 42 U.S.C. § 1320f-1(e). Congress did not define the terms "10," "drug product," or "biological

product," but there was no need to. The reference to the number "10" is unambiguous. And the terms "drug product" and "biological product" have well-established and commonly accepted meanings. Congress was undoubtedly aware of these settled definitions when it enacted the IRA and there is no indication that Congress authorized or intended CMS to depart from them.

91. Ignoring the statute's plain language, CMS's guidance re-defines "drug product" to mean an aggregated grouping of multiple products, even across multiple NDAs, with the same "active moiety," and it redefines "biological product" to mean an aggregated grouping of multiple products with the same "active ingredient," even across multiple BLAs. Final Guidance § 30.

92. The terms "active moiety" and "active ingredient" are themselves defined regulatory terms. They do not mean the same thing as each other, and they do not mean the same thing as "drug product" or "biological product." An "active moiety" is the "molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3. An "active ingredient" is "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals." *Id*. The latter term, but not the former, includes "those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." *Id*.

93. CMS's guidance also ignores the definition of "drug substance," as well as the very idea that drug substances are distinct from drug products.

94. "Drug substance" includes the "active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body," but does *not* include "intermediates used in the synthesis of such ingredient." *Id*.

95. Encompassing all of these carefully calibrated definitions, "[d]rug product[]"—which is the precise term that Congress used in the IRA, *see* 42 U.S.C. § 1320f-1(e)(1)(A)—refers to "[t]he finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients." *Drugs@FDA Glossary of Terms*, FDA.gov (Nov. 14, 2017), https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms; *see also* 21 U.S.C. § 355; 21 C.F.R. § 314.3. Similarly, "biological product"—also the precise term Congress used in the IRA *see* 42 U.S.C. § 1320f-1(e)(1)(B)—refers to a unique biological product in finished dosage form. *See* 42 U.S.C. § 262(a)(1), (a)(2)(C); 21 C.F.R. § 600.3.

96. By ignoring these well-settled definitions and instead fashioning its own concept of "drug product" that is both contrary to basic English usage and never before used in the regulation and approval of pharmaceutical and biopharmaceutical products, CMS's guidance—and thereby its implementation of the IRA's price control provisions—violates the IRA's clear and express mandates and sets up conflicts with longstanding regulatory definitions and programs, which form the regulatory backdrop against which Congress legislated.

97. ***First***, CMS's re-definition radically changes the scope of the statute, dramatically increasing the number of medications subject to price controls. The statute limits CMS to imposing price controls on 10 "selected drugs" in the first year of the price control program. The statute also expressly provides that drug and biological products are not subject to price controls unless

they have been approved and marketed for at least 7 years (in the case of a drug product) or 11 years (in the case of a biologic product).

98. CMS has violated these clear and express mandates by treating all of a manufacturer's drug or biologic products containing the same active ingredient or active moiety as a single "product" and sweeping them together into the price "negotiation" process—regardless of whether the individual products meet the necessary statutory requirements set forth by Congress, and irrespective of whether development of second and subsequent products required further research and whether such products were approved or may be approved in the future for different therapeutic disease states or modes of administration. As a result, the list of first year drugs required to be subject to price controls, published by CMS on August 29, 2023, identifies far more than 10 drug and biological products, and includes numerous products that have not been approved or market for at least 7 or 11 years.

99. CMS's approach will have disastrous consequences for the public interest and, in particular, the public's interest in balancing any price controls against the need to encourage innovation and ensure that manufacturers have proper incentives to improve and expand existing products and to develop new, ground-breaking products, including those needed to treat rare and chronic diseases. If a biological product is subject to CMS-imposed price controls, and a different biological product containing the same active ingredient is in clinical development for a different disease or therapeutic area, the second biological product would be subject to the first biological product's "maximum fair price" *on the very first day* after it receives FDA approval—flatly contrary to Congress's express command that price controls can be applied only on products that have been marketed for 11 years without any marketed competition. CMS's approach violates the

statute command that price controls shall not be imposed on newer products given the costs associated with continuous innovation and improvement.

100. CMS has thus acted in ultra vires fashion to transform the IRA's product selection and price control process to an active ingredient/moiety selection and price control process, capturing all of the NovoLog® Products and all of the FIASP® Products based on their active ingredient alone. That is far afield from what Congress intended and directed in creating a price negotiation process for 10 drug or biological products that have been approved and marketed for 7 or 11 years, respectively. CMS cannot through mere guidance alter the substantive balance between controlling costs and encouraging innovation. CMS cannot adopt an extreme, ultra vires interpretation of the IRA and, in doing so, take on the legislative function reserved for Congress. Nor can CMS unilaterally deviate from Congress's express mandate to capture the top 10 drug and biological products according to Medicare spend by aggregating multiple products that each independently would not qualify for price controls but that in the aggregate may rise to the top 10.

101. ***Second***, by subjecting aggregated clusters of products instead of individual products to price controls, CMS has rendered the statutory scheme incoherent. For example, Congress directed CMS to impose price controls only on "drug products," 42 U.S.C. § 1320f-1(e)(1)(A), that were "approved" under section 505(c) of the Federal Food, Drug, and Cosmetic Act, *id*. § 1320f-1(e)(1)(A)(i), or on "biological products," *id*. § 1320f-1(e)(1)(B), that were "licensed" under section 351(a) of the PHSA, *id*. § 1320f-1(e)(1)(B)(i). But approvals under section 505(c) and licensures under section 351(a) are specific to the approved drug or biological *product*. They are not predicated on "active moiety" or "active ingredient." *See* 21 U.S.C. § 355(c); 21 C.F.R. § 314.200; 21 C.F.R. § 314.50 (requiring applications to include data and information pertaining to the "drug product"); 42 U.S.C. § 262(a)(2)(C) (approving an application

based on a demonstration that the "biological product that is the subject of the application is safe, pure, and potent"); *see also* 21 C.F.R. §§ 314.70, 601.12 (requiring applicants to report to FDA changes to an approved drug product or biological product).

102. Similarly, by defining "drug," as that term is used in section 1320f-1(e)(1)(A)(i) and (ii) to mean "active moiety," CMS's guidance creates an irreconcilable conflict with the same term—"drug"—in section 1320f-1(e)(1)(A)(iii), where it necessarily means drug *product*, since that is how reference listed drugs are defined. By defining "biological product" as that term is used in section 1320f-1(e)(1)(B)(i) and (ii) to mean "active ingredient," CMS's guidance also creates an irreconcilable conflict with the same term—"biological product"—in section 1320f-1(e)(1)(B)(iii), where it necessarily means a single biological *product*, since that is how reference products are defined.

103. CMS's interpretation is also at odds with—and indeed may impermissibly render superfluous—the IRA's orphan drug exclusion provision. Recognizing the importance of orphan drug development, Congress expressly excluded certain orphan drugs from price controls. *See* 42 U.S.C. § 1320f-1(e)(3)(A). By aggregating "drug products" and "biological products," however, CMS ensures that the IRA's orphan drug exclusion applies only if the entire aggregate grouping of products with the same active ingredient or active moiety is devoted to treatment of a single orphan-designated disease or condition. *See id.* § 1320f-1(e)(3)(A); Final Guidance § 30.1.1. A special pediatric formulation for use in treating a rare pediatric disease, for example, would not meet the exclusion criteria. *See* Guidance § 30.1.1. CMS's approach thus undermines the incentives that Congress has provided for orphan drug development, truncating the value of orphan drug exclusivity.

104. ***Third***, CMS's approach renders other provisions of the IRA superfluous, *see* 42 U.S.C. §§ 1320f-1(d)(3)(B), 1320f-5(a)(2), and it makes the IRA's price control provisions unworkable and unconstitutionally arbitrary.

105. By setting a price for an aggregation of products with the same "active moiety" and "active ingredient," CMS must address therapeutic alternatives, clinical effectiveness, and unmet medical needs for whole groups of products, many of which will have vastly divergent clinical benefits and therapeutic uses—and in a way that deviates from the product-specific way that FDA addresses these same issues. CMS will also have to consider research and development costs of a wide swath of drug or biological products simultaneously—and whether a manufacturer has recouped those costs. *Id.* § 1320f-3(e)(1)(A). And the agency must ultimately create a single "offer" price applicable to multiple products with different indications, device presentations, and routes of administration (e.g., a subcutaneous injection versus an oral tablet), in different NDAs and BLAs, and even with different clinical impacts merely because they share the same "active moiety" or "active ingredient." Indeed, that price will even apply to *future* products with the same active moiety or active ingredient.

106. CMS's ultra vires approach allows the agency to consolidate distinct groups of products that Congress expressly kept separate and condemns all future products that rely on the same active moiety or ingredient to the same government-imposed price controls, even though they are not yet on the market. The resulting inability to recoup development costs for these drug development programs, including the costs of related programs for products that may never have made it to market, will deter manufacturers from pursing expensive innovation, at a great expense to public health and patients (especially those living with chronic diseases).

107. ***Fourth***, CMS's ultra vires approach conflates the statute's careful distinctions between products reimbursed under Part B (including the FIASP® Penfill® and FIASP® Pumpcart Cartridge), and products reimbursed under Part D (including other FIASP® and NovoLog® Products). Congress directed that the latter can be captured by the IRA's price controls beginning in IPAY 2026, but the former must not be "negotiated" until IPAY 2028. 42 U.S.C. § 1320f-1(a)(1)–(2). But in some cases, as with the FIASP® and NovoLog® Products, Part D will cover certain of a manufacturer's drug or biological products, while Part B may cover others—even though they share the same active moiety or active ingredient. A drug product that is packaged in a pre-filled syringe for patient self-administration, for example, would be Part D, while a lyophilized drug product for physician (office) administration would be Part B—even though both had the same active ingredient or active moiety. CMS's aggregation of Novo's products explicitly invites this contradiction.

108. ***Fifth***, CMS's distinction between "active moiety" and "active ingredient" creates an irreconcilable conflict with FDA's definition of those terms and with the way that agency regulates approves drugs and biological products.

109. Congress has delegated to FDA oversight over whether and under what conditions drug and biologic products should be made available; that agency has decades of experience regulating drug and biologic products. In contrast, CMS has no experience or expertise regarding the technical ways in which drug and biological products (and generic and biosimilar products) are regulated. By directing CMS to proceed only by guidance for the first three years, Congress made clear that CMS would have no authority to reinvent the meaning of well-settled regulatory definitions of the critical terms that Congress used in the IRA.

110. FDA has carefully and deliberately defined "active moiety" to mean one thing and "active ingredient" to mean another. *See* 21 C.F.R. § 314.3; *see also Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 212 (D.D.C. 2015). Under FDA's accepted definition, drug products may share an active moiety but differ in active ingredients, and active ingredients may contain multiple active moieties. These differences matter. For example, a generic drug generally must have the same active ingredient(s) as its listed drug—sameness in active moiety will not suffice. *See* 21 C.F.R. § 314.92(a)(1). Biological product active ingredients may not even always be readily discernable or easily evaluated for "sameness" with other products. *See* 42 U.S.C. § 262(k) (discussing evaluation of "high[] similar[ity]" in the context of biosimilars). CMS's guidance results in a regime under which market *access* is determined on a per-product basis but prices are assigned based solely on active moiety or active ingredient.

111. As noted above, approvals under section 505(c) of the FDCA and licensure under section 351(a) of the PHSA are specific to an approved drug or biological *product*. That is different from approval of an active moiety or an active ingredient. Instead, and as Congress undoubtedly was aware when it implemented the IRA, "a product-specific interpretation of 'new drug' underpins FDA's drug regulatory system." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). As FDA recently explained:

> For decades, FDA has interpreted the word "drug" in the term "new drug" to refer to the entire drug product and not just its active ingredient. This interpretation has significant implications for public health. An active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration (*e.g.*, topical vs. intravenous), among other things. That is why when it reviews an application, FDA carefully evaluates, *for each drug product*, not only the active ingredient but also information about the drug's formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes. In accordance with this approach, FDA has consistently argued in the courts that the term "drug" in "new drug" means

> the entire drug product and not only an active ingredient, and courts, including the U.S. Supreme Court, have agreed with FDA's interpretation.

Id. (emphasis added) (footnote omitted) (citing *United States v. Generix Drug Corp.*, 460 U.S. 453, 458–59 (1983); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980)).

112. Similarly, generic drug and biosimilar approvals are specific to reference listed drugs and reference products, which in turn are limited to specific FDA-approved drug or biological products. While a manufacturer can have several different drug or biological products with the same active moiety or active ingredient, the generic or biosimilar drug must match the specific drug product, including the strength, dosage form, route of administration, and conditions of use of the reference listed drug or reference product. CMS's interpretation means that multiple drug and biological products are aggregated even if only one such product could have a generic or biosimilar on the market and the others could not.

113. CMS's extra-statutory approach creates significant and irreconcilable conflicts with FDA's treatment of drug and biological products under the FDCA and the PHSA. The structure and language of those statutes' exclusivity provisions are drug- and biological-product specific, requiring FDA to determine whether exclusivity is available for any given drug product or biological product, including those submitted in certain supplements or subsequent applications.

114. For example, FDA makes drug product-specific exclusivity determinations pursuant to the FDCA. If Novo developed a new route of administration and conducted a clinical trial essential to obtaining FDA approval for that route of administration, that drug product with its new route of administration would be eligible for three years of exclusivity (and the ability to set prices during the exclusivity period without competition). *See* 21 U.S.C. § 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv); *see also* FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, ADB 1 (43d ed. 2023). Yet under CMS's approach, that new product would be

assigned price controls upon approval, undermining the value of this exclusivity and rendering FDA's careful analysis meaningless.

115. To determine whether a biological product submitted by the same sponsor in a subsequent application under the PHSA is eligible for reference-product exclusivity, FDA looks at the specific biological product—not just the active ingredient. This determination requires evaluating whether the subsequent application is for "a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength" or for "a modification to the structure of the biological product that does not result in a change in safety, purity, or potency." *See* 42 U.S.C. § 262(k)(7)(C). Only a biological product that makes a structural modification resulting in a "change in safety, purity, or potency" will be eligible for its own exclusivity period.

116. The PHSA defines a biosimilar's reference product as the "*single* biological product licensed under subsection (a) against which" the biosimilar is evaluated. *Id*. § 262(i)(4) (emphasis added). As a result, a proposed biosimilar insulin aspart product could not reference both NovoLog® and another insulin aspart product, such as FIASP®, at the same time; it would have to choose one insulin aspart biological product to reference. Moreover, the application would need to demonstrate that the biosimilar is highly similar to and has no clinically meaningful differences with the reference product (either a NovoLog® Product or a FIASP® Product). *See id*. § 262(i)(2), (k)(2)(A). That is the case no matter the active ingredient or ingredients of the reference biological product.

117. CMS's approach takes no account of the fact that different drug and biological products, often in different NDAs and BLAs, can have widely divergent clinical profiles, as well

as research and development costs and recoupment of such costs, regardless of whether they share an active moiety or active ingredient.

118. CMS's ultra vires approach consolidates distinct groups of products that Congress kept separate and condemns all future products that rely on the same active moiety or ingredient to the same government-imposed price controls, even though they are not yet on the market. The resulting inability to recoup development costs for these drug development programs will deter manufacturers from pursing these expensive endeavors, at a great cost to patients and public health.

119. CMS's approach also vitiates Congress's clear intent that certain drug products remain outside of the IRA's price control scheme—those that are excluded from coverage or otherwise restricted from coverage under § 1860D-2(e)(2) of the Social Security Act. Seemingly recognizing the conundrum of including products that the statute expressly and unambiguously prohibits, CMS has suggested that such excluded indications will not be considered in identifying therapeutic alternatives. *See* Final Guidance § 60.3.1. But that approach is particularly nonsensical for a product that has no other approved indications. CMS's interpretive pretzel-twisting highlights how its grouping of drug and biological products by active moiety and active ingredient is incompatible with a statute—and an overall regulatory paradigm—that demands decision making on a drug product- and biological product-specific basis.

2. CMS's Redefinition of Qualifying Single Source Drugs

120. In addition to transforming the meaning of drug product and biological product to impose price controls on more products than Congress authorized, CMS's guidance also uses its new ultra vires definitions to capture drug and biological products that, standing alone, could not possibly qualify as a "qualifying single source drug" ("QSSD") under the express language set forth by Congress in the statute.

121. CMS's approach of joining together all drug products or biological products with the same active moiety or active ingredient means that it is consolidating drug products approved more than 7- and 11-years earlier with those that have not been approved for the required period of time. *See* Final Guidance § 60.5.1. It also means that CMS is aggregating products approved in more than one NDA or licensed in more than one BLA.

122. As described above, CMS has included all of the FIASP® Products in an insulin aspart QSSD alongside the NovoLog® Products, even though the FIASP® Products were approved under BLA 208751, not BLA 020986 (like the NovoLog® Products) and even though ***none*** of those products have been licensed for more than 7 years, let alone the required 11. Under CMS's regime, any new, innovative medicine subsequently approved (even many years later) after a selected drug is assigned price controls will effectively be grandfathered into an MFP as of its approval date—just because it shares an active ingredient or active moiety with an older "selected" aggregation of products. That would be the case despite the novelty of the new product, including improvements that can make significant contributions to patient care (for example, by developing a tablet rather than an injection) or extend a medicine's use to a whole new disease area.

123. To be selected for price controls under the IRA, Congress made clear that a drug or biological product must first be determined to be a QSSD.

124. Under the IRA, a "drug product" or "biological product" must satisfy several criteria to fall within the statutory definition of QSSD: (a) it must be "a covered part D drug … or a drug or biological product for which payment may be made under part B," (b) it must be FDA approved (for a drug) or licensed (for a biologic), (c) it must have been approved or licensed for at least 7 years (for a drug) or 11 years (for a biologic), and (d) it must not be the reference listed

drug for an approved and marketed generic drug or the reference product for an approved and marketed biosimilar. 42 U.S.C. § 1320f-1(e).

125. CMS's guidance redefines "QSSD" to be an aggregation of all products with an active moiety or active ingredient based on the date on which the *earliest* single drug or biological product within that group was approved or licensed.

126. In this way, the agency's ultra vires approach sets up the entire family of "insulin aspart" products as a QSSD—rather than each individual insulin aspart-containing *product*, as Congress intended. And it does so based on the first licensure date of any insulin aspart product.

127. FIASP® was first approved on September 29, 2017. Under any reading of the statute's plain language, these biological products are therefore ineligible for price controls until the first initial price applicability year the selected drug list for which will be published after September 29, 2028. Yet CMS has aggregated the NovoLog® Products together, and has aggregated the FIASP® Products together, and has then further aggregated the NovoLog® and FIASP® Products together, across different BLAs, even though *none* of the FIASP® Products has been approved for the 11 years required under the statute (and even though *some* of the FIASP® Products are part *B* drugs, not eligible for negotiation for two more years).

128. Had CMS complied with the statute and Congress' express directives, Novo's insulin aspart drugs would not have been aggregated into one QSSD, and, standing alone, they would not have achieved the Medicare spend levels necessary to qualify as a top-10 spend and eligible for selection and price negotiations in IPAY 2026. Instead, under CMS's ultra vires approach, if a new product is launched, no matter the innovation, no matter the unmet need it serves—and, critically, no matter whether that product meets the statutory criteria—if it contains

the same active moiety or active ingredient as a drug subject to negotiation (owned by the same manufacturer), CMS's guidance dooms that product to its assigned "maximum fair price."

3. CMS's Extra-Statutory "Bona Fide Marketing" Standard

129. The IRA contains a clear and mandatory command that a drug or biologic product does not fit within the definition of QSSD and must be exited from the drug negotiation process whenever a generic drug or biosimilar product is "approved" or "licensed" and "marketed." 42 U.S.C. § 1320f-1(c) (noting that products that are subject to approved and marketed competition "shall not be subject to the negotiation process"). That requirement reflects Congress's clear intention that CMS has no authority to impose or maintain price controls on any products that are (or become subject to) generic or biosimilar marketed competition.

130. Rather than comply with that clear and express mandate, CMS's guidance states that it will still consider a reference listed drug or biological reference product to be a QSSD and will not exit it from the "negotiation" process, until a generic or biosimilar competitor has engaged in what CMS deems by its own lights to be "bona fide" marketing. The guidance further asserts that CMS will "continuously monitor" such marketing to determine whether ongoing "bona fide" marketing warrants continued treatment of the reference listed drug or reference product as not a QSSD. Final Guidance § 90.4. According to the guidance, CMS will review generic drugs and biosimilars "holistically" based on a "totality of the circumstances" to determine if "meaningful competition" exists before considering a generic or biosimilar to be "marketed." *Id*.

131. By changing the statutory test and expanding its powers to determine when a competitor has engaged in "bona fide" marketing of a biosimilar insulin aspart product, or whether such competitor continues to engage in such marketing on an ongoing basis—both functions that Congress did not assign to CMS and for which CMS lacks expertise—CMS's guidance exceeds the agency's statutory authority and violates the statute's mandatory commands.

132. "Commercial marketing" is a well-established term that refers to the introduction or delivery for introduction into interstate commerce of a drug product. Indeed, in Appendix C of its initial guidance, CMS defined marketing as "the introduction or delivery for introduction into interstate commerce of a drug product" (only to remove that definition in its final guidance). *See* Final Guidance, Appendix C at 194. "Marketing" is also defined in this way elsewhere in regulations. *See* 21 C.F.R. § 314.3 (defining "commercial marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant"); 21 C.F.R. § 330.14(b)(2) (describing market history requirements for inclusion in the OTC drug monograph system). CMS itself has embraced this understood meaning of "marketing" in other contexts. *See* CMS, Medicare Part B Inflation Rebates Paid by Manufacturers: Initial Memorandum § 50.3 (Feb. 9, 2023) (proposing that a product is "marketed" upon the "date of first sale" that a manufacturer must report).

133. The timing and specific data identified in the guidance that CMS intends to use to calculate "bona fide marketing" also violates the statute and far exceeds what the statute authorizes. CMS has indicated that it will look at the "totality of the circumstances," including both Prescription Drug Event ("PDE") data and Average Manufacturer Price ("AMP") data reported by manufacturers, to determine whether and when a biosimilar is marketed—and that it will consider data only from August 16, 2022, to August 16, 2023. But AMP data may not even exist for a generic or biosimilar competitor, for example if it is not a participant in the Medicaid Drug Rebate Program. The statute does not require that the biosimilar have been marketed only during that window, and there is often a lag with PDE data, as formulary access can take months and mid-year formulary changes for biosimilars are often delayed. *See* CMS, Part D Requirements

for Biosimilar Follow-On Biological Products, at 1–2 (Mar. 30, 2015); Medicare Prescription Drug Benefit Manual, ch. 6, § 30.3.3 (rev. Jan. 15, 2016) (regarding midyear formulary changes).

134. In any event, how CMS will apply this ambiguous and made-up standard is fatally unclear. And because CMS has refused to follow proper notice-and-comment procedures, it has not responded adequately to comments or provided any meaningful indication of how it intends to evaluate when a product is subject to bona fide competition. The lack of transparency and accountability only further underscores the problems with CMS's extreme statutory violations and departures.

135. The consequences of CMS's extra-statutory approach will be to destabilize the regulatory landscape and strip away predictability with the threat that a product may or may not be subjected to price controls, year in and year out, depending on the whims of the agency. With competition from biosimilars to NovoLog® anticipated imminently, these challenges are particularly acute for Novo.

4. CMS's Extra-Statutory Information Requirements

136. CMS's guidance is also unlawful and far in excess of CMS's statutory authority because it seeks to impose new substantive obligations on manufacturers without complying with required notice-and-comment rulemaking procedures.

137. The IRA is constitutionally problematic because it includes inadequate processes to protect the line between CMS as a regulator and CMS as a market participant. That concern is particularly acute with respect to the extensive data and information that manufacturers must disclose to CMS, including trade secret and other confidential and proprietary information that Novo would not ordinarily reveal publicly or share with another market participant or potential contracting counterparty, all "in a form and manner specified by the Secretary." *Id.* § 1320f-2(a)(4). Manufacturers must provide this information under the threat of *one million dollar-per-*

day penalties if CMS believes that they have not timely provided all the information that the government has demanded. *Id.* §§ 1320f-2(a)(4)–(5), 1320f-6(b).

138. CMS's guidance exacerbates these problems by, on one hand, imposing additional data-sharing requirements that are not included in the statute, are internally inconsistent, and often are borderline nonsensical, while on the other hand, refusing to consider relevant costs incurred by manufacturers and limiting what information manufacturers may provide. CMS's additional requirements are set forth both in 11 pages of the guidance (appendix C) and as an information request.

139. For example, CMS has broken the statutory requirement to report "research and development costs of the manufacturer for the [selected] drug and the extent to which the manufacturer has recouped research and development costs" into five unique sub-elements (e.g., "R&D: Basic Pre-Clinical Research Costs"), all of which include additional definitions, instructions, and de-facto sub-requirements. "Costs of production" are divided into four sub-elements; "costs of distribution" into four sub-elements; and "unit costs of production and distribution" an additional five sub-elements. In addition, CMS proposes to require that manufacturers report eight distinct product price points, not all of which are defined by the IRA, any other law, or otherwise required to be devised or reported by manufacturers (e.g., "U.S. commercial average net unit price ─ without patient assistance program"). *See* Final Guidance Appendix C.

140. CMS's guidance also creates distinctions between manufacturers that are found nowhere in the statute. For instance, if a so-called Secondary Manufacturer markets a selected drug, the so-called Primary Manufacturer must gather from its competitor this sensitive information and provide it to the government.

141. CMS's guidance also limits what information and in what form manufacturers are permitted to provide as part of the "negotiation," CMS has claimed that it is free to ignore costs that manufacturers have incurred in developing their medications, and CMS has indicated that when deciding what drugs to include on its list, it will consider only gross prices, without taking into account the actual discounts that manufacturers provide.

D. CMS's New Price Control Regime Is Not Voluntary

142. CMS has asserted that manufacturers, like Novo, have no basis to object to the statute and the extra-statutory requirements that CMS has invented and imposed on the view that the "negotiation" process and price-control program is purportedly "voluntary." That is not correct.

143. Even if the program were voluntary, manufacturers cannot be required to relinquish their constitutional rights—including their rights to due process and free speech—as a condition of participating in government programs.

144. Nor may the government take over a large segment of the market, displacing private market participants, and then demand that parties relinquish their constitutional rights as a condition of continuing to sell their products in interstate commerce. While the government has limited authority under its procurement powers when serving as a market participant to decide what price it will pay for products purchased by the government for the government itself, the government has no authority to abuse those powers to regulate the sale of products across markets and impose regulatory burdens on private parties that would otherwise be constitutionally impermissible. Executive agencies cannot escape the bounds of the Constitution by legally or economically coercing private parties into participating in government programs.

145. Withdrawing *all* of a manufacturer's drugs from federal healthcare programs is neither a practical nor viable option. Because Medicare and Medicaid dominate the healthcare market, no major manufacturer could afford to withdraw all of its drugs from the federal programs.

146. Nor would the government actually want manufacturers to do so. Withdrawal of the entirety of a manufacturer's portfolio of drugs from the federal healthcare programs would place vulnerable patients at risk, as access to important medications by those patient populations would be greatly inhibited or eliminated. If enough manufacturers were to withdraw, Medicare and Medicaid patients would quickly run out of therapeutic options. Withdrawing from the federal healthcare programs would also dramatically impact manufacturers' financial ability to invest in researching and developing innovations on existing therapies, as well as wholly new therapies and other life-saving medications.

147. Even if a manufacturer wanted to withdraw, it has no ability under the statute to do so in a timely fashion to avoid the excessive "excise tax" penalty. For example, it takes 11 to 23 months, depending on the timing during the calendar year, for a notice of withdrawal from a Medicare Part D Coverage Gap agreement to take effect. Under the statute, the manufacturer has no way of avoiding this debilitating penalty—other than by "agreeing" to "negotiate"—confirming the involuntary nature of the "agreement."

148. CMS's guidance asserts that the agency will permit a manufacturer to withdraw from Medicare Part D within 30 days. *See* Final Guidance § 40.1. But that also rewrites the statute—confusing when CMS has authority to exit a manufacturer for good cause, and when a manufacturer is entitled to leave the program at its own discretion. The agency has no statutory basis to make that change, and even if it could, manufacturers cannot rely on CMS's assertions

since they are reflected only in guidance without following the procedures necessary to create binding rules and regulations.

BASIS FOR INJUNCTIVE RELIEF

149. Harm is irreparable when it cannot be undone through monetary remedies. "[I]n instances where the injured parties cannot recover monetary damages after the fact, even purely economic harm is considered irreparable." *N.J. Staffing All. v. Fais,* No. 1:23-cv-02494, 2023 WL 4760464, at *6 (D.N.J. July 26, 2023) (quoting *ITServe All., Inc. v. Scalia*, No. 20-14604, 2020 WL 7074391, at *9 (D.N.J. Dec. 3, 2020)). Accordingly, when damages are not recoverable because a government defendant enjoys sovereign immunity from monetary damages, irreparable harm generally exists. *See Temple Univ. v. White*, 941 F.2d 201, 214 (3d Cir. 1991); *see also Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam) ("The moratorium [on collecting rent during COVID-10 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery."). In addition, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Amalgamated Transit Union Loc. 85 v. Port Auth.*, 39 F.4th 95, 107–08 (3d Cir. 2022) (citing *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

150. Forcing Novo to be subjected to an unconstitutional and one-sided "negotiation" process for drug products that are not properly subject to price controls under the plain terms of the statute enacted by Congress would impose irreparable harm. Moreover, if CMS's unlawful price-control scheme is not enjoined as applied to Novo, Novo faces potential devastating unrecoverable economic harms as a result of having its six insulin aspart products subject to government-imposed price controls.

151. Granting an injunction would not harm CMS. CMS has no interest in violating the statute or violating constitutional requirements. The balance of interests strongly weighs in favor of Nov because the hardship imposed on CMS by an injunction is only that it "obey the law," including complying with constitutional requirements and the limits that Congress imposed in the statute. *See ARCHforensic, LLC v. Arch Eng'g, LLC*, No. 21-16022, 2023 WL 2662584, at *5 (D.N.J. Mar. 28, 2023) (quoting *Malibu Media, LLC v. Toshi Yamada*, No. 17-1183, 2019 WL 1586813, at *3 (D.N.J. Apr. 12, 2019)). The public interest also weighs strongly in favor of maintaining the status quo, enforcing the Constitution, and striking down ultra vires agency action that violates clear and express statutory mandates

CLAIMS FOR RELIEF

COUNT I

(Challenge to the Statute: Separation of Powers and Due Process)

152. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

153. The first three articles of the Constitution provide for the separate roles of each branch of the federal government. Article I vests "[a]ll legislative Powers" in the "Congress of the United States." U.S. Const. art. I, § 1. Article II vests the power to implement the laws in the President. Article III vests the power to interpret the laws in the courts.

154. This separation of powers is critical to the systems of checks and balances that is an essential part of our constitutional democracy. When Congress fashions statutory programs, in order to comply with separation of powers principles, it must articulate "intelligible principle[s]" to guide and constrain the executing agency administering such programs. *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality op.) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

155. The Supreme Court has invalidated statutes that confer "virtually unfettered" discretion on the executive branch—including by creating massive new regulatory schemes without appropriate guidance, standards, or guardrails. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935); *see also Pan. Refining Co. v. Ryan*, 293 U.S. 388 (1935).

156. The Supreme Court has also made clear that Congress may not remove multiple layers of constitutional safeguards necessary to protect separation of powers. *See Seila Law*, 140 S. Ct. 2183; *Free Enter. Fund*, 561 U.S. 477. A very broad delegation of powers to an executive branch agency might be constitutionally permissible if the agency operates with tolerably fair procedures and there are meaningful opportunities for regulated parties to obtain judicial review. But Congress cannot—as it does in the case of the IRA's price control provisions—delegate sweeping powers to an agency and then remove the time-tested procedural safeguards necessary to ensure that those powers are appropriately exercised, including the essential requirements of complying with public notice and comment rulemaking procedures and ensuring adequate opportunities for judicial review.

157. Separation of powers is fundamental because it protects the public interest and the private rights of individuals, including their essential rights to due process of law.

158. Under the Fifth Amendment's Due Process Clause the government may not deprive a person of property without first following constitutionally sufficient procedures. *See Ky. Dep't of Corr. v. Thompson*, 490 U.S. 454, 460 (1989). Those procedures include 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), as well as other procedural protections that work to prevent, to the extent possible, an erroneous deprivation of property. *See Gilbert v. Homar*, 520 U.S. 924, 930–32 (1997).

159. A price-control statute violates the Due Process Clause if it does not "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return," which includes "a fair and reasonable rate of return on investment." *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 593 (6th Cir. 2001); *see also Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508 (9th Cir. 1990), *as amended* (Nov. 8, 1990) (invalidating statute freezing insurance rates). "[D]ue process *guarantees* a fair and reasonable regulatory rate, not just the *possibility* of acquiring such a rate from an authority selecting rates within a prescribed range containing confiscatory and fair rates." *Michigan Bell*, 257 F.3d at 595 n.4 (emphasis added).

160. In the context of price-control laws, the Supreme Court has long held that a "[p]rice control is 'unconstitutional ... if arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt.'" *In Re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968) (quoting *Nebbia v. New York*, 291 U.S. 502, 539 (1934)). Government-set prices must at least be "just and reasonable." *Id.* (citing *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 586 (1942)). Absent "adequate safeguards"—statutory standards, notice-and-comment procedures, and judicial review—there is not just insufficient protection against the "imposition of confiscatory rates," *Michigan Bell*, 257 F.3d at 594, there is no protection at all.

161. The IRA is a massive new price-setting scheme and an exercise of significant "policy discretion," with potentially massive consequences for industry, patients, and innovation. *See DOT v. Ass'n of Am R.Rs.*, 575 U.S. 43, 78–81 (2015) (Thomas, J., concurring) (discussing *Marshall & Field & Co. v. Clark*, 143 U.S. 649 (1892)). It centralizes vast power over our nation's healthcare system in the hands of an administrative agency, but it provides none of the safeguards necessary to ensure separation of powers or to protect due process. It includes no statutory standard requiring just and reasonable prices, delegating all critical decisions to CMS; it lacks

adequate procedures for implementing the statutory price controls; and it expressly prohibits judicial review of CMS's unilateral price determinations.

162. The Secretary's price controls will have a profound effect on private interests. Medicare and Medicaid patients may be deprived of access to life-saving medications and the program will have significant consequences for all patients who depend on research and development necessary for identifying new and innovative treatments, especially for rare and chronic diseases. Manufacturers *have and will* suffer significant losses—even the IRA's ceiling for "negotiations" is well below market prices, and the IRA directs the Secretary to go lower than that "to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1). Manufacturers have constitutionally protected property interests in their patent rights and their investment-backed expectations to be free from price controls that are "arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt." *In re Permian Basin Area Rate Cases*, 390 U.S. at 769–70 (quoting *Nebbia*, 291 U.S. at 539). The IRA takes away those property interests, without affording manufacturers a meaningful opportunity to be heard, and does so without putting in place any safeguards to prevent CMS from imposing confiscatory rates.

163. Moreover, while it is misleadingly labeled a "negotiation" process, suggesting that the prices should be seen as the result of open negotiations between the government and manufacturers, that is a lie. The IRA's "negotiation" process is a sham. The statute forces manufacturers to agree to whatever "maximum fair prices" that CMS unilaterally imposes and, if they do not agree, saddles them with massive penalties that are so large that no manufacturer could ever afford to pay them (as even the Congressional budget office has acknowledged, forecasting that the statute's "excise tax" will generate exactly zero dollars in revenues, *see* CBO, How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation

Act (Feb. 2023), https://www.cbo. gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.). The government cannot seize control of almost half of the nation's healthcare markets, force market participants to relinquish their constitutional rights as a condition of selling their products or else face excessive debilitating penalties, and then pretend that manufacturers can simply avoid that "gun to the head" by withdrawing completely from the federal markets and leaving millions of Americans deprived of critical, life-saving medications.

164. If that were not enough, the IRA guarantees no return at all—let alone requires the agency to meet the constitutional minimum of a "fair and reasonable return on investment." *Michigan Bell*, 257 F.3d at 595 n.3 (quotation marks omitted). Instead of reasonable procedures, the IRA deprives drug manufacturers of their constitutionally protected property interests in and their investment-backed expectations without procedural safeguards, directing the Secretary to fix prices at the "lowest" level. While the agency is supposed to "consider," among other unspecified "factors," information from the manufacturer such as "unit costs"; "[r]esearch and development costs ... for the drug" (including "the extent to which the manufacturer has recouped [them]"); and "revenue and sales volume data," 42 U.S.C. § 1320f-3(e), the agency has acknowledged that the statute does not tell it *how* it should consider those factors. While trying to create an illusion of fairness with the label "maximum fair price," the IRA grants CMS authority to choose any price it likes and to call it the "maximum fair price." The IRA establishes an across-the-board *ceiling* well below market prices, *see id*. § 1320f-3(c)(1)(C), (b)(2)(F), and directs CMS to aim for "the lowest" price below that ceiling, *id.* § 1320f-3(b)(1).

165. In addition to undermining manufacturers' ability to set their own prices, the IRA also undermines manufacturers' ability to recoup investments and meet their reasonable investment-backed expectations that they will be able to sell their drugs at a reasonable price.

166. CMS's implementation exacerbates these problems, adding administrative insult to the statute's constitutional injuries. The agency's approach prevents manufacturers from recouping the large investments made in drug and biologic products that were not ultimately brought to market or were related to improving patients' lives beyond the minimum required for FDA approval. In addition, the agency's extra-statutory aggregation of all drug products with the same active moiety and biological products with the same active ingredient means that manufacturers will not recoup marginal costs for innovations made to existing products, nor even reap the statutorily conferred benefits of regulatory exclusivity. Indeed, a drug product that is not yet approved and is currently being subjected to substantial research and development costs in a company's clinical program may be unable to achieve the recovery of virtually any of these costs if it contains the same active ingredient or moiety as a previously selected QSSD and will be subjected to a previously set MFP right out of the gate.

167. Because the overall arrangement results in a violation of the separation of powers and due process, the IRA is unconstitutional and should be enjoined.

COUNT II

(Challenge to the Statute: First Amendment)

168. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

169. The First Amendment provides that "Congress shall make no law ... abridging the freedom of speech." U.S. Const. amend. 1.

170. The First Amendment protects not only the right to speak but it also protects the right to refrain from speaking. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977).

171. Compelled speech may be even more objectionable than censorship. Forced speech coerces the speaker "into betraying their convictions." *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018).

172. The First Amendment prohibits the government from compelling private businesses to espouse the government's favored viewpoints. Yet that is precisely what the IRA does. The IRA requires manufacturers not only to submit to government-set confiscatory prices, but it also requires manufacturers to say that they entered into "negotiations" and "agreed" to those prices and to endorse those prices as the "maximum fair price." These requirements compel manufacturers to express their agreement that the Secretary's confiscatory price is "fair" and that no price higher could also be fair. That "involuntary affirmation" is compelled speech.

173. Laws that compel private speech are presumptively unconstitutional and may stand only if narrowly tailored to serve compelling interests.

174. The IRA's speech provisions do not serve a compelling state interest. The government has no compelling reason to mandate this speech other than to shield itself from criticism by obscuring this confiscatory pricing regime as voluntary negotiations.

175. Nor are these requirements narrowly tailored. Congress could have authorized CMS to set prices without dictating that the process be called a "negotiation" whereby the parties "agree" to a "maximum fair price."

176. The IRA's compelled-speech provisions are therefore unconstitutional under the First Amendment and should be enjoined.

COUNT III

(Challenge to CMS's Actions:
Violation of the Administrative Procedure Act
and Social Security Act)

177. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

178. The procedures required by both the APA and the Social Security Act are grounded in the Constitution. They protect citizens' due process and equal protection rights, by ensuring that citizens have fair notice of what the law requires, and that agency decision-making is not

arbitrary or capricious. In short, the "fundamental notions of fairness implicit in due process and with the ideal of reasoned decisionmaking … undergird[] all of our administrative law." *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 56 (D.C. Cir. 1977).

179. Under the APA, an agency may not employ guidance to impose new substantive obligations on regulated parties. Courts have characterized agency guidance and policy statements as "musings"—agency statements about how the agency may act in the future that are "no more subject to review than a press release." *Columbia Broad. Sys., Inc. v. United States,* 316 U.S. 407, 422 (1942) *see also Nat'l Mining Ass'n v. McCarthy,* 758 F.3d 243, 252 (D.C. Cir. 2014). Guidance documents, like other policy statements and interpretive rules, are "not supposed to 'have the force and effect of law'—or, otherwise said, to bind private parties." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (quoting *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015)). They "are meant only to 'advise the public' of how the agency understands, and is likely to apply, its binding statutes and legislative rules." *Id.* (quoting *Perez*, 575 U.S. at 97).

180. The D.C. Circuit has reasoned that "it is a considerable leap from concluding that [CMS] has considerable contractual discretion to concluding that the agency has received a blank check from Congress to adopt any contractual provision whatsoever without undertaking notice and comment review ... any contract provisions that are legislative are subject to § 553's notice and comment requirements." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987); *Cal-Almond, Inc. v. Dep't of Agric.*, 14 F.3d 429, 446–47 (9th Cir. 1993); *see also Nat'l Ass'n of Psychiatric Treatment Ctrs. for Child. v. Weinberger*, 658 F. Supp. 48, 54 (D. Colo. 1987) (holding APA applied to agency attempt to make "prescriptive changes in overall contents of all participation agreements … [that] amount[ed] to policy changes of significant import").

181. When an agency imposes substantive obligations that go beyond a statute's express requirements—that is, when an agency seeks to adopt "legislative rules"—the agency must comply with rulemaking procedures with an opportunity for public notice and comment. *See Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992) (explaining that "legislative rules" are those agency actions that "'create new law, rights, or duties'" (quoting *United Techs. Corp. v. EPA*, 821 F.2d 714, 718 (D.C. Cir. 1987))). As courts have explained, those bedrock procedural requirements are essential to avoiding arbitrary decision-making when an agency is exercising a quasi-legislative rulemaking function. *See Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 170–71 (7th Cir. 1996); *see also Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 495 (D.C. Cir. 2010). These requirements—as reflected in both the APA, *see* 5 U.S.C. § 553 *et seq*., and the Social Security Act, *see* 42 U.S.C. § 1395hh(a)(2)—are designed to help "secure the values of government transparency and public participation," *Iowa League of Cities v. EPA*, 711 F.3d 844, 873 (8th Cir. 2013), by ensuring that agencies provide reasoned explanations for their decisions after evaluating and responding to comments. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019).

182. The IRA directs CMS to implement the statute's unprecedented provisions on a gradual basis, first through program instruction and policy guidance, *see* IRA, Pub. L. No. 117-169, §§ 11001(c), 11002(c), 136 Stat. 1818, 1833–62. Congress thus expressed its intent that CMS would hew very closely to the statute's provisions and issue guidance that does not impose new substantive obligations on regulated parties. Nothing in the IRA indicates that Congress relieved CMS of its obligations to comply with proper rulemaking procedures if it seeks to impose obligations on regulated parties that go beyond the statute and bear the force and effect of law.

183. Where (as here) private rights are at stake, an agency cannot exercise rulemaking powers and simultaneously escape the constitutional procedures required to promulgate rules

through proper procedures. That is true no matter what political exigencies might have driven Congress to favor a rapid implementation of its policies. An agency cannot avoid rulemaking procedures by "the simple expedient of call[ing]" its actions "mere statements of policy." *Allina*, 139 S. Ct. at 1811 (quotation marks omitted); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022–24 (D.C. Cir. 2000). Nor do statutory deadlines on their own qualify as "good cause" for avoiding public notice-and-comment procedures. *See Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998); *Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1381 (Fed. Cir. 2017). Especially in light of the constitutional concerns that arise whenever an agency engages in a legislative rulemaking function, notice and comment procedure may be waived only when a delay would result in "real harm." *Nat. Res. Def. Council, Inc. v. Evans*, 316 F.3d 904, 911 (9th Cir. 2003) (quoting *Haw. Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995)).

184. These concerns are particularly acute where, as here, an agency makes clear that its new substantive rules will bind regulated parties. CMS's template agreement turns its already impermissible guidance into a hammer: it is a unilateral contract that binds one party (the manufacturer) to open-ended terms that the other party (CMS) can change on a whim, without notice and comment and without judicial review. As provided in the Template Agreement, a manufacturer must agree that it "shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations." Template Agreement at 3. In the Agreement, CMS states that it "retains authority to amend this Agreement to reflect changes in law, regulation, or guidance" at any time. *Id.* at 4. Offering little more than cold comfort, CMS provides that it will give a manufacturer 60-day notice of such a change "[w]hen possible." *Id.*

185. Manufacturers should not be required to sign an Agreement that requires them to adhere to otherwise non-binding guidance, particularly non-binding *future* guidance. These sorts of form agreements should "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them ...[; they] contain no negotiable terms." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011).

186. CMS's final guidance and template agreement are unlawful because they impose substantive requirements in addition to the statute's requirements and make plain CMS's intent to bind manufacturers to substantive obligations not subject to notice and comment rulemaking, and they should be enjoined.

COUNT IV

(Challenge to CMS's Actions:
Ultra Vires and Unlawful Conduct)

187. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

188. An executive agency's powers are limited to those delegated by Congress. Because an agency has no power to act unless Congress confers power upon it, an agency's actions are ultra vires whenever it exceeds the scope of its delegated powers. *See City of Arlington*, 569 U.S. at 299; *see also La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) (explaining that "an agency literally has no power to act … unless and until Congress confers power upon it"); *United States v. Cortez*, 930 F.3d 350, 357 (4th Cir. 2009) (noting that "*any* 'improper[]' agency action is 'ultra vires'" (quoting *City of Arlington*, 569 U.S. at 297). An agency's actions are ultra vires when it "patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute." *Hunter v. FERC*, 569 F. Supp. 2d 12, 16 (D.D.C. 2008) (citing *Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988)).

189. That is precisely what CMS has done here. Despite the IRA's already unprecedented price-control provisions (which on their own violate multiple constitutional requirements), CMS has ignored even those provisions and has rewritten the statute to reach more drug and biological products and to acquire more authority than the statute permits.

190. There are many examples where CMS's final guidance and template agreement not only impose substantive obligations on manufacturers without complying with proper procedures, but also impose requirements far outside the scope of any authority granted by Congress.

191. Chief among them is CMS's approach to defining "drug product" and "biological product" in order to vastly expand the reach and breadth of products subject to price controls. CMS's guidance rewrites the definitions of "QSSD," and, in turn, "negotiation-eligible drug," in ways that violate express statutory commands, while simultaneously refusing to consider any public comment on its new definitions.

192. The IRA imposes a discrete limit on the number of "drug products" and "biological products" subject to price controls, with a slow and deliberate escalation over time. Under CMS's aggregation approach, however, many more than the 10 drug and biological products permitted by the statute are subject to price controls beginning in IPAY 2026, including six from Novo alone. Many of those products would not otherwise be eligible for negotiation, including because they have not been marketed for the requisite 7- or 11-year period. *See* Final Guidance §§ 30.1, 60.5.1.

193. The statute does not permit groupings of products by active moiety or active ingredient. It also does not permit selection of all insulin aspart products as a single product, nor does it authorize CMS to undertake the definitional gymnastics necessary to make sense of such a formulation. The NovoLog® Products and the FIASP® Products are different, with distinct biological products approved in a different BLAs, and developed with separate formulations at

different times and with different sets of development and production costs. These individual products do not satisfy the statutory criteria for being subject to the IRA's price controls.

194. CMS has no authority to combine Novo's six different insulin aspart products and subject them to price controls under the IRA. Because CMS's guidance and its decision to select Novo's products for price controls violate express statutory mandates and exceed the scope of its authority granted by Congress, CMS's actions are manifestly contrary to law and ultra vires, and should be enjoined.

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court:

A. Declare that the IRA's drug price control program violates the Constitution's separation of powers;

B. Declare that the IRA's drug price control program violates the Due Process Clause of the Constitution's Fifth Amendment;

C. Declare that CMS's Guidance and Template Agreement, finalized on June 30, 2023, violate the APA and SSA;

D. Declare that the CMS's final revised guidance is invalid, unconstitutional, ultra vires, and/or unenforceable;

E. Declare that Novo's products have been improperly aggregated and are not properly subject to price controls under the statute;

F. Enjoin CMS from implementing the IRA's drug price control program;

G. Enjoin CMS from extending the scope of the IRA's drug price control program by considering multiple drug products or multiple biological products to be a single "drug," QSSD, or negotiation-eligible drug;

H. Enjoin CMS from applying price controls to any of Novo's products that are improperly aggregated and as individual products do not meet the statutory requirements to be subject to price controls;

I. Award Plaintiffs reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

J. Grant such other and further relief as the Court may deem appropriate.

Dated: September 29, 2023

Respectfully submitted,

/s/ Israel Dahan

Israel Dahan (NJ Bar No. 042701997)
KING & SPALDING LLP
1185 Avenue of the Americas, 34th Floor
New York, NY 10036
Telephone: (212) 556-2114
Facsimile: (212) 556-2222
idahan@kslaw.com

Ashley C. Parrish
(application for *pro hac vice* forthcoming)
John D. Shakow
(application for *pro hac vice* forthcoming)
Eva A. Temkin
(application for *pro hac vice* forthcoming)
KING & SPALDING LLP
1700 Pennsylvania Avenue NW, Suite 900
Washington, D.C. 20006
Telephone: (202) 737-3945
Facsimile: (202) 626-3737
aparrish@kslaw.com
jshakow@kslaw.com
etemkin@kslaw.com

Counsel for
Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.