IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENENTECH, INC.,
1 DNA Way
South San Francisco, CA 94080,

Plaintiff,

v.

DOROTHY FINK, in her official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201,

and

DIANA ESPINOSA, in her official capacity, and HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

Civil Action No. 1:25-cv-290

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Under the federal 340B Drug Pricing Program, certain health care facilities receive greatly reduced prices on prescription medications. Among the list of entities eligible for this valuable benefit are clinics that treat sexually transmitted diseases (STDs) using grant funding obtained from state or local governments. To prevent abuse of the program, Congress requires the U.S. Department of Health and Human Services (HHS) to certify—and to recertify annually—the eligibility of all such clinics in accordance with a statutorily defined process. This case concerns the agency's failure to lawfully perform that mandatory task. For years, the agency has been certifying (and repeatedly recertifying) supposed STD clinics that do not meet the statutory criteria. As a result, millions of dollars have improperly been funneled to ineligible entities. The agency's unlawful certifications and recertifications contravene the governing statute and the agency's own rules, and this Court should set them aside.

2. Section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. § 256b, commonly known as the 340B program, caps the prices that manufacturers can charge for outpatient medications sold to several categories of health care facilities, called "covered entities."

3. One category of covered entity includes providers that receive "funds . . . through a State or unit of local government" under certain federal grants "relating to treatment of sexually transmitted diseases." 42 U.S.C. § 256b(a)(4)(K). These STD subgrantees may gain access to the 340B program only after "certification" of eligibility by the Health Resources and Services Administration (HRSA), the sub-agency that administers the program. *Id.* § 256b(a)(7)(A). HRSA also must "recertif[y]" the eligibility of these covered entities on an annual basis. *Id.* § 256b(a)(7)(E). The process for both certification and recertification is specified by statute. *See id.* § 256b(a)(7).

4. However, HRSA has repeatedly certified (and later recertified) numerous covered entities that purport to be STD subgrantees, yet are ineligible to participate in the 340B program for one or more of the following reasons:

a. Although these entities claim eligibility as STD clinics, in fact, some exclusively practice rheumatology, dermatology, or other types of medicine unrelated to STD treatment. They have nonetheless received millions of dollars in 340B-priced medicines that lack any indications for STDs, including from Plaintiff Genentech, Inc. (Genentech).

b. Some entities regularly transfer 340B-priced medicines to "person[s] who [are] not . . . patient[s] of the entity," *id.* § 256(a)(5)(B)—*i.e.*, to individuals who are *not* receiving STD-related treatment. That violates a statutory condition for maintaining 340B eligibility. *See id.* § 256b(a)(4).

c. Some supposed STD subgrantees receive no direct funding from state or local governments under STD treatment and prevention grants. Instead, they receive contributions *only from other subgrant recipients*, rendering them (at best) extra-statutory *sub*-subgrantees.

d. Some entities receive only in-kind contributions of goods and services, rather than grant "funds" as the statute requires, 42 U.S.C. § 256b(a)(4)(K). Many of these entities have claimed 340B eligibility—and millions of dollars in price reductions—merely based on their receipt of small quantities of condoms or marketing materials.

For all of these certifications, HRSA has either failed to require "that an entity . . . submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's

subsequent purchases of covered outpatient drugs at discounted prices" or failed to properly deny certification or recertification based on such information. *Id.* § 256b(a)(7)(B); *see id.* § 256b(a)(7)(E).

5. Sagebrush Health Services (Sagebrush), a Nevada company, epitomizes abuse of the 340B program by supposed STD subgrantees, including through its extensive purchasing of product from Genentech. HRSA has certified and recertified dozens of "subdivisions" of Sagebrush as supposed 340B-eligible STD clinics, allowing them to obtain reduced prices on Genentech medicines that do not treat or prevent STDs. Yet each of these entities is ineligible for the program for one or more of the reasons listed above: They use 340B-priced drugs to provide rheumatology, dermatology, or other services not within the scope of an STD grant; they transfer 340B-priced drugs to individuals for purposes other than STD treatment; they are sub-subgrantees that receive contributions from Sagebrush, not from any government entity; and/or they receive only in-kind contributions like condoms, not grant funds.

6. This action challenges HRSA's decisions to certify and recertify eleven Sagebrush "subdivisions" that are ineligible for the 340B program: (1) Fire Mesa ID, (2) Rainbow Rheumatology, (3) Southington Clinic - CT, (4) Centennial SACI, (5) Hummingbird Medical Group, (6) Dr. Ann Wierman, MD, (7) Danbury Rd Clinic, (8) Eastern Rheumatology, (9) Battleborn Health Care, (10) Southbury Clinic - CT, and (11) Reno Clinic.

7. From 2022 to 2025, these eleven Sagebrush subdivisions, which appear to be for-profit entities, sought and obtained $8,613,312 in 340B price reductions on Genentech medicines. None of the Genentech medicines that the Sagebrush entities purchased at 340B prices treat or prevent STDs, so *all* of those purchases are unrelated to STD treatment, *and* all transfers of such drugs are to non-340B patients. After wrongfully obtaining Genentech medicines at reduced 340B

prices, the Sagebrush entities can then bill insurers for the full price of those products, generating additional revenue for themselves.

8. HRSA's certifications and recertifications of these eleven entities are final agency actions that are arbitrary, capricious, and not in accordance with law, and that exceed the agency's statutory authority. HRSA may not certify or recertify entities that are statutorily ineligible for the 340B program. The Court should set aside the agency's unlawful certifications and recertifications of these ineligible entities and enjoin the agency from certifying or recertifying these entities in the future.

JURISDICTION AND VENUE

9. This action arises under, and asserts violations of, the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*., and Section 340B of the PHS Act, 42 U.S.C. § 256b. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, and 5 U.S.C. §§ 701-06. 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. §§ 2201-02 and 5 U.S.C. §§ 705-06.

10. HRSA's certification or recertification of an entity as a "covered entity" under the 340B program is a final agency action that is judicially reviewable under the APA. *See* 5 U.S.C. §§ 704, 706.

11. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities; at least one defendant is located in this district; and a substantial part of the events or omissions giving rise to the claim occurred in this district.

PARTIES

12. Plaintiff Genentech, Inc. is a Delaware corporation with a principal place of business in South San Francisco, California. Genentech participates in the 340B program.

13. Defendant Dorothy Fink is the acting Secretary of the U.S. Department of Health and Human Services. She has ultimate responsibility for oversight of the activities of HRSA, including with regard to the administration of the 340B program and the actions complained of herein. She is being sued in her official capacity only. Acting Secretary Fink maintains an office at 200 Independence Avenue, S.W., Washington, DC 20201.

14. Defendant HHS is an executive department of the United States government that is responsible for HRSA and the 340B program. HHS is headquartered in Washington, D.C.

15. Defendant Diana Espinosa is the Principal Deputy Administrator of HRSA and the current most senior official at that agency. Currently, Principal Deputy Administrator Espinosa has ultimate responsibility for HRSA's Office of Pharmacy Affairs and its administration of the 340B program, among other duties. She is being sued in her official capacity only. Principal Deputy Administrator Espinosa maintains an office at 5600 Fishers Lane, Rockville, MD 20857.

16. Defendant HRSA is an administrative agency of the United States government within HHS. It is the division of HHS charged with administering the 340B program. HRSA is headquartered in Rockville, Maryland.

FACTUAL ALLEGATIONS

A Provider That Receives STD Grant Funds Through a State or Local Government May Be Certified by HRSA as a Covered Entity Eligible for 340B Pricing

17. Section 340B of the PHS Act "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide health care to certain underserved populations. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 31

(D.D.C. 2014) (quoting *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011)). As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. *See* 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified reduced price "if such drug is made available to any other purchaser at any price." *Id.*

18. Section 340B defines "covered entity" to include fifteen carefully drawn categories of health care providers. *Id.* § 256b(a)(4)(A)-(O).

19. Eligibility to participate in the 340B program confers an extremely valuable financial benefit on covered entities, which use the program to generate "extra revenue from serving insured patients: they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023); *see Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024) (covered entities generate revenue from the "spread between the discounted price and the higher insurance reimbursement rate"). The ability to earn arbitrage revenue gives covered entities "a financial incentive to catalog as many prescriptions as possible as eligible for [a 340B] discount." *Id.* Congress accordingly defined the specified types of covered entity "with a high degree of precision," maintaining a narrow scope for the program to assure its integrity and minimize abuse. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021).

20. Of particular relevance here, one category of eligible covered entity is "[a]n entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or

unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph [(a)](7)" of the statute. 42 U.S.C. § 256b(a)(4)(K).

21. The phrase "under section 247c of this title" refers to Section 318 of the PHS Act, 42 U.S.C. § 247c, which authorizes the Secretary to make "grants" to States, local government units, and other entities for the prevention, control, and treatment of STDs.

22. The phrase "under . . . section 247b(j)(2) of this title" refers to former Section 317(b)(2) of the PHS Act, which was repealed after Section 340B was enacted. HRSA now interprets that phrase as referring to entities receiving tuberculosis treatment grants from the Centers for Disease Control and Prevention (CDC) under Section 317E(a) of the PHS Act, 42 U.S.C. § 247b-6(a).[1]

23. STD grantees were the fastest-growing category of covered entities in 2023, with a 38% increase in 340B purchasing over the previous year and a total of $1.66 billion in reduced-price purchases. Adam Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html.

24. Recognizing that STD grantees pose a special risk of abusing the 340B program, Congress imposed additional requirements applicable to those entities in the 340B statute. Paragraph (a)(7) of Section 340B directs HHS to establish "a process for the certification of" STD grantees that apply for 340B eligibility. *Id.* § 256b(a)(7)(A). The agency must make these "criteria for certification" available to manufacturers. *Id.* § 256b(a)(7)(C).

[1] This action does not challenge HRSA's interpretation of § 256b(a)(4)(K) as referring to Section 317E grants; Genentech reserves the right to raise such a challenge in the future.

25. The certification process "shall include a requirement that an entity applying for certification … submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices." *Id.* § 256b(a)(7)(B). And the annual recertification process for STD grantees "shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities." *Id.* § 256b(a)(7)(E). Consistent with that statutory command, HHS guidance requires States to certify that covered entities receive grant funds and requires PHS directors annually to compile a list of covered entities and an estimate of each entity's covered drug purchases within the preceding fiscal year. 58 Fed. Reg. 27,289, 27,290 (May 7, 1993).

26. In litigation, HRSA has emphasized the importance of properly and publicly certifying 340B-eligible covered entities. To allow covered entities to access 340B-priced medicines "without . . . any verification of their eligibility," HRSA has explained, "would functionally undermine HRSA's responsibility to oversee the fundamental rules that make it possible for this program . . . to operate smoothly and in compliance with statutory requirements." Reply Mem. of P. & A. in Supp. of Defs.' Cross-Mot. for Summ. J. at 1, *Albany Med. Health Sys. v. HRSA*, No. 23-cv-3252 (D.D.C. Apr. 19, 2024), ECF No. 24. If the agency were to fail to appropriately verify eligibility, HRSA continued, "the government [would be] play[ing] fast and loose with others' (drugmakers') money on the line. And the agreements that manufacturers execute to enter the 340B Program only obligate them to provide discount prices to providers who qualify as covered entities under § 256(a)(4). Manufacturers cannot satisfy that obligation (nor can

HRSA hold them to it) without knowing which provider sites are, indeed, 'covered entities.'" *Id.* at 17 (citations and quotation marks omitted).

27. Yet despite acknowledging that HRSA's responsibility to verify covered entity eligibility is "fundamental" to the 340B program, *id.* at 1—and despite its statutory obligation to make "criteria for certification" available to manufacturers, 42 U.S.C. § 256b(a)(7)(C)—HRSA has *never* made its certification criteria available to manufacturers. Nor has it otherwise disclosed the steps it has taken (if any) to verify the eligibility of STD grantees or require the submission of purchase information.

28. In addition to certifying eligible STD grantees, HRSA must also require recertification of such entities on a "not more frequent than annual basis." *Id.* § 256b(a)(7)(E). Each certification or recertification of a covered entity is a new and independent final agency action.

29. The problem carries over into the recertification process as well. HRSA has never made its recertification criteria available to manufacturers either, nor has it disclosed the steps it has taken (if any) to verify the continued eligibility of STD grantees that are recertified.

30. Section 340B also restricts the definition of "covered entity" in another manner relevant here, providing: "the term 'covered entity' means an entity that meets the requirements described in paragraph [(a)](5)." *Id.* § 256b(a)(4). One such requirement is that "a covered entity shall not resell or otherwise transfer [any covered outpatient] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Thus, if an entity transfers 340B-priced drugs to non-patients—a type of misconduct commonly known as diversion—then the entity does not "meet[] the requirements described in paragraph [a](5)" and so does not qualify as a covered entity entitled to 340B pricing, even if it satisfies other eligibility criteria.

31. HRSA has promulgated guidance regarding the definition of the statutory term "patient of the entity." For entities made eligible for the 340B program through receipt of federal grant funding, the guidance provides that "[a]n individual is a 'patient' of [such a] covered entity . . . only if . . . the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding . . . has been provided to the entity." 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996). Accordingly, an individual who does not receive STD-related services from an STD subgrantee is not a "'patient' of [that] entity" unless the entity qualifies as a different type of 340B-eligible covered entity. *Id.*

32. To ensure compliance with the anti-diversion requirement of subparagraph (a)(5) and with other requirements, Congress required a covered entity applying for certification or recertification to submit information concerning its past purchases of covered outpatient drugs. HRSA must then review the submission to "evaluat[e] the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices." 42 U.S.C. § 256b(a)(7)(B); *see id.* § 256b(a)(7)(E) (recertifications). In addition to losing eligibility for recertification, a covered entity that "knowingly and intentionally" engages in diversion must pay monetary penalties. *Id.* § 256b(d)(2)(v)(I).

HRSA's Certification and Recertification of Entities Associated with Sagebrush Health Services

33. This action concerns HRSA's certification and recertification of entities in Nevada and Connecticut that claim an association with a Nevada company, Sagebrush Health Services.[2]

[2] Although Genentech challenges only HRSA's certification and recertification decisions here, it reserves the right to pursue claims against Sagebrush and related entities for any wrongfully-obtained price reductions.

34. HRSA maintains an online database of 340B program participants, the 340B Office of Pharmacy Affairs Information System (OPAIS).[3] The database contains several categories of information about each covered entity. These include a unique "340B ID"; the "entity type," which identifies the statutory category that makes the entity eligible for the program; the entity's "Name"; its "Sub Name" or "Subdivision Name"; its "street address," "billing address," and points of contact; and its date of initial certification and most-recent recertification.[4]

35. OPAIS includes 84 covered entities that have "Sagebrush Health Services" in the "Name" field, each of which has a different "Subdivision Name."

36. According to its website, Sagebrush is a Nevada-based company that operates thirteen clinics in Nevada, Connecticut, and South Carolina that provide rheumatology, neurology, infectious disease, infusion, and mental health services.[5]

37. Ten of those facilities are listed in OPAIS with "Sagebrush Health Services" in the "Name" field and the name of a clinic from Sagebrush's website in the "Sub Name" field. The "entity type" field for all ten shows "STD," indicating they have each been certified by HRSA as eligible for the 340B program under 42 U.S.C. § 256b(a)(4)(K).

38. Aside from those entities listed on Sagebrush's website that Sagebrush itself operates, OPAIS lists 74 additional covered entities that have "Sagebrush Health Services" in the "Name" field and a different name in the "Subdivision" field. All are certified as STD funding recipients. Yet the "Sub Name[s]" of most of these entities and their websites indicate that they

[3] HRSA, 340B OPAIS, https://340bopais.hrsa.gov/.

[4] HRSA, 340B OPAIS, https://340bopais.hrsa.gov/CoveredEntitySearch.

[5] Sagebrush Health, Locations, https://sagebrushhealth.com/locations/.

provide services like rheumatology or dermatology, rather than any services related to STD treatment.

39. In this action, Genentech challenges HRSA's certification and recertification of eleven entities listed in OPAIS as Sagebrush subdivisions: (1) Fire Mesa ID, (2) Rainbow Rheumatology, (3) Southington Clinic - CT, (4) Centennial SACI, (5) Hummingbird Medical Group, (6) Dr. Ann Wierman, MD, (7) Danbury Rd Clinic, (8) Eastern Rheumatology, (9) Battleborn Health Care, (10) Southbury Clinic - CT, and (11) Reno Clinic.

40. Despite Congress's direction that 340B price reductions for STD grantees should go to "clinics providing . . . sexually transmitted disease treatment," H.R. Rep. No. 102-384, pt. 2, at 13 (1992), these Sagebrush entities appear to be for-profit providers who have accessed Genentech's products for non-STD-related services.

41. **Fire Mesa ID** is a Las Vegas provider identified on Sagebrush's website as an "Infectious Disease Clinic." HRSA recertified Fire Mesa ID on June 11, 2024.[6]

42. Despite describing itself as an infectious disease clinic, Fire Mesa ID routinely purchases 340B-priced Genentech products that do not treat or prevent STDs—or any infectious diseases.

43. From 2022 to 2025, Fire Mesa ID made 4,584 purchases of Genentech medicines, including purchases of Actemra, Cathflo Activase, Cellcept, Erivedge, Herceptin, Ocrevus, Perjeta, Polivy, Pulmozyme, Rituxan, Tecentriq, and Xolair. None of these products treats or prevents STDs. Actemra treats rheumatoid arthritis and certain pulmonary conditions. Cathflo Activase helps restore the function of central venous catheters. Cellcept is an immunosuppressant

[6] Sagebrush Health, Infectious Disease Clinic, https://sagebrushhealth.com/locations/infectious-disease-clinic/

used following organ transplants. Erivedge is a skin cancer drug. Herceptin treats early-stage breast and metastatic stomach cancer. Ocrevus treats multiple sclerosis. Perjeta is a treatment for certain breast cancers. Polivy treats certain blood cancers. Pulmozyme helps manage cystic fibrosis. Rituxan treats certain autoimmune disorders and cancers. Tecentriq treats certain lung cancers. Xolair treats asthma, chronic rhinosinusitis, nasal polyps, hives, and serious food allergy reactions.

44. Fire Mesa ID sought and obtained $6,915,816 in 340B price reductions for these purchases, including $4,021,228 for Ocrevus purchases alone.

45. **Rainbow Rheumatology** is a rheumatology provider based in Las Vegas, Nevada. HRSA last recertified Rainbow Rheumatology on June 4, 2024.[7]

46. From 2022 to 2025, Rainbow Rheumatology made 575 purchases of Genentech medications for which it sought 340B price reductions totaling $477,359. Rainbow Rheumatology purchased nine different Genentech products, including 494 orders of Actemra.

47. **Southington Clinic - CT** is a provider located in Southington, Connecticut.[8] Sagebrush's website identifies the location as "Southington Rheumatology" and states that it offers rheumatology services.[9] HRSA last recertified Southington Clinic - CT on June 4, 2024.

48. Southington Clinic - CT's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Connecticut Department of Public Health.[10] However, a

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[7] Sagebrush Health, Rainbow Rheumatology, https://sagebrushhealth.com/locations/rainbow-rheumatology/. The website describes the two medical providers associated with Rainbow Rheumatology as providing "Rheumatology" services.

[8] *See* 340B Office of Pharmacy Affairs, HRSA, STD06489 Sagebrush Health Services (Active), https://340bopais.hrsa.gov/cedetails/92162 (OPAIS entry for Southington Clinic).

[9] Sagebrush Health, Southington Rheumatology, https://sagebrushhealth.com/locations/southington-rheumatology/.

[10] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Active), https://340bopais.hrsa.gov/cedetails/92162 (listing Grant Number NU62PS924521); see HHS,

field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Southington Clinic - CT lists "Rapid HIV kits."

49. From 2022 to 2025, Southington Clinic - CT made 213 purchases of Genentech medications for which it sought 340B price reductions totaling $222,758. Southington Clinic - CT purchased six different Genentech products, including 141 orders of Actemra.

50. **Centennial SACI** is a Las Vegas, Nevada, location of the Skin and Cancer Institute (SACI), a multi-state dermatology company with clinics in Nevada, California, and Arizona. HRSA last recertified Centennial SACI on June 4, 2024.[11]

51. SACI has no apparent and identifiable corporate relationship with Sagebrush; no SACI locations are listed in Sagebrush's website. Yet six SACI locations, including Centennial SACI, are listed in OPAIS as Sagebrush "subdivisions." Each SACI location's listing identifies Sagebrush as the entity name, has a Sagebrush official listed as the entity's point of contact, and shows a Sagebrush facility as the entity's billing address.[12] The only information in each listing that appears to relate to the SACI facility itself is the facility's street address.[13] The six SACI

Connecticut Department of Public Health (CT DPH) PS18-1802 Integrated HIV Surveillance and Prevention Programs for Health Departments, https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NU62PS924521&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NU62PS924521).

[11] *See* Skin and Cancer Institute, Locations, https://skinandcancerinstitute.com/locations/.

[12] *See, e.g.,* 340B Office of Pharmacy Affairs, HRSA, STD891491 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/93907 (OPAIS entry for Centennial SACI)

[13] *See, e.g.*, *id.* (showing street address that matches the location of Centennial SACI shown on SACI's website).

listings in OPAIS, other than their different street addresses, are materially identical to database listings for the facilities that Sagebrush lists on its own website.[14]

52. On information and belief, the SACI locations, including Centennial SACI, are subgrantees of Sagebrush, claiming their 340B eligibility through contributions from Sagebrush, not any direct contribution from a state or local government.

53. Centennial SACI's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Nevada Department of Health and Human Services (DHHS).[15] However, a field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Centennial SACI lists "Condoms and Marketing Materials."

54. From 2022 to 2025, Centennial SACI placed two orders for Genentech's product Xolair, for which it sought 340B price reductions totaling $1,039.

55. **Hummingbird Medical Group** is a rheumatology and infusion therapy clinic based in Las Vegas, Nevada.[16] HRSA last recertified Hummingbird Medical Group on June 4, 2024.

56. Hummingbird Medical Group has no apparent and identifiable corporate relationship with Sagebrush; the address where Hummingbird Medical Group is located is not

[14] *See, e.g.*, 340B Office of Pharmacy Affairs, HRSA, STD89118 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/86348 (OPAIS entry for Rainbow Rheumatology).

[15] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/93907 (listing Grant Number NH25PS005179); *see* HHS, Strengthening STD Prevention and Control for Health Department (STD PCHD), https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NH25PS005179&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NH25PS005179).

[16] *See* Hummingbird Medical Group, About Us, https://www.hummingbirdmed.org/about-us.

listed on Sagebrush's website. Yet Hummingbird is listed in OPAIS as a Sagebrush "subdivision." Hummingbird's OPAIS listing identifies Sagebrush as the entity name, has a Sagebrush official listed as the entity's point of contact, and shows a Sagebrush facility as the entity's billing address.[17] The only information in each listing that appears to relate to Hummingbird itself is the facility's street address.[18] Hummingbird's OPAIS listing, other than its different street address, is materially identical to database listings for the facilities that Sagebrush lists on its own website.[19]

57. On information and belief, Hummingbird Medical Group is a subgrantee of Sagebrush, claiming its 340B eligibility through contributions from Sagebrush, not any direct contribution from a state or local government.

58. Hummingbird Medical Group's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Nevada DHHS.[20] However, a field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Hummingbird Medical Group lists "Condoms and Marketing Materials."

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[17] *See* 340B Office of Pharmacy Affairs, HRSA, STD89149 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/91290 (OPAIS listing for Hummingbird Medical Group).

[18] *See id.* (showing street address that matches the location of Hummingbird shown on Hummingbird's website).

[19] *See, e.g.*, 340B Office of Pharmacy Affairs, HRSA, STD89118 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/86348 (OPAIS entry for Rainbow Rheumatology).

[20] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/91290 (listing Grant Number NH25PS005179); *see* HHS, Strengthening STD Prevention and Control for Health Department (STD PCHD), https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NH25PS005179&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NH25PS005179).

59. From 2022 to 2025, Hummingbird Medical Group placed 226 orders for Genentech medicines Actemra, Rituxan, and Xolair, for which it sought 340B price reductions totaling $142,737.

60. **Dr. Ann Wierman, MD** is a Las Vegas, Nevada medical provider whose specialties are "adult oncology, adult hematology and internal medicine."[21] HRSA last recertified Dr. Ann Wierman, MD on June 1, 2024.

61. Dr. Ann Wierman, MD has no apparent and identifiable corporate relationship with Sagebrush; the address where Dr. Ann Wierman, MD is located is not listed on Sagebrush's website. Yet Dr. Ann Wierman, MD is listed in OPAIS as a Sagebrush "subdivision." The OPAIS location listing identifies Sagebrush as the entity name, has a Sagebrush official listed as the entity's point of contact, and shows a Sagebrush facility as the entity's billing address.[22] The only information in each listing that appears to relate to the Dr. Ann Wierman, MD entity itself is the facility's street address.[23] Dr. Ann Wierman, MD's OPAIS listing, other than its different street address, is materially identical to database listings for the facilities that Sagebrush lists on its own website.[24]

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[21] *See* Dr. Ann M. Wierman, MD, FACP, Expertise, http://annwiermanmd.com/expertise.htm.

[22] *See* 340B Office of Pharmacy Affairs, HRSA, STD891286 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/94073 (OPAIS entry for Dr. Ann Wierman, MD).

[23] *See id.* (showing street address that matches the location of Dr. Ann Wierman, MD shown on Dr. Ann Wierman, MD's website).

[24] *See, e.g.*, 340B Office of Pharmacy Affairs, HRSA, STD89118 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/86348 (OPAIS entry for Rainbow Rheumatology).

62. On information and belief, Dr. Ann Wierman, MD is a subgrantee of Sagebrush, claiming its 340B eligibility through contributions from Sagebrush, not any direct contribution from a state or local government.

63. Dr. Ann Wierman, MD's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Nevada DHHS.[25] However, a field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Dr. Ann Wierman, MD lists "Condoms and Marketing Materials."

64. From 2022 to 2025, Dr. Ann Wierman, MD placed 60 orders for Genentech medicines Cathflo and Rituxan, for which it sought 340B price reductions totaling $50,327.

65. **Danbury Rd Clinic** is a provider located in Danbury, Connecticut. Sagebrush's website identifies the location as "Danbury Rheumatology" and states that it offers rheumatology services.[26] HRSA last recertified Danbury Rd Clinic on May 31, 2024.

66. Danbury Rd Clinic's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Connecticut Department of Public Health.[27] However, a

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[25] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/94073 (listing Grant Number NH25PS005179); *see* HHS, Strengthening STD Prevention and Control for Health Department (STD PCHD), https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NH25PS005179&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NH25PS005179).

[26] Sagebrush Health, Danbury Rheumatology, https://sagebrushhealth.com/locations/danbury-rheumatology/. The website lists the services associated with Danbury Rheumatology as "Rheumatology" services.

[27] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/93052 (listing Grant Number NU62PS924521); *see* HHS, Connecticut Department of Public Health (CT DPH) PS18-1802 Integrated HIV Surveillance and Prevention Programs for Health Departments, https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NU62PS924521&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NU62PS924521).

field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Danbury Rd Clinic lists "Rapid HIV test kits."

67. From 2022 to 2025, Danbury Rd Clinic made 28 purchases of Genentech medications Actemra and Rituxan, for which it sought 340B price reductions totaling $73,514.

68. **Eastern Rheumatology** is a provider located in Las Vegas, Nevada. Sagebrush's website identifies this location under the same name, "Eastern Rheumatology," and states that it offers rheumatology services.[28] HRSA last recertified Eastern Rheumatology on June 11, 2024.

69. From 2022 to 2025, Eastern Rheumatology made 820 purchases of Genentech medications Actemra, Ocrevus, and Ritxuan, for which it sought 340B price reductions totaling $699,737.

70. **Battleborn Health Care** is listed in OPAIS as a Sagebrush subdivision. HRSA last recertified Battleborn Health Care on June 11, 2024.

71. Battleborn Health Care has no apparent and identifiable corporate relationship with Sagebrush or discernable online footprint. But the address listed in OPAIS as Battleborn's "street address" and "billing address" is the same address listed on Sagebrush's website as the site of Sagebrush Health's corporate headquarters.[29] Additionally, Battleborn Health Care's OPAIS listing identifies Sagebrush as the "entity name" and has a Sagebrush official listed as the entity's

[28] Sagebrush Health, Eastern Rheumatology, https://sagebrushhealth.com/locations/eastern-rheumatology/. The website lists the services associated with Eastern Rheumatology as "Rheumatology" services and each of the providers listed are categorized as providing "Rheumatology."

[29] *See* 340B Office of Pharmacy Affairs, HRSA, STD891132 Sagebrush Health Services (Active), https://340bopais.hrsa.gov/cedetails/96823 (OPAIS entry for Battleborn Health Care); Sagebrush Health, Contact Us, https://sagebrushhealthcare.org/contact-us/.

point of contact. Battleborn Health Care's OPAIS listing, other than its different street address, is materially identical to database listings for the facilities that Sagebrush lists on its own website.

72. Battleborn Health Care's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Nevada Department of Health and Human Services (DHHS).[30] However, a field titled "Nature of Support" lists both "Direct Funding (dollars received from CDC or an intermediate organization)" and "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Battleborn Health Care lists "Condoms and Marketing Materials."

73. On information and belief, Battleborn Health Care is a subgrantee of Sagebrush, claiming its 340B eligibility through contributions from Sagebrush, not any direct contribution from a state or local government.

74. From 2022 to 2025, Battleborn Health Care made 46 purchases of Genentech's medicine Actemra, for which it sought 340B price reductions totaling $28,561.

75. **Southbury Clinic - CT** is a provider located in Southbury, Connecticut. Sagebrush's website identifies this location with the name "Southbury Rheumatology" and states that it offers rheumatology services.[31] HRSA last recertified Southbury Clinic - CT on May 22, 2023.

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[30] *See* 340B Office of Pharmacy Affairs, HRSA, STD891132 Sagebrush Health Services (Active), https://340bopais.hrsa.gov/cedetails/96823 (OPAIS entry for Battleborn Health Care); (listing Grant Number NH25PS005179); *see* HHS, Strengthening STD Prevention and Control for Health Department (STD PCHD), https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NH25PS005179&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NH25PS005179).

[31] Sagebrush Health, Southbury Clinic - CT, https://sagebrushhealth.com/locations/southbury-rheumatology/.

76. Southbury Clinic - CT's OPAIS listing shows a "Grant Number" associated with an STD grant award from the CDC to the Connecticut Department of Public Health.[32] However, a field titled "Nature of Support" lists "In-Kind products or services (see note below; must have been purchased with section 318 funds)." In a field labeled "Please Describe the 'in-kind' Support," Southbury Clinic - CT lists "Rapid HIV test kits."

77. From 2022 to 2025, Southbury Clinic made two purchases of Genentech's medicine Actemra, for which it sought 340B discounts totaling $957.

78. **Reno Clinic** is a provider located in Las Vegas, Nevada. Sagebrush's website identifies this location with the name "Reno" and states that it offers rheumatology services and infectious disease care.[33] HRSA last recertified Reno Clinic on June 11, 2024.

79. Between 2022 and 2025, Reno Clinic made one purchase of Genentech's medication Rituxan, for which it sought a 340B discount of $507.

80. Altogether, these eleven entities purchased $12,626,725 in Genentech medicines at the 340B-reduced price between 2022 and 2025. They received $8,613,312 in 340B price reductions for those purchases.

[32] 340B Office of Pharmacy Affairs, HRSA, Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/93056 (listing Grant Number NU62PS924521); *see* HHS, Connecticut Department of Public Health (CT DPH) PS18-1802 Integrated HIV Surveillance and Prevention Programs for Health Departments, https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=NU62PS924521&arg_ProgOfficeCode=143 (HHS grant-tracking page for CDC grant award number NU62PS924521).

[33] Sagebrush Health, Reno, https://sagebrushhealth.com/locations/reno/. The website lists the services associated with Reno as "Rheumatology, Infectious Disease," and the only provider listed is categorized as providing "Rheumatology."

HRSA's Enforcement Against Sagebrush

81. On February 2, 2024, HRSA sent a letter to Sagebrush stating that it was conducting a review of 53 Sagebrush entities listed in OPAIS for compliance with 340B program requirements, focusing on each entity's receipt of grant funding and determinations of patient eligibility. *See* Decl. of Guru Charan ¶ 5 (Charan Decl.), *Sagebrush Health Servs. v. Becerra* (*Sagebrush*), No. 1:25-cv-127 (D.D.C. Jan. 16, 2025), ECF No. 2-2. The letter included eleven inquiries and document requests. *Id.* Sagebrush sent a letter in response on March 4, 2024, and produced documents to HRSA. *Id.* ¶ 6.

82. HRSA replied on July 3, 2024, posing eight additional questions and making further document requests. *Id.* ¶ 7. Among other things, the letter also noted that HRSA had terminated two of Sagebrush's sites in Connecticut, including Southbury Clinic - CT. *See* Charan Decl. Ex. C at 1.

83. Sagebrush responded to HRSA's letter on August 2, 2024, attaching ten responsive documents. Charan Decl. ¶ 8. HRSA wrote to Sagebrush again on September 19, 2024, asserting that three Sagebrush sites were not eligible to participate in the 340B program because the Connecticut Department of Public Health (CDPH) grant on which their eligibility relied had expired. *Id.* ¶ 9. HRSA stated that it would terminate those sites from the 340B program effective September 27, 2024, unless Sagebrush demonstrated their eligibility. *Id.* Sagebrush replied on September 25, enclosing documents relating to the CDPH grant. *Id.* ¶ 10.

84. On December 20, 2024, HRSA sent another letter to Sagebrush stating that HRSA would terminate 20 Sagebrush sites from the 340B program by December 30 unless Sagebrush terminated them voluntarily by December 27. *Id.* ¶ 11. The letter said that HRSA had determined that 55 sites that currently are or previously were registered in OPAIS were not eligible to

participate in the 340B program, notwithstanding HRSA's prior certification and recertification of those entities. *Id.* ¶ 11.

85. Sagebrush responded to HRSA later the same day. Sagebrush's response disagreed with HRSA's determination, attached relevant documentation, and requested withdrawal of HRSA's direction to terminate the 20 sites and an extension until January 31, 2025 for Sagebrush to demonstrate their eligibility. *Id.* ¶¶ 12-13. The same day, HRSA sent Sagebrush an email agreeing to suspend the deadline for Sagebrush to voluntarily terminate the sites pending HRSA's review of the submitted information. *Id.* ¶ 14.

86. Sagebrush sent an additional email to HRSA on January 9, 2025 raising concerns about the procedures HRSA followed in its oversight of Sagebrush. *Id.* ¶ 15. On January 13, HRSA responded defending its procedures and informing Sagebrush that it was close to finalizing its review of the documentation Sagebrush had submitted on December 20, 2024. *Id.* ¶ 16.

87. Later on January 13, 2025, HRSA sent Sagebrush a letter stating that it had reviewed the materials Sagebrush had submitted and affirming its determination that termination of the sites identified in its December 20, 2024, letter to Sagebrush was required. *Id.* ¶ 17. HRSA stated that it would effectuate the terminations that day. *Id.*

88. Currently, the 20 entities identified in HRSA's December 20, 2024 letter, which include all entities at issue in this action other than Southington Clinic - CT and Battleborn Health Care, are marked in OPAIS as having been terminated from the 340B program on January 14, 2025.

89. On January 16, 2025, Sagebrush filed an action in this district against the then-Secretary of Health and Human Services and the then-HRSA Administrator alleging that the terminations of the 20 entities were unlawful. *See Sagebrush*, ECF No. 1. The complaint seeks,

inter alia, injunctive relief preventing implementation of the terminations and a declaration that the terminations were unlawful. The complaint was accompanied by a motion for a temporary restraining order and preliminary injunction that sought an order barring HRSA from terminating Sagebrush entities from the 340B program. *Sagebrush*, ECF No. 2-1.

90. The *Sagebrush* Court issued an administrative stay relating to HRSA's terminations on January 17, 2025. *Sagebrush*, ECF No. 8. On January 21, 2025, Sagebrush filed an emergency motion to enforce the administrative stay. *Sagebrush*, ECF No. 11. On January 22, the Court ordered the defendants to show cause why they were not in contempt of the Court's administrative stay. *Sagebrush*, ECF No. 13. The defendants responded to the order to show cause and the motion for a temporary restraining order on January 24. *Sagebrush*, ECF Nos. 15, 16. Both motions remain pending, and a hearing is scheduled for January 31.

91. On January 26, 2025, the *Sagebrush* action was reassigned to Chief Judge Boasberg, *Sagebrush*, ECF No. 19, who had been assigned a previously filed suit by three drug manufacturers challenging the eligibility of nine of the eleven Sagebrush entities challenged in this suit. *See Amgen v. Becerra*, No. 24-cv-3571 (D.D.C. filed Dec. 20, 2024).

LEGAL ALLEGATIONS

92. Notwithstanding HRSA's recent moves to terminate certain Sagebrush entities on limited grounds,[34] its decisions to certify and recertify Sagebrush entities as 340B-eligibleare final agency actions that are arbitrary, capricious, and not in accordance with law, and they exceed the

[34] These enforcement efforts have not resolved the harm to Genentech caused by Sagebrush. As detailed further below, the bases on which HRSA determined that the 20 Sagebrush entities are ineligible to participate in the 340B program are narrower than the grounds of ineligibility identified in this Complaint. In addition, as noted above, two of the eleven Sagebrush entities at issue in this action (Southington Clinic - CT and Battleborn Health Care) have not been terminated from the program. Finally, in its steps to enforce program requirements against Sagebrush, HRSA still has not made available to manufacturers its criteria for certification of STD grantees.

agency's statutory jurisdiction and authority. None of these entities is eligible to participate in the 340B program, for one or more of the following reasons: (1) the identified entities use drugs acquired at 340B prices for purposes other than STD prevention and treatment; (2) they regularly transfer (divert) such 340B-priced drugs to non-patients, contrary to the statutory definition of "covered entity"; (3) they are "sub-subgrantees" that have received federal grant funds only from subgrantees, rather than from state or local governments; (4) they have received only in-kind contributions such as pamphlets or condoms, not grant "funds" (*i.e.*, cash); or (5) HRSA has failed to comply with Paragraph (a)(7) of Section 340B, which directs HHS to establish a process for the certification of STD grantees and to make "criteria for certification" available to manufacturers under which information concerning past purchases of covered outpatient drugs must be submitted to determine eligibility for subsequent purchases of such drugs at the 340B price.

Entities Receiving STD Grant Funds Can Access Only 340B Drugs That Treat or Prevent STDs

93. To be eligible to receive 340B-priced drugs based on receipt of funds "under" the federal STD grant program, an entity must use those funds for "treatment of sexually transmitted diseases"—that is, for purposes consistent with the scope of the grant. 42 U.S.C. § 256b(a)(4)(K) ("relating to treatment of sexually transmitted diseases"). Congress could not have reasonably intended for entities that provide no STD treatment services to qualify for 340B pricing on drugs not used to treat sexually transmitted diseases based on receipt of grant funds for STD treatment.

94. Indeed, when an entity obtains its eligibility by "receiving funds under" the federal STD grant program "through a State or unit of local government," *id.*, the entity stands in the shoes of the relevant State or unit of local government from which funds are received. When an entity acts in such a capacity, it is accordingly limited to what the direct funding recipient may do under the grant. *See* 2 C.F.R. § 200.1 ("an award provided by a pass-through entity to a subrecipient [is]

for the subrecipient to contribute to the goals and objectives of the project by carrying out part of a Federal award received by the pass-through entity"); *accord* Jonathan D. Shaffer & Daniel H. Ramish, *Federal Grant Practice* § 1:6 (2024 ed.). In this case, that is preventing and treating "sexually transmitted diseases." 42 U.S.C. § 247c(c)-(d). An entity whose 340B eligibility is based on receiving STD grant funds accordingly acts as an STD subgrantee only when it is engaged in preventing and treating sexually transmitted diseases. Conversely, when such an entity engages in unrelated activity—activity outside of the scope of the grant to the State or unit of local government from which the entity receives funds—the entity is *not* acting as an STD subgrantee and is not 340B-eligible (or is not eligible for 340B pricing on drugs not used for or indicated for treating STDs).

95. The history of the 340B statute supports this reading of the text. Congress enacted the 340B program as part of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943. The original draft of the bill covered only disproportionate share hospitals. But a subsequent draft directed HHS to study coverage for "*entities providing treatment* for sexually transmitted diseases . . . and receiving Federal funds through a State or unit of local government." H.R. Rep. No. 102-384, pt. 2, at 18-19 (emphasis added). This statutory history confirms that, when Congress later revised the bill to add STD grant recipients as covered entities, 42 U.S.C. § 256b(a)(4)(K), it contemplated eligibility for 340B pricing only insofar as those entities "provid[e] treatment for" STDs.

96. In guidance, HRSA has endorsed the view that only entities providing STD treatment can qualify as covered entities by virtue of their receipt of STD grant funds, and that such entities accordingly may access 340B drugs only in connection with providing STD treatment. HRSA has explained that STD clinics participating in the 340B Program "may purchase

and dispense any 340B drugs *associated with a service* for which the covered entity is responsible, including contraceptives, to that patient, *to the extent it . . . is consistent with the scope of the grant*."[35]

97. Notwithstanding the statutory instruction that an entity is 340B-eligible only if it uses STD funds for the treatment of sexually transmitted diseases, and notwithstanding HRSA's own guidance that STD grantees must use 340B drugs to provide services consistent with the scope of the grant, HRSA has repeatedly certified and recertified entities that use 340B-priced drugs to provide non-STD treatment.

98. Rainbow Rheumatology and Eastern Rheumatology are two examples of such ineligible entities. As noted in paragraphs 45-46 and 68-69, *supra*, these entities do not provide STD treatment services using Genentech medicines—and indeed, it is possible they do not provide *any* STD treatment services. Yet from 2022 to 2025 these entities together received $1,177,096 in 340B price reductions for Actemra, Rituxan, and Xolair—medications that have no use or indication for treating or preventing STDs.

Entities That Divert Reduced-Price Medicines to Non-Patients Are Disqualified from the 340B Program

99. To qualify and maintain eligibility as a covered entity under Section 340B, an entity must "meet[] the requirements described in paragraph [(a)](5)" relating to program compliance. 42 U.S.C. § 256b(a)(4).

100. Under paragraph (a)(5), "a covered entity shall not resell or otherwise transfer [any covered outpatient] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). An

[35] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs (emphases added).

entity that transfers drugs to non-patients does not "meet[] the requirements described in paragraph [(a)](5)" and thus does not qualify as a covered entity. *Id.* § 256b(a)(4).

101. HRSA's longstanding guidance provides that an individual is a "patient" of an STD grant recipient for purposes of program eligibility "only if . . . the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding . . . has been provided to the entity." 61 Fed. Reg. at 55,157-58.

102. Guidance on HRSA's website similarly states that "STD (318 grantee) clinics that participate in the 340B Program may purchase 340B drugs (including prescribed contraceptives), for grantee patients *that meet the patient definition criteria*," and that an STD clinic "may purchase and dispense any 340B drugs associated with a service for which the covered entity is responsible, including contraceptives, to that patient, *to the extent it aligns with* [*the*] *patient definition and is consistent with the scope of the grant*."[36]

103. Construing "patient[s]" of an STD subgrant recipient to include only individuals receiving STD treatment also comports with the statute's structure and purpose. Section 340B allows STD subgrantees to obtain reduced-price drugs to facilitate the purpose of those federal grants: namely, "treatment of sexually transmitted diseases." 42 U.S.C. § 256b(a)(4)(K). Permitting STD subgrantees to obtain 340B-priced drugs with no nexus to STD treatment advances neither the purpose of the federal grants nor the interests of the individuals whom the grants seek to benefit. Instead, it encourages abuse of the 340B program.

104. Under Section 340B and HRSA's definition of "patient," if an entity has been certified as 340B-eligible based on its receipt of STD grant funds, but the entity provides 340B-

[36] HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs (emphases added).

priced medicines to individuals who are *not* receiving STD treatment (or the 340B-priced medicines are not used or indicated for treating STDs), the entity has "transfer[ed] [a covered outpatient drug] to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Such an entity no longer satisfies the statutory definition of what "the term 'covered entity' means," *id.* § 256b(a)(4), and is thus ineligible to participate in the 340B program.

105. The 340B statute also imposes an affirmative obligation on HRSA to ensure that an entity applying for certification or recertification submits information necessary to assess whether the entity's 340B-priced medicine purchases comply with statutory eligibility criteria, including paragraph (a)(5)'s prohibition on transferring covered drugs to non-patients. *Id.* § 256b(a)(7). The statute thus requires HRSA to "evaluat[e] the validity" of each entity's drug purchases before HRSA certifies or recertifies a covered entity. *Id.* § 256b(a)(7)(B), (E).

106. Notwithstanding the statutory instruction that covered entities are ineligible for recertification if they divert 340B drugs to non-patients, and notwithstanding HRSA's guidance that an individual is a "patient" of an STD subgrantee only if the subgrantee uses 340B drugs to provide services consistent with the scope of the grant, HRSA has repeatedly recertified ineligible entities that routinely use 340B-priced drugs, including Genentech's drugs, to provide non-STD services.

107. Fire Mesa ID is just one such example of an entity that has been recertified despite its routine diversion of 340B-priced drugs. As noted in paragraphs 41-44, *supra*, Fire Mesa ID has purchased thousands of units of Genentech's drugs that did not treat or prevent STDs. Any individual to whom Fire Mesa ID transfers a 340B-priced drug is, by definition, not a "patient" of Fire Mesa ID with respect to that drug. Fire Mesa ID has thus engaged in unlawful diversion of

340B-priced drugs and is therefore ineligible for recertification. Yet HRSA has repeatedly recertified Fire Mesa ID as eligible for the 340B program.

108. Indeed, all of the Sagebrush subdivisions identified herein routinely transfer 340B-priced medicines to non-patients, and each is ineligible for recertification for that reason as well. Because *none* of the purchased Genentech products are for STD treatment or prevention, the entities' repeated distribution of Genentech's medicines outside the scope of STD grants necessarily constitutes unlawful diversion. These entities accordingly do not "meet[] the requirements described in paragraph [(a)](5)" prohibiting diversion, and they do not satisfy the statutory definition of "the term 'covered entity.'" 42 U.S.C. § 256b(a)(4).

109. These transfers of Genentech's products to non-patients constitute unlawful diversion that renders the provider ineligible to benefit from the 340B program.

Sub-subgrantees Are Ineligible for the 340B Program

110. Under Section 340B, an entity qualifies as a covered entity based on its receipt of STD grant funds only if it is "receiving funds . . . through a State or unit of local government." 42 U.S.C. § 256b(a)(4)(K). This provision addresses federal grants that are issued to state and local public health agencies under Section 318 of the PHS Act and then distributed to local providers offering STD treatment.

111. The statute does not authorize such a grantee to pass on 340B eligibility even further down the chain, by transferring a portion of its *own* grant funds to other "sub-subgrantee" providers. Interpreting the statute that way would effectively rewrite the statutory text, conferring eligibility on providers that "receiv[e] funds … through a State or unit of local government *or through a subgrantee*."

112. Rewriting the statute that way would also give a covered entity the power, by choosing other providers on which to bestow a share of its grant funds, to create brand new covered

entities. Congress has never allowed covered entities to unilaterally create *other* independent covered entities. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998) ("a statute should not be construed to produce" a result that is "contrary to common sense" or "inconsistent with the clear intentions of the statute's drafters").

113. Allowing a subgrantee to pass on 340B eligibility by transferring grant funds to other entities also has no limiting principle or logical stopping point. It would allow a pool of STD grant funds to be transferred *ad infinitum* from provider to provider to provider—all of which could declare themselves covered entities because the funds once passed, however distantly, through a state agency. The care and precision with which Section 340B identifies and defines the list of eligible covered entities underscores that Congress never intended to create such a perpetually cascading authorization structure.

114. Notwithstanding the statutory instruction that an entity is eligible only if it receives funds through a State or unit of local government, HRSA has repeatedly certified and recertified entities that have received contributions only through subgrant recipients and are therefore ineligible.

115. Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Battleborn Health Care are examples of such ineligible sub-subgrantees. In OPAIS, each of these entities is registered as a Sagebrush "subdivision," with Sagebrush officials listed as its points of contact and a Sagebrush facility listed as its billing address.[37] On information and belief, these

[37] *See* 340B Office of Pharmacy Affairs, HRSA, STD891491 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/93907 (OPAIS entry for Centennial SACI); STD89149 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/91290 (OPAIS entry for Hummingbird Medical Group); STD891286 Sagebrush Health Services (Terminated), https://340bopais.hrsa.gov/cedetails/94073 (OPAIS entry for Dr. Ann Wierman, MD); STD891132 Sagebrush Health Services (Active), https://340bopais.hrsa.gov/cedetails/96823 (OPAIS entry for Battleborn Health Care).

entities are sub-subgrantees that obtain STD funds or in-kind contributions exclusively through Sagebrush, and therefore are ineligible for the 340B program.

Entities Receiving Only In-Kind Contributions Are Ineligible for the 340B Program

116. Section 340B further limits 340B eligibility to "entit[ies] receiving *funds* under section 247c of this title (relating to treatment of sexually transmitted diseases)." *Id.* § 256b(a)(4)(K) (emphasis added).

117. The plain meaning of "funds" is "money, often money for a specific purpose."[38] Thus, only entities that receive *money*, not those that receive goods, qualify as covered entities under this statutory definition.

118. This plain meaning is supported by the fact that the cross-referenced provision, Section 247c, authorizes States and units of local government to receive "grants," *id.* § 247c(b)-(d), a term that likewise refers only to "an amount of money."[39] States and units of local governments receive *money* as grant-recipients under Section 247c; and when they transmit a portion of that money to an STD clinic, the recipient may become "[a]n entity receiving funds under section 247c." *Id.* § 256b(a)(4)(K). The associated reference to "grants" thus reinforces the monetary meaning of "funds." *See United States v. Williams*, 553 U.S. 285, 294 (2008) (applying "the commonsense canon of noscitur a sociis").

119. The cross-referenced provision also expressly distinguishes "grants" from "supplies or equipment," by authorizing the Secretary to "reduce [a] grant by the fair market value

[38] Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/funds; *see Fund*, Black's Law Dictionary (11th ed. 2019). The word similarly denotes money even if "funds" is used as the plural of "fund." *See* Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/fund.

[39] Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/grant ("an amount of money given especially by the government to a person or organization for a special purpose").

of any supplies or equipment furnished to such recipient." 42 U.S.C. § 247c(e)(4). The provision thus makes clear that a "grant" is distinct from in-kind contributions of supplies or equipment, and also "show[s] that Congress knows how" to refer to in-kind contributions in the context of federal public health grants when it intends to do so. *Pereida v. Wilkinson*, 592 U.S. 224, 232 (2021).

120. HRSA has expressed a contrary view in guidance on its website, which states that "the receipt of in-kind contributions" can qualify a recipient as a 340B-eligible STD clinic.[40] That statement cannot be squared with the text of the 340B statute. An entity receiving only in-kind contributions for STD treatment does not receive "funds" through a State or local unit of government. 42 U.S.C. § 256b(a)(4)(K). In posting this guidance, HRSA neither claimed any interpretative authority in this area, nor offered any justification or reasoning for its view that in-kind contributions suffice to qualify the recipient as a covered entity. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2259 (2024); *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

121. Notwithstanding the statutory instruction that an entity is eligible only if it receives "funds" under an STD grant, HRSA has repeatedly certified and recertified entities that have received no such funds, but instead have received only in-kind contributions.

122. Southington Clinic - CT, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, and Southbury Clinic - CT are examples of such ineligible entities. As noted in paragraphs 47-48; 50-53; 55-58; 60-63; and 65-66, *supra*, these entities receive only in-kind contributions (e.g., "Rapid HIV Kits"), not funds. These entities accordingly are ineligible for the 340B program.

[40] *See* HRSA, 340B FAQs, https://www.hrsa.gov/opa/faqs.

HRSA Must Determine Eligibility for 340B Pricing Based on Information Regarding Past Purchases

123. As noted, an STD subgrantee meets the definition of a covered entity "only if the entity is certified by the Secretary pursuant to paragraph [a](7)." 42 U.S.C. § 256b(a)(4)(K).

124. Paragraph (a)(7) of Section 340B requires HHS to establish "a process for the certification of" STD grantees that apply for 340B eligibility. *Id.* § 256b(a)(7)(A). That process "shall include a requirement that an entity applying for certification . . . submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices." *Id.* § 256b(a)(7)(B).

125. In addition, the agency must make its "criteria for certification" "available to all manufacturers" participating in the 340B program. *Id.* § 256b(a)(7)(C).

126. The agency must also require recertification of STD grantees that apply for 340B eligibility "on a not more frequent than annual basis." *Id.* § 256b(a)(7)(E). As part of the recertification process, the agency shall require that entities applying for recertification submit purchase information "to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required" for initial certification. *Id.*

127. Contrary to this statutory mandate, HRSA has never made its certification or recertification criteria available to manufacturers.

128. HRSA also has never disclosed any steps it has taken (if any) to require the submission of purchase information or to use that information to verify the eligibility of STD grantees for certification or recertification. Indeed, such data would have readily indicated that the entities identified above purchased products outside the scope of the relevant grants, such that recertification would clearly have been unlawful.

129. The Sagebrush entities have accordingly not been certified or recertified "pursuant to paragraph [(a)](7)." *Id.* § 256b(a)(4)(K).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
(Declaratory/Injunctive Relief - HRSA's decisions to certify and recertify entities that do not provide services within the scope of an STD grant exceed the agency's statutory authority and are arbitrary, capricious, and an abuse of discretion)

130. Genentech realleges and incorporates by reference all prior and subsequent paragraphs.

131. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C).

132. Agency action is arbitrary and capricious when the agency relies on impermissible factors or fails to consider important factors, or gives an inadequate, implausible, or counterintuitive explanation for its decision. *See, e.g.*, *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 663 (D.C. Cir. 2019); *Cal. Cmtys. Against Toxics v. EPA*, 928 F.3d 1041, 1056-57 (D.C. Cir. 2019).

133. Courts also must set aside agency action that is *ultra vires*. *See Nat'l Ass'n of Postal Supervisors v. USPS*, 26 F.4th 960, 970 (D.C. Cir. 2022).

134. For an entity to qualify for covered-entity status based on its receipt of funds "under" a federal STD grant, the entity must use those funds for activities and provision of drugs within the scope of the grant—*i.e.*, for the treatment or prevention of STDs. 42 U.S.C. § 256b(a)(4)(K). HRSA may not certify or recertify entities that do not offer those services or furnish 340B-priced drugs for STD treatment or prevention.

135. HRSA has nevertheless certified and recertified Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic, which have repeatedly obtained 340B price reductions on Plaintiffs' medications that do not treat or prevent STDs.

136. HRSA's decisions to certify and recertify these entities are final agency actions that are "not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction" or "authority," *id.* § 706(2)(C), and *ultra vires*.

137. Even if HRSA's decisions to certify and recertify Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic were permissible under Section 340B (though they are not), those decisions are arbitrary, capricious, and abuse of discretion. 5 U.S.C. § 706(2)(A). HRSA has offered no explanation for its decisions to certify and recertify these entities notwithstanding their failure to perform services within the scope of the grants that purportedly entitle them to access 340B-priced medications. These decisions also violate HRSA's own guidance, under which 340B medicines must be associated with a service that is consistent with the scope of the grant through which eligibility is claimed.

138. HRSA's decisions to certify and recertify these entities must accordingly be set aside.

SECOND CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
(Declaratory/Injunctive Relief - HRSA's decisions to recertify entities that divert 340B-priced drugs to non-patients exceed the agency's statutory authority and are arbitrary, capricious, and an abuse of discretion)

139. Genentech realleges and incorporates by reference all prior and subsequent paragraphs.

140. An entity does not meet the statutory definition of "covered entity" unless it "meets the requirements described in paragraph [(a)](5)," including that it does "not resell or otherwise transfer [any covered outpatient] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(4), (a)(5)(B). Under the statute and HRSA's own guidance, an individual is a patient of a federal STD grant recipient "only if . . . the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding . . . has been provided to the entity." 61 Fed. Reg. at 55,157-58.

141. HRSA has nonetheless recertified Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic, even though they have repeatedly furnished 340B-priced drugs from Plaintiffs to individuals who do not receive STD treatment. Because these entities routinely transfer 340B-priced medicines to non-patients, they do not satisfy the statutory conditions for eligibility to participate in the 340B programs.

142. HRSA's decisions to recertify these entities are final agency actions that are "not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction" or "authority," *id.* § 706(2)(C), and *ultra vires*.

143. Even if HRSA's decisions to recertify these entities were permissible under Section 340B (though they are not), those decisions are arbitrary, capricious, and an abuse of discretion. 5 U.S.C. § 706(2)(A). HRSA has offered no explanation for its decisions to recertify these entities even though they provide 340B-priced medicines to non-patients. HRSA's decisions also violate HRSA's own guidance.

144. HRSA's decisions to recertify these entities accordingly must be set aside.

THIRD CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
(Declaratory/Injunctive Relief - HRSA's decisions certifying and recertifying sub-subgrantees exceed the agency's statutory authority and are arbitrary, capricious, an abuse of discretion, and not in accordance with law)

145. Genentech realleges and incorporates by reference all prior and subsequent paragraphs.

146. HRSA's authority to certify and recertify entities as 340B-eligible STD clinics is limited to entities that receive STD grant funds "through a State or unit of local government." 42 U.S.C. § 256b(a)(4)(K). Entities that receive such funds only from a subgrantee—that is, *sub*-subgrantees—are ineligible for certification.

147. HRSA has nevertheless certified and recertified Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Battleborn Health Care, which on information and belief claim eligibility for the 340B program solely through contributions from Sagebrush.

148. HRSA's decisions to certify and recertify Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Battleborn Health Care are final agency actions that are "not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction" or "authority," *id.* § 706(2)(C), and *ultra vires*.

149. HRSA's decisions to certify and recertify Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Battleborn Health Care are also arbitrary, capricious, and an abuse of discretion. 5 U.S.C. § 706(2)(A). HRSA has offered an inadequate explanation—indeed, no explanation—for its decisions to certify and recertify these four entities notwithstanding their failure to receive funds "through a State or unit of local government." 42 U.S.C. § 256b(a)(4)(K).

150. HRSA's decisions to certify and recertify Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Battleborn Health Care are accordingly unlawful and must be set aside.

FOURTH CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
(Declaratory/Injunctive Relief - HRSA's decisions certifying and recertifying entities receiving only in-kind contributions exceed the agency's statutory authority and are arbitrary, capricious, and an abuse of discretion)

151. Genentech realleges and incorporates by reference all prior and subsequent paragraphs.

152. Only an entity "receiving *funds* under [an STD grant] through a State or unit of local government" may be certified as a 340B-eligible STD clinic. 42 U.S.C. § 256b(a)(4)(K). HRSA may not certify or recertify entities that receive only goods or services, rather than funds.

153. HRSA has nevertheless certified and recertified Southington Clinic - CT, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, and Southbury Clinic - CT, which receive only in-kind contributions under a federal STD subgrant.

154. HRSA's decisions to certify and recertify these entities are final agency actions that are "not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction" or "authority," *id.* § 706(2)(C), and *ultra vires*.

155. Even if HRSA's decisions to certify and recertify Southington Clinic - CT, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Danbury Rd Clinic were permissible under Section 340B (though they are not), those decisions are arbitrary, capricious, and abuse of discretion. 5 U.S.C. § 706(2)(A). HRSA has not explained at all, let alone provided a reasoned decision supporting, its conclusion that entities receiving only in-kind contributions may be 340B-eligible notwithstanding the fact that they have not received funds. Although HRSA's guidance states that the receipt of in-kind contributions can qualify a recipient as a 340B-eligible STD clinic, the guidance contains no reasoning or analysis of the relevant statutory language.

156. HRSA's decisions to certify and recertify the eligibility of Southington Clinic - CT, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, and Danbury Rd Clinic, and its guidance stating that entities receiving only in-kind contributions are 340B-eligible, are accordingly unlawful and must be set aside.

FIFTH CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
(Declaratory/Injunctive Relief – HRSA's failure to establish the requisite process for the certification of STD grantees and to make its criteria for certification available to manufacturers exceeds the agency's statutory authority and is arbitrary, capricious, and an abuse of discretion)

157. Genentech realleges and incorporates by reference all prior and subsequent paragraphs.

158. An STD grantee is 340B-eligible "only if the entity is certified by the Secretary pursuant to paragraph [(a)](7)," 42 U.S.C. § 256b(a)(4)(K), which imposes a mandatory duty on HHS to establish "a process for the certification of" STD grantees that apply for 340B eligibility, *id.* § 256b(a)(7)(A).

159. The agency's process for certification must include a requirement that an entity applying for certification submit purchase information to enable the agency to "evaluat[e] the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices." *Id.* § 256b(a)(7)(B). The agency must also require an entity applying for recertification to submit purchase information to permit the agency to evaluate the validity of the entity's purchases "in the same manner" as for initial certification. *Id.* § 256b(a)(7)(E).

160. The agency also must make its "criteria for certification" "available to all manufacturers" participating in the program. *Id.* § 256b(a)(7)(C).

161. HRSA has never made its certification or recertification criteria available to manufacturers.

162. HRSA also has never disclosed any steps it has taken (if any) to require the submission of purchase information or to use that information to verify the eligibility of STD grantees for certification or recertification.

163. HRSA's failure to establish a process for certification or recertification of STD grantees consistent with statutory requirements, and to make its certification and recertification criteria available to manufacturers, exceeds its statutory authority and is arbitrary, capricious, and an abuse of discretion.

164. Because HRSA has not established a process for certification or recertification of STD grantees consistent with statutory requirements, its certification and recertification of the Sagebrush-related entities exceeds its statutory authority and is arbitrary, capricious, and an abuse of discretion. 5 U.S.C. § 706(2)(A), (C).

165. HRSA's decisions to certify and recertify the eligibility of Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann

Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic, which were not undertaken "pursuant to paragraph [(a)](7)," *id.* § 256b(a)(4)(K), are accordingly unlawful and must be set aside.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff requests judgment in its favor against Defendants as follows:

1. Declare that Defendants' failure to comply with Paragraph (a)(7) of Section 340B, by establishing the requisite "process for the certification of" STD grantees and making "criteria for certification" available to manufacturers, is contrary to law;

2. Declare that Defendants' certifications and recertifications of subgrantees that use 340B-priced medicines to provide services not within the scope of an STD grant, transfer 340B-priced drugs to individuals for purposes other than STD prevention, do not directly receive contributions from any government, or receive only in-kind contributions like condoms, are contrary to law;

3. Declare that Defendants' certifications and recertifications of Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic are arbitrary and capricious, an abuse of discretion, and unlawful under the APA and the applicable governing statutes;

4. Set aside the certifications and recertifications of Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic as covered entities under the 340B program;

5. Enter an injunction requiring Defendants to rescind certification or recertification of Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic as covered entities under the 340B program;

6. Enter an injunction prohibiting Defendants from certifying or recertifying Fire Mesa ID, Rainbow Rheumatology, Southington Clinic, Centennial SACI, Hummingbird Medical Group, Dr. Ann Wierman, MD, Danbury Rd Clinic, Eastern Rheumatology, Battleborn Health Care, Southbury Clinic, and Reno Clinic as covered entities under the 340B program;

7. Award Plaintiff reasonable attorneys' fees and costs; and

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

Dated: January 31, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

/s/ Allon Kedem

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