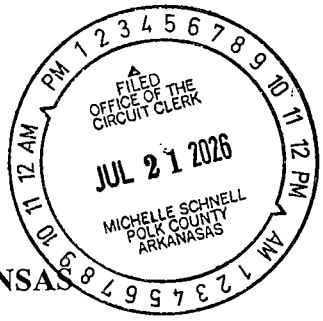

IN THE CIRCUIT COURT OF POLK COUNTY, ARKANSAS
civil DIVISION

CASE NUMBER: 57CV-26-184

STATE OF ARKANSAS, *ex rel.*
TIM GRIFFIN, ATTORNEY GENERAL — PLAINTIFF

v.

ABBVIE, INC.
AMGEN, INC.
AMGEN MANUFACTURING, LIMITED;
ASTRAZENECA LP;
ASTRAZENECA PHARMACEUTICALS LP;
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC;
BRISTOL MYERS SQUIBB COMPANY;
ELI LILLY AND COMPANY;
GENZYME CORPORATION;
GLAXOSMITHKLINE LLC;
IMMUNEX CORPORATION;
JOHNSON AND JOHNSON;
MERCK & CO., INC.;
NOVARTIS AG;
NOVARTIS PHARMACEUTICALS CORPORATION;
NOVO NORDISK A/S;
NOVO NORDISK, INC.;
PFIZER, INC.;
SANOFI-AVENTIS U.S. LLC;
SANOFI S.A.;
SANOFI US SERVICES INC.;
SECOND SIGHT SOLUTIONS, LLC,
DEFENDANTS

COMPLAINT

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I. INTRODUCTION

1. This case is about pharmaceutical manufacturers choosing profits over patients. After dramatically increasing the prices of their drugs—and thereby increasing their financial obligations under the federal 340B Drug Program—Defendants embarked on a coordinated campaign to reduce their obligation to provide discounted drugs to eligible safety-net healthcare providers. In response, Arkansas enacted legislation to protect its healthcare providers' continued access to the discounted drugs. But that law failed to deter Defendants, who circumvented its protections by imposing a series of shifting, burdensome, and unlawful requirements on Arkansas healthcare providers to obtain Defendants' discounted drugs. Those requirements were designed to effectively deny Arkansas providers access to Defendants' discounted drugs and thereby reduce Defendants' costs. Defendants' plan worked, but to the detriment of the State. Defendants' actions exacerbated Arkansas's growing healthcare crisis, threatened the viability of hospitals and community clinics serving vulnerable populations, and jeopardized access to essential, life-saving care throughout the State.

2. More than 30 years ago, Congress enacted Section 340B of the Public Health Service Act, requiring pharmaceutical manufacturers participating in Medicaid and Medicare to provide discounted outpatient drugs to certain safety-net providers known as "Covered Entities." 42 U.S.C. § 256b (the "340B Program"). The program reflects a clear and longstanding public policy judgment: manufacturers that benefit from participation in taxpayer-funded healthcare programs must, in turn, help support the providers that care for low-income, uninsured, and underserved populations. For Arkansas hospitals, community health centers, and clinics operating with scarce resources, the 340B Program has become indispensable.

3. For decades, the 340B Program worked as intended. Arkansas Covered Entities used 340B savings to keep clinics open, fund critical services, expand access to medications, and

provide care to those who otherwise might go without treatment. Rural communities, low-income patients, and uninsured Arkansans all benefited from the program. During this period, pharmaceutical manufacturers routinely honored Covered Entities' use of contract pharmacies and did not attempt to obstruct access to 340B drugs.

4. Beginning in 2020, however, Defendants abruptly changed course. Under the 340B Program, manufacturers that increase drug prices faster than inflation must provide correspondingly larger discounts to Covered Entities. Repeated price increases can drive those discounts close to 100 percent of a drug's selling price. Defendants nevertheless made the deliberate business decision to raise the prices of many of their drugs at rates far exceeding inflation. Since 2019, the average retail price of brand-name prescription drugs has more than doubled in inflation-adjusted dollars.[1] Between 1996 and 2019, Defendant Eli Lilly increased the list price of Humalog, its top-selling insulin product, by approximately 1,200 percent.[2]

5. Rather than accept the consequences of their own pricing decisions, Defendants sought to dictate a series of extra-statutory restrictions designed to limit Covered Entities' access to discounted drugs. Defendants restricted the use of contract pharmacies, imposed arbitrary geographic limitations, demanded valuable claims and medical data, and created a constantly changing patchwork of requirements that no statute or regulation authorized.

6. These new requirements were not innocuous administrative changes. They represented a fundamental departure from decades of industry practice and a direct assault on the healthcare of Arkansans. Defendants knew that most Arkansas Covered Entities depended on

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[1] Prescription Drugs: Spending, Use, and Prices, CONG. BUDGET OFF. 2 (Jan. 2022), https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf (last visited Jul. 9, 2026).

[2] Maureen Testoni, *Pursuit of Profits is Driving Drug Companies to Break the 340B Law*, STAT. (June 10, 2022).

contract pharmacies to dispense medications and access 340B pricing. They likewise knew that many Covered Entities lacked the financial resources, bargaining power, staff, or infrastructure necessary to comply with Defendants' ever-changing demands. The predictable result was that Covered Entities would lose access to discounts and Defendants would reduce the amount of 340B drugs they were required to deliver.

7. Defendants understood exactly what they were doing and why they were doing it. To investors, a senior Eli Lilly executive described the company's 340B restrictions as a "tailwind" for profits.[3] To Arkansas patients and providers, those same restrictions meant the loss of funding used to support healthcare services, reduced access to medications, and additional strain on an already fragile healthcare system.

8. Defendants' conduct is unconscionable within the meaning of the Arkansas Deceptive Trade Practices Act ("ADTPA"). Ark. Code Ann. §§ 4-88-101 et seq. Arkansas law recognizes that conduct is unconscionable when it affronts the sense of justice, decency, or reasonableness, including by improperly using economic leverage in a trade transaction; or violates established public policy. Defendants' conduct does both.

9. Defendants exploited their superior market and economic power to impose conditions that Covered Entities had no meaningful ability to resist. They forced Arkansas safety-net providers into an impossible choice: comply with burdensome and unlawful demands or forfeit access to the discounted drugs that are essential to their operations and their patients' care.

10. Defendants' conduct is further unconscionable because it directly contravenes Arkansas law. In 2021, the Arkansas General Assembly enacted Act 1103 to protect Covered

[3] Eli Lilly & Company's (LLY) Management on UBS Global Healthcare Virtual Conference (May 26, 2021), https://www.340Bhealth.org/files/Lilly_Transcript.pdf (last visited Jul. 9, 2026).

Entities' ability to access 340B drugs through contract-pharmacy arrangements—a necessity in a State where in-house pharmacies historically have been rare. *See* Ark. Code Ann. § 23-92-601 to -606. Defendants and their industry representatives challenged that law, arguing that federal law preempted Arkansas's protections. They lost. Federal courts upheld Act 1103, confirming that the 340B statute does not prohibit Arkansas from providing "an additional, and important, layer of consumer protection that complements [the 340B] regulation." *Pharm. Rsch. & Mfrs. Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024). Yet Defendants persisted in imposing new barriers designed to deprive Covered Entities of the very protections Act 1103 was enacted to secure.

11. The consequences of Defendants' conduct have been immediate, substantial, and ongoing. Covered Entities lost critical funding used to serve patients, maintain services, hire staff, and expand care into underserved areas. Some were forced to reduce services, eliminate positions, postpone expansion plans, or absorb significant financial losses. Patients, particularly those in rural communities, experienced reduced access to affordable medications and healthcare services.

12. These harms occurred at a time when Arkansas's healthcare system was already under extraordinary pressure. Approximately two-thirds of Arkansas rural hospitals are at risk of closure, one of the highest rates in the Nation.[4] Since 2020, roughly twenty-seven percent of rural hospital labor and delivery units have closed.[5] Hospitals across the State, including over eighty percent of rural hospitals, have reduced or eliminated services, including emergency care, inpatient

[4] Rural Hospitals at Risk of Closing, CTR. HEALTHCARE QUALITY & PAYMENT REFORM (May 2026), https://chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf (last visited Jul. 9, 2026).

[5] Stopping the Loss of Rural Maternity Care, CTR. HEALTHCARE QUALITY & PAYMENT REFORM (June 2026), https://chqpr.org/downloads/Rural_Maternity_Care_Crisis.pdf (last visited Jul. 9, 2026).

services, and specialized units.[6] Many Arkansans continue to report foregoing necessary medical treatment because of cost, distance, or other barriers.[7]

13. In a healthcare system confronting hospital closures, collapsing rural healthcare infrastructure, and unprecedented financial strain, Defendants' conduct has compounded an already acute crisis.

14. Tim Griffin, Attorney General of the State of Arkansas, brings this action under the ADTPA to hold Defendants accountable for their unconscionable business practices and to protect Arkansas patients, healthcare providers, and communities from further harm.

II. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction under Ark. Code Ann. § 4-88-113.

16. This Court has personal jurisdiction over Defendants under the long-arm statute of the State of Arkansas (Ark. Code Ann. § 16-4-101), and the United States Constitution, because Defendants conduct business in Arkansas, purposefully direct or directed their actions toward Arkansas, and have the requisite minimum contacts with Arkansas necessary to permit the Court to exercise jurisdiction.

17. Venue in this Court is proper under Ark. Code Ann. §§ 4-88-113 and 16-60-104.

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[6] George Mitchell, *Arkansas Seeks Funding as Rural Hospitals Cut Services, Face Financial Strain*, TIMES RECORD (Nov. 11, 2025), https://www.swtimes.com/story/news/2025/11/11/arkansas-seeks-aid-as-nearly-two-thirds-of-rural-hospitals-face-closure-risk/87200373007/?gnt-cfr=1&gca-cat=p&gca-uir=false&gca-epti=z111707p001750c001750e007100v111707&gca-ft=149&gca-ds=sophi (last visited Jul. 9, 2026).

[7] CTR. HEALTHCARE, ARKANSAS SCORECARD, https://westhealth.gallup.com/explore/scorecards/arkansas?tab=cost (last visited Jul. 9, 2026)).

III. PARTIES

A. Plaintiff

18. Plaintiff is the State of Arkansas, *ex rel.* Tim Griffin, Attorney General. Attorney General Griffin is the chief legal officer of the State. Under Ark. Code Ann. §§ 4-88-104 and 4-88-113, the Attorney General is authorized to file a civil action to enforce the ADTPA.

B. Manufacturer Defendants

a. AbbVie

19. Defendant **AbbVie Inc.** ("AbbVie") is incorporated in Delaware and has its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

20. At all times relevant to this Complaint AbbVie participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

21. To circumvent the 340B Program's requirement that AbbVie provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, AbbVie imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

22. AbbVie, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

23. AbbVie manufactures several 340B drugs, including Synthroid and Armour Thyroid, medications used to treat hypothyroidism and to manage certain thyroid cancers that work by replacing a hormone typically produced naturally by the thyroid gland; Qulipta and Ubrelvy,

medications that treat and prevent chronic migraines in adults; Linzess, a medication used to treat various gastrointestinal conditions; Lo Loestrin Fe, a low dose combination birth control pill; Rinvoq, Skyrizi, and Humira, medications used to treat several inflammatory conditions like rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, ulcerative colitis, and Crohn's disease; Vraylar, a medication used to treat types of bipolar disorder, major depressive disorder, and schizophrenia; Venclexta, a medication used to treat chronic lymphocytic leukemia and small lymphocytic lymphoma; Lumigan, an eye drop medication used to treat certain types of glaucoma and other causes of high eye pressure; Bystolic, a medication used to treat hypertension by slowing the heart and relaxing blood vessels; Savella, a medication used to treat chronic pain caused by fibromyalgia; and Refresh Tears, an eye lubricant medication that treats dry and irritated eyes,

b. Amgen

24. Defendant **Amgen, Inc.** is incorporated in Delaware and has its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

25. Defendant **Amgen Manufacturing, Limited** is a corporation existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 Km 24.6, Juncos, Puerto Rico 00777. Amgen Manufacturing is a wholly owned subsidiary of Amgen Inc.

26. Defendant **Immunex Corporation** is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly owned subsidiary of Amgen Inc.

27. Amgen, Inc., Amgen Manufacturing, Limited, and Immunex Corporation are collectively referred to herein as "Amgen."

28. At all times relevant to this Complaint Amgen participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

29. To circumvent the 340B Program's requirement that Amgen provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Amgen imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

30. Amgen, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

31. Amgen manufactures several 340B drugs, including Aimovig, an injectable medication that prevents migraines and reduces the number of migraines per month; Repatha, an injectable medication that lowers cholesterol and reduces the risk of heart attacks and strokes; Enbrel and Otezla, medications used to treat autoimmune diseases that cause the body to mistakenly attack its own healthy cells; and Tezspire, an injectable medication used to treat severe asthma and chronic rhinosinusitis with nasal polyps that are not controlled by any other medication.

c. AstraZeneca

32. Defendant **AstraZeneca Pharmaceuticals LP** is a limited partnership organized under the laws of the State of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

33. Defendant **AstraZeneca LP** is a limited partnership organized under the laws of the State of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

34. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP are collectively referred to herein as "AstraZeneca."

35. At all times relevant to this Complaint AstraZeneca participated in the 340B program, selling covered outpatient drugs to Covered Entities, including Covered Entities in Arkansas.

36. To circumvent the 340B Program's requirement that AstraZeneca provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, AstraZeneca imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

37. AstraZeneca, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs, and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

38. AstraZeneca manufactures certain drugs that, under the 340B Program, it must provide to Covered Entities at a discounted price. These drugs include: Farxiga, a prescription medication used to manage type 2 diabetes, heart failure, and chronic kidney disease; Symbicort, Breztri, Bevespi, Budesonide-Formoterol, Airspura, and Pulmicort, prescription inhalers used daily to prevent asthma symptoms and to manage airflow obstruction for patients suffering from

chronic obstructive pulmonary disorder (COPD); Brilinta, an oral prescription medication that prevents blood platelets from sticking together to form clots, primarily used to reduce the risk of heart attacks, strokes, and cardiovascular death in patients with acute coronary syndrome, coronary artery disease, or a history of a previous heart attack or stroke; Tagrisso, used to treat certain lung cancers; Xigduo XR and Onglyza, oral medications used to control blood sugar levels in type 2 diabetics; Daliresp, a prescription tablet used to reduce lung inflammation in adults suffering from COPD; Bydureon BCise and Byetta, injectable diabetes medications that help type 2 diabetics produce insulin more efficiently and manage their blood sugar levels; Lynparza, used to treat certain ovarian, breast, fallopian tube, pancreatic, prostate, and peritoneal cancers; Nexium, a proton pump inhibitor used to treat certain gastrointestinal conditions; and Lokelma, a medication used to treat high blood potassium levels typically found in patients with chronic kidney disease.

d. Boehringer Ingelheim

39. Defendant **Boehringer Ingelheim Pharmaceuticals, Inc.** ("Boehringer Ingelheim") is incorporated in Delaware and has its principal place of business in Ridgefield, Connecticut.

40. At all times relevant to this Complaint Boehringer Ingelheim participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

41. To circumvent the 340B Program's requirement that Boehringer Ingelheim provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Boehringer Ingelheim imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

42. Boehringer Ingelheim, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

43. Boehringer Ingelheim manufactures a number of 340B drugs, including Jardiance, Synjardy, Glyxambi, and Trijardy, medications used to control blood sugar levels and lower liver glucose production in diabetes patients, and to lower the risk of death from heart attack, stroke, and heart failure in type 2 diabetes patients; Spiriva, Stiolto, Combivent, Striverdi, and Atrovent, medications that prevent airflow obstruction, relax airways for easier breathing, and reduce flare ups in patients suffering from COPD and asthma; Tradjenta, an oral diabetes medication used to control blood sugar levels in type 2 diabetics; Ofev, a medication that slows the decline of lung functionality and scar tissue build up in patients suffering from serious lung diseases like pulmonary fibrosis; and Pradaxa, an anticoagulant medication that prevents and treats blood clots.

e. Bristol Myers Squibb

44. **Bristol Myers Squibb Company** ("Bristol") is incorporated in Delaware and has its principal place of business in Lawrenceville, New Jersey.

45. At all times relevant to this Complaint Bristol participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

46. To circumvent the 340B Program's requirement that Bristol provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Bristol imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions

were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

47. Bristol, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Covered Entities.

48. Bristol manufactures several 340B drugs, including Eliquis, a medication that prevents blood clotting and is used to lower the risk of stroke in patients with atrial fibrillation or deep vein thrombosis, or who have undergone knee or hip replacement surgery; and Orencia, an injectable medication that stops the body from attacking healthy joints in patients suffering from autoimmune conditions like rheumatoid arthritis.

f. Eli Lilly

49. Defendant **Eli Lilly and Company** ("Eli Lilly") is a corporation organized under the laws of the State of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285.

50. At all times relevant to this Complaint Eli Lilly participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

51. To circumvent the 340B Program's requirement that Eli Lilly provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Eli Lilly imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

52. Eli Lilly, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Covered Entities.

53. Eli Lilly manufactures various 340B drugs, including Basaglar and Rezvoglar, long-acting insulin medications used to control blood sugar levels in diabetes patients; Humulin R, a short-acting insulin medication used to control blood sugar levels in diabetes patients; Insulin Lispro, Humalog, and Lyumjev, rapid-acting insulin medications used to control blood sugar levels in diabetes patients; Humulin N and Humulin 70/30, intermediate-acting insulin medications used to control blood sugar levels in diabetes patients; Emgality, a medication used to prevent migraines and treat episodic cluster headaches; Trulicity, Mounjaro, and Zepbound, injectable medications that help type 2 diabetics produce insulin more efficiently and manage their blood sugar levels, help manage obesity and other weight related medical conditions, and treat obstructive sleep apnea; Reyvow, a medication used to treat migraine headaches; Taltz, an injection medication used to treat autoimmune disorders including psoriatic arthritis, nonradiographic axial spondyloarthritis, and ankylosing spondylitis; and Forteo, an injection medication used to treat osteoporosis and postmenopausal women at high risk for bone fracture.

g. GlaxoSmithKline

54. Defendant **GlaxoSmithKline LLC** is incorporated in Delaware and has its principal place of business at 2929 Walnut Street, Suite 1700, Philadelphia, Pennsylvania.

55. At all times relevant to this Complaint GSK participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

56. To circumvent the 340B Program's requirement that GlaxoSmithKline provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, GlaxoSmithKline imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

57. GlaxoSmithKline, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

58. GlaxoSmithKline manufactures various 340B drugs, including Trelegy, Advair, Breo, Flovent, Anoro, Incruse, Serevent Diskus, Ventolin, and Arnuity, inhaler medications used to treat patients with asthma and COPD by relaxing airways, preventing airflow obstruction, and reducing flare ups; Nucala, an injectable anti-inflammatory medication used to treat severe asthma, COPD, chronic rhinosinusitis with nasal polyps, Eosinophilic Granulomatosis with Polyangiitis, and Hypereosinophilic Syndrome; and Benlysta, a medication used to treat lupus erythematosus, an autoimmune disease that causes severe inflammation of the skin, joints, kidneys, and other organs.

h. Johnson & Johnson

59. Defendant **Johnson and Johnson** ("J&J") is incorporated in New Jersey and has its principal place of business in New Brunswick, New Jersey.

60. At all times relevant to this Complaint J&J participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

61. To circumvent the 340B Program's requirement that J&J provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, J&J imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

62. J&J, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

63. J&J manufactures a number of 340B drugs, including Xarelto, a medication that prevents blood clotting and is used to lower the risk of stroke in patients with atrial fibrillation or deep vein thrombosis, or who have undergone knee or hip replacement surgery; Invega, an antipsychotic medication used to treat schizophrenia; Invokana, an oral diabetes medication that helps control blood sugar levels and lower the risk of death from heart attack, stroke, or heart failure for type 2 diabetics; and Tremfya and Stelara, injectable medications used to treat autoimmune diseases like Crohn's disease, plaque psoriasis, psoriatic arthritis, and ulcerative colitis.

i. Merck

64. Defendant **Merck & Co., Inc.** ("Merck") is a New Jersey corporation with its principal place of business in Rahway, New Jersey.

65. At all times relevant to this Complaint Merck participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

66. To circumvent the 340B Program's requirement that Merck provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Merck imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

67. Merck, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

68. Merck manufactures various 340B drugs, including Januvia, Steglatro, Steglujan, and Janumet, medications used to treat diabetes by regulating insulin after eating, decreasing absorption of glucose in the intestines, and helping the kidneys get rid of blood glucose; Lagevrio, an antiviral medication used to treat mild-to-moderate COVID-19 for patients who are at high risk of progression to severe COVID-19; Belsomra, a sedative medication used to treat insomnia; and Verquvo, a medication that treats patients who have recently been hospitalized and who have chronic heart failure by lowering their risk of death and further hospitalization.

j. Novartis

69. Defendant **Novartis AG** is a Swiss corporation with its principal place of business at Lichstrasse 35, CH-4002 Basel, Switzerland.

70. Defendant **Novartis Pharmaceuticals Corporation** is a corporation organized under the laws of the State of Delaware with its principal place of business in East Hanover, New

Jersey. Defendant Novartis Pharmaceuticals Corporation is a subsidiary of Defendant Novartis AG.

71. Defendants Novartis Pharmaceuticals Corporation and Novartis AG are collectively referred to herein as "Novartis."

72. At all times relevant to this Complaint Novartis participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

73. To circumvent the 340B Program's requirement that Novartis provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Novartis imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

74. Novartis, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Covered Entities.

75. Novartis manufactures a number of 340B drugs, including Entresto, an oral prescription medication used to treat chronic heart failure; Focalin, a medication used to treat attention deficit hyperactivity disorder; Kesimpta, a medication for relapsing forms of multiple sclerosis; Kisqali, an oral medication used to treat certain types of breast cancer; Xiidra, a droplet medication for symptoms of dry eye disease ("DED"); Pataday, an antihistamine that reduces allergy symptoms in the eyes; Ciprodex, a medication containing an antibiotic and a steroid used

to treat bacterial ear infections; and Tasigna, a medication used to treat chronic myeloid leukemia, a cancer of the blood.

k. Novo Nordisk

76. Defendant **Novo Nordisk A/S** is a Danish corporation with its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

77. Defendant **Novo Nordisk Inc.** is a corporation organized under the laws of the State of Delaware, with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Defendant Novo Nordisk Inc. is a subsidiary of Novo Nordisk A/S.

78. Novo Nordisk Inc. and Novo Nordisk A/S are collectively referred to herein as "Novo Nordisk."

79. At all times relevant to this Complaint Novo Nordisk participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

80. To circumvent the 340B Program's requirement that Novo Nordisk provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Novo Nordisk imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

81. Novo Nordisk, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Covered Entities.

82. Novo Nordisk manufactures various 340B drugs, including Levemir, Insulin Degludec, Xultophy, and Tresiba, long-acting insulin medications used to control blood sugar levels in diabetes patients; Novolog, Insulin Aspart, Fiasp, and Novolog 70/30, rapid-acting insulin medications, Novolin R, a short-acting insulin medication; Novolin 70/30 and Novolin N, intermediate-acting insulin medications; and Ozempic, Victoza, Rybelsus, and Wegovy, medications that help type 2 diabetics produce insulin more efficiently and manage their blood sugar levels, help manage obesity and other weight related medical conditions, and treat obstructive sleep apnea.

l. Pfizer

83. Defendant **Pfizer, Inc.** ("Pfizer") is a corporation existing under the laws of Delaware, with its principal place of business in New York.

84. At all times relevant to this Complaint Pfizer participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

85. To circumvent the 340B Program's requirement that Pfizer provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Pfizer imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program

86. Defendant Pfizer, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Arkansas Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Arkansas Covered Entities.

87. Pfizer manufactures a number of 340B drugs, including Paxlovid, an antiviral medication used to lower the risk of severe COVID-19, including hospitalization or death; Ibrance, a medication used to treat certain kinds of breast cancer; Abrysvo, a vaccine used to prevent respiratory syncytial virus (RSV) in pregnant women, adults 60 years and older, and other adults at increased risk of lower respiratory tract disease; Zavzpret, a nasal spray medication used to treat acute migraine; Premarin and Prempro, medications used to treat menopausal women with symptoms like osteoporosis and hot flashes; Norvasc, a medication that lowers blood pressure by relaxing blood vessels in patients with coronary artery disease; Eucrisa, a medication used to treat eczema by improving itching, redness, oozing, and crusting; and Xeljanz, a medication used to treat autoimmune conditions like rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis.

m. Sanofi

88. Defendant **Sanofi S.A.**, also known as Sanofi Consumer Healthcare, is a French multinational pharmaceutical company with its principal place of business in Paris, France. Defendant Sanofi S.A. was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthélabo, which were each the product of several previous mergers.

89. Defendant **Sanofi-Aventis U.S. LLC** is a corporation organized under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

90. Defendant **Sanofi US Services Inc.** is a corporation organized under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

91. Defendant **Genzyme Corporation** is a corporation organized under the laws of the Commonwealth of Massachusetts with its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

92. At all relevant times, Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Genzyme Corporation have been wholly owned subsidiaries of Defendant Sanofi S.A., with the profits of each inuring to Defendant Sanofi S.A. All of these entities are collectively referred to herein as "Sanofi."

93. At all times relevant to this Complaint Sanofi participated in the 340B program, selling covered outpatient drugs to Covered Entities in Arkansas.

94. To circumvent the 340B Program's requirement that Sanofi provide its covered outpatient drugs to Covered Entities at steeply discounted prices, a requirement which was increasingly cutting into its revenue, Sanofi imposed on Covered Entities, including in Arkansas, additional restrictions beyond those required by the 340B Program. Those additional restrictions were intended to deter or prevent Covered Entities, including in Arkansas, from being able to obtain discounted drugs under the 340B Program.

95. Sanofi, through its actions in Arkansas, effectively prohibited Arkansas pharmacies from contracting with Covered Entities by denying those pharmacies access to its drugs; and denied delivery of 340B drugs to Arkansas pharmacies that contract with Covered Entities.

96. Sanofi manufactures various 340B drugs, including Lantus, Soliqua, Insulin Glargine, and Toujeo, long-acting insulin medications used to control blood sugar levels in diabetes patients; Admelog and Apidra, rapid-acting insulin medications; Kevzara, a medication that reduces pain, stiffness, and swelling in patients with rheumatoid arthritis, polymyalgia rheumatica, and polyarticular juvenile idiopathic arthritis; Multaq, a heart rhythm medication that

helps maintain normal heartbeats in patients with life-threatening rhythm disorders of the atrium; Aubagio, a medication used to treat relapsing forms of multiple sclerosis; Dupixent, an anti-inflammatory medication used to treat several severe conditions like asthma, COPD, eosinophilic esophagitis, and chronic spontaneous urticaria; Irbesartan-HCTZ, a combination medication used to treat high blood pressure; and Zolpidem, a sedative medication used to treat insomnia.

C. Non-Manufacturer Defendant

97. Defendant **Second Sight Solutions, LLC** ("Second Sight") is a Delaware corporation with its principal place of business in Emeryville, California.

98. Second Sight operates 340BESP, a web platform used by Manufacturer Defendants to receive and analyze claims data from Covered Entities, including Covered Entities in Arkansas, and which posts restrictions imposed by Manufacturer Defendants, including those affecting only Covered Entities in Arkansas.

99. Second Sight is a wholly owned subsidiary of Berkeley Research Group, a consulting firm that has conducted several studies funded by PhRMA.

100. Second Sight facilitated Manufacturer Defendants' restrictions imposed on Covered Entities, including those in Arkansas, by operating the sole web platform mandated by the Manufacturer Defendants for Covered Entities to upload data and for Covered Entities to designate a single contract pharmacy within the state.

IV. FACTUAL ALLEGATIONS

A. The 340B Program and the Use of Contract Pharmacies

101. In 1992, Congress enacted Section 340B of the Public Health Service Act, which was intended to lower drug costs for certain public and not-for-profit hospitals, community health centers, and other government funded clinics that serve large numbers of low-income

communities, known as "Covered Entities." Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4967 (Nov. 4, 1992) (codified at 42 U.S.C. § 256b).

102. The 340B Program requires participating drug manufacturers to provide "covered outpatient drugs," which are defined generally as outpatient prescription drugs and biological products other than vaccines, 42 U.S.C. § 1396r-8(k)(2), to Covered Entities at substantially reduced prices "to enable these 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 10 (1992). The 340B statute provides a clear, straightforward formula for calculating the maximum price a manufacturer may charge a Covered Entity for a 340B drug, called the "Ceiling Price."

103. Manufacturers are not required to participate in the 340B Program. However, if they wish to have their drugs covered and reimbursed by Medicaid and the Medicare Part B outpatient insurance program, they must also participate in the 340B Program.

104. Covered Entities use the savings generated by the drug discounts they receive under the 340B Program to provide critical safety-net healthcare services for their communities, including low-income and underserved populations within those communities. For example, those cost-savings have enabled Covered Entities to provide free or discounted drugs and other health and case management services, increase service locations, develop patient education programs, and provide translation and transportation services to improve patients' access to high-quality care.

105. When the 340B statute was first enacted in 1992, Covered Entities included federally funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for profit hospitals serving low-income populations. Pub. L. No. 102-585, § 340B(a)(4)(A)-(L), 106 Stat. at 4967-68.

106. In 2010, recognizing the value of the 340B Program, Congress expanded the definition of Covered Entities to include certain critical access hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat 119, 821-22 (Mar. 23, 2010).

107. Currently, six types of hospitals and ten types of federally funded clinics are eligible to participate in the 340B Program. A Covered Entity may have multiple sites participate in the 340B Program as long as each site is an integral part of the Covered Entity, is registered with the Health Resources and Services Administration ("HRSA") (a subcomponent of the federal Department of Health and Human Services ("HHS")), and follows the 340B Program's rules.

108. Covered Entities purchase 340B-eligible drugs at or below a statutorily calculated 340B "Ceiling Price," but charge payors based on the reimbursement agreements that the Covered Entities have with these payors. By design, therefore, the 340B Program provides Covered Entities with two related benefits:

a. First, in cases in which the Covered Entity's patients are uninsured or under-insured, the 340B statute enables the Covered Entity to stretch its already scarce resources by spending less to purchase drugs needed by such patients.

b. Second, in cases in which the Covered Entity's patients have insurance that reimburses the Covered Entity above its actual acquisition cost ("AAC") for the 340B-eligible drug, the Covered Entity receives a financial benefit that is used to provide needed services to vulnerable populations.

109. Pharmaceutical manufacturers that choose to participate in Medicaid and Medicare Part B are required to participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1). Each pharmaceutical manufacturer that participates in the 340B Program, including Manufacturer

Defendants, must sign a Pharmaceutical Pricing Agreement ("PPA") with the HHS Secretary. The PPA requires the manufacturer to abide by the rules of the 340B Program, including the Ceiling Price. *Id.* § 256b(a)(1).

110. PPAs are effective for one year and are automatically renewed for successive one-year terms unless the pharmaceutical manufacturer gives written notice of its intent not to renew.

111. Each Manufacturer Defendant signed a PPA.

112. Each Manufacturer Defendant was also required to, and did, sign a PPA Addendum under which it agreed to "furnish the [HHS] Secretary with reports, on a quarterly basis, that include the price of each covered outpatient drug that is subject to the Agreement, that according to the manufacturer, represents the maximum price that Covered Entities may permissibly be required to pay for the drug" (*i.e.*, the manufacturers' calculation of the Ceiling Price), and to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." *See* HRSA, *Pharmaceutical Pricing Agreement – Addendum,* https://www.hrsa.gov/sites/default/files/opa/manufacturers/ppa_addendum.pdf (last visited June 22, 2026).

113. Drug manufacturers are responsible for ensuring that a Covered Entity is not charged more than the Ceiling Price for any covered outpatient drug, regardless of whether the Covered Entity purchases drugs from a wholesaler or directly from the manufacturer. The 340B statute establishes a straightforward statutory formula for calculating the Ceiling Price: the difference between the drug's average manufacturer price ("AMP") from the previous quarter and its unit rebate amount ("URA"):

Ceiling Price = (AMP – URA) × drug package size

42 U.S.C. § 1396r-8(c). The AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers (for drugs distributed to retail community pharmacies) and by retail community pharmacies (that purchase drugs directly from the manufacturer). 42 U.S.C. § 1396r-8(k)(1)(A).

114. The URA includes an "inflationary penalty" that increases the URA, and therefore lowers the Ceiling Price, when drug manufacturers implement price increases above the rate of inflation. 42 U.S.C. 1396r-(c)(2). Accordingly, price increases that outpace inflation cause a corresponding decrease in the Ceiling Price that Manufacturer Defendants may charge for 340B drugs. Indeed, under the statutory formula, it is possible for the Ceiling Price to go as low as zero. In these instances, HRSA requires that manufacturers charge $0.01 for the drug. 42 C.F.R. § 10.10(b). The inflationary penalty was originally limited to single-source (brand-name) drugs, but Congress extended the penalty to generic drugs under the Bipartisan Budget Act of 2015. Pub. L. 114-74, § 602(a)(2), 129 Stat. 584, 596-97 (Nov. 2, 2015).

115. In the wake of complaints that drug manufacturers were overcharging Covered Entities and not complying with the Ceiling Price, Congress amended the 340B statute to empower HRSA to impose civil penalties on non-compliant manufacturers. Following that amendment, HRSA published a final rule, effective January 1, 2019, that authorized the imposition of hefty civil penalties on manufacturers that fail to comply with the 340B Ceiling Price formula. *See 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1216, 1220-21 (Jan. 5, 2017). HRSA's final rule also provides that, if the Ceiling Price calculates to zero under the 340B statutory formula, manufacturers may charge up to $0.01. *Id.* at 1214-15.

116. Section 340B subjects Covered Entities to two restrictions. First, it bans duplicate discounts: Covered Entities cannot get the 340B discount on drugs already subject to a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A)(i). Second, it bans diversion: Covered Entities can sell 340B drugs only to their own patients. § 256b(a)(5)(B). Covered Entities are subject to audits by either HRSA or manufacturers to ensure compliance with these restrictions. 42 U.S.C. § 256b(a)(5)(C).

117. The 340B statute provides for an administrative dispute resolution mechanism to resolve disputes between manufacturers and Covered Entities. Covered Entities that fail to comply with the 340B Program's requirements are liable to manufacturers in the amount of the discount and can be required to pay interest. They can also be terminated from the program if their violation is knowing, intentional, systematic, and egregious. When payment, pricing, diversion, or discount disputes arise between manufacturers and Covered Entities, the 340B statute requires that the parties first go through HHS's dispute resolution process to resolve the issue. 42 U.S.C. § 256b(d)(3); *see Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 121 (2011).

118. Since the very beginning of the 340B Program, Covered Entities have routinely contracted with contract pharmacies to deliver discounted drugs to their patients under the 340B Program. In part, that is because many Covered Entities cannot afford to "expend precious resources to develop their own in-house pharmacies," because constructing and managing a pharmacy is expensive and requires special expertise. 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). In addition, the use of contract pharmacies allows Covered Entities to deliver drugs closer to where their patients reside, rather than relying on one single pharmacy at the Covered Entity's in-house pharmacy, if it even has one.

119. Contract pharmacies allow Covered Entities with large service areas to offer more accessible pharmacy services to their patients. Additionally, some medications require special storage and handling and can be dispensed only by specialty pharmacies[8] through a mail order program, or are subject to a manufacturer-imposed "limited distribution network."[9] Covered Entities could not provide their patients these life-saving medications without these contract pharmacies.

120. Although contract pharmacies have been used throughout the life of the 340B Program, contract pharmacies are not themselves permitted to purchase 340B drugs. Instead, a Covered Entity typically creates a 340B purchasing account with a drug wholesaler. It then creates a "ship to, bill to" arrangement under which the drugs are billed to the Covered Entity, but shipped to the contract pharmacy. 2010 Guidance, 75 Fed. Reg. at 10,277.[10] The contract pharmacy then dispenses the drugs to the Covered Entity's patients, collects reimbursement for the drugs from both the patient and the patient's third-party payor (if any), and remits the collected reimbursement to the Covered Entity. The Covered Entity, in turn, pays the contract pharmacy a fee for dispensing and billing drugs on the Covered Entity's behalf.

121. During the Complaint's relevant time period, from July 28, 2021, until present, only nine Covered Entities in Arkansas operated an in-house pharmacy. In fact, Arkansas law prohibited

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[8] *See Specialty Pharmacy*, AM. PHARMACISTS ASS'N, https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty (last visited Jul. 9, 2026).

[9] *Limited Distribution Drugs 101*, CLARIVATE (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101/ (last visited Jul. 9, 2026) ("Under a limited distribution network, a manufacturer contracts with one or a few specialty pharmacies to dispense high-maintenance medications.").

[10] *See also FAQs*, HRSA, https://www.hrsa.gov/opa/faqs (last visited Jul. 9, 2026) ("What is a 'ship to bill to' arrangement?").

nonprofit hospitals from operating an in-house pharmacy until 2025. Ark. Code. Ann. § 17-92-607(a). Thus, in Arkansas, most Covered Entities used contract pharmacies for delivering or dispensing 340B drugs to their patients.

122. Although the 340B statute is silent as to how 340B drugs are delivered or dispensed to patients of Covered Entities, HRSA long acknowledged Covered Entities' right to use contract pharmacies by ordering 340B drugs to be shipped directly to those pharmacies based on state agency law. In 1996, HHS issued guidance reflecting that that practice, expressly permitting each Covered Entity to use one contract pharmacy. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). HRSA observed that almost all Covered Entities rely on contract pharmacies, with only about four percent of Covered Entities using in-house pharmacies. 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).

123. In 2010, in response to Covered Entities' requests for greater flexibility for pharmacy arrangements to better serve their patients, HHS published new guidance allowing Covered Entities to use multiple contract pharmacies as long as they comply with the requirements to prevent diversion and duplicate discounts. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) ("2010 Guidance"). The new guidance recognized that permitting use of multiple contract pharmacies could improve patient care by making it easier for patients to fill prescriptions and "would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served." *Id.*

124. After the issuance of the 2010 guidance and Congress's expansion of Covered Entities, the use of contract pharmacies increased and continued until 2020. During this period, Defendant Manufacturers executed their PPA Addendums, explicitly agreeing to participate in a program that included multiple contract pharmacy arrangements. In short, for twenty-four years, every drug manufacturer participating in the 340B Program, including Manufacturer Defendants, routinely honored contract pharmacy arrangements by allowing delivery of 340B discounted drugs purchased by Covered Entities for dispensing through contract pharmacies.

B. Manufacturer Defendants' Restrictive 340B Policies

125. In 2020, however, during the height of the global COVID-19 pandemic, the drug manufacturers, including Manufacturer Defendants, changed course and began to push back on the use of contract pharmacies. They collectively began pouring hundreds of millions of dollars into lobbying Congress to prohibit Covered Entities from using contract pharmacies.

126. After those lobbying efforts failed, starting in 2020, many of the manufacturers, including Manufacturer Defendants, took the matter into their own hands. The Manufacturer Defendants each unilaterally implemented similar or identical policies limiting, prohibiting, or discouraging Covered Entities from using contract pharmacies to dispense 340B-covered drugs to their patients.

127. In response to these policies and Covered Entities' reactions, HHS issued an advisory opinion in December 2020, declaring that the 340B statute requires drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. HHS began sending violation letters to drug manufacturers whose restrictive policies were not consistent with its advisory opinion.

128. The drug manufacturers sued to invalidate HHS' advisory opinion, as well as the violation letters, and won in two federal circuits. The Third and D.C. Circuits held that the 340B

statute does not authorize the federal government to regulate delivery because the statute is silent about delivery. *Sanofi Aventis U.S. LLC v. HHS.*, 58 F.4th 696, 703 (3d Cir. 2023); *Novartis v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024); *but see Eli Lilly & Co. v. United States Dep't of Health & Human Srvs.*, No. 1:21-cv-00081, 2021 WL 5039566, at *24 (S.D. Ind. Oct. 29, 2021) (holding that the 340B statute does not allow manufacturers to impose unilateral contract pharmacy restrictions), *appeal docketed*, No. 21-3405 (7th Cir. Dec. 30, 2021).

129. Manufacturer Defendants subsequently proceeded not only with their desired restrictions on Covered Entities' use of contract pharmacies, many of which effectively prohibited the use of contract pharmacies altogether, but also with additional restrictions that were designed to prevent Covered Entities from obtaining 340B discounted drugs. It also encouraged additional manufacturers to impose contract pharmacy restrictions.

130. Indeed, Manufacturer Defendants imposed a series of changing and burdensome requirements on Covered Entities that were not addressed in, or directly prohibited by, the 340B statute. Those requirements and restrictions initially focused on the use of contract pharmacies, such as by precluding a Covered Entity without an in-house pharmacy from using more than one contract pharmacy and prohibiting entirely the use of contract pharmacies for Covered Entities that had an in-house pharmacy. Manufacturer Defendants later extended their restrictions beyond the use of contract pharmacies to include, for example, imposing requirements that Covered Entities provide certain categories of data for in-house pharmacy and medical claims in order to obtain 340B pricing for the manufacturers' drugs.

131. These manufacturer-imposed restrictions on the use of contract pharmacies (and the other restrictions Manufacturer Defendants later adopted) were designed to make it too difficult or burdensome for Covered Entities to participate in the 340B program, and to limit any benefit they

could derive from the program. That's because Defendants knew that most Covered Entities lacked in-house pharmacies and needed to use contract pharmacies to be able to take advantage of 340B drug pricing and deliver the drugs to their patients. Yet Defendants took these steps to reduce their costs, despite receiving the benefits of having their drugs covered and reimbursed by Medicaid and the Medicare Part B in exchange for being part of the 340B Program. As a result, restrictions on contract pharmacies—and the additional conditions layered on top of them—directly impaired Covered Entities' ability to access discounted drugs.

132. The 340B Program was estimated to cost pharmaceutical manufacturers $46.5 billion dollars a year for discounts to 340B hospitals in 2022. But that figure must be viewed in appropriate context. The 340B discounts provided to Covered Entity hospitals in 2022 accounted for approximately just 7 percent of the U.S. drug market, and only about 3.1 percent of global pharmaceutical revenues, which were estimated at $1.48 trillion.[11]

133. During the same period, overall drug company revenues grew substantially. Additionally, although the 340B Program grew by about $30 billion between 2017 and 2022, drug company revenues during that same time grew by about $347 billion, and the U.S. drug market grew by $330 billion. *Id.* at 4. The cost of the 340B Program to Manufacturer Defendants, therefore, is dwarfed by their revenue and growth. These figures underscore that the restrictions described above were not necessary to preserve the viability of the 340B Program, but instead functioned to reduce manufacturers' discount obligations.

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[11] The 340B Drug Pricing Program: A Small Part of the Prescription Drug Market, Delivering Large Benefits to Patients and Communities, HEALTHSPERIEN (2024), https://www.aha.org/guidesreports/2024-03-12-340B-drug-pricing-program (last visited Jul. 9, 2026).

134. Nothing in the 340B statute prohibits Covered Entities from using contract pharmacies or authorizes the Manufacturer Defendants to restrict Covered Entities' use of contract pharmacies, which had been the practice for over twenty years.

135. Moreover, Manufacturer Defendants' restrictive contract pharmacy policies significantly impacted healthcare in the State of Arkansas. Arkansas leads the nation in rural hospitals vulnerable to closure. Many of these rural hospitals rely on contract pharmacies and the 340B program to keep the lights on. When Manufacturer Defendants each began implementing their own disparate policies to restrict or prohibit Covered Entities' use of contract pharmacies, it jeopardized Covered Entities' ability to obtain discounted drugs from Manufacturer Defendants, further straining the healthcare of poor and rural communities in Arkansas.

136. In practice, those restrictions reduced the financial benefits of the 340B Program, which Covered Entities rely on to fund services, maintain staffing, and expand access to care. As those resources declined, Covered Entities were forced to scale back services or delay expansion, reducing access to care for patients in rural and underserved communities.

C. Act 1103: Arkansas Responds

137. In response to these devastating effects that these restrictions had on Covered Entities and healthcare in Arkansas resulting from pharmaceutical companies' restrictions on contract pharmacies, the Arkansas General Assembly enacted Act 1103 in May 2021. Act 1103 went into effect on July 28, 2021. Recognizing that the significant 340B discounts on covered outpatient drugs help Covered Entities in Arkansas stay "afloat," the statute was designed to prevent manufacturers from "discriminating" against Covered Entities' by restricting delivery of 340B drugs to contract pharmacies, which otherwise result in Covered Entities and their patients being deprived of the 340B drugs. To Establish the 340B Drug Pricing Nondiscrimination Act,

April 20, 2021 Hearing on H.B. 1881 Before the Ark. H.R., 93d Gen. Assemb. Reg. Sess. (Ark. 2021) (statement of Rep. Michelle Gray).

138. Act 1103 protects Covered Entities' use of contract pharmacies in the 340B Program. In relevant part, Act 1103 provides that:

> (c) A pharmaceutical manufacturer shall not:
>
> (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
>
> (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Ark. Code Ann. § 23-92-604(c).

139. Act 1103 tasked the Arkansas Insurance Commissioner with promulgating rules for its implementation, Ark. Code Ann. § 23-92-606, which the Arkansas Insurance Department ("AID") did in 2022. *See* Ark. Admin. Code 003.22.123-I to 003.22.123-VII. An "Arkansas-based community pharmacy" is defined as "a Pharmacy licensed and located in this State." Ark. Admin. Code 003.22.123-II(1).

140. AID's rule mirrors Act 1103, prohibiting drug manufacturers from denying 340B drug pricing to pharmacies that contract with Covered Entities or prohibiting pharmacies from contracting with Covered Entities by denying pharmacies access to their drugs. Ark. Admin. Code 003.22.123-IV(c)(1)-(2). AID's rules also provide that the Insurance Commissioner may enforce violations of the rule under sections 23-66-209 and 23-66-210 of the Trade Practices Act, which authorize penalties and other relief. Ark. Admin. Code 003.22.123-VI.

141. Following the passage of Act 1103, other states adopted their own, similar laws to protect Covered Entities' ability to use contract pharmacies under the 340B Program. In fact, to

date, twenty-two states have adopted state laws similar to Arkansas's Act 1103, to prevent manufacturers from restricting delivery of 340B covered drugs to contract pharmacies used by Covered Entities.

142. The drug manufacturers, as well as PhRMA, brought legal challenges to these various state laws in court; however, almost all those legal challenges have been unsuccessful. *See, e.g.*, *Pharm. Rsch. & Mfrs. Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (holding that Arkansas's Act 1103 was not federally preempted); *Novartis Pharmaceuticals Corp. v. Hanaway*, No. 25-1619, 2026 U.S. App. LEXIS 17185 (8th Cir. July 1, 2026) (upholding similar Missouri law); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 645 (5th Cir. 2025) (upholding similar Mississippi law); *AbbVie, Inc. v. Murrill*, No. 24-30645 (5th Cir. July 6, 2026) (upholding similar Louisiana law); *Novartis Pharmaceuticals Corp v. Brown*, 26-cv-05302 (W.D. Wash. June 9, 2026) (upholding similar Washington law); *AstraZeneca Pharms. LP v. Lopez*, Case No. 25-00369, 2026 WL 497141, at *15–16 (D. Haw. Feb. 23, 2026) (upholding similar Hawaii law), *appeal pending*, Case No. 26-1172 (9th Cir.); *AbbVie, Inc. v. Weiser*, 811 F. Supp. 3d 1264, 1275–1276 (D. Colo. 2025) (upholding similar Colorado law), *appeal pending*, Case No. 25-1439 (10th Cir.).[12]

143. As Manufacturer Defendants' efforts to invalidate Act 1103 and other state laws were unsuccessful, they tried to find other ways to circumvent or limit their obligations under the 340B Program that would not run afoul of these state laws.

[12] Only one federal court of appeals has concluded that a similar state law was preempted by the federal 340B statute. *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026). On June 2, 2026, however, the Fourth Circuit granted rehearing *en banc*. *See* 176 F.4th 830.

D. The New Wave of Non-Compliance

144. Over time, the drug manufacturers' restrictions morphed into other, additional or successive restrictions on Covered Entities. There were six primary restrictions or requirements that the Manufacturer Defendants imposed on Covered Entities at various times:

- Limiting Covered Entities to only one contract pharmacy if the Covered Entity does not have an in-house pharmacy
- Prohibiting the use of contract pharmacies if the Covered Entity has an in-house pharmacy
- Limiting Covered Entities to contract pharmacies within a 40-mile radius of the Covered Entity
- Limiting the distribution network of specialty drugs
- Requiring claims data from Covered Entities
- Requiring in-house and medical data from Covered Entities

145. None of these requirements are imposed by the 340B Program.

146. While framed as administrative or compliance measures, these policies operated in practice to restrict access to 340B drugs and had immediate and practical consequences in Arkansas.

147. Many Manufacturer Defendants adopted a restriction that limited Covered Entities to using only one contract pharmacy each, and only if the Covered Entity did not have an in-house pharmacy. This limitation was in stark contrast to the practice that had been in effect since the 340B Program's inception, in which the drug manufacturers had provided the 340B discounts to Covered Entities regardless of whether the drugs were shipped directly to the Covered Entities themselves or to a contract pharmacy.[13]

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[13] Several of the drug manufacturers exempted, at points in time, Covered Entities that received federal grants. There are 12 Covered Entity types considered "Federal Grantees" which are listed below:

- Federally Qualified Health Centers (FQHCs)
- Ryan White Clinics (Parts A and B of the Ryan White statute)
- Sexually Transmitted Disease (STD) Clinics

148. Most Covered Entities in the State do not operate in-house pharmacies and instead rely on contract pharmacies to deliver 340B drugs to their patients. As a result, restricting the use of contract pharmacies does not merely limit an administrative option—it directly limits a Covered Entity's ability to access and deliver 340B-priced drugs at all.

149. Some Manufacturer Defendants likewise adopted a restriction that permitted Covered Entities to use a contract pharmacy only if it was within a 40-mile radius of the Covered Entity's parent location. This new restriction had the effect of significantly harming Covered Entities in rural communities in Arkansas and elsewhere, where patients may have to travel longer distances to their hospital or medical provider and their pharmacies.

150. Defendant Manufacturers also imposed restrictions on the distribution network for 340B specialty drugs. Specialty drugs include high-cost medications used to treat complex, chronic, or rare diseases (such as cancer, HIV, or autoimmune disorders). Specialty drugs are among the most critical drugs for patients suffering from these serious medical conditions. Because they are also among the most expensive drugs and garner significant 340B discounts, Manufacturer Defendants had an incentive to specifically limit the distribution of these high-cost drugs. By limiting a Covered Entity for certain 340B specialty drugs to use of only one designated specialty pharmacy, Manufacturer Defendants artificially and without any legal basis made it more difficult

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- Tuberculosis (TB) Clinics
- Family Planning Clinics (Title X Clinics)
- Native Hawaiian Health Centers
- Urban Indian Organizations
- Public Housing Primary Care Programs
- Black Lung Clinics
- Hemophilia Treatment Centers
- State-Operated AIDS Drug Assistance Programs (ADAPs)
- Early Intervention HIV Services (Parts C and D of the Ryan White statute)

for the Covered Entity's patients to obtain these drugs, and therefore the Covered Entity to receive the benefit of the discounted drugs, causing harm to both patients and Covered Entities.

151. Manufacturer Defendants also, at times, required Arkansas Covered Entities to provide claims data to purchase 340B discounts. Under the pretextual guise of searching for duplicate billing, Manufacturer Defendants demanded claims data, which is information about the dispensing of the prescription drug from the contract pharmacy. Claims data includes the prescription number, the National Drug Code for the prescription drug, volume, pharmacy, date of service, prescription date, and, in some cases, the bank information for the payor and the identification number of the prescribing doctor. Drug manufacturers typically have to pay outside data vendors like IQVIA for this detailed drug dispensing information for marketing purposes. By demanding such information for free from Covered Entities, Manufacturer Defendants unjustly enriched themselves by extracting a benefit to which they were not entitled and by unlawfully burdening Covered Entities, many of whom do not have direct access to such data because they rely on third-party administrators to manage such data.

152. Beginning in 2026, some Manufacturer Defendants also demanded Covered Entities' in-house pharmacy and medical data as a requirement of obtaining 340B-discounted drugs. Medical data includes fields such as claim number, NDC-11 code of the medication, quantity of drug dispensed, date of service, physician ID, and HCPCS code (which provides information about the medical services provided). The data system that Covered Entities must use to retrieve such information is different than the claims data referenced above and is generally far more burdensome to obtain, resulting in some Covered Entities being unable to obtain the discount altogether.

153. These restrictions were not merely burdensome—they were often impractical or impossible for Covered Entities to satisfy. Many Covered Entities lacked the systems, personnel, or contractual access necessary to gather and transmit the required data. Gathering claims data and in-house pharmacy and medical data is an extremely burdensome and resource-intensive undertaking for Covered Entities, and that was the point. Although Defendant Manufacturers claim that this data would enable it to identify duplicate discounts and diversion, that appears to be a pretextual reason to mask its value to Defendant Manufacturers in marketing and lobbying efforts and suppressing the delivery of 340B drugs. A recent economics study analyzing the comparative value of claims data for different purposes found that the value that claims data provides in terms of duplicate discount identification was dwarfed when compared to its value for other purposes like lobbying, sublicensing, and marketing research.[14]

154. Compounding this problem, the manufacturers' policies changed frequently and without uniformity, making it difficult for Covered Entities to establish stable processes for compliance. Moreover, each Manufacturer Defendant imposed its own version of these restrictions, with different timelines, conditions, and technical requirements. As a result, Covered Entities were required to navigate a constantly shifting and inconsistent set of rules across multiple manufacturers at once. Even when a Covered Entity could comply with one manufacturer's requirements, it could not reasonably comply with all of them simultaneously.

155. Because Covered Entities depend on 340B pricing to sustain their operations and serve their patients, these restrictions left them with no meaningful choice. To obtain discounted

[14] Charles J. Courtemanche, *340B Data From the ESP and Beacon Platforms Hold Considerable Value for Drug Manufacturers*, INST. STUD. FREE ENTER. Apr. 2026, at 30-31.

drugs, they were required to comply with conditions not imposed by law. If they could not comply, they lost access to the discounts altogether.

156. The effect was direct and predictable. By restricting contract pharmacy use and conditioning access to 340B pricing on unattainable requirements, Manufacturer Defendants reduced the volume of 340B drugs available to Arkansas Covered Entities. That reduction diminished the financial resources those entities rely on to provide care, forcing some to cut services, reduce staff, or delay expansion into underserved areas. Patients—particularly in rural communities—faced reduced access to medications and care as a result.

157. For example, one Arkansas Covered Entity wanted to expand its obstetrics offerings to areas of the State where healthcare for pregnant women had evaporated. But the Covered Entity had been so severely damaged financially by Manufacturer Defendants' policies that it could not do so. As a result, pregnant women in that part of the State were forced to travel farther to get the care they need, hurting them financially.

158. Manufacturer Defendants' restrictive policies also caused Covered Entities to lay off staff and consolidate departments that offer critical services like dental care and behavioral health care. One Covered Entity had 20% of its budget impacted by the restrictions and still has not recovered financially from the 120-day time period in which the manufacturers shut off delivery of 340B drugs completely through these restrictive policies.

159. As another example, Community Clinic, a federally qualified health center (FQHC) in Springdale, Arkansas, with over 30 locations in Northwest Arkansas, has suffered severe financial losses due to AstraZeneca's policies restricting the use of contract pharmacies. Community Clinic is a Covered Entity in Arkansas that lacks its own in-house pharmacy and therefore relies on contract pharmacies for its patients to access 340B drugs. In three months

alone, following the adoption of Defendant AstraZeneca's policy limiting Covered Entities to use of a single contract pharmacy, Community Clinic suffered $202,000 in losses. In addition, AstraZeneca's policy harmed patients, because that policy drastically reduced the number of AstraZeneca prescriptions that Community Clinic could fill at 340B prices for uninsured and underinsured patients. Approximately 60% of Community Clinic's 340B prescription claims are for uninsured or underinsured patients. Without broader access to 340B drugs for those drugs, Community Clinic would not be able to serve such a large population of uninsured or underinsured patients.

160. Manufacturer Defendants knew that individual Covered Entities would have no effective means to resist their demands or requirements. The Manufacturer Defendants were aware that most Covered Entities heavily rely on 340B discounts to keep afloat, and would therefore need to acquiesce to Manufacturer Defendants' demands to be able to continue to serve their patients. Alternatively, if they could not comply with those demands as a practical matter, then Manufacturer Defendants would not need to provide the 340B discounts to the Covered Entities. Either way was a win-win for Manufacturer Defendants. Manufacturer Defendants further knew that Covered Entities, unlike Manufacturer Defendants, have no lobbying organization to protect their interests, and that each individual Covered Entity would have no power to protest a Manufacturer Defendant's restrictive policies.

161. Although each Manufacturer Defendant enacted its own policies, Manufacturer Defendants coordinated their actions. Each of the manufacturer-specific policies described below are highly similar to each other, some involving identical language and identical highly specific requirements. For example, several Manufacturer Defendants at one time implemented a restriction that Covered Entities could only use a contract pharmacy located within 40-miles of the

Covered Entity. Each Manufacturer Defendant that used a distance limit used the 40-mile limit. Similarly, not by happenstance, Manufacturer Defendants also use the same web platform, provided by Defendant Second Sight, to assist them in extracting data from the Covered Entities' systems.

a. AbbVie's 340B Restrictions

162. On February 1, 2022, AbbVie began limiting Covered Entities to use of only a single contract pharmacy without submitting claims data. The policy allowed Covered Entities to use multiple contract pharmacies if they provided AbbVie with claims data. Federal grantees were exempted from the policy. AbbVie's letter announcing this policy stated that, "AbbVie will decline to facilitate bill to/ship to replenishment orders of 340B priced medicines to contract pharmacies for which claims data are not provided."

163. On April 17, 2023, AbbVie further restricted hospital Covered Entities to use of only one single contract pharmacy within 40 miles of the parent site and prohibited Covered Entities with an in-house pharmacy from using any contract pharmacy. The policy continued to require claims data submissions for the single designated contract pharmacy. AbbVie's announcement of this restriction provided that:

> A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

164. On April 30, 2024, following the Eight Circuit's opinion in *Pharmaceutical Research & Manufacturers America v. McClain*, 95 F.4th 1136, 1146 (8th Cir. 2024), which

affirmed the constitutionality of Arkansas's Act 1103, AbbVie exempted Arkansas Covered Entities from its restrictive contract pharmacy policy.

b. Amgen's 340B Restrictions

165. In January 2022, Amgen began restricting hospital Covered Entities from using more than a single contract pharmacy to dispense certain 340B drugs and prohibited hospital Covered Entities with in-house pharmacies from using any contract pharmacy.[15] Federal grantees were exempted from this policy. The text of Amgen's letter announcing the policy read as follows:

> I am writing to inform you that Amgen Inc. (Amgen) is altering its policy regarding the offering of 340B discounts to contract pharmacies. Effective January 3, 2022, Amgen will provide products purchased at the 340B price exclusively to locations registered as a 340B covered entity or other locations designated in accordance with Amgen's policy, as described further below. Subject to the exceptions described below, pharmacies registered as contract pharmacies will no longer be eligible for Bill To / Ship To orders. Federal grantees will remain eligible to place Bill To / Ship To orders of drugs at the 340B price for their contract pharmacies.
>
> To ensure all 340B covered entities can access Amgen products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location. Amgen is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.
>
> Covered entities may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through contract pharmacies. Any covered entity that elects to submit their 340B claims will be allowed to continue Bill To / Ship To orders for its contract pharmacies. Covered entities that are interested in submitting claims data will need to register an account with 340B ESP™ to get started.
>
> Contract pharmacies that are wholly owned by a 340B hospital or have common ownership with a health system, will remain eligible to receive Bill To / Ship To orders of drugs purchased at the 340B price. These pharmacies must be registered with HRSA as a contract pharmacy of the 340B hospital. Furthermore, if a covered entity or health system is granted an exemption from Amgen's 340B distribution policy for its wholly owned contract pharmacy(ies), it may not also designate an independent contract pharmacy. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application.

166. In April 2023, Amgen amended its policy, restricting Covered Entities from using even a single contract pharmacy to dispense 340B drugs unless the pharmacy is located within 40 miles of the Covered Entity's main, parent site. Federal grantees were exempted from this policy.

[15] The January 2022 policy applied to four drugs: Aimovig, Enbrel, Otezla, and Repatha.

167. In March 2024, Amgen stopped exempting federal grantees from its restrictive 340B contract pharmacy policies.

168. On April 2, 2024, following the Eight Circuit's opinion in *PhRMA v. McClain*, Amgen specifically exempted Arkansas Covered Entities using Arkansas contract pharmacies from its restrictive contract pharmacy policy.

169. On June 1, 2026, Amgen imposed a nationwide requirement (but exempted Arkansas) that Covered Entities provide in-house and medical data for covered drugs in order to receive Amgen's 340B discounted drugs.

c. AstraZeneca's 340B Restrictions

170. On September 14, 2020, AstraZeneca announced that it would start nationwide restrictions on the use of contract pharmacies for 340B Covered Entities and would no longer comply with HRSA's 2010 guidance, which it had previously followed for a decade: "AstraZeneca to date has provided 340B pricing to pharmacies associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Service Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed on the enclosed attachment[16], such that AstraZeneca 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." Although not detailed in the letter or otherwise announced to Covered Entities, AstraZeneca temporarily, on an ad hoc basis, exempted from this requirement certain Covered Entities (hospitals or FQHCS) that requested it.

[16] The AstraZeneca products affected by this restriction included: Bevespi Aerosphere, Brilinta, Bydureon, Byetta, Crestor, Daliresp, Farxiga, Kombiglyze XR, Lokelma, Nexium, Onglyza, Pulmicort, Qtern, Seroquel, Seroquel XR, Symbicort, Symlin, and Xigduo XR.

171. In August 2023, AstraZeneca eliminated any informal exemptions for FQHCs and hospitals and mandated that all Covered Entities, including FQHCs and hospitals, use only a single contract pharmacy for 340B drugs.

172. In October 2024, AstraZeneca changed its policy again, requiring Covered Entities to provide claims data[17] in order to continue to dispense 340B drugs through their sole designated contract pharmacy: "Effective October 1, 2024, AstraZeneca will begin mandating the submission of claims data on 340B utilization filled at contract pharmacies. All specified claims data must be submitted on the 340B ESP™ platform within 45 days of the dispense date. This requirement applies to covered entities, without an in-house pharmacy that have designated a single contract pharmacy via the 340B ESP™ platform."

173. In April 2025, AstraZeneca again amended its policy, allowing Covered Entities without an in-house pharmacy capable of dispensing certain specialty medications to designate one additional specialty contract pharmacy to access those specialty medications.. These specialty medications included Lynparza, a medication used to treat certain ovarian, breast, fallopian tube, pancreatic, prostate, and peritoneal cancers. AstraZeneca required this additional contract pharmacy to be part of the product's limited distribution network ("LDN"), meaning that it must be one of the small number of pharmacies that AstraZeneca has designated to dispense certain drugs.

174. After AID brought an enforcement action against AstraZeneca for its violation of Act 1103, AstraZeneca exempted Arkansas covered entities from its contract pharmacy policy

[17] For all Manufacturer Defendants, claims data includes the following data fields: Contracted Entity ID; Date of Service; Date Prescribed; NDC; Prescriber ID; Quantity; Rx Number; and Service Provider ID. Depending on the specific manufacturer, claims data may also include: Wholesaler Invoice Number; Payer BIN; Payer PCN; Ship to Date; Ship to Location; 340B Account Number; Product Serialization Number; and Fill Number.

effective April 1, 2025. Finally, beginning in May 2026, AstraZeneca required all Covered Entities, regardless of whether it uses contract pharmacies or an in-house pharmacy, to provide medical data[18] to obtain 340B discounted drugs. Arkansas covered entities are not exempted from this requirement.

d. Boehringer Ingelheim's 340B Restrictions

175. On August 1, 2021, Boehringer Ingelheim began limiting Covered Entities without an in-house pharmacy to using only a single contract pharmacy. Federal grantees were exempted from this policy. The announcement of this policy stated the following:

> First, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location to receive and dispense 340B purchased products. BI is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy, and have not already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a single contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.

176. On December 1, 2021, Boehringer Ingelheim amended its policy to allow Covered Entities without an in-house pharmacy to use one additional contract pharmacy if their single designated pharmacy could not dispense OFEV, a drug that could be distributed only through specialty pharmacies.

177. On September 1, 2022, Boehringer Ingelheim began restricting FQHCs to a single designated retail contract pharmacy and one specialty contract pharmacy unless they submitted claims-level data to Boehringer Ingelheim. This amendment stated that "for any CH/CHC covered entity type that provides specified 340B contract pharmacy claims data through the 340B ESP™

[18] For all Manufacturer Defendants, medical data includes the following data fields: 340B ID; Claim Number; Claim Line Number; Date of Service; Health Plan Name; Health Plan ID; NCD-11; Quantity; and Service Provider ID. Depending on the particular manufacturer, medical data may also include: HCPCS Code; HCPCS Code Modifier; Rendering Physician ID; Unit of Measure; and Wholesaler Invoice Number.

platform, such entity may continue to purchase BI products at the 340B discounted price and have such discounted product shipped to those contract pharmacies that are registered on the HRSA website as a contract pharmacy of the entity and identified in the submitted contract pharmacy claims data."

178. On August 1, 2023, Boehringer Ingelheim further amended its policy to restrict Covered Entities from using even a single contract pharmacy unless such pharmacy was located within 40 miles of the Covered Entity. This restriction applied also to federal grantees. This amendment stated that "[t]he designated contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within a forty (40) mile radius of the covered entity parent site, and cannot be a central fill pharmacy."[19]

179. On May 1, 2024, following the Eighth Circuit decision in *PhRMA v. McClain*, Boehringer Ingelheim began specifically exempting Arkansas Covered Entities using contract pharmacies in Arkansas from its 340B contract pharmacy policy.

e. Bristol's 340B Restrictions

180. On March 1, 2022, Bristol started restricting hospital Covered Entities lacking an in-house pharmacy to use of up to two contract pharmacies, one for Revlimid, Pomalys, and Thalomid ("IMiD products"), and one for other drugs. Bristol also required Covered Entities to upload claims data for all IMiD specialty contract pharmacy claims. Federal grantees were exempted from this policy for retail covered drugs, but not for IMiD products.

181. On November 1, 2023, Bristol amended its policy to restrict all Covered Entities to use of three contract pharmacies: (1) one for non-IMIDs, (2) one for IMIDs, and (3) one for

[19] OPAIS stands for Office of Pharmacy Affairs Information System.

Camzyos, which was a limited distribution drug used to treat obstructive hypertrophic cardiomyopathy.

182. On March 28, 2024, Bristol exempted Arkansas Covered Entities temporarily and partially from some of its restrictive 340B contract pharmacy policies.

183. On July 1, 2024, Bristol started requiring claims data for non-IMiD retail (i.e., self-administered) drugs.

184. On May 1, 2026, Bristol began requiring in-house pharmacy and medical claims data for each covered drug. Arkansas Covered Entities were not exempted from this onerous requirement.

f. Eli Lilly's 340B Restrictions

185. On September 1, 2020, Eli Lilly began limiting Covered Entities without an in-house pharmacy to use of a single contract pharmacy to dispense 340B drugs. Covered Entities with an in-house pharmacy were prohibited from using even a single contract pharmacy. Covered Entities could contact the company to seek an exception for insulin products, specifically, but the terms of the exception were so onerous and limited that, in practice, no Covered Entity qualified: only Covered Entities which kept the entirety of the discounts (without remitting any percentage going to the pharmacies for dispensing or to third-party administrators that assisted most Covered Entities with the logistics) could qualify for such an exception.

186. On December 16, 2021, Eli Lilly amended its policy to allow Covered Entities to use unlimited contract pharmacies to dispense 340B drugs to their patients, but only if the Covered Entities provided claims-level data associated with each and every contract pharmacy order. Eli Lilly's announcement of this new policy provided no legal authority for requiring Covered Entities to submit such data.

187. On November 16, 2023, Eli Lilly reverted to its 2020 restrictions on a nationwide basis, restricting Covered Entities without an in-house pharmacy to using only a single contract pharmacy. Covered Entities did not have to provide claims data under this policy. Eli Lilly exempted Arkansas Covered Entities from the single contract pharmacy restriction but demanded that Arkansas Covered Entities continue providing claims data in order to use multiple contract pharmacies.

188. On July 1, 2024, Eli Lilly again amended its nationwide policy to require all Covered Entities lacking an in-house pharmacy to provide claims data in order to use a single contract pharmacy.

189. Finally, in January 2026, Eli Lilly amended its restrictive policy to require Covered Entities to provide not only claims-level data, but also in-house and medical data, effective February 1, 2026.

g. GlaxoSmithKline's 340B Restrictions

190. On April 1, 2022, GlaxoSmithKline began restricting Covered Entities to using only a single, designated contract pharmacy if the covered entity did not have an in-house pharmacy and prohibited the use of contract pharmacies if the covered entity had an in-house pharmacy.. Alternatively, Covered Entities could use more than one contract pharmacy if they submitted claims data for all contract pharmacy claims. GlaxoSmithKline briefly exempted federal grantees (but not hospitals or other non-federal grantees) from this burdensome policy for about a year. GlaxoSmithKline's announcement of its policy stated:

To ensure all 340B covered entities can access GSK products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location. GSK is utilizing the 340B ESP™ platform to support this designation. 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™, can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab. If you have questions regarding the change in our 340B distribution model, please contact us at support@340Besp.com.

Covered entities may also elect to submit 340B claims through 340B ESP™ for all utilization dispensed through contract pharmacies. Any covered entity that elects to submit its 340B claims will be allowed to continue Bill To / Ship To replenishment orders for its contract pharmacies. Covered entities that are interested in submitting 340B claims will need to register an account with 340B ESP™ and must submit the 340B claims within 45 days of the dispense date.

191. On May 1, 2023, GlaxoSmithKline revoked the exemption for federal grantees, applied its policy to all its products, and eliminated the alternative option of submitting claims data as a condition for shipping 340B drugs to more than one contract pharmacy.

192. On November 1, 2023, GlaxoSmithKline exempted Arkansas Covered Entities from its 340B contract pharmacy policy with respect to contract pharmacies located within Arkansas. It further purported to honor replenishment orders in Arkansas associated with covered products dispensed on or after August 1, 2023. However, this retroactive replenishment model depended on contract pharmacies being willing to receive the added inventory. If the contract pharmacies did not accept the sudden infusion of added inventory, then the covered entities would not receive the benefit of any retroactive discount.

h. J&J's 340B Restrictions

193. On May 2, 2022, Johnson & Johnson began requiring Covered Entities to submit claims data in order to use more than one contract pharmacy to dispense 340B drugs to their patients. When J&J announced this new policy on March 21, 2022, it stated that "Covered Entities may continue to use an unlimited number of contract pharmacies if they elect to provide the

requested limited claims data." J&J further stated that, if Covered Entities "choose not to provide limited claims data, they still may designate a single contract pharmacy location for purchases of covered outpatient drugs." Federal grantees were exempt from this policy.

194. On March 7, 2023, J&J amended its policy to limit Covered Entities to use of a single contract pharmacy within a 40-mile radius, and use of one additional contract pharmacy within the limited distribution network. Under this amendment, J&J also required Covered Entities to submit claims data for the single contract pharmacy.

195. On August 20, 2024, J&J exempted Arkansas Covered Entities from its 340B policy, allowing them to use multiple contract pharmacies in Arkansas.

i. Merck's 340B Restrictions

196. On September 1, 2021, Merck began limiting Covered Entities to use of only a single contract pharmacy without submitting claims data. The policy allowed Covered Entities to use multiple contract pharmacies if they provided Merck with claims data. Federal grantees were exempted from the policy. Merck's letter announcing this policy stated that, "effective September 1, 2021, we will no longer voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for hospital covered entities that have not begun to provide 340B claims data for all claims originating from its contract pharmacies, unless the hospital covered entity lacks its own in-house pharmacy and designates a single contract pharmacy site of its choice as described below. If 340B claims data are provided as required under the updated Merck Program, we will again voluntarily honor 340B discounts or chargebacks for contract pharmacy transactions for hospital covered entities."

197. On May 31, 2022, Merck amended its 340B policy to subject FQHCs to these restrictions.

198. On June 12, 2023, Merck further tightened its policy, specifying that the single designated contract pharmacy must be within 40 miles of the Covered Entity. Under the new policy, even if a Covered Entity provided claims data, it would only be permitted to designate one contract pharmacy within 40 miles of the Covered Entity. Merck's announcement of this policy change provided: "[t]his update to the 340B Program integrity initiative will allow a hospital or CH/CHC covered entity that lacks its own in-house outpatient pharmacy to designate a single contract pharmacy location of its choice, provided that the single contract pharmacy is located within 40 miles of the covered entity parent site and registered on the HRSA database."

199. On July 31, 2023, Merck specifically amended its policy to allow Arkansas Covered Entities to use multiple contract pharmacies if the Covered Entities submitted claims data. If the Covered Entity did not provide claims data, it was limited to use of a single contract pharmacy within 40 miles of the Covered Entity. Merck's announcement stated:

> If a hospital or CH covered entity is not registered and submitting data by **August 25, 2023**, Merck will no longer voluntarily honor 340B contract pharmacy discounts and chargebacks; however, registration will continue to be available through Merck's vendor, Second Sight Solutions (see www.340BESP.com). If the hospital or CH covered entity subsequently registers and submits 340B claims data originating from all eligible contract pharmacies, 340B discounts and chargebacks will be voluntarily honored for transactions at all eligible contract pharmacies once the registration and 340B claims data has been processed.
>
> If a hospital or CH covered entity chooses not to provide 340B claims data originating from all eligible contract pharmacies and lacks its own in-house outpatient pharmacy, a single contract pharmacy location of its choice may be designated through Merck's vendor, Second Sight Solutions (see www.340BESP.com), provided that the single contract pharmacy is located within 40 miles of the covered entity parent site and registered on the HRSA database. Covered Entities that have already designated a single contract pharmacy on 340B ESP™ located within 40 miles of the covered entity parent site and registered on the HRSA database **will not need to re-designate** a single contract pharmacy on the platform. If a hospital or CH covered entity lacks an in-house outpatient pharmacy and is unable to identify an eligible contract pharmacy within 40 miles, Merck's vendor, Second Sight Solutions (see www.340BESP.com), will work with the covered entity to identify an available option for a contract pharmacy that is able to dispense covered outpatient drugs to the entity's patients.

200. On April 12, 2024, Merck added Winrevair, a medication used to treat pulmonary arterial hypertension, to the list of drugs subject to its restrictive policies. It provided that Covered Entities could designate one additional specialty contract pharmacy to dispense Winrevair.

201. On March 31, 2025, Merck again amended its policy, providing that if Covered Entities did not submit claims data, they could not designate even a single contract pharmacy, effectively forcing these Covered Entities to turn over their data or otherwise be left with *no* means to distribute the drugs they were purchasing for their patients. Merck's announcement stated: "Merck will no longer permit a hospital or CH covered entity that lacks its own in-house outpatient pharmacy to designate a single contract pharmacy location if the hospital or CH covered entity chooses not to provide 340B claims data for claims originating from its contract pharmacies to Merck's vendor, Second Sight Solutions."

j. Novartis' 340B Restrictions

202. On November 16, 2020, Novartis began restricting Covered Entities to using only contract pharmacies within 40 miles. Federal grantees were exempted from this policy. Novartis' announcement stated that, "[f]or all other covered entities, beginning on November 16, 2020, we will continue to honor contract pharmacy (CP) arrangements as long as the CP is located within a 40-mile radius of its parent facility for all Novartis Pharmaceutical Corporation products." Although other Manufacturer Defendants later mimicked this exact "40-mile radius" requirement for contract pharmacies, Novartis appears to have created it out of whole cloth and was the first to implement it.

203. On May 1, 2023, Novartis amended its policy to limit Covered Entities to using only a single contract pharmacy to dispense 340B drugs to its patients. The amendment provided:

> For hospital covered entities, beginning on May 1, 2023, Novartis will ship all units ordered at the 340B discounted price directly to covered entities. Novartis will allow all covered entities without an in-house pharmacy to select one contract pharmacy location where Novartis will ship 340B discounted units.
>
> In addition, Novartis will recognize any arrangements with contract pharmacies that are fully owned and controlled by a covered entity.
>
> All federal grantee covered entities continue to be exempt from our contract pharmacy policy.

204. On March 18, 2024, following the Eight Circuit's decision in *PhRMA v. McClain* upholding Act 1103, Novartis specifically exempted Arkansas hospital Covered Entities only from its restrictive policy, allowing them to maintain contract pharmacy arrangements with Arkansas-based community pharmacies.

205. On January 1, 2025, Novartis began requiring Covered Entities to upload claims data in order to continue using their single designated contract pharmacy. Arkansas Covered Entities were exempt from this policy.

k. Novo Nordisk's 340B Restrictions

206. On January 1, 2021, Novo Nordisk began prohibiting hospital Covered Entities from using any contract pharmacies if they had an in-house pharmacy. Hospital Covered Entities without an in-house pharmacy were permitted to use a single contract pharmacy. Federal grantees were exempt from this policy. As the manufacturer explained: "Novo Nordisk will no longer facilitate 'bill-to/ship-to' distribution of 340B product to a contract pharmacy of any of the six 'hospital' covered entity types. If a 'hospital' covered entity does not have an in-house pharmacy capable of dispensing products to outpatients, that covered entity may designate one contract pharmacy location to which product purchased by that covered entity may be shipped."

207. On January 1, 2023, Novo Nordisk began allowing hospital Covered Entities to use multiple contract pharmacies to dispense 340B drugs to their patients, but only if they provided claims-level data associated with each and every contract pharmacy order to Novo Nordisk. Under this policy, if a hospital Covered Entity could not or would not provide this claims data, it could use only one retail contract pharmacy and one specialty contract pharmacy to dispense 340B drugs to its patients.

208. On July 1, 2023, Novo Nordisk amended its policy to eliminate the claims data requirement unless the Covered Entities have wholly-owned contract pharmacies.

209. On February 1, 2024, pursuant to a Temporary Regulatory Settlement between Novo Nordisk and the AID effective on December 27, 2023, Novo Nordisk implemented a new policy specific to Arkansas Covered Entities. Under this policy, Covered Entities could contract with two contract pharmacies without providing claims data, and could contract with an unlimited number of contract pharmacies if they provided claims data. This policy also included a new requirement that does not exist under the 340B Program: for a prescription to qualify for 340B drug pricing, the Covered Entity needed to have seen the patient within the last six months. Covered Entities needed to maintain medical record data and submit claims data to prove that this requirement was met.

l. Pfizer's 340B Restrictions

210. On March 1, 2022, Pfizer began requiring hospital Covered Entities to provide claims data in order to use more than one contract pharmacy. This policy applied to oral oncology medications and Xeliganz, and exempted federal grantees. Covered Entities who were unable or unwilling to provide claims data were permitted to designate only a single contract pharmacy for Xeliganz and one additional contract pharmacy for oral oncology medications. Pfizer's letter announcing this new policy stated:

Fourth, to ensure that all 340B eligible covered entities and their patients continue to have access to Xeljanz® and oral oncology products at 340B ceiling prices, any 340B hospital covered entity, which (1) declines to provide the requested limited claims data and (2) does not have an in-house pharmacy capable of dispensing 340B priced drugs to its patients, may designate a contract pharmacy location online via the 340B ESP™ platform:

- 340B hospital covered entities may designate a single contract pharmacy location for Xeljanz®
- 340B hospital covered entities may designate a single specialty contract pharmacy location participating in Pfizer's DON for oral oncology products at the 340B price.[3]
- The contract pharmacy location(s) selected must also be registered on the HRSA 340B OPAIS contract pharmacy database Search Contract Pharmacies (hrsa.gov)
- Please visit https://www.340besp.com/designations to exercise this option.

211. On May 1, 2023, Pfizer restricted hospital Covered Entities to only a single contract pharmacy to dispense Xeliganz. Under the new policy, even if Covered Entities provided claims data, they would now be permitted to designate only one contract pharmacy.

212. On November 1, 2023, Pfizer applied its restrictive contract pharmacy policy to many other of its prescription drugs. The list of expanded drugs included Genotropin, a medication that treats growth failure in children, and Zirabev, an injectable oncological medication used to treat a variety of cancers including colorectal and brain cancers. Under the policy, hospital Covered Entities could still submit claims data in exchange for multiple contract pharmacy designations for distribution of oral oncology medications.

213. On May 6, 2024, following the Eight Circuit's decision in *PhRMA v. McClain* upholding Act 1103, Pfizer specifically exempted Arkansas hospital Covered Entities from its restrictive policy, allowing them to designate multiple contract pharmacies without submitting claims data.

m. Sanofi's 340B Restrictions

214. On October 1, 2020, Sanofi began requiring all Covered Entities to provide claims-level data associated with each and every contract pharmacy order in order to continue receiving 340B drug pricing. Sanofi's policy announcement stated: "Sanofi will require 340B covered

entities to submit claims data for 340B prescriptions of Sanofi products filled through its contract pharmacies. Sanofi will use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts. This initiative is enabled through 340ESP, a Second Sight Solutions technology. Sanofi is requiring 340B covered entities to register at www.340BESP.com by October 1, 2020."

215. On June 1, 2023, Sanofi amended its policy to restrict certain hospital Covered Entities to use of a single contract pharmacy to dispense 340B drugs to their patients. FQHCs were exempted from the single contract pharmacy designation portion of this policy, but Sanofi demanded that they upload claims data in order to receive 340B drug pricing. This amendment removed the requirement to provide claims data from each contract pharmacy. Sanofi's announcement provided:

> If a CH does not have an in-house pharmacy location registered on the covered entity database as a shipping address or child site of the covered entity, they may designate a single contract pharmacy for this purpose. A qualifying covered entity may choose a single contract pharmacy for the covered entity and its child sites and Sanofi will provide 340B pricing in this circumstance, irrespective of whether the covered entity provides the data Sanofi requests. If you already have a designation in place, you do not need to take any action at this time.

216. On March 18, 2024, Sanofi exempted Arkansas Covered Entities from its restrictive 340B contract pharmacy policies. Covered Entities in Arkansas could use multiple contract pharmacies under this policy.

217. On July 1, 2024, Sanofi began requiring hospitals using a single contract pharmacy to upload claims data and requiring FQHCs to have a single designated contract pharmacy. Arkansas Covered Entities were exempted from this claims data requirement.

218. On September 23, 2024, Sanofi began requiring certain hospital Arkansas Covered Entities to "provide evidence or, alternatively, attestation that it retains legal title to Sanofi 340B-

priced drugs delivered to its contract pharmacies until the contract pharmacies dispense those drugs to 340B-eligible patients, consistent with federal law." Sanofi refers to this requirement as its "Contract Pharmacy Anti-Diversion Policy."

219. On September 3, 2025, Sanofi started allowing FQHCs to use one additional contract pharmacy within the limited distribution network.

220. On June 15, 2026, Sanofi began imposing a requirement that Covered Entities provide in-house pharmacy and medical claims data to receive 340B discounted drugs subject to its policy. Arkansas hospital Covered Entities are exempt from this requirement.

V. CLAIMS FOR RELIEF

COUNT I
(Against All Manufacturer Defendants)
Violation of the ADTPA, Ark. Code Ann. § 4-88-107(a)(10).

221. The State repeats and incorporates by reference every allegation contained in the preceding paragraphs as if fully set forth herein.

222. The ADTPA authorizes the Attorney General to file a civil action against "any person" "engaging in any deceptive or unlawful practice." Ark. Code Ann. § 4-88-104.

223. ADTPA violations are subject to injunctive relief, including the suspension of a company or individual to conduct business in Arkansas, and monetary penalties up to $10,000 per violation, as well as any other measure necessary to prevent the same illegal practices from occurring. *Id.* § 4-88-113.

224. A "person" is "an individual, organization, group, association, partnership, corporation, or any combination" thereof. *Id.* § 4-88-102(5).

225. Manufacturer Defendants are "persons" within the meaning of the ADTPA.

226. The ADTPA broadly prohibits certain categories of deceptive and unconscionable trade practices, including engaging in any "unconscionable, false, or deceptive act or practice in

business, commerce, or trade," *Id.* § 4-88-107(a)(10), and "[k]nowingly facilitating, assisting, intermediating, or in any way aiding the operation or continuance of an act or practice that is in violation of this chapter," *Id.* § 4-88-107(a)(12).

227. Manufacturer Defendants' conduct alleged herein, which occurred while selling their prescription drugs to Covered Entities in Arkansas under the 340B Program, occurred "in business, commerce, or trade." Ark. Code Ann. § 4-88-107(a)(10).

228. Manufacturer Defendants have engaged in unconscionable trade practices in violation of section 4-88-107(a)(10), and have knowingly facilitated, assisted, intermediated, and aided the operation or continuance of unconscionable trade practices, in violation of section 4-88-107(a)(12).

229. An "unconscionable act" is one that "affronts the sense of justice, decency, or reasonableness." *Baptist Health v. Murphy*, 365 Ark. 115, 128, 226 S.W.3d 800, 811 n.6 (Ark. 2006). Such unconscionable acts include the "improper use of economic leverage in a trade transaction." *Universal Cooperatives, Inc. v. AAC Flying Serv., Inc.*, 710 F.3d 790, 796 (8th Cir. 2013) (citing *Baptist Health,* 365 Ark. 115, 226 S.W.3d at 811 and *State ex rel. Bryant v. R & A Inv. Co.*, 336 Ark. 289, 985 S.W.2d 299, 300-03 (Ark. 1999)).

230. Unconscionable trade practices also "include[] conduct violative of public policy or statute." *Baptist Health*, 365 Ark. 115 at 128, 226 S.W.3d at 811.

a. Unconscionable acts affronting the sense of justice, decency, or reasonableness

231. Manufacturer Defendants' conduct was unconscionable in that it offends justice, decency, and reasonableness. Manufacturer Defendants' conduct was carried out entirely to protect their extraordinary profits and to the detriment of Arkansas patients and the Arkansas healthcare system. Providing 340B discounted drugs imposes a substantial cost on drug

manufacturers, but those costs are a small fraction of their overall revenue. Moreover, Manufacturer Defendants voluntarily participate in the 340B program, and at any time could stop if they do not want to comply with its requirements. Yet Manufacturer Defendants instead agreed to provide 340B drugs while simultaneously attempting to circumvent their obligations and hurting the public, patients, and overall healthcare in Arkansas. Indeed, Manufacturer Defendants knew that their conduct would hurt, rather than improve healthcare in rural and underserved communities. In short, their conduct was unconscionable because they put their own profits over the health interests of Arkansans.

232. That unconscionability is even worse because the 340B costs that Manufacturer Defendants sought to avoid were, in part, a problem of their own making. One of the reasons the 340B Program cost drug manufacturers so much is because they raised their drug prices so drastically, faster than the rate of inflation. Under the 340B statutory formula for calculating the Ceiling Price, when drug manufacturers increase their drug prices faster than the rate of inflation, the Ceiling Price falls and the drug manufacturers have to provide greater discounts under the 340B Program. As a result, participating in the 340B Program effectively costs the drug manufacturers more. If, on the other hand, the drug manufacturers had not raised the prices of their drugs so quickly and significantly, the Ceiling Prices would have been higher, and their costs of providing 340B discounted drugs would have been less.

233. Manufacturer Defendants' restrictive 340B policies were also unconscionable because, by restricting Covered Entities' use of contract pharmacies, they made it more difficult for Covered Entity patients to obtain the drugs they were prescribed by the Covered Entity. Some patients had to travel much farther distances to reach the one designated contract pharmacy where they could receive their 340B drugs, and other patients were blocked entirely from getting their

340B drugs, because the Covered Entity was unable to comply with Manufacturer Defendants' burdensome and changing restrictions. Even if patients opted to fill their prescriptions at more convenient pharmacies, those pharmacies could not offer the discounts that contract pharmacies can, which made it particularly difficult for poorer patients to afford their medications. In short, the Manufacturer Defendants' restrictive policies harmed Arkansas patients and healthcare in Arkansas, all for the sake of protecting their profits.

234. Manufacturers Defendants' restrictive 340B policies were also unconscionable because, by prohibiting or restricting Covered Entities' use of contract pharmacies, they made it more difficult for Covered Entities to obtain the 340B discounted drugs. That, in turn, meant that, as a practical matter, many Covered Entities were unable to obtain the financial benefit of the discounts, which were intended to help them stretch their services to more patients in rural and other underserved communities, in contravention of Act 1103's protection for contract pharmacy arrangements.

235. In addition, Manufacturer Defendants' specific restrictive policies that required claims data or medical data were also unconscionable. The 340B Program does not require Covered Entities to provide such data to drug manufacturers. But the drug manufacturers used their drug discounts, and the drugs themselves, some of which were life-saving necessities for Covered Entity patients, as leverage to extract that valuable data from Covered Entities or as an excuse to deny 340B drugs to Covered Entities that either refused to, or could not, provide such data. These tactics affront the sense of justice, decency, or reasonableness because they limit patients' access to affordable medication with no legal basis.

236. Manufacturer Defendants also exploited their superior market and industry power over that of Covered Entities, which lack a similar network or lobbying organization to protect

their interests, as well as very limited financial resources. Manufacturer Defendants knew, therefore, that the Covered Entities would have no means or resources to resist their policies, even if there was no legal basis for Manufacturer Defendants' demands. They forced Arkansas safety-net providers into an impossible choice: comply with burdensome and unlawful demands or forfeit access to the discounted drugs that are essential to their operations and their patients' care. Manufacturer Defendants' conduct was unconscionable for that reason as well.

b. Unconscionable acts violating public policy

237. Manufacturer Defendants' restrictive 340B policies were also unconscionable because they violated the public policy purpose of Act 1103. Act 1103 was specifically enacted to protect Covered Entities' ability to use contract pharmacies to deliver or dispense discounted drugs to their patients. Manufacturer Defendants' various policies, such as restricting Covered Entities to use of one contract pharmacy, and only if they lack an in-house pharmacy; restricting Covered Entities to use of one contract pharmacy within a 40-mile radius; not permitting use of contract pharmacies unless they meet the onerous burdens of providing claims data or medical data, were all directly contrary to Act 1103's purpose.

238. Each of Manufacturer Defendants' restrictive 340B policies made it more difficult for Covered Entities to use contract pharmacies, contrary to Act 1103's purpose. Moreover, by constantly shifting and changing their policies, Manufacturer Defendants created a complex, administrative nightmare for the Covered Entities that imposed a new expense on them: to comply with Manufacturer Defendants' restrictive 340B policies, the Covered Entities had to keep track of each manufacturer's policy, the frequent changes in the policy, figure out how to comply with that policy, and how to reconcile that policy with the distinct policies of every other manufacturer from whom they obtained drugs. Many Covered Entities did not have the resources or expertise

to figure out a path to comply with these requirements to enable them to continue to obtain Manufacturer Defendants' discounted 340B drugs. They also lacked the resources to navigate the 340B ESP platform, which is error prone and difficult to upload claims data to. Moreover, Covered Entities, unlike Manufacturer Defendants, do not have a lobbying organization or trade association to represent their collective interests. Manufacturer Defendants exploited that fact, knowing that Covered Entities would be unable to resist their policies, especially when acting in coordination. The Manufacturer Defendants' restrictive 340B policies, therefore, are contrary to Act 1103's purpose of ensuring that the Manufacturer Defendants were not artificially creating roadblocks for Covered Entities that prevent Covered Entities from receiving 340B discounted drugs.

239. Although some of Manufacturer Defendants eventually exempted certain Arkansas Covered Entities from some of their restrictive policies during some of the relevant time period, all of those exemptions were put into place long after Act 1103's enactment. And almost all were only partial exemptions from the restrictive 340B policies described herein. For example, although some of Manufacturer Defendants permitted Arkansas Covered Entities to use multiple contract pharmacies, they nevertheless required Arkansas Covered Entities to provide claims data or medical data. In other words, all of Defendant Manufacturers engaged in restrictive 340B policies in Arkansas for some, if not all, of the relevant time period that were contrary to the public policy embodied in Act 1103 and were therefore unconscionable. Manufacturer Defendants' Arkansas exemptions, therefore, do not preclude their liability under the ADTPA.

240. Each of Manufacturer Defendants engaged in various restrictive 340B policies, as described herein. Each policy had the same purpose of circumventing or reducing Manufacturer Defendants' obligation to provide 340B discounted drugs to Covered Entities and Act 1103's requirement that manufacturers not discriminate against Covered Entities that use contract

pharmacies. Although these restrictive 340B policies varied slightly amongst the different Manufacturer Defendants as well as over time, they were all unconscionable because of their common purpose. None of Manufacturer Defendants' restrictive policies were authorized or even contemplated by the 340B statute, and most, if not all, were in direct violation of Act 1103.

COUNT II
(Against All Defendants)
Violation of the ADTPA, Ark. Code Ann. § 4-88-107(a)(12).

241. The State repeats and incorporates by reference every allegation contained in the preceding paragraphs as if fully set forth herein. Ark. R. Civ. P. 10(c).

242. Under the ADTPA, it is unlawful to engage in any "unconscionable, false, or deceptive act or practice in business, commerce, or trade." Ark. Code Ann. § 4-88-107(a)(10). An "unconscionable act" is one that "affronts the sense of justice, decency, or reasonableness" or violates public policy or statute. *Baptist Health v. Murphy,* 365 Ark. 115, 226 S.W.3d 800, 811 (2006).

243. As alleged above, Manufacturer Defendants engaged in unconscionable acts or practices in business, commerce, or trade by applying restrictive 340B policies in selling, or causing the sale of, prescription drugs in Arkansas that violated public policy, contravened the purposes of Act 1103, and harmed patients, Covered Entities, and the healthcare system in Arkansas.

244. The ADTPA likewise prohibits "[k]nowingly facilitating, assisting, intermediating, or in any way aiding the operation or continuance of an act or practice that is in violation of this chapter." Ark. Code Ann. § 4-88-107(a)(12).

245. As detailed in the above allegations, Manufacturer Defendants knowingly facilitated, assisted, intermediated, and aided each other in their unconscionable acts and practices, to wit, their 340B restrictions, which were designed to circumvent Act 1103. Manufacturer

Defendants implemented similar 340B restrictive policies along similar timelines. They knew that by working in tandem, to create a patchwork of varying requirements at different times implemented separately by each Manufacturer Defendant, Arkansas Covered Entities would be faced with a burdensome logistical challenge simply to figure out how to comply with all the different Manufacturer Defendants' requirements. Moreover, the Manufacturer Defendants knew that the substantive 340B restrictions they were adopting would make it very difficult, if not impossible, for Arkansas Covered Entities to be able to jump through the necessary hoops to obtain the 340B discounted drugs to which they were entitled.

246. Manufacturer Defendants knowingly assisted each other by implementing similar, but different, 340B restrictions on different timelines, including the restrictions on contract pharmacies that violated Act 1103. Manufacturer Defendants' similar, substantive restrictions demonstrate a coordinated and calculated joint effort by Manufacturer Defendants to circumvent Act 1103's protections. Manufacturer Defendants used the same six restrictions, some of which used identical language to describe those restrictions. For example, each Manufacturer Defendant that restricted Covered Entities to use of a contract pharmacy within a certain distance of the Covered Entity chose the exact same distance: 40 miles. That was not mere coincidence, but active coordination. That coordination occurred, in part, through use of Second Sight's platform, which enabled each Manufacturer Defendant to view the other Manufacturer Defendants' restrictions and monitor when changes were made. In addition, Manufacturer Defendants coordinated through PhRMA, the association that lobbies on behalf of Defendant Manufacturers, which played a pivotal role in ensuring that tandem restrictions would have the desired effect of limiting the strength of the 340B program. Manufacturer Defendants, therefore, knowingly facilitated, assisted, and aided each other in their unconscionable acts, in violation of Ark. Code Ann. § 4-88-107(a)(12). In short,

Manufacturer Defendants used their market power and coordination to gang up on the Covered Entities, whom Manufacturer Defendants knew had no comparable resources to resist their demands.

247. Second Sight Solutions, LLC also knowingly facilitated, assisted, intermediated, and aided Manufacturer Defendants' unconscionable acts. Second Sight assisted all of Manufacturer Defendants in implementing their 340B restriction requiring Arkansas Covered Entities to provide claims data or in-house and medical data. Second Sight provided Manufacturer Defendants the platform by which to restrict the delivery of covered drugs to multiple contract pharmacies; Manufacturer Defendants required the Covered Entities to designate a single contract pharmacy in the state through the Second Sight platform. Second Sight also provided the Manufacturer Defendants with a platform that facilitated the collection and transfer of that data from Arkansas Covered Entities to Manufacturer Defendants. Second Sight, therefore, knowingly facilitated and assisted Manufacturer Defendants in extracting valuable data from Arkansas Covered Entities in order to receive delivery of 340B drugs for their patients, even though the 340B Program does not impose any requirement on Covered Entities to provide claims data or medical data to a pharmaceutical manufacturer to receive 340B discounted drugs. Finally, Second Sight provided Manufacturer Defendants a means to collude on their restrictions; by posting all the manufacturer restrictions in one place, Manufacturer Defendants could see what other manufacturer restrictions were in place and adjust their restrictions accordingly without having to communicate directly with other manufacturers.

248. Second Sight thus facilitated Defendant Manufacturers' unconscionable efforts to extract valuable data from Covered Entities and preclude Covered Entities and their patients from receiving discounted drugs under the 340B Program.

VI. PRAYER FOR RELIEF

249. The State of Arkansas respectfully requests that this Court:

a. Impose civil penalties under Ark. Code Ann. § 4-88-113(b), to be paid to the State by the Defendants in the amount of $10,000.00 per each violation; as set forth above, each Defendant committed thousands of violations and, collectively, the Manufacturer Defendants committed a minimum of 300,000 violations; therefore, this Court should impose civil penalties for each identified, and not yet identified, violation of the ADTPA proved at trial in this matter.

b. Issue an order, in accordance with Ark. Code Ann. § 4-88-113(e), requiring Defendants to pay the State's costs in this investigation and litigation, including, but not limited to, attorneys' fees and costs;

c. Issue an order enjoining Defendants from engaging in the conduct alleged herein that is contrary to the public policy underlying Act 1103 and in violation of the ADTPA, to include: limiting Covered Entities in Arkansas with an in-house pharmacy to use of only one contract pharmacy for delivery of 340B drugs; prohibiting Covered Entities in Arkansas with an in-house pharmacy from using contract pharmacies to deliver 340B drugs; limiting Covered Entities in Arkansas to use of a single contract pharmacy, within a specific distance of the Covered Entity, for delivery of 340B drugs; limiting the distribution network of specialty drugs covered under the 340B Program; requiring claims data from Covered Entities to receive 340B drugs; requiring in-house and medical data from Covered Entities to receive 340B drugs, and any other injunctive relief this Court may find warranted.

d. Order all other just and proper relief to which the State may be entitled.

VII. JURY DEMAND

250. The State demands a trial by jury on all issues so triable.

Respectfully submitted,

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* *Pro hac vice* application forthcoming