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Attorney for the Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001,

340B HEALTH,
1101 15th Street, NW, Suite 910
Washington, DC 20005,

AMERICA'S ESSENTIAL HOSPITALS,
401 Ninth Street, NW, Suite 900
Washington, DC 20004,

THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES,
655 K Street, NW, Suite 100
Washington, DC 20001,

THE CHILDREN'S HOSPITAL ASSOCIATION,
600 13th Street, NW, Suite 500
Washington, DC 20005,

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS,
4500 East-West Highway, Suite 900
Bethesda, MD 20814,

AVERA ST. MARY'S HOSPITAL,
801 E Sioux Avenue
Pierre, SD 57501,

RIVERSIDE REGIONAL MEDICAL CENTER,
500 J. Clyde Morris Boulevard
Newport News, VA 23601,

Case No. 3:20-cv-08806

ST. MARY'S MEDICAL CENTER,
450 Stanyan Street
San Francisco, CA 94117,

Plaintiffs,

–v–

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

COMPLAINT
Administrative Procedure Act Case

Plaintiffs the American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center ("SMMC") bring this complaint against Defendants Department of Health and Human Services ("HHS") and Alex M. Azar II, in his official capacity as the Secretary of Health and Human Services (the "Secretary"), and allege the following.

NATURE OF ACTION

1. This action challenges as a violation of the Administrative Procedure Act Defendants' determination that they lack the authority to require six pharmaceutical companies—Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), AstraZeneca PLC ("AstraZeneca"),

Novartis Pharmaceuticals Corporation ("Novartis"), United Therapeutics Corporation ("United Therapeutics"), and Novo Nordisk, Inc. and Novo Nordisk Pharma ("Novo Nordisk") (collectively, the "Drug Companies")—to offer certain drugs to covered hospitals and other facilities at statutorily required discounted prices when the drugs are dispensed through community pharmacies via contractual arrangements.

2. The 340B Program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, directs the Secretary to require as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discount to certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve large numbers of patients with low income, including many living in rural communities, in order to increase the funding these entities have available to meet the needs of their patients.

3. The hospitals and other facilities that are eligible for and enroll in the 340B Program are known as "covered entities." 42 U.S.C. § 256b(a)(4). The 340B statute requires the setting of "ceiling prices," *i.e.*, the maximum prices that drug companies can charge to covered entities for covered outpatient drugs, to ensure that covered entities have access to drugs at a lower cost. *See id.* § 256b(a)(1); *see also* 42 C.F.R. § 10.10. By lowering the purchase costs for drugs covered by the 340B Program, Congress enabled these covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102–384(II), at 12 (1992).

4. 340B covered entities dispense covered outpatient drugs to their patients through in-house pharmacies or through community pharmacies that have entered into written contracts with the covered entity ("contract pharmacies"). Under such arrangements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy, whose function is to dispense the drugs to the covered entity's patients.

5. The 340B statute requires manufacturers to offer 340B pricing to covered entities irrespective of how the drugs are dispensed and requires the Secretary to ensure the availability of those statutorily required discounts. HHS recognized the importance of contract pharmacies to the 340B Program when the program began in 1992 and issued its first guidance formally recognizing contract pharmacies in 1996. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

6. In 1996 and again in 2010, HHS recognized that under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. *Id.*; Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010).

7. In defiance of their statutory obligations and despite this long history of regulatory guidance, the Drug Companies have instituted policies refusing to offer 340B discounts for covered drugs if a covered entity dispenses the drug through a contract pharmacy.

8. Despite Plaintiffs' and others' repeated requests that Defendants enforce the 340B statute and require the Drug Companies to sell 340B drugs to covered entities at or below 340B ceiling prices regardless of whether the drugs are to be dispensed via contract pharmacies, Defendants have refused to take action against the Drug Companies or to even inform them that their conduct violates the 340B statute. Instead, on July 8, 2020, Defendants determined that they lack the authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices when dispensed through contract pharmacies.

9. Plaintiffs the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System

Pharmacists (collectively, the "Association Plaintiffs") are associations whose members include 340B covered entities that dispense 340B discount drugs through contract pharmacies.

10. Avera St. Mary's Hospital, Riverside Regional Medical Center, and SMMC (collectively, the "Hospital Plaintiffs"), are 340B covered entities that dispense 340B discount drugs through contract pharmacies.

11. Plaintiffs have no cause of action directly against the Drug Companies for their refusal to comply with the 340B statute. *See Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113–14 (2011). They must rely on Defendants to correctly interpret and apply the statute.

12. Defendants' refusal to require the Drug Companies to sell 340B drugs to covered entities at or below 340B ceiling prices when dispensed through contract pharmacy arrangements is causing significant harm to the Association Plaintiffs' hospital members and pharmacists and to the Hospital Plaintiffs and, by extension, their patients.

PARTIES

13. Plaintiff the American Hospital Association ("AHA") is a national, not-for-profit organization headquartered in Washington, D.C. The AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also ensures members' perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

14. Plaintiff 340B Health is a national, not-for-profit organization headquartered in Washington, D.C. The organization was founded in 1993 to advocate on behalf of 340B hospitals,

which are a vital part of the nation's health care safety net. 340B Health's mission is to be the leading 340B advocate and resource in helping hospitals serve their patients, so that 340B hospitals and health systems fulfill their mission to provide care for patients with low income and those living in rural communities. 340B Health monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to the 340B Program. 340B Health represents more than 1,400 public and private nonprofit hospitals and health systems that participate in the 340B Program.

15. Plaintiff America's Essential Hospitals ("AEH") is a national not-for-profit association headquartered in Washington, D.C. AEH is a champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Since 1981, AEH has initiated, advanced, and preserved programs and policies that help these hospitals ensure access to care. Its more than 300 hospital members are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

16. Plaintiff Association of American Medical Colleges ("AAMC") is a national, not-for-profit association incorporated in Illinois. AAMC represents and serves all 155 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Many AAMC member hospitals and health systems are 340B covered entities and rely on the funds received through the 340B Program to expand care to vulnerable populations. AAMC has a principal place of business located at 655 K Street, N.W., Suite 100, Washington, D.C. 20001.

17. Plaintiff National Association of Children's Hospitals d/b/a Children's Hospital Association ("CHA") is a national, not-for-profit association with a principal place of business in

Washington, D.C. Representing more than 220 children's hospitals, CHA is the voice of children's hospitals nationally. With its members, CHA champions policies that enable children's hospitals to better serve children, leverages its position as the pediatric leader in data analytics to facilitate national collaborative and research efforts to improve performance, and spreads best practices to benefit the nation's children.

18. Plaintiff American Society of Health-System Pharmacists ("ASHP") represents pharmacists and pharmacy technicians who serve as patient care providers in acute and ambulatory settings. The organization's more than 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 78 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. Pharmacists and pharmacy technicians dispense medications at 340B covered entities and contract pharmacies and provide clinical pharmacy services funded by resources generated by 340B discounts and contract pharmacies.

19. Plaintiff Avera St. Mary's Hospital ("Avera St. Mary's") is a 50-bed Sole Community Hospital located in Pierre, South Dakota. The communities Avera St. Mary's serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries and a large number of Medicaid beneficiaries. Avera St. Mary's also provides hospital services to the residents of four nearby Indian Reservations, all of which have limited access to Indian Health Service ("IHS") hospitals.

20. Plaintiff Riverside Regional Medical Center, a 450-bed hospital located in Newport News, VA, is a community-based, not-for-profit teaching hospital, providing many one-of-a-kind services for the region's 447,378 residents. HHS has classified the city of Newport News as an urban medically underserved area, which means it has too few primary care providers, high infant mortality, high poverty, and a high elderly population. The region has a higher than average proportion of residents who smoke and who suffer from chronic health conditions, including diabetes,

hypertension, heart disease, and obesity. The region's death rate is also above the state and national average, primarily driven by lung cancer, chronic obstructive pulmonary disease ("COPD"), Alzheimer's disease, and heart disease. Additionally, the region has a higher rate of teen births, low birth weights, and infant deaths.

21. Plaintiff SMMC is a community hospital in San Francisco, California that provides health care to many underserved communities. The hospital has almost 15,000 emergency department visits annually and serves a large number of patients who are homeless and/or suffering from mental illness and/or drug or alcohol intoxication. The hospital also includes the Sister Mary Philippa Health Center ("SMPHC"), which is an outpatient department of SMMC and an important part of SMMC's support for community health needs. The SMPHC offers adult primary care and specialty care to citizens of San Francisco who meet financial eligibility criteria. For qualifying patients, SMPHC also covers the co-pay for medically appropriate drugs for its patients, which is vital for the area's HIV/AIDS patients.

22. All of 340B Health's member hospitals, including the Hospital Plaintiffs, either participate or have applied to participate in the 340B Program. AHA, AEH, AAMC, and CHA each have many member hospitals that participate in the 340B Program. Those members rely heavily on the statutory discounts created by Congress through the 340B Program to increase the funding these entities have available to provide critical health care programs for the populations they serve. Many of these member hospitals rely on contract pharmacies to help finance care for their low-income and rural patient populations and to facilitate their patients' access to the drugs they need. ASHP members provide clinical pharmacy services funded by resources generated by 340B discounts and contract pharmacies. The Association Plaintiffs' members have been significantly harmed by Defendants' decision not to enforce the statutory requirement that the Drug Companies provide

discounted 340B drugs to covered entities when using contract pharmacies. The Association Plaintiffs bring this action on behalf of their members.

23. The Hospital Plaintiffs rely heavily on the statutory discounts created by Congress through the 340B Program to ensure resources are available to provide critical health care programs for the populations they serve. The Hospital Plaintiffs rely on contract pharmacies to help finance care for low-income and/or rural populations and to facilitate their patients' access to the drugs they need. Defendants' decision not to enforce the statutory requirement that the Drug Companies provide discounted 340B drugs to covered entities when using contract pharmacies has threatened the Hospital Plaintiffs' ability to continue to provide critical health care programs to their communities.

24. Defendant HHS is a cabinet-level department of the United States government headquartered at 200 Independence Avenue, S.W., Washington, D.C. 20201. The Health Resources and Services Administration ("HRSA"), an agency within HHS, is responsible for administering the 340B Program and made the determination that it lacked authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices when dispensed through contract pharmacies.

25. Defendant Alex M. Azar II is the Secretary of Health and Human Services and maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201. In that capacity, he is responsible for the conduct and policies of HHS, including the conduct and policies of HRSA. Secretary Azar is sued in his official capacity.

JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because this action arises under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA"), and section 340B of the Public Health Services Act, 42 U.S.C. § 256b.

27. The APA instructs courts to "set aside agency action, findings, and conclusions" that are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with

law," 5 U.S.C. § 706(2), as well as to compel agency action that has been "unlawfully withheld or unreasonably delayed," *id.* § 706(1). The APA provides a right to judicial review of all "final agency action for which there is no other adequate remedy in a court." *Id.* § 704.

28. Defendants' determination that HHS cannot require the Drug Companies to provide covered entities with 340B drugs at or below 340B ceiling prices when the drugs are dispensed through contract pharmacies constitutes final agency action as to which Plaintiffs are entitled to judicial review under the APA.

29. Alternatively, Defendants' refusal to decide whether the Drug Companies' conduct complies with the 340B statute's requirements constitutes agency action unlawfully withheld or unreasonably delayed to which Plaintiffs are entitled to judicial review under the APA.

30. There exists an actual substantial and continuing controversy between the parties regarding Defendants' determination. This Court has jurisdiction to declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201–2202.

31. The Association Plaintiffs have standing because at least one of each association's members, including the Hospital Plaintiffs, has been and continues to be significantly harmed by Defendants' decision that HHS lacks authority to compel the Drug Companies to offer 340B pricing to covered entities when drugs are dispensed through contract pharmacies. Through this lawsuit, the Association Plaintiffs seek to vindicate interests that are germane to the associations' purposes.

32. The Hospital Plaintiffs and the Association Plaintiffs' members have been harmed by being overcharged for 340B drugs sold by the Drug Companies, particularly as the COVID-19 pandemic ravages the communities they serve. The discounts that have been lost due to Defendants' decision that HHS lacks authority to compel the Drug Companies to offer 340B pricing could have been used to support or expand services for the communities Plaintiffs serve, as Congress intended when it passed the 340B statute.

33. Plaintiffs' injuries would be redressed by a decision that Defendants have authority to bring the Drug Companies into compliance with the 340B statute, that requires Defendants to use that authority, and that affirms Plaintiffs' statutory right to purchase 340B drugs at or below 340B ceiling prices, regardless of whether the drugs are dispensed in-house or through a contract pharmacy.

34. Dignity Health d/b/a SMMC is incorporated in California and is located in this judicial district. Venue lies in this judicial district pursuant to 28 U.S.C. § 1391(e)(1)(C), as a "plaintiff resides" in this district and "no real property is involved in the action," and 28 U.S.C. § 1391(e)(1)(B), as "a substantial part of the events or omissions giving rise to the claim[s] occurred" in this district.

STATUTORY AND REGULATORY BACKGROUND

35. After Congress enacted the Medicaid drug rebate program, which provides outpatient prescription drug rebates to state Medicaid agencies, it was concerned that other entities, including federally funded clinics and public hospitals, were experiencing substantial increases in their outpatient drug costs. *See* H.R. REP. No. 102–384(II), at 11 (1992). In 1992, Congress enacted a statute to lower those drug costs for certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve large numbers of low-income patients, in order to generate funds they can use to serve their patients. The program was established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

36. The Hospital Plaintiffs and many other of the Association Plaintiffs' members are covered entities under the 340B Program.

37. The 340B Program is administered by the Office of Pharmacy Affairs of the Healthcare Systems Bureau, a division of HRSA.

38. Under the 340B Program, prescription drug companies, as a condition of having their outpatient drugs be reimbursable through state Medicaid programs and Medicare Part B, are required

to offer covered entities discounts on certain drugs, calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1); *see also* 42 C.F.R. 10.10. As Congress and HRSA have recognized, the purpose of the 340B Program is to enable eligible public and not-for-profit hospitals and other covered institutions to expand their scarce resources to reach more vulnerable patients who might not otherwise have access to needed services.

39. Since the 340B Program was first implemented, covered entities have used the financial resources generated through the program to provide additional critical health care services for their communities, including underserved populations within those communities—for example, by increasing service locations, developing patient education programs, providing free or discounted drugs and other services, and providing translation and transportation services to improve patients' access to high-quality care.

40. Recognizing the value of the 340B Program, Congress expanded and made other improvements to the program as part of the 2010 Affordable Care Act ("ACA"). Among other things, Congress expanded the categories of covered entities to include critical access hospitals and other hospitals serving patients who live in isolated rural areas. *See* 42 U.S.C. § 256b(a)(4)(M)–(O).

41. Congress also recognized that to "improve . . . compliance by manufacturers," there needed to be a threat of financial penalties to "prevent overcharges and other violations of the discounted pricing requirements." 42 U.S.C. § 256b(d)(1)(A). Therefore, Congress required the Secretary to impose "sanctions in the form of civil monetary penalties" against drug companies that "knowingly and intentionally" "overcharg[e] a covered entity," up to $5,000 "for each instance of overcharging." *Id.* § 256b(d)(1)(B)(vi).

42. In addition, Congress directed the Secretary to "establish[] procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including . . . [o]versight by the Secretary to ensure that the refunds are issued

accurately and within a reasonable period of time, both in instances of retroactive adjustments to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs." 42 U.S.C. § 256b(d)(1)(B)(ii). HRSA has adopted a process pursuant to which covered entities can submit information concerning overcharges directly to HRSA on a form that has been developed by HRSA's 340B prime vendor.[1]

43. The regulations governing 340B civil monetary penalties state that "[a]n instance of overcharging is any order for a covered outpatient drug . . . which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." 42 C.F.R. § 10.11(b). Importantly, "[t]his includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* § 10.11(b)(1). The preamble to the final rule adopting these regulations indicates that an overcharge may occur when there is a documented refusal by a manufacturer to sell a drug at or below the 340B ceiling price. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,226 (Jan. 5, 2017).

44. In 1996, HRSA issued "final guidelines" that acknowledged that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients." 61 Fed. Reg. at 43,550. HRSA also made clear that "[u]nder section 340B, . . . if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis added).

[1] The form is available at: https://docs.340bpvp.com/documents/public/resourcecenter/HRSA_Notification_340B_Price_Unavailable.docx. The 340B Prime Vendor Program provides free technical assistance to all 340B stakeholders to support their management of 340B-compliant operations. The 340B Prime Vendor Program, as part of its agreement with HRSA, provides online tutorials, a variety of templates, and other tools to aid with program compliance. In addition, under the terms of the agreement with HRSA, it offers two educational programs and a national call center. 340B Educational Resources, HRSA, https://www.hrsa.gov/opa/educational-resources/index.html.

45. In 2010, HRSA again acknowledged that "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer *the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*." 75 Fed. Reg. at 10,278 (emphasis added).

THE DRUG COMPANIES' UNLAWFUL CONDUCT

46. On information and belief, since the beginning of the 340B Program, the Drug Companies accepted HRSA's interpretation and abided by the 340B statute's requirement to provide 340B discounts to covered entities for covered outpatient drugs, regardless of whether they dispense the drugs through in-house pharmacies or contract pharmacies.

47. In June 2020, HRSA posted a notice from Lilly on its website stating that, effective July 1, 2020, the company would no longer provide 340B discount pricing on three formulations of its drug Cialis® when a 340B covered entity purchasing the drug elects to have it shipped to a 340B contract pharmacy. *See Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs*, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf. Lilly's notice directed covered entities that do not have their own in-house pharmacy to contact Lilly regarding an exception process. *Id.*

48. On or around September 1, 2020, Lilly issued another notice extending its refusal to provide 340B discount pricing to covered entities dispensing drugs through contract pharmacies to all Lilly drugs, effective September 1, 2020, with the same exception process for covered entities without an in-house pharmacy and a complicated exception process for insulin products.

49. In July 2020, Sanofi notified covered entities that it would be joining Lilly. Effective October 1, 2020, to be eligible to order Sanofi drugs for contract pharmacies at 340B prices, 340B covered entities must submit claims data for 340B prescriptions of Sanofi products filled through

contract pharmacies. Those that do not are no longer eligible to order Sanofi drugs at 340B prices if those drugs are dispensed through contract pharmacies.

50. On August 17, 2020, AstraZeneca jumped on board and issued notices to covered entities stating that, effective October 1, 2020, the company would no longer honor 340B pricing for contract pharmacy arrangements and "only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." AstraZeneca implemented that policy on October 1, 2020.

51. Also on August 17, 2020, Novartis became the fourth pharmaceutical manufacturer to put restrictions on 340B pricing with respect to drugs dispensed through contract pharmacies, notifying covered entities that, effective October 1, 2020, "all 340B covered entities will be required to . . . provide 340B claims data originating from [contract pharmacy] utilization in order to receive 340B reimbursements from Novartis." Novartis did not implement that policy, but on October 30, 2020, Novartis announced in notices to 340B hospitals a modified restriction on 340B pricing for drugs dispensed through contract pharmacies that is applicable only to 340B hospitals. Effective November 16, 2020, Novartis is honoring contract pharmacy arrangements only within a 40-mile radius of the hospital's "parent facility" but is not providing 340B pricing to hospitals for arrangements with pharmacies outside this 40-mile radius.

52. In response to the Drug Companies' unlawful conduct, 340B Health sent letters to Lilly and Sanofi on August 11, 2020, and to AstraZeneca and Novartis on August 26, 2020, expressing opposition to the companies' actions, stating that denial of 340B pricing to covered entities for drugs dispensed under contract pharmacy arrangements violates the 340B statute, and urging them to "withdraw" their "unilateral initiative[s]."

53. On August 21, 2020, the AHA also sent letters to each of these four Drug Companies, urging them "to cease this conduct immediately and to work to ensure that 340B drugs are available and accessible to vulnerable communities and populations."

54. On November 18, 2020, United Therapeutics became the fifth drug manufacturer to announce restrictions related to contract pharmacies, informing covered entities that the company would institute its changes in two phases. First, on or after November 20, 2020, United Therapeutics would accept 340B contract pharmacy orders only if the contract pharmacy had been utilized by the covered entity for a valid 340B purchase of a United Therapeutics covered outpatient drug during the first three full quarters of the 2020 calendar year. The announcement included a link that identifies which contract pharmacies are eligible for this phase, though to date the link does not include that information. The announcement indicated that covered entities without on-site pharmacies could apply for an exception that would allow the covered entity "to designate a single contract pharmacy for which United Therapeutics Corporation will accept 340B orders." United Therapeutics further announced that, in the second phase, the company "will accept 340B contract pharmacy orders placed on or after May 13, 2021 only if the covered entity also has agreed to provide to United Therapeutics Corporation, and is providing on an ongoing basis, claims data associated with all 340B contract pharmacy orders of United Therapeutics Corporation's covered outpatient drugs placed after May 13, 2021." United Therapeutics included no exception as to the second phase, even for covered entities without an in-house pharmacy.

55. On December 1, 2020, Novo Nordisk announced that on January 1, 2021, it would join the other five drug manufacturers in imposing restrictions related to 340B contract pharmacies, effectively denying 340B hospitals the discounts for 340B drugs dispensed through contract pharmacies. Novo Nordisk has stated that its restrictions will apply only to hospitals and will include an exception for hospitals that do not have their own on-site pharmacy.

DEFENDANTS' DECISION NOT TO REQUIRE COMPLIANCE WITH THE 340B STATUTE

56. On May 18, 2020, Lilly sent a letter to HRSA informing the agency that, effective July 1, 2020, the company would no longer provide certain Cialis® formulations at or below the 340B ceiling price to covered entities dispensing the drug through contract pharmacy arrangements. On June 26, 2020, Lilly provided HRSA with a notice regarding its decision for the agency to post on its website. HRSA published the notice and allowed Lilly to proceed with its restriction.

57. On July 8, 2020, shortly after HRSA posted Lilly's notice that it would no longer offer Cialis® at 340B ceiling prices to covered entities using contract pharmacies, 340B Health requested from HRSA its official response to Lilly's decision. In response, HRSA stated that contract pharmacies "serve a vital function in covered entities' ability to serve underserved and vulnerable populations" and that "[m]anufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions."

58. As to its legal authority, HRSA stated that it cannot require manufacturers to offer 340B discounts on drugs sold to covered entities but dispensed through contract pharmacies because, although the agency recognized the use of contract pharmacies in its 2010 guidelines, *see* 75 Fed. Reg. 10,272, HRSA's "guidance is not legally enforceable." HRSA explained that its "current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute," and that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program."

59. The Association Plaintiffs, as well as numerous other associations and entities concerned with the Drug Companies' illegal policies, contacted Defendants and requested they enforce the Drug Companies' statutory requirements to provide 340B drugs at or below 340B ceiling price to covered entities.

60. On July 16, 2020, 340B Health, along with other organizations representing 340B covered entities, sent a letter to the Secretary asking him to "use [HHS's] legal authority to halt these actions and protect vital institutions and their patients." On July 30, 2020, the AHA sent a letter to the Secretary asking him to "address these abuses . . . and request [the Drug Companies] cease this activity and work to ensure 340B drugs are available and accessible to communities and vulnerable populations." On August 26, 2020, the Association Plaintiffs sent a joint letter to the Secretary describing the Drug Companies' unlawful conduct and requesting that HHS "use its authority to require that these and other pharmaceutical manufacturers comply with the law." On August 28, 2020, AEH sent a letter to the Secretary asking "the agency to intervene to prevent manufacturers from undermining the 340B program and violating their statutory obligations." And on September 10, 2020, Avera St. Mary's Hospital and SMMC joined a letter to the Secretary signed by more than 1,100 340B hospitals stating that the Drug Companies' "collective actions to deny access to 340B pricing are clear violations of the 340B statute" and urging the Secretary to use his authority to end these practices.

61. Member hospitals of the Association Plaintiffs submitted to HRSA notices of overcharges by the Drug Companies for drugs dispensed through contract pharmacies, using the form prescribed by HRSA for notification of when a drug manufacturer's covered outpatient drugs are unavailable at or below 340B ceiling prices or when the covered entity is charged a price greater than the ceiling price. HRSA has not notified the member hospitals that it has taken any action or intends to take any action to require the Drug Companies to issue refunds to the hospitals.

62. The AHA sent additional letters to the Secretary on September 8, 2020 ("[W]e urge you to act immediately against any drug manufacturer employing these pernicious tactics to ensure that 340B drugs are available and accessible to vulnerable communities."), and October 16, 2020 ("[W]e request that HHS immediately direct [Lilly, AstraZeneca, and Sanofi] to cease charging hospitals and covered entities more than the 340B ceiling price for drugs being dispensed by a contract pharmacy and . . . to issue refunds for each overcharge instance. We also request that the matter be referred to the HHS Office of Inspector General for assessment of civil money penalties."). 340B Health sent an additional letter to the Secretary on September 21, 2020, advising him of how the Drug Companies' actions are harming safety-net hospitals and undermining the 340B benefit for these hospitals and their patients at a time when hospitals' resources are severely strained by the COVID-19 pandemic. The letter reiterated that "HHS clearly has authority under the statute and the civil monetary penalties regulation to take action to stop manufacturer actions that restrict covered entities' access to 340B pricing for covered outpatient drugs."

63. Despite the numerous requests to stop the Drug Companies from implementing their unlawful actions, Defendants have not revised their July 8, 2020 final determination that HRSA lacks the authority to require the Drug Companies to provide 340B drugs at or below 340B ceiling prices when dispensed through contract pharmacies.

COUNT 1

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT: UNLAWFUL AND ARBITRARY AND CAPRICIOUS AGENCY ACTION

64. Plaintiffs incorporate by reference paragraphs 1-63.

65. The APA requires this Court to hold unlawful any agency action that is arbitrary and capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A).

66. Under the terms of the 340B statute, the Drug Companies must charge covered entities no more than the 340B ceiling price for any covered outpatient drug, regardless of whether the drug is delivered to the covered entity's in-house pharmacy or to a contract pharmacy. Under the applicable law, HRSA had the duty to require the Drug Companies to charge no more than the 340B ceiling price for covered outpatient drugs, even if those drugs are delivered to a contract pharmacy, and to refund to covered entities the difference between what each covered entity paid for their covered outpatient drugs and the 340B ceiling price. HRSA also had the duty to refer the matter to the HHS Office of the Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.

67. Defendants' decision that HRSA lacks authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is contrary to section 340B of the Public Health Service Act, in violation of section 706(2)(A) of the APA, and Defendants' failure to take actions to assure that the law is followed is both arbitrary and capricious and an abuse of discretion, also in violation of section 706(2)(A).

68. Defendants' decision constitutes final agency action, as it marked the consummation of the decision-making process with respect to what authority Defendants believe HRSA possesses, and it prevented the agency from bringing actions against the Drug Companies, resulting in Plaintiffs' inability to purchase the Drug Companies' products at or below 340B ceiling prices despite having sought redress from HRSA.

COUNT 2

VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT: AGENCY ACTION UNLAWFULLY WITHHELD OR UNREASONABLY DELAYED

69. Plaintiffs incorporate by reference paragraphs 1-63.

70. The APA requires this Court to "compel agency action" that has been "unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

71. If the statement that HRSA lacks authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is not a final agency action, Defendants' failure to reach a decision as to whether the Drug Companies' conduct is lawful and Defendants' failure to require the Drug Companies to provide 340B drugs at or below 340B ceiling prices to covered entities regardless of whether the drugs are delivered to contract pharmacies constitute agency action unlawfully withheld and unreasonably delayed, in violation of section 706(1) of the APA.

* * * * *

72. The injury to Plaintiffs and the patients they and their members serve is substantial and grows with each passing day, as the Drug Companies continue to overcharge for 340B drugs dispensed through contract pharmacies. The Drug Companies' conduct reduces the 340B benefit that hospitals use to finance critical health care services, which impacts the patients and communities Plaintiffs serve at the same time the COVID-19 pandemic wreaks havoc in these same communities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and issue the following relief:

A. A declaratory judgment that Defendants' decision that HRSA lacks the authority to require the Drug Companies to provide 340B covered entities with covered drugs at or below 340B ceiling prices when they dispense those drugs through contract pharmacies is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A);

B. An order directing Defendants to require the Drug Companies to provide covered outpatient drugs at or below 340B ceiling prices to covered entities when they dispense those drugs through contract pharmacies;

C. An order directing Defendants to require the Drug Companies to refund the Hospital Plaintiffs and the Association Plaintiffs' members the difference between what each covered entity paid for covered outpatient drugs and the 340B ceiling price;

D. An order directing Defendants to refer the matter to the HHS Office of the Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 10003;

E. If the Court finds that the decision that HRSA lacks authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is not a final agency action:

1. A declaratory judgment that Defendants' failure to decide whether the Drug Companies' conduct complies with the 340B statute is agency action unlawfully withheld or unreasonably delayed, in violation of 5 U.S.C. § 706(1);

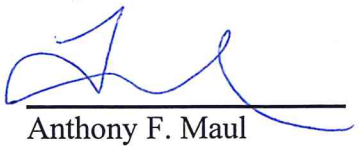
2. An order directing Defendants, within 30 days, to issue a decision on whether the Drug Companies' decision not to sell 340B drugs at or below the 340B ceiling price when dispensed through contract pharmacies complies with the 340B statute and to inform the Court of its decision, and

3. If Defendants determine that the Drug Companies' conduct violates the 340B statute, an order directing Defendants also to inform the Court as to the actions they will take to address that illegal conduct; and

F. Such other relief as this Court may deem just and proper.

Dated: December 11, 2020

Respectfully submitted,



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