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Marilyn Burgess - District Clerk Harris County
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CAUSE NO. _____

COUNTY OF HARRIS, TEXAS *Plaintiff,* v. ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; CVS HEALTH CORPORATION; CAREMARK RX, L.L.C.; CAREMARK PCS HEALTH, L.L.C.; CAREMARK, L.L.C.; CAREMARK TEXAS MAIL PHARMACY, LLC; OPTUM, INC.; OPTUMRX INC.; AETNA RX HOME DELIVERY, LLC AND AETNA PHARMACY MANAGEMENT SERVICES, LLC. *Defendants.*	IN THE DISTRICT COURT OF _____ JUDICIAL DISTRICT HARRIS COUNTY, TEXAS JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL PETITION

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Plaintiff, Harris County, Texas, by and through the undersigned attorneys ("Plaintiff" or "Harris County") brings this lawsuit against Defendants: Eli Lilly and Company; Novo Nordisk Inc.; Sanofi-Aventis U.S. LLC; Express Scripts Holding Company; Express Scripts, Inc.; ESI Mail Pharmacy Service, Inc.; Express Scripts Pharmacy, Inc.; CVS Health Corporation; Caremark Rx, L.L.C.; Caremark PCS Health, L.L.C.; Caremark, L.L.C.; Caremark Texas Mail Pharmacy, LLC; Optum, Inc.; OptumRx Inc.; Aetna Rx Home Delivery, LLC and Aetna Pharmacy Management Services, LLC (collectively, "Defendants"). Plaintiff alleges on information and belief as follows:

I. INTRODUCTION

1. Diabetes is an epidemic in the United States. The total estimated cost of diagnosed diabetes in 2017 was $327 billion, including $237 billion in direct medical costs and $90 billion in reduced productivity.[1] In Houston, Texas alone, diabetes-related costs reached $4.1 billion in 2015.[2] One in four health care dollars is spent caring for people with diabetes.[3] In total, nearly 30 million people, 9.3% of the country, live with this disease.[4] Of this number, approximately six million people rely on daily insulin treatments to survive.[5]

[1] *See* American Diabetes Association, *The Staggering Cost of Diabetes*, March 2018, available at https://www.diabetes.org/resources/statistics/cost-diabetes.
[2] *See* Tom Dart, *Houston's Health Crisis: By 2040, One in Five Residents Will Be Diabetic*, The Guardian, Feb. 11, 2016, available at https://www.theguardian.com/cities/2016/feb/11/houston-health-crisis-diabetes-sugar-cars-diabetic
[3] *Supra* note 1.
[4] *Supra* note 1.
[5] Carolyn Y. Johnson, *Why treating diabetes keeps getting more expensive*, WASH. POST (Oct. 31, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin- prices-have-kept-rising-for-95-years/.

2. Defendants Eli Lilly, Novo Nordisk and Sanofi (collectively, "Manufacturer Defendants") manufacture the vast majority of insulins and other diabetes medications currently on the market in the United States.

3. Defendants CVS Caremark, Express Scripts, OptumRx and Aetna Rx (collectively "PBM Defendants") manage the pharmacy benefits for the vast majority of individuals in the United States. As part of this work, PBM Defendants establish national formularies that, among other things, set the baseline for which diabetes medications are covered by insurance and which are not.

4. Over the course of the last fifteen years, Manufacturer Defendants have in lockstep raised the reported prices of their respective diabetes drugs in an astounding manner.

5. Insulins that today cost Manufacturer Defendants just $5 to produce and that were originally priced at $20 when released in the late 1990s, now range between $300 and $700.[6]

6. In the last decade alone, Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, taking the same price increase down to the decimal point within a few days of each other.[7]

7. Figure 1 illustrates the rate in which Defendant Eli Lilly raised the price of its analog insulin, Humalog, compared to the rate of inflation for select consumer goods from 1997-2018.

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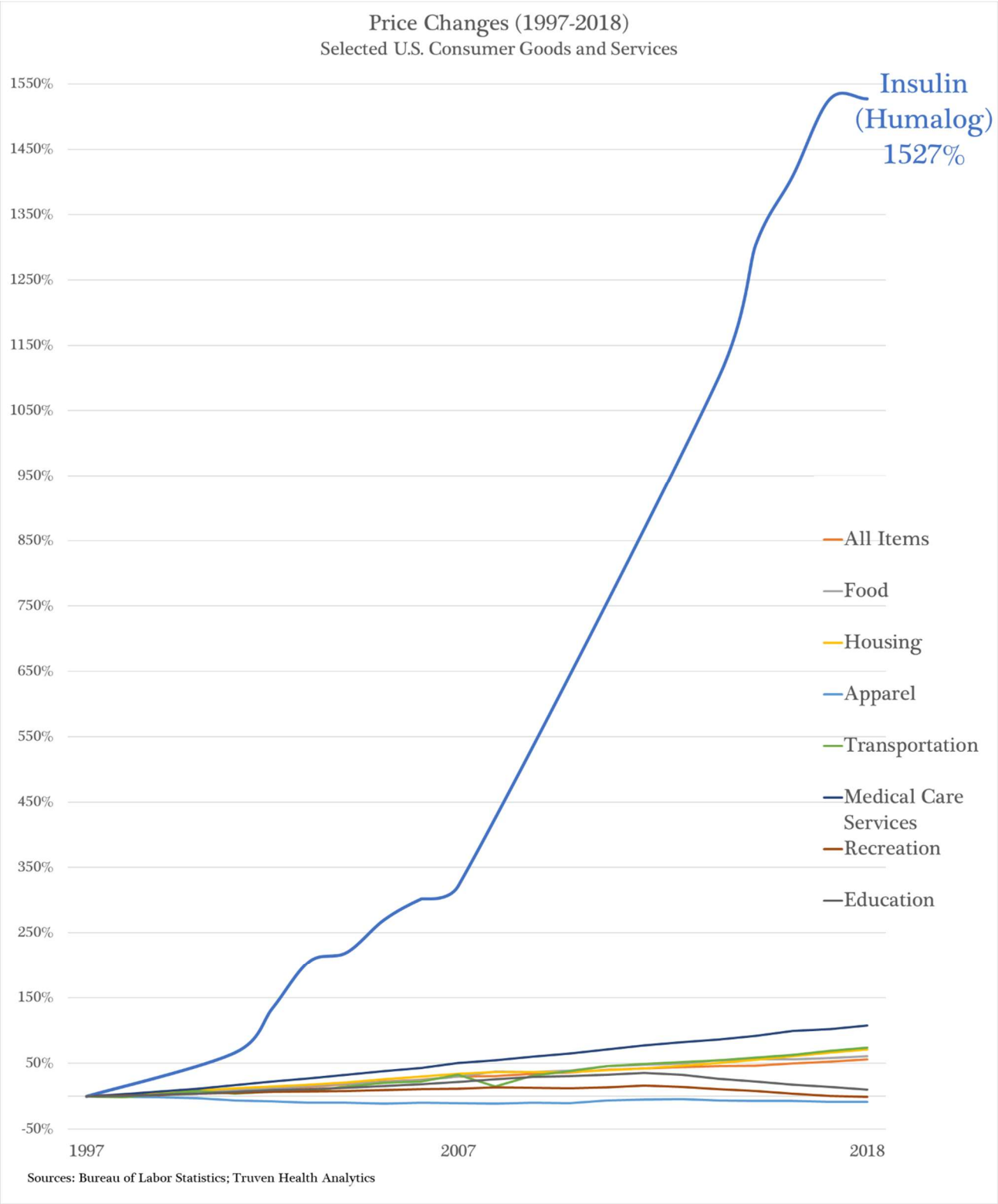
[6] *See* Dzintars Gotham, Melissa J. Barber, Andrew Hill, *Production Costs And Potential Prices For Biosimilars Of Human Insulin And Insulin Analogues*, BMJ Global Health, Vol. 3, Issue 5, available at https://gh.bmj.com/content/3/5/e000850; Table 1 of this Complaint.

[7] *See* Irl B. Hirsch, MD, *Changing Cost of Insulin Therapy in the U.S.* (Mar. 6, 2016), http://professional.diabetes.org/files/media/Changing_Cost_Insulin.pdf; Figure 1 of this Complaint.

Figure 1: Price Increase of Insulin Vs. Selected Consumer Goods from 1997-2018



8. Remarkably, nothing about these medications has *changed* during that time period; today's $350 drug is the exact same one Defendants sold decades ago for $20.[8]

9. The current exorbitant price stands in stark contrast to insulin's origins: the discoverers sold the original patent for $1 to ensure that the medication would remain affordable. Today, insulin has become the poster child for pharmaceutical price gouging.

10. It has now become apparent that the reason behind the lockstep price increases is a price fixing conspiracy between PBM and Manufacturer Defendants to create a secret spread between the reported price for diabetic treatments (on which Harris County's payments are based) and the true net price of those same drugs.[9]

11. This conspiracy between Manufacturer and PBM Defendants is at the root of the instant complaint and referred to herein as the "Insulin Pricing Scheme."[10]

12. Both Manufacturer and PBM Defendants play vital roles and profit immensely from the Insulin Pricing Scheme.

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[8] Indianapolis Business Journal, *Lilly Insulin Prices Under Microscope*, The Republic, Sept. 2. 2017, available at http://www.therepublic.com/2017/09/03/lilly_insulin_prices_under_microscope/#:~:targetText=Lilly%20launched%20Humalog%20in%201996,month's%20supply%20for%20many%20patients.&targetText=Instead%2C%20the%20company%20said%2C%20they,negotiate%20drug%20prices%20for%20insurers; see also Table 1 of this Complaint.

[9] For the purposes of this Complaint, "net price" refers to Manufacturer Defendants' reported price minus all payments made by Manufacturer Defendants to PBM Defendants.

[10] The diabetes medications at issue in this case are Eli Lilly's Humulin N, Humilin R, Humalog, Trulicity and Basaglar; Sanofi's Lantus, Toujeo, Soliqua and Apidra; and Novo Nordisk's Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic. All of these drugs are insulins, except Trulicity, Victoza and Ozempic, which are non-insulin medications used in conjunction with insulins to treat type 2 diabetes. While these drugs are clinically different than insulins, the relevant facts in this Complaint regarding Defendants' fraudulent pricing scheme apply equally to Trulicity, Victoza and Ozempic. For the purposes of this Complaint, the Insulin Pricing Scheme includes the non-insulin drugs Trulicity, Victoza and Ozempic.

13. Given their market power and role in formulary and plan design, PBM Defendants wield enormous control over drug purchasing behavior.

14. PBM Defendants represent both publicly and to their clients that they use their market power to drive down prices for diabetes medications by forcing manufacturers to compete on price for formulary placement.

15. This representation is patently false. Instead, PBM Defendants exploit their market power to cause substantial increases in the price of diabetes medications in order to create massive profits for themselves and Manufacturer Defendants—entirely at the cost of consumers and employers, such as Harris County, who provide employee health benefits.

16. To gain formulary access, Manufacturer Defendants artificially and willingly raise their reported prices, and then secretly refund a significant portion of that price back to PBM Defendants. These refunds are provided under a variety of labels—rebates, discounts, credits, concession fees, etc.[11] But, however they are described, they are a *quid pro quo* for formulary inclusion.

17. PBMs then grant formulary status based upon the highest inflated price and the largest refund amount.

18. This Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. Manufacturer Defendants are able to make these secret payments to buy preferred formulary position—which significantly increases their revenue—without

[11] In the context of this Complaint, "refunds" are defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants, either directly via contract or indirectly via Manufacturer-controlled intermediaries. By way of example, "refunds" includes rebates, administrative fees, volume discounts, price or margin guarantees and any other form of consideration exchanged.

sacrificing their profit margins. PBM Defendants profit from the inflated reported price by: (1) retaining a significant percentage of Manufacturers' payments; (2) pocketing an additional pricing spread between what a health plan pays the PBM for an insulin script based on this inflated price and a lower price that the PBM reimburses the pharmacy for the same drug ("Pharmacy Spread"); and (3) diverting sales to their profitable mail order pharmacies.

19. The Insulin Pricing Scheme has resulted in record profits for Defendants at the expense of Plaintiff Harris County.

20. Harris County now spends more money on diabetes medications than for medications related to any other disease.

21. In 2015 alone, the amount that Harris County spent on diabetes medications increased over 60% from the previous year.

22. Since 2013, Harris County has spent more than $27 million on the at issue diabetes medications.[12]

23. A substantial portion of this $27 million is attributable to Defendants' inflated prices that did not arise from transparent market forces, but rather from the secret dealings between Manufacturer and PBM Defendants—the Insulin Pricing Scheme described herein.

24. This action alleges that Defendants violated the Texas Free Enterprise and Anti-Trust Act and various Texas common laws by engaging in the Insulin Pricing

[12] *See* Appendix A attached hereto for a chart detailing Harris County's spends on the at issue drugs from 2013-2018. To note, 2013-2018 is only a subset of the damages period alleged in this Complaint.

Scheme. This scheme directly and foreseeably caused and continues to cause harm to Harris County, as well as harm to competition in the insulin market.

25. This action seeks damages, damage multipliers and injunctive relief to address and abate the harm caused by the Insulin Pricing Scheme.

II. DISCOVERY CONTROL LEVEL

26. Discovery in this suit is intended to be conducted under Level 3, in accordance with TEX. R. CIV. P. 190.4.

III. PARTIES

A. Plaintiff

27. **Plaintiff, Harris County**, is a body corporate and politic under the laws of the State of Texas.

28. The Harris County government serves its almost 5 million residents by providing vital services throughout the County. As a large government employer, Harris County provides health benefits to approximately 38,000 employees, retirees and their dependents ("Beneficiaries"). One of the benefits that Harris County offers its Beneficiaries is subsidizing their purchases of the pharmaceutical drugs, including diabetes medications, they need to survive. Harris County also purchases diabetes medications to administer directly to inmates in Harris County jails.

29. As detailed in Appendix A, Harris County spends millions of dollars every year on the at issue drugs.

30. Any increase in spending can have a detrimental effect on Harris County's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

31. The Insulin Pricing Scheme has had such an effect.

B. Manufacturer Defendants

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

33. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

34. In Texas and nationally, Eli Lilly manufactures, promotes and distributes several diabetes medications paid for by Plaintiff and at issue in this case: Humulin N, Humilin R, Humalog, Trulicity and Basaglar.

35. Eli Lilly's revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.[13]

36. Eli Lilly's Revenues in 2017 were $2.03 billion from Trulicity, $2.85 billion from Humalog, $1.33 billion from Humulin and $432 million from Basaglar.[14]

37. Eli Lilly transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

38. Eli Lilly employs sales representatives throughout Texas, including in Harris County, to promote and sell Humulin N, Humilin R, Humalog, Trulicity and Basaglar. For example, Eli Lilly recently advertised online that it was seeking sales representatives in its diabetes primary care division to service Houston, Texas and the surrounding communities.[15]

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[13] Eli Lilly, Annual Report (Form 10-K) (Dec. 31, 2018).
[14] *Id.*
[15] *See* https://careers.lilly.com/business/custom_fields.multipleregion/north%20america/410/5

39. Eli Lilly also directs advertising and informational materials to Harris County physicians and potential users of Eli Lilly's products.

40. At all times relevant hereto, Eli Lilly published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

41. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over $11.9 million on Eli Lilly's at issue drugs.

42. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

43. Sanofi may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

44. Sanofi manufactures, promotes and distributes pharmaceutical drugs both in Texas and nationally, including insulins and diabetes medications paid for by Plaintiff and at issue in this case: Lantus, Toujeo, Soliqua and Apidra.

45. Sanofi's revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $79 million for Soliqua.[16]

46. Sanofi's revenues in the U.S. in 2018 were $5.08 billion from Lantus and $896 million from Toujeo, $414 million from Apidra and $28.5 million from Soliqua.[17]

47. Sanofi transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

[16] Sanofi, Annual Report (Form 20-F) (Dec. 31, 2018).
[17] *Id.*

48. Sanofi employs sales representatives throughout Texas, including in Harris County, to promote and sell Lantus, Toujeo, Soliqua and Apidra. For example, Sanofi recently advertised online that it was seeking Diabetes Specialty Sales Representatives in Texas.[18]

49. Sanofi also directs advertising and informational materials to Texas physicians and potential users of Sanofi's products.

50. At all times relevant hereto, Sanofi published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

51. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over $6.6 million on Sanofi's at issue drugs.

52. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation. Its headquarters are at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

53. Novo Nordisk may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

54. Novo Nordisk manufactures, promotes and distributes pharmaceutical drugs both in Texas and nationally, including insulins and diabetic medications paid for by Plaintiff and at issue in this case: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic.

[18] *See* https://jobs.sanofi.us/search-jobs/texas/Texas%2C%20US/507-18104/1/3/6252001-4736286/31x25044/-99x25061/50/2

55. Novo Nordisk's revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba and $3.61 billion from Victoza.[19]

56. Nordisk's U.S. revenues in 2017 were $1.65 billion from Novolog, $1.05 billion from Levemir, $781.4 million from Tresiba and $2.68 billion from Victoza.[20]

57. Novo Nordisk transacts business in Texas, targeting the Harris County market for its products, including the diabetes medications at issue in this lawsuit.

58. Novo Nordisk employs sales representatives throughout Texas, including in Harris County, to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic. For example, Novo Nordisk recently advertised online that it was seeking Pharma Field Sales—Diabetes Care Specialists in Texas.[21]

59. Novo Nordisk also directs advertising and informational materials to Texas physicians and potential users of Novo Nordisk's products.

60. At all times relevant hereto, Novo Nordisk published its reported prices of its diabetes medications at issue in this lawsuit throughout the United States and Texas, including in Harris County.

61. Between 2013-2018 alone (a subset of the total damages period at issue), Harris County spent over $8.9 million on Novo Nordisk's at issue drugs.

62. Collectively, Defendants Eli Lilly, Novo Nordisk and Sanofi are referred to as "Manufacturer Defendants."

[19] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2018).
[20] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2017).
[21] *See* https://www.novonordisk-jobs.com/search/?createNewAlert=false&q=&locationsearch=texas.

C. PBM Defendants

63. **Defendant CVS Health Corporation** ("CVS Health") is a corporation organized under the laws of Delaware and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Texas.

64. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

65. **Defendant Caremark Rx, L.L.C.** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail order subsidiaries. Caremark Rx, L.L.C. is a subsidiary of Defendant CVS Health and its principal place of business is at the same location as CVS Health.

66. Caremark Rx, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

67. **Defendant Caremark L.L.C.** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, L.L.C. is a subsidiary of CVS Health. Caremark, L.L.C. is also the direct or indirect parent of dozens of limited liability companies all over the U.S. that provide mail-order pharmacy services in the U.S. and in Texas.

68. Caremark L.L.C. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

69. **Defendant CaremarkPCS Health, L.L.C.** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

70. CaremarkPCS Health LLC, doing business as CVS Caremark, provides pharmacy benefit management services and has been registered to do business in Texas since at least 2009.

71. CaremarkPCS Health, L.L.C. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

72. **Defendant Caremark Texas Mail Pharmacy, LLC**, doing business as CVS Caremark, is a Texas limited liability company whose principal place of business is at the same location as CVS Health.

73. Caremark Texas Mail Pharmacy, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

74. Caremark Texas Mail Pharmacy, LLC is licensed with the Texas Board of Pharmacy and is registered with the Drug Enforcement Administration ("DEA") to dispense controlled substances, including diabetes medications.

75. Collectively, Defendants CVS Health Corporation, Caremark Rx, L.L.C., Caremark, L.L.C., CaremarkPCS Health, L.L.C and Caremark Texas Mail Pharmacy, LLC are referred to as "CVS Caremark."

76. CVS Caremark is named as a defendant in its capacities as a PBM and mail order pharmacy.

77. In its capacity as a PBM, CVS Caremark negotiates on behalf of health plans and insurers with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of diabetes

medications, as well as for the placement of these firms' diabetes medications on CVS Caremark's drug formularies.

78. CVS Caremark filled or managed approximately 1.9 billion prescriptions during the year ending December 31, 2018.[22]

79. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing 36% of the market.[23] CVS Caremark's pharmacy services segment, which includes PBM activities, but not its retail/long-term care segment, generated $120 billion in total revenues last year.[24]

80. CVS Caremark describes its PBM business as follows:

> [CVS Caremark's] formularies provide recommended products in numerous drug classes to help ensure member access to clinically appropriate drugs with alternatives within a class under the client's pharmacy benefit plan, **while helping to drive the lowest net cost for clients** that select one of [CVS Caremark's] formularies.[25]

81. At all times relevant hereto, CVS Caremark derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

82. At all times relevant hereto, CVS Caremark derived substantial revenue providing mail order pharmacy services in Texas, including in Harris County.

83. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and Harris County. At all times relevant

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[22] CVS Caremark Annual Report (Form 10-K) (Dec. 31, 2018).
[23] National Community Pharmacists Association, PBM Resources, http://www.ncpanet.org/advocacy/thetools/pbm-resources.
[24] Ed Kaplan & Wendy Pongracz, *Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans*, Strafford (June 21, 2016), http://media.straffordpub.com/products/negotiating-and-drafting-pharmacy-benefit-manager-contracts-for-self-funded-plans-2016-06-21/presentation.pdf.
[25] CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2018).

hereto, those formularies included diabetes medications, including those at issue in this case.

84. At all times relevant hereto, CVS Caremark dispensed diabetes medications, including diabetes medications at issue in this case, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

85. **Defendant Express Scripts Holding Company** is a Delaware corporation. Its principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

86. Express Scripts Holding Company may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

87. **Defendant Express Scripts, Inc.** is a corporation organized under the laws of Delaware and headquartered at 1 Express Way, St. Louis, Missouri 63121.

88. **Express Scripts, Inc.** may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

89. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation with its principal place of business in St. Louis, Missouri.

90. Defendant ESI Mail Pharmacy Service, Inc. may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

91. ESI Mail Pharmacy Services, Inc. is licensed as an out-of-state prescription drug distributor with the Texas Department of State Health Services.

92. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation with its principal place of business in St. Louis, Missouri.

93. Defendant Express Scripts Pharmacy, Inc. may be served through its registered agent: Corporation Service Company DBS CSC – Lawyers Incorporating Service Company, 211 East 7th Street, Suite 620, Austin, Texas 78701.

94. Defendants Express Scripts, Inc., ESI Mail Pharmacy Service, Inc. and Express Scripts Pharmacy, Inc. are subsidiaries of Defendant Express Scripts Holdings Company.

95. Collectively, Defendant Express Scripts, Inc., Defendant Express Scripts Holding Company, Defendant ESI Mail Pharmacy Service, Inc. and Defendant Express Scripts Pharmacy, Inc. are referred to as "Express Scripts."

96. Express Scripts is named as a defendant in its capacities as a PBM and mail order pharmacy.

97. In its capacity as a PBM, Express Scripts negotiates on behalf of health plans and insurers with Novo Nordisk, Eli Lilly and Sanofi regarding the purchase price of diabetes medications, as well as for the placement of these firms' diabetes medications on the PBM's drug formularies.

98. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States.[26] During the relevant period of this complaint, Express Scripts controlled 30% of the PBM market.[27]

99. In 2017, annual revenue for Express Scripts was over $100 billion.[28]

[26] Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017).
[27] *See supra* note 23.
[28] *See supra* note 26.

100. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.[29]

101. Express Scripts transacts business throughout the United States and Texas, including in Harris County.

102. Express Scripts describes its PBM business as follows:

> Our core PBM services involve management of prescription drug utilization to drive **high quality, cost-effective pharmaceutical care**. We consult with clients to assist in the selection of plan design features that balance clients' requirements for **cost control** with member choice and convenience. We focus our solutions to enable better decisions in four important and interrelated areas: benefit choices, drug choices, pharmacy choices and health choices. As a result, we believe we deliver healthier outcomes, higher member satisfaction and a **more affordable prescription drug benefit**.[30]

103. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

104. At all times relevant hereto, Express Scripts derived substantial revenue providing mail order pharmacy services in Texas, including in Harris County.

105. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this case.

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[29] *Id.*
[30] *Id.*

106. At all times relevant hereto, Express Scripts dispensed diabetes medications, including diabetes medications at issue in this case, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

107. **Defendant OptumRx, Inc.** is a corporation organized under the laws of California and headquartered at 2300 Main St., Irvine, California, 92614.

108. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

109. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc.

110. Optum Rx has been registered to do business in Texas since at least 2010.

111. OptumRx has several mail-order locations licensed with the Texas Board of Pharmacy and registered with the DEA to dispense controlled substances, including diabetes medications.

112. **Defendant Optum, Inc.**, is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including OptumRx, Inc.

113. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

114. Collectively, Defendants OptumRx, Inc. and Optum, Inc. are referred to as "OptumRx."

115. OptumRx is named as a defendant in its capacities as a PBM and mail order pharmacy.

116. OptumRx is a pharmacy benefit manager and, as such, negotiates on behalf of health plans and insurers with Novo Nordisk, Eli Lilly, and Sanofi for the purchase price of the diabetes medications, as well as for the placement of the firms' diabetes medications on the PBM's drug formularies.

117. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[31]

118. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the market.[32] OptumRx's 2018 revenue was $69 billion.[33]

119. OptumRx describes its PBM business as follows:

> OptumRx is a pharmacy care services company helping clients and more than 66 million members achieve better health outcomes and **lower overall costs through innovative prescription drug benefits management services**, including network claims processing, clinical programs, formulary management and specialty pharmacy care.[34]

120. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Texas, including in Harris County.

121. At all times relevant hereto, OptumRx derived substantial revenue through its mail order pharmacies in Texas, including in Harris County.

122. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies

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[31] United Healthcare/OptumRx Annual Report (Form 10-K) (Dec. 31, 2018).
[32] *See supra* note 23.
[33] *Id.*
[34] UnitedHealth Group, OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients (Aug. 22, 2017), https://www.unitedhealthgroup.com/newsroom/2017/0822opioidriskmanagement programhtml.

that are used nationwide, including in Texas and Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this case.

123. At all times relevant hereto, OptumRx dispensed diabetes medications, including diabetes medications at issue in this case, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

124. **Aetna Rx Home Delivery, LLC** was formed under the laws of Delaware with its principal place of business located in Hartford, CT.

125. Aetna Rx Home Delivery, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

126. **Aetna Pharmacy Management Services, LLC** was formed under the laws of Delaware, with its principal place of business located in Hartford, CT. Aetna Pharmacy Management Services, LLC is a wholly owned subsidiary of CVS Health.

127. Aetna Pharmacy Management Services, LLC may be served through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

128. Collectively, Aetna Rx Home Delivery, LLC and Aetna Pharmacy Management Services, LLC are referred to as "Aetna Rx."

129. Aetna Rx is named as a defendant in its capacities as a PBM and mail order pharmacy.

130. In its capacity as a PBM, Aetna Rx negotiates on behalf of health plans and insurers with Novo Nordisk, Eli Lilly, and Sanofi for the purchase price of the diabetes medications, as well as for the placement of the firms' diabetes medications on Aetna Rx's drug formularies.

131. At all times relevant hereto, Aetna Rx derived substantial revenue providing pharmacy benefit services in Texas to health plans, including in Harris County.

132. At all times relevant hereto, Aetna Rx derived substantial revenue through its mail order pharmacies in Texas, including in Harris County.

133. At all times relevant hereto, Aetna Rx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas and in Harris County. At all times relevant hereto, those formularies included diabetes medications, including those at issue in this case.

134. At all times relevant hereto, Aetna Rx dispensed diabetes medications, including diabetes medications at issue in this case, nationwide and in Texas, including in Harris County, through its mail order pharmacies.

135. Collectively, CVS Caremark, Optum Rx, Express Scripts and Aetna Rx are referred to as "PBM Defendants."

IV. JURISDICTION AND VENUE

136. This Court has jurisdiction over the subject matter of the case because the amount in controversy exceeds this Court's minimum jurisdictional requirements. Pursuant to TEX. R. OF CIV. P. 47(C), Plaintiffs seek monetary relief over $1,000,000.

137. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, reported false prices and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout Texas, including in Harris County. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons and local

governments residing in, located in, or doing business throughout Texas, including in Harris County.

138. Venue is proper in Harris County, Texas pursuant to Section 15.002(a)(1) and 15.005 of the TEX. CIV. PRAC. & REM. CODE because a substantial part of the events giving rise to the claims occurred in Harris County, Texas. Venue is also proper in Harris County, Texas, pursuant to Section 15.21(a)(1) of the TEX. BUS. & COM. CODE because Plaintiff was a resident of Harris County at all times relevant to the claims asserted herein. In the alternative, venue is proper pursuant to Section 15.002(a)(4) of the TEX. CIV. PRAC. & REM. CODE because Plaintiff resides in Harris County, Texas.

V. FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

Diabetes: A Growing Epidemic

139. Diabetes is a disease that occurs when a person's blood glucose, also called blood sugar, is too high. In a non-diabetic person, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to glucose, or sugar, in the blood. When there is not enough insulin or cells stop responding to insulin, too much blood sugar stays in the bloodstream. Over time, that can cause serious health problems, such as heart disease, vision loss, and kidney disease.[35]

140. There are two basic types of diabetes. Roughly 90-95% of diabetics developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce.[36] Known as Type 2, this more common

[35] Centers for Disease Control and Prevention, *Diabetes?*, https://www.cdc.gov/media/presskits/aahd/diabetes.pdf.
[36] *Id.*

form of diabetes is often developed later in life. While Type 2 patients can initially be treated with tablets, in the long term most patients have to switch to insulin injections.[37]

141. Type 1 diabetes occurs when a patient completely ceases insulin production.[38] In contrast to Type 2 patients, people with Type 1 diabetes do not produce any insulin and, without regular injections of insulin, they will die.

142. Interruptions to a diabetic's insulin regimen can have severe consequences.[39] Missed or inadequate insulin therapy can trigger hyperglycemia and then diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days.

143. Diabetes is the leading cause of blindness, kidney failure and lower limb amputations and is the seventh leading cause of death in the United States despite the availability of effective treatment.[40]

144. The financial burden caused by diabetes is staggering. In 2017, the total direct and indirect cost is estimated to be $327 billion, of which $237 billion represents direct costs and $90 billion results from work-related absenteeism and reduced productivity.[41] Excess costs associated with diabetic medications constitute 43% of the total direct burden, including nearly $15 billion for insulin.[42]

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[37] *Id.*
[38] National Institute of Health, *What is Diabetes* (Nov. 2016), https://www.niddk.nih.gov/health- information/diabetes/overview/what-is-diabetes.
[39] Centers for Disease Control and Prevention, *Diabetes?*, https://www.cdc.gov/media/presskits/aahd/diabetes.pdf.
[40] *Id.*
[41] Am. Diabetes Assoc., *Economic Costs of Diabetes in the U.S. in 2017*, March 22, 2018, available at https://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf.
[42] *Id.*

145. The number of Americans with diabetes has exploded in the last half century.[43] In 1958, only 1.6 million people in the United States had diabetes.[44] By the turn of the century, that number had grown to over 10 million.[45] Fourteen (14) years later, the count tripled again. Now over 30 million people—9.4% of the country—live with the disease.[46]

Insulin: A Century Old Drug

146. Despite its potentially deadly impact, diabetes is a highly treatable illness. For patients who are able to follow a prescribed treatment plan consistently, the health complications associated with the disease are avoidable.

147. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

148. In 1922, Frederick Banting and Charles Best pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes.[47] After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 each (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[48]

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[43] Center for Disease Control and Prevention, National Diabetes Statistics Report, 2017, available at https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] Valencia Higuera, *Everything You Need to Know About Insulin*, Healthline (Dec. 7, 2016), http://www.healthline.com/health/type-2-diabetes/insulin.
[48] M. Bliss, The Discovery of Insulin (2013).

149. After purchasing the patent, the University of Toronto contracted with Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

150. Although early iterations of insulin were immediately perceived as lifesaving,[49] there have been numerous incremental improvements since its discovery. The earliest insulin was derived from animals and, until the 1980s, was the only treatment for diabetes.[50]

151. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly.[51] Eli Lilly marketed this insulin as Humulin.

152. Over a decade later, Eli Lilly released the first analog insulin.

153. Analog insulin refers to laboratory grown and genetically altered insulin. Analogs are slight variations on human insulin to make the injected treatment act more like the insulin naturally produced and regulated by the body.

154. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

155. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, with similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

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[49] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172 (2015).
[50] Irl B. Hirsch, MD, *Changing Cost of Insulin Therapy in the U.S.* (Mar. 6, 2016), http://professional.diabetes.org/files/media/Changing_Cost_Insulin.pdf.
[51] *History of Insulin*, Diabetes.co.uk (2007), http://www.diabetes.co.uk/insulin/history-of-insulin.html.

156. Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

157. In 2015, Sanofi introduced Toujeo, another long-acting insulin also similar to Lantus, however Toujeo is highly concentrated, making injection volume smaller than Lantus.

158. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin that is biologically similar to Sanofi's Lantus.

159. Even though insulin was first extracted nearly 100 years ago, only Defendants Eli Lilly, Novo Nordisk and Sanofi hold the patents in the United States to manufacture insulin.[52]

160. Manufacturer Defendants make 99% of the insulins in the market today.[53]

Current Insulin Landscape

161. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions whether the overall efficacy of the drugs have significantly improved over the last twenty years.

162. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes.[54]

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[52] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. ENG. J. MED. 1171, 1172–73 (2015).
[53] D. Beran et al, A perspective on global access to insulin: a descriptive study of the market, trade flows and prices, DIABETIC MED. 726, 726 (2019).
[54] *Id.*; *see also* Riddle MC, Rosenstock J, Gerich J, Insulin Glargine 4002 Study Investigators. The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care 2003.

163. A recent study published in the Journal of American Medical Association suggests that older human insulins may work just as well as newer analog insulins for patients with Type 2 diabetes.[55]

164. When discussing the latest iterations of insulins, Harvard Medical School professor David Nathan recently stated:

> I don't think it takes a cynic such as myself to see most of these [insulins] are being developed to preserve patent protection. The truth is they are marginally different, and the clinical benefits of them over the older drugs have been zero.[56]

165. Moreover, all of the insulins at issue in this case have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins that were available then.

166. In addition, in the last ten years, the production costs of insulin have decreased as manufacturers simplified and optimized processes. A September 2018 study published in BMJ Global Health calculated that based on production costs, a reasonable price for a year's supply of human insulin is $48 to $71 per person and between $78 and $133 for analog insulins—which includes delivering a profit to manufacturers.[57] These figures stand in stark contrast to the $5,705 that a diabetic spent, on average, for insulin in 2016.[58]

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[55] Jing Luo, MD, Nazleen F. Khan, MS, Thomas Manetti, MPH, *Implementation of a Health Plan Program for Switching from Analogue to Human Insulin and Glycemic Control Among Medicare Beneficiaries with Type 2 Diabetes*, AMA. 2019;321(4):374-384, January 29, 2019.
[56] *See* Johnson, *supra* note 5.
[57] Dzintars Gotham, Melissa J. Barber, Andrew Hill, *Production Costs And Potential Prices For Biosimilars Of Human Insulin And Insulin Analogues*, BMJ Global Health, Vol. 3, Issue 5, available at https://gh.bmj.com/content/3/5/e000850.
[58] *See* Robin Respaut, *U.S. Insulin Costs Per Patient Nearly Doubled From 2012 to 2016: Study*, Reuters Health News, January 22, 2019, available at https://www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-

167. Further, while research and development costs often make up a large percentage of the price of a drug, in the case of insulin the initial basic research—original drug discovery and patient trials—was performed 100 years ago.

168. Even the more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred decades ago.[59]

169. Despite this decrease in production costs and no new research and development, the reported price of insulins has risen astronomically over the last fifteen (15) years.

Insulin Adjuncts: Type 2 Medications

170. Over the past decade, Manufacturer Defendants have also released a number of non-insulin medications that help control the level of insulin in the bloodstream of Type 2 diabetics.

171. In 2010, Novo Nordisk released Victoza as an adjunct to insulin to improve glycemic control. In 2014, Eli Lilly released a similar drug, Trulicity, and in 2017, Novo Nordisk did the same with Ozempic.

172. Victoza, Trulicity and Ozempic are all medications known as glucagon-like peptide-1 receptor agonists ("GLP-1") and are similar to the GLP-1 hormone that is already produced in the body. Each of these drugs can be used in conjunction with insulins to control diabetes.

idUSKCN1PG136#:~:targetText=A%20person%20with%20type%201,Care%20Cost%20Institute%20(HCCI).

[59] *See* Greene, *supra* note 44.

173. Today, Manufacturer Defendants have a dominant position in the market for all diabetes medications. The following is a list of diabetes medications at issue in this lawsuit:

Table 1: Diabetes medications at issue in this case					
Insulin Type	***Action***	***Name***	***Company***	***FDA Approval***	***Current Reported Price***
Human	**Rapid-Acting**	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1,784 (vial) $689 (pen)
		Novolin R	Novo Nordisk	1991	$172 (vial)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial) $566 (pen)
		Humulin 70/30	Eli Lilly	1989	$178 (vial) $566 (pen)
		Novolin N	Novo Nordisk	1991	$172 (vial)
Analog	**Rapid-Acting**	Humalog	Eli Lilly	1996	$350 (vial) $636 (pen)
		Novolog	Novo Nordisk	2000	$347 (vial) $671 (pen)
		Apidra	Sanofi	2004	$341 (vial) $658 (pen)
	Long-Acting	Lantus	Sanofi	2000	$ 340 (vial) $510 (pen)
		Levemir	Novo Nordisk	2005	$ 370 (vial) $ 555 (pen)
		Basaglar (Kwikpen)	Eli Lilly	2016	$392 (pen)
		Toujeo (Solostar)	Sanofi	2015	$466 (pen) $622 (max pen)
		Tresiba (FlexTouch)	Novo Nordisk	2016	$610 (pen – 100u) $732 (pen – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$911.28 (pen)

		Victoza	Novo Nordisk	2010	$737 (2 pens) $1,106 (3 pens)
		Ozempic	Novo Nordisk	2017	$927 (pen)
		Soliqua	Sanfoi	2016	$848 (pen)

B. The Dramatic Rise in the Price of Diabetes Medications

174. The Medicare Modernization Act in 2003 installed PBMs as intermediaries to the newly expanded Medicare drug benefit program and, consequently, helped set off PBMs' rise to power (which will be discussed in greater detail in the next section).

175. That same year, the price of insulin began its dramatic rise to its current exorbitant prices.

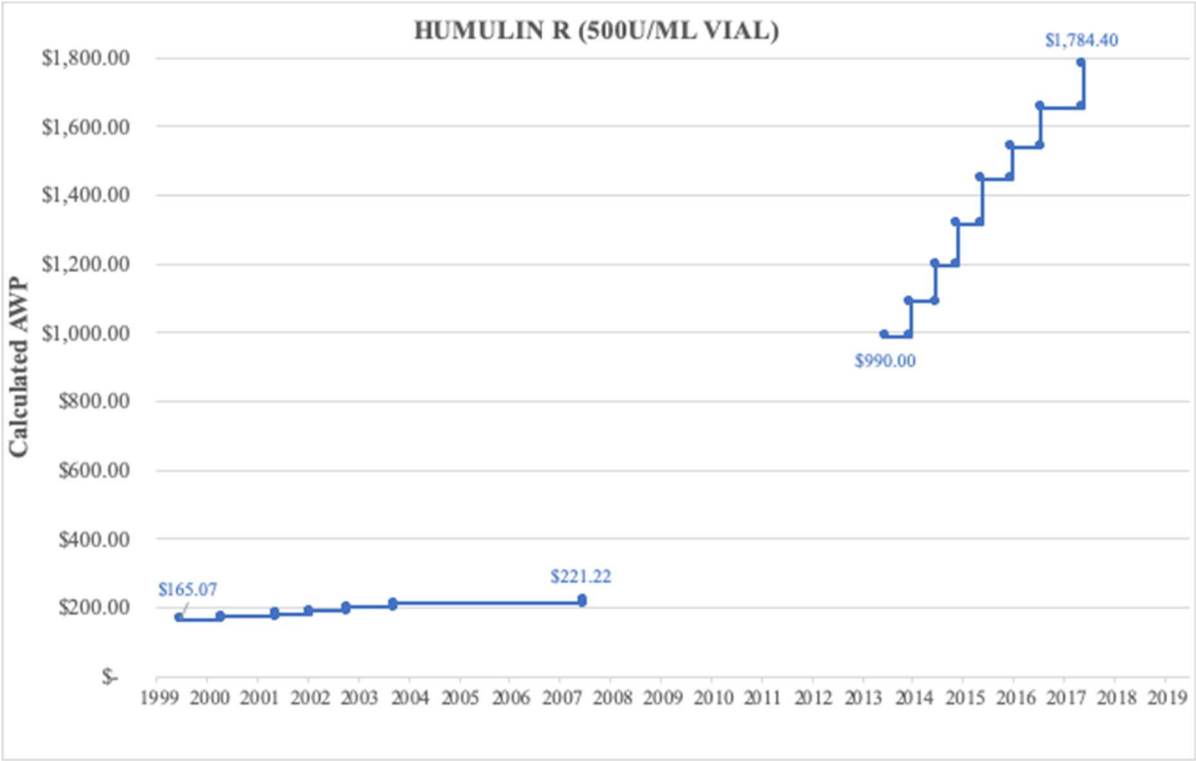
176. Since 2003, the reported price of certain insulins has increased in some cases by more than 1000%; an astounding increase especially when compared to a general inflation rate of 8.3% and a medical inflation rate of 46% in this time period.[60]

177. By 2016, the average price per month of the four most popular types of insulin rose to $450 — and costs continue to rise, so much so that as many as one in four people with diabetes are now skimping on or skipping lifesaving doses.[61]

178. Since 1999, Defendant Eli Lilly has raised the price of a vial of Humulin R (500U/ML) from $165 to $1784 (See Figure 2).

[60] *See* Hirsch, *supra* note 6.
[61] https://www.nytimes.com/2019/04/03/health/drug-prices-insulin-express-scripts.html.

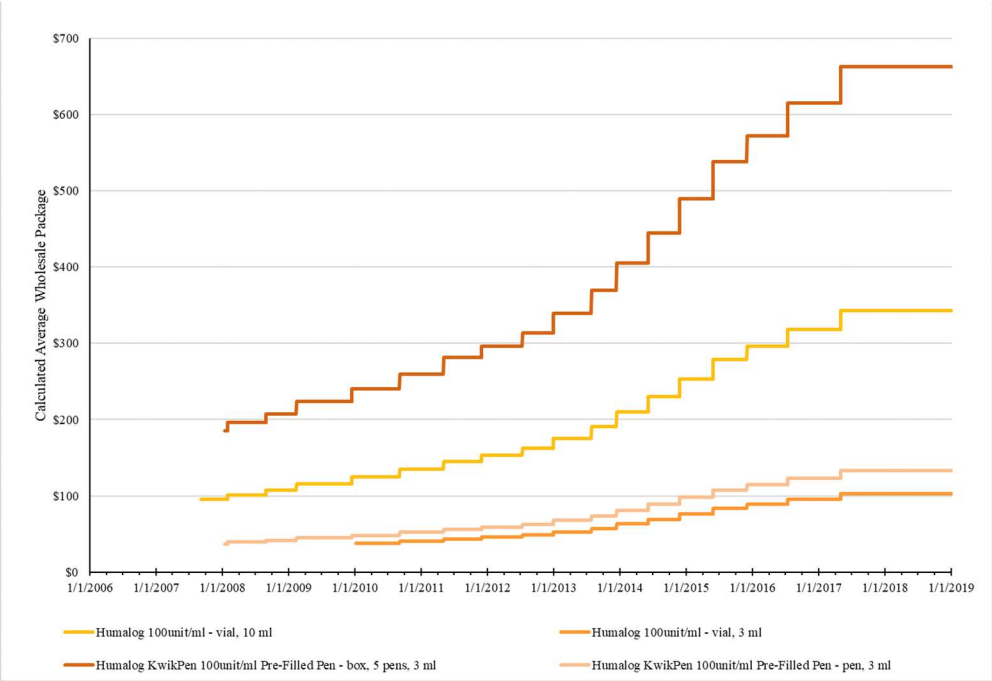
Figure 2: Rising reported prices of Humulin R (500U/ML) from 1999-2019[62]



179. Since 2008, Defendant Eli Lilly has raised the reported price for a package of pens of Humalog from less than $200 to $663 and from less than $100 for a box of cartridges to $343 (See Figure 3).

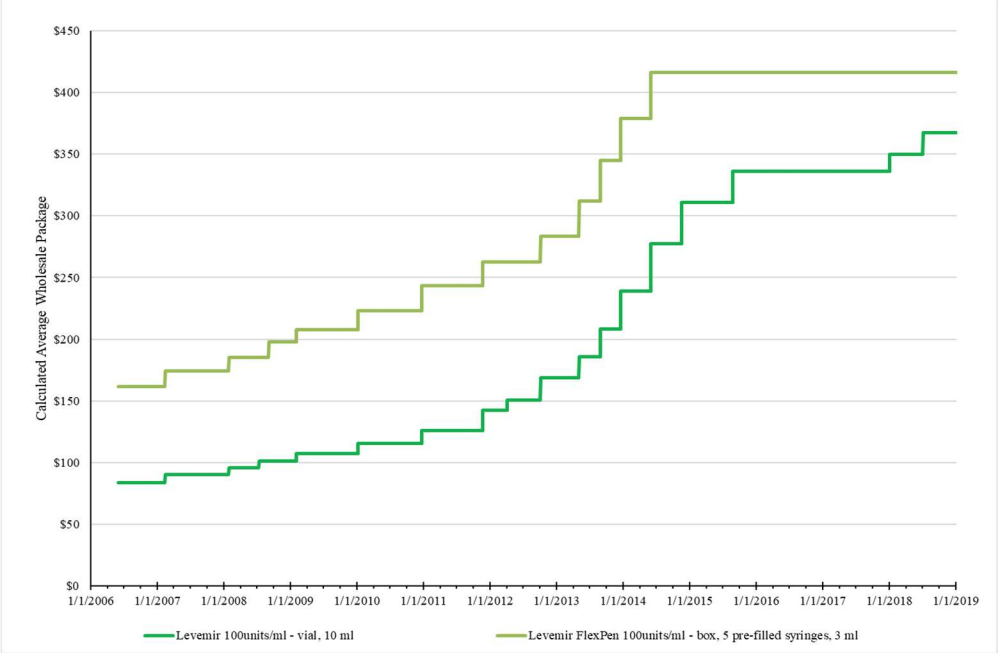
[62] Eli Lilly did not report the price of Humulin R to all publishing compendiums from 2008-2014.

Figure 3: Rising reported prices of Humalog vials and pens from 2008-2019



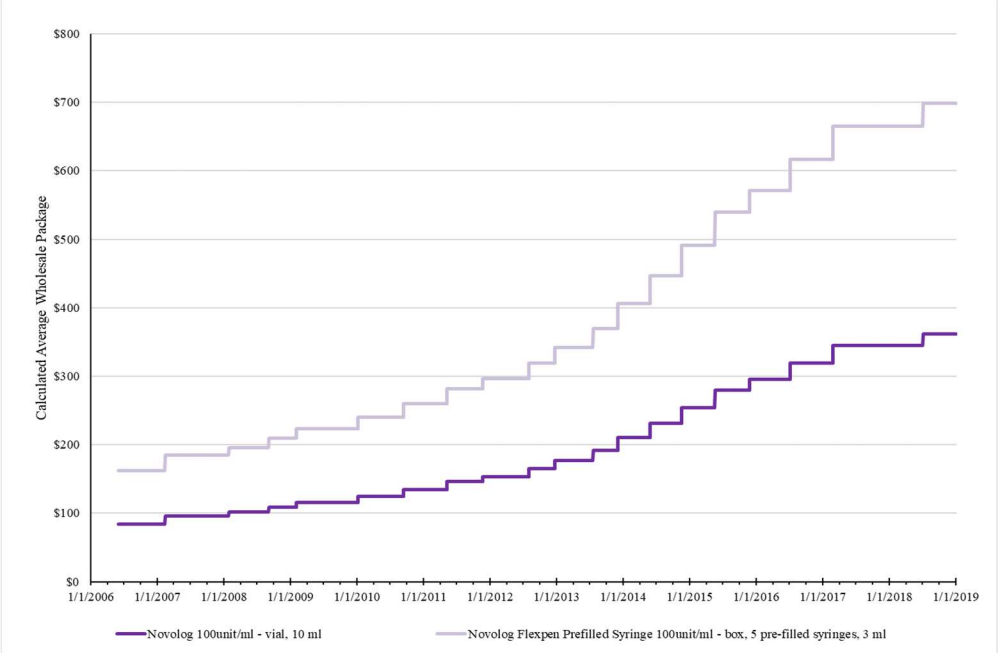
180. Novo Nordisk has also increased its prices—from 2007 to 2018 Levemir rose from $155 to $430 for pens and from under $100 to $367 per vial (See Figure 4).

Figure 4: Rising reported prices of Levemir 2006-2019



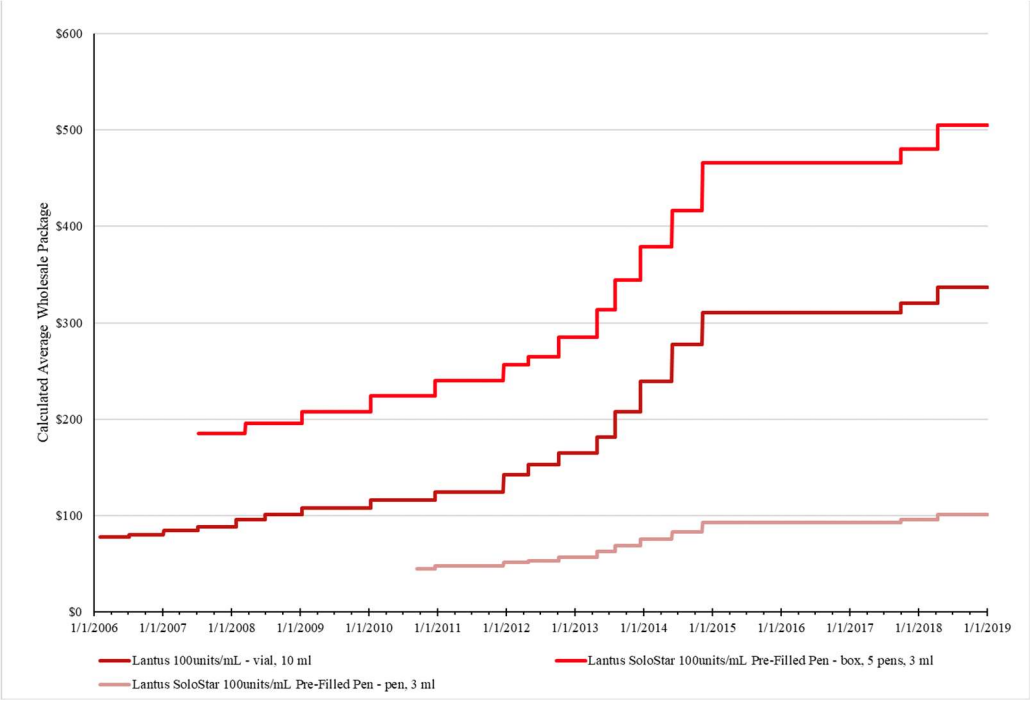
181. From 2007 to 2018, Novo Nordisk raised the price of Novolog from $160 to $698 for a package of pens and from less than $100 to $362 for a vial (See Figure 5).

Figure 5: Rising reported prices of Novolog vials and pens from 2006-2019



182. Defendant Sanofi has kept pace as well, increasing the reported prices for Lantus, the top-selling analog insulin, from less than $200 in 2006 to over $500 in 2019 for a package of pens and from less than $100 to $340 for a vial (See Figure 6).

Figure 6: Rising reported prices of Lantus vials and pens from 2006-2019



183. Manufacturer Defendants' non-insulin medications have experienced similar recent price increases. For example, since 2015 Eli Lilly has increased the price of Trulicity almost 50%.

184. Driven by these price hikes, health plan spending on diabetes medications, and insulins in particular, has skyrocketed with totals in the tens of billions of dollars. According to the Journal of the American Medical Association, more money is spent per patient on insulin than all other diabetes medications combined.[63]

Defendant Manufacturers Have Increased Prices In Lockstep

185. The timing of the price increases reveal that each Manufacturer Defendant has not only dramatically increased reported prices for diabetes treatments, they have acted in collusion by raising prices in perfect lockstep.

186. In thirteen instances since 2009, competitors Sanofi and Novo Nordisk raised the reported prices of their insulins, Lantus and Levemir, in tandem, "taking the same price increase down to the decimal point within a few days of each other."[64]

187. This practice of increasing drug prices in lockstep with competitors is known as "shadow pricing" and, as one healthcare analyst put it: "is pretty much a clear signal that your competitor does not intend to price-compete with you."[65]

188. In 2016, Novo Nordisk and Sanofi's lockstep increases were responsible for the highest reported drug price increases in the entire pharmaceutical industry.

189. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 7

[63] Johnson, *supra* note 37.
[64] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2015).
[65] *Id*.

demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 8 demonstrates this behavior with respect to Novolog and Humalog.

Figure 7: Rising reported prices of long-acting insulins

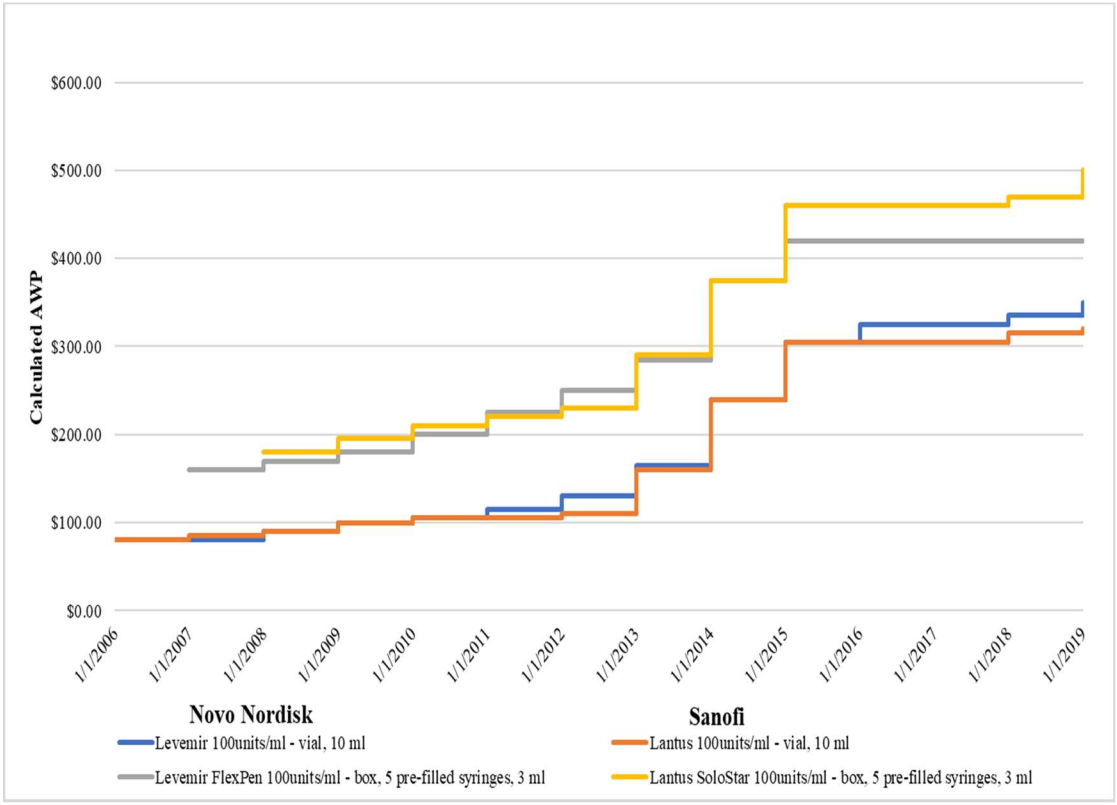
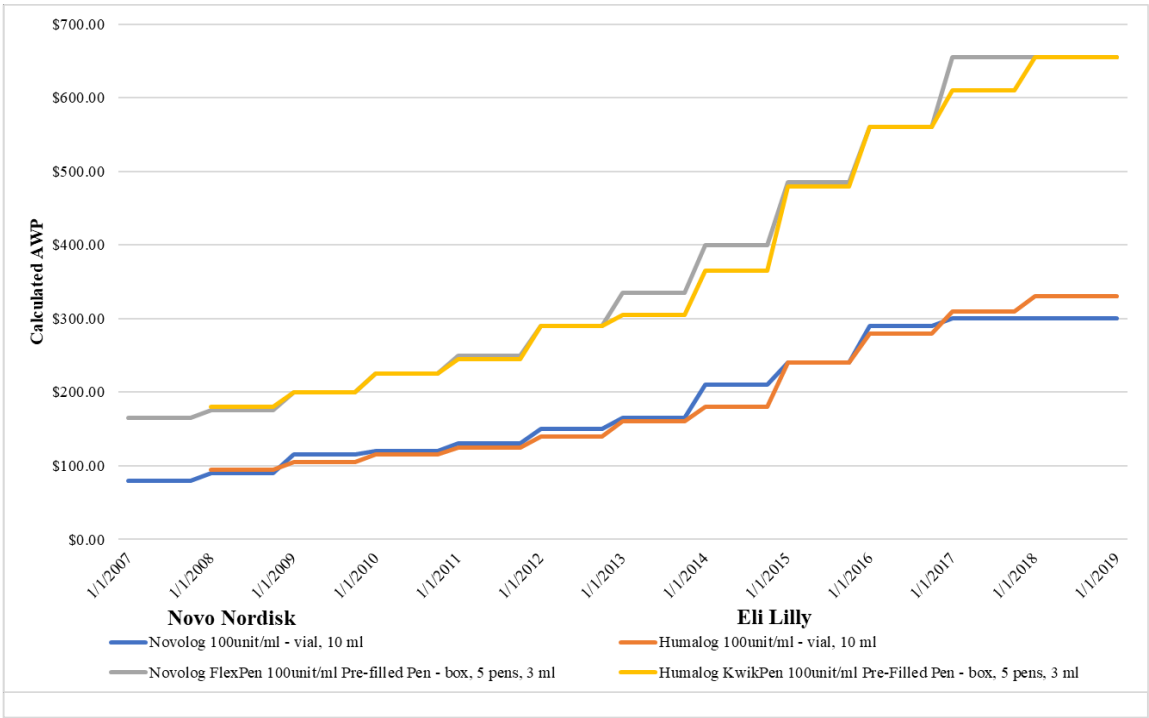
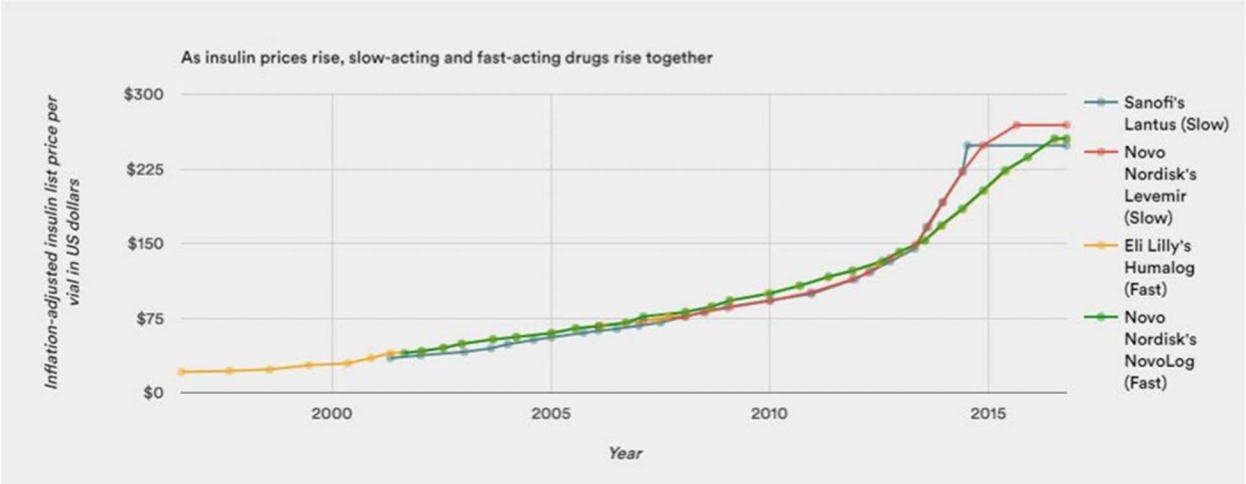


Figure 8: Rising reported prices of rapid-acting insulins



190. Figure 9 shows how, collectively, Manufacturer Defendants have exponentially raised the reported prices of insulin products in near perfect unison.

Figure 9: Rising insulin reported prices from 2000-2015



191. Because of Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin the price of diabetes medications has become unaffordable for many diabetics.

192. Governmental entities, like Harris County, who purchase diabetes medications through their health plans and to be administered directly in government-run facilities, have been burdened with paying these skyrocketing prices.

193. In most cases, health plans are paying for nearly identical drugs that were available fifteen to twenty years ago, only now they are paying up to 1000% more.

194. While the reported price for diabetes medications has increased exponentially, the net price tellingly has not.

195. The gap between these two prices—and Defendants' ability to manipulate this pricing disconnect—is a critical element to the Insulin Pricing Scheme and will be discussed in greater detail below. However, to understand the Insulin Pricing Scheme first requires an understanding of how insulin is distributed and priced in the United States.

C. PBMs and the Pharmaceutical Payment and Supply Chain

Drug Payment and Distribution Chain

196. The prescription drug industry consists of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third party payors (institutional insurers, self-insured employers), pharmacy benefit managers, and patient-consumers.

197. Generally speaking, branded prescription drugs, such as insulin, are distributed from manufacturer to wholesaler, wholesaler to retail or mail order pharmacy, and pharmacy to patient/consumer.

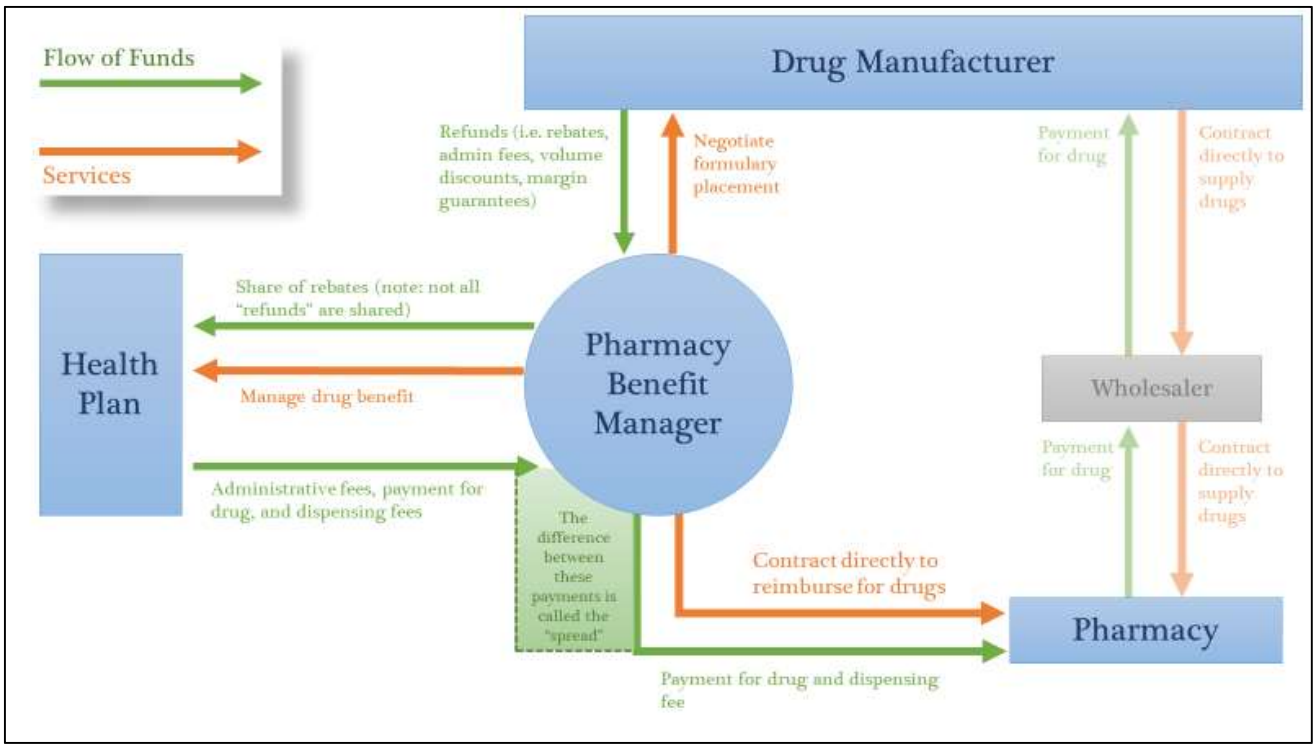
198. The price for the drugs distributed in the pharmaceutical chain are different for each participating entity: different actors pay different prices for the same drugs.

199. There is no transparency in this pricing system; typically, only a brand drug's reported price—also known as its Average Wholesale Price (AWP) or the mathematically-related (for brand drugs), Wholesale Acquisition Cost (WAC)—is available.

200. Drug manufacturers self report AWP or other prices upon which AWP is based to companies such as First DataBank, Redbook and others who then publish that price.

201. PBMs are at the center of this convoluted payment structure, as illustrated in Figure 10:

Figure 10: Insulin distribution and payment chain



202. PBMs administer a health plan's, such as Harris County's, prescription drug program. A PBM develops the health plan's drug formulary, processes claims, creates a network of retail pharmacies, and negotiates prices that the health plan will pay for prescription drugs.

203. The amount that a health plan pays for prescription drugs is directly tied to the reported price, often the AWP price less some percentage discount.

204. PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and PBMs pay the pharmacies for the drugs dispensed.

205. The amount PBMs pay pharmacies is not the same as the amount paid by the health plan. It is instead negotiated between the PBM and the pharmacy and not disclosed.

206. Many PBMs also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at issue here, and directly supply those drugs to patients by mail.

207. In addition, and of particular significance here, PBMs contract with pharmaceutical manufacturers, such as Manufacturer Defendants. PBMs negotiate rebates, fees, and other concessions with the manufacturers that are paid back to the PBM.

208. These relationships allow PBMs to exert tremendous influence over what drugs are made available to health plans, on what terms and at what price.

209. Thus, PBMs are at the center of the flow of money in the pharmaceutical supply chain—PBMs negotiate the price that health plans pay for a prescription drug; they separately negotiate a different price that pharmacies receive for that same drug; and they also negotiate the amount that manufacturers pay back to the PBM for each drug sold.

210. Yet, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the exact same drugs.

211. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

The Rise of the PBMs in the Pharmaceutical Supply Chain

212. When they first came into existence in the 1960s, PBMs merely provided administrative services to health plans by processing claims and maintaining formularies. Over time, however, they have taken on a larger and larger role in the pharmaceutical industry. Today PBMs wield significant control over the drug pricing system.

213. One of the roles PBMs took on was negotiating prices on behalf of health plans. In doing so, PBMs affirmatively represented that they were using their leverage to negotiate lower reimbursement rates with pharmacies and discounts from drug manufacturers.[66]

214. In the early 2000s, PBMs started buying pharmacies. When a PBM combines with a pharmacy, they "lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them."[67]

215. More recently, further consolidation in the industry has afforded PBMs a disproportionate amount of market power.

216. In total, twenty-four different PBM entities have merged or otherwise been absorbed into what are now the PBM Defendants.

217. In addition, each of the most powerful PBM Defendants are now owned by other significant players within the pharmaceutical chain: Express Scripts merged with Cigna in a $67 billion-dollar deal,[68] Caremark was bought by the largest pharmacy in the United States, CVS for $21 billion,[69] CVS also now owns Aetna Rx following a $69 billion-dollar deal[70] and OptumRx was acquired by the largest health insurance company in the United States, United Healthcare.[71]

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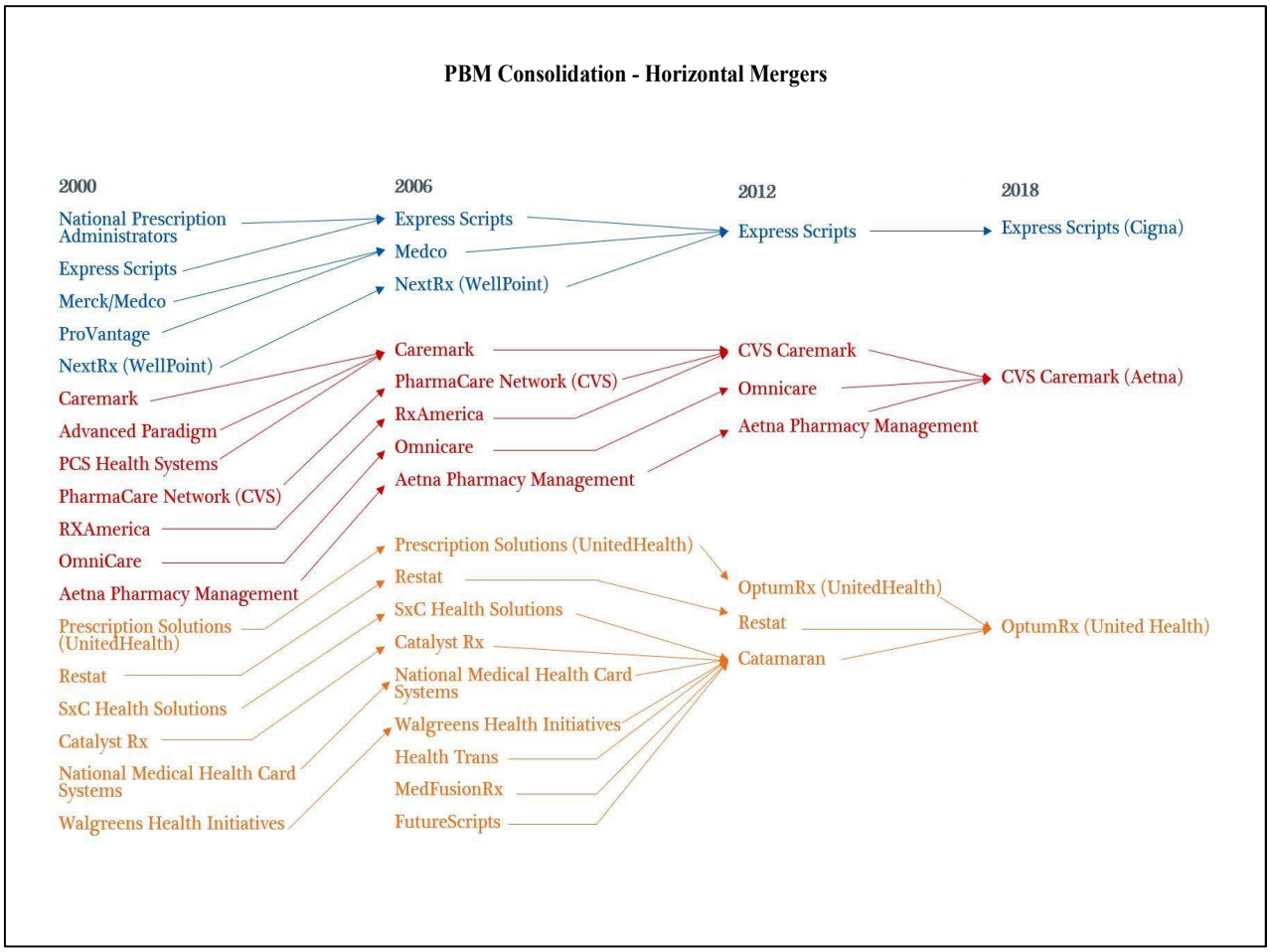
[66] Brian Feldman, *Big pharmacies are dismantling the industry that keeps US drug costs evensort-of under control* (Mar. 17, 2016), https://qz.com/636823/big-pharmacies-are-dismantlingthe-industry-that-keeps-us-drug-costs-even-sort-of-under-control/.
[67] *Id*.
[68] *See* https://www.cigna.com/about-us/newsroom/innovation/cigna-completes-combination-with-express-scripts.
[69] *See* https://www.forbes.com/2007/03/16/caremark-approves-update-markets-equity-cx_er_0316markets29.html#77fa558a3380.
[70] *See* https://cvshealth.com/aetna.
[71] *See* https://www.unitedhealthgroup.com/about/history.html.

218. Figure 11 depicts this consolidation within the PBM market.

Figure 11: PBM consolidation



219. After merging or acquiring all of their competitors and now backed by multi-billion dollar corporations, PBM Defendants have taken over the market in the past decade—controlling approximately 75% of the private market and managing pharmacy benefits for over 270 million Americans.[72]

220. Business is booming for PBM Defendants. Together, they report more than $300 billion in annual revenue.[73]

[72] Adam J. Fein, *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, February 2018.
[73] *Id.*

221. PBMs are able to leverage this market power to make outsize profits by exploiting the United States' complex pharmaceutical pricing system. Earlier this year, an industry expert described this imbalance in power, "it's really difficult to engage in any type of fair negotiations when one of the parties has that kind of monopoly power . . . I think that is something that is going to continue getting attention, especially as we see more of these payers and PBMs continue to try to further consolidate."[74]

D. The Insulin Pricing Scheme

222. Leveraging their dominant market power, PBM Defendants have teamed up with Manufacturer Defendants to create the Insulin Pricing Scheme that permits them to extract exorbitant profits from the pharmaceutical distribution chain.

223. There are three interrelated components to this scheme: (1) Manufacturer Defendants have agreed with each other and with PBM Defendants to artificially inflate the reported price for diabetes medications; (2) Manufacturer Defendants have agreed to send payments back to PBMs for each unit sold; and (3) in exchange for (1) and (2), PBMs have agreed to give Manufacturer Defendants' diabetes medications preferred placement on PBM's standard formularies resulting in increased utilization of those products.

224. While this agreement greatly benefits both PBM and Manufacturer Defendants, it has severely damaged both Harris County and consumers in the insulin market.

[74] *See* https://www.fiercehealthcare.com/payer/senate-hearing-puts-spotlight-debate-over-consolidation-pbm-market.

Artificially Inflating the Reported Price and The Secret Payment Game

225. The Insulin Pricing Scheme begins with Manufacturer Defendants purposefully inflating the reported price of their diabetes medications in order to receive favorable formulary treatment by PBM Defendants.

226. In a transparent and competitive marketplace, drug manufacturers would set the prices of their drugs at levels that account for multiple competitive factors, including: the drug's ingredient cost, relative safety and efficacy profiles, the prices of available treatment alternatives and the total cost to the manufacturer of research and development for the drug entering the marketplace.

227. Here, however, the competing products at issue are the same drugs they were when initially released. And most of the drugs at issue have been on the market for 15-20 years. The clinical benefits of these medications has not changed.

228. Dr. Kasia Lipska, a Yale researcher and author of a 2018 study in the Journal of the American Medical Association on the cost of insulin, explained:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[75]

229. Nor have the production or research and development costs increased.

230. Thus, there must be another factor motivating these price increases.

231. The real reason Manufacturer Defendants have increased their reported prices is because of the Insulin Pricing Scheme.

232. PBM Defendants control the formularies that determine whether diabetics will use Eli Lilly's, Novo Nordisk's or Sanofi's products. Drug formularies identify which

[75] Natalie Shure, *The Insulin Racket*, available at https://prospect.org/health/insulin-racket/

drugs insurance or health plans will pay for, and at what rate. Thus, preferred placement on a formulary increases a drug's utilization and the manufacturer makes more money.

233. Controlling the baseline national formularies gives PBM Defendants a crucial point of leverage over the system. Because PBM Defendants have such a dominant market share, if they chose to exclude a particular diabetes medication from these formularies, or give it a non-preferred position, it could mean billions of dollars in profit loss for Manufacturer Defendants.

234. Olivier Brandicourt, Sanofi's Chief Executive Officer, stressed the continuing importance of maintaining a favorable formulary position: "if you look at the way [CVS Caremark] is organized in the U.S., they are covering about 30 million lives as a PBM . . . I think it's actually 34 million. 15 million are part of the national formulary and that's very strict, all right. So, [if we were excluded from their formulary] we wouldn't have access to those 15 million lives."[76]

235. PBMs have the greatest leverage in negotiating with drug manufacturers for formulary placement when the manufacturers' drugs have similar efficacy and risk profiles, as is the case with the at issue diabetes medications. In such a scenario, in a competitive market, manufacturers would compete on *lower* reported prices for formulary placement.

236. The Insulin Pricing Scheme, however, does not operate in such a manner. Rather, Manufacturer Defendants have agreed with each other and PBM Defendants to raise their publicly reported prices, but largely maintain the net price by paying a significant portion of this price back to PBM Defendants.

[76] Bank Of America Merrill Lynch Global Health Conference, London, UK (Sept. 16, 2016), available: http://edge.media-server.com/m/p/7neehd6y

237. In exchange for this price spread enlargement, PBM Defendants grant Manufacturer Defendants' diabetes medications with the most elevated reported price and the highest rebates preferred formulary status.

238. This pricing disconnect creates what is, in effect, a massive slush fund derived from the difference between the reported and net prices. As discussed in greater detail next, PBM Defendants can use this "fund" to extract hidden profits from the other participants within the pharmaceutical distribution system—namely health plans, consumers and pharmacies.

239. The scheme affords Manufacturer Defendants the ability to pay back to PBM Defendants a significant, yet undisclosed, portion of their reported prices in exchange for formulary placement—which garners Manufacturer Defendants greater revenues from sales to more people—without decreasing their profit margins.

240. Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated reported price.

241. Unfortunately for health plans like Harris County, and consumers in the insulin market in general, this scheme artificially drives up the price paid for diabetes medications.

242. Thus, far from using their prodigious bargaining power to lower drug prices as they claim, PBM Defendants use their position to benefit both themselves and Manufacturer Defendants.

243. This Insulin Pricing Scheme is an extremely profitable enterprise for all Defendants, though deeply damaging to health plans and consumers who shoulder the burden of the higher prices.

Defendants Admit To Artificially Inflating Price to Buy Formulary Position

244. Manufacturer Defendants have admitted that their price hikes are unrelated to any increase in clinical benefit, production costs or research and development.

245. Instead, the inflated price is part of the Insulin Pricing Scheme: Manufacturer Defendants have agreed with PBM Defendants to raise their reported prices while secretly rebating a portion of that price back to PBMs to buy formulary position.

246. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on Defendants' Insulin Pricing Scheme titled, "Priced Out Of A Lifesaving Drug: Getting Answers on the Rising Cost of Insulin."

247. Nearly all of Defendants testified at that hearing and each acknowledged before Congress the price for insulin has increased exponentially in the past fifteen (15) years. Yet, none of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased costs or improved clinical benefit.

248. Rather, Manufacturer Defendants have admitted how both they and PBM Defendants agreed to and did participate in the Insulin Pricing Scheme and that the rise in insulin prices was a direct result of the scheme.

249. For example, in explaining the company's increases to the reported price of its diabetes medications, Novo Nordisk directly admitted that "as the manufacturer, we do set the [reported] price and have full accountability for those increases." The

statement continued on to explain that raising the reported price is necessary, "in order for [Novo Nordisk's] medicines to stay on [PBMs] preferred drug list or formulary."[77]

250. At the April 2019 Congressional hearing Novo Nordisk's President, Doug Langa, elaborated on Novo Nordisk's and PBM Defendants' role in perpetuating the "perverse incentives" of the Insulin Pricing Scheme:

> There is this perverse incentive and misaligned incentives (in the insulin pricing system) and this encouragement to keep [reported] prices high. And we've been participating in that system because the higher the [reported] price, the higher the rebate . . . There is a significant demand for rebates. We spend almost $18 billion in rebates in 2018 . . . If we eliminate all the rebates . . . we would be in jeopardy of losing [our formulary] positions.[78]

251. Eli Lilly, too, has admitted that it raises reported prices as a *quid pro quo* for formulary positions: "The reason drug makers sharply raise reported prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists."[79]

252. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly testified:

> Seventy-five percent of our [reported] price is paid for rebates and discounts to secure [formulary position] . . . $210 of a vial of Humalog is paid for discounts and rebates. . . We have to provide rebates [to PBMs] in order to provide and compete for [formulary position].

253. Sanofi has also conceded its participation in the Insulin Pricing Scheme:

> [S]ince 2014, we have increased the level of rebates granted for Lantus in order to maintain favorable formulary positions.[80]

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[77] Novo Nordisk Press Release, http://press.novonordisk-us.com/leadership-perspectives?item=1.
[78] *Priced Out Of A Lifesaving Drug: Getting Answer On The Rising Cost Of Insulin*, Hearing Before the Subcomm. on Energy and Commerce, (April 10, 2019).
[79] Denise Roland & Peter Loftus, *Middlemen Fuel Insulin Price Rise*, Wall St. J., at B1.
[80] Sanofi, Annual Report (Form 20-F) (Dec. 31, 2016).

254. When testifying at the April 2019 Congressional hearing, Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi, testified:

> The rebates are how the system has evolved. The rebates are part of the negotiation to secure formulary placement . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices . . .[81]

255. PBM Defendants also admitted at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher rebates paid by Manufacturer Defendants. For example, Amy Bricker, Senior Vice President of Express Scripts, when asked to explain why Express Scripts did not grant an insulin with a lower reported price preferred formulary status, answered, "[m]anufacturers do give higher [rebates] for exclusive [formulary] position."[82]

Data Corroborates Defendants' Admission To The Insulin Pricing Scheme

256. The data corroborates Defendants' admissions that they have inflated the reported prices and paid back to PBM Defendants larger and larger amounts in exchange for PBM Defendants granting Manufacturer Defendants' diabetes medications preferred formulary status.

257. Over the last fifteen years, while Manufacturer Defendant's reported price has risen dramatically, the net price realized by these firms has not.

258. Figures 12 and 13 illustrate how Novo Nordisk's reported price has significantly diverged from its net price post rebate.

[81] *Id.*
[82] *Id.*

Figure 12: Net prices versus reported prices of NovoLog vial

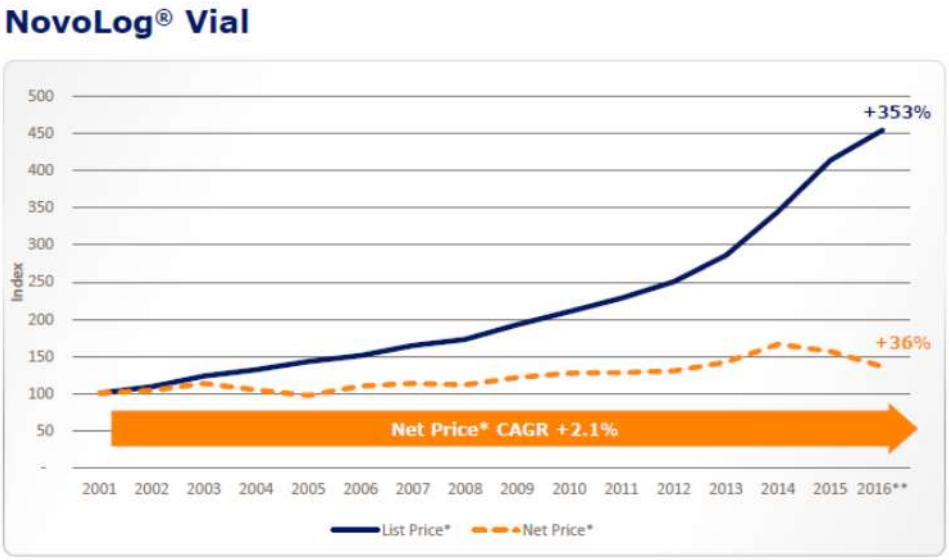
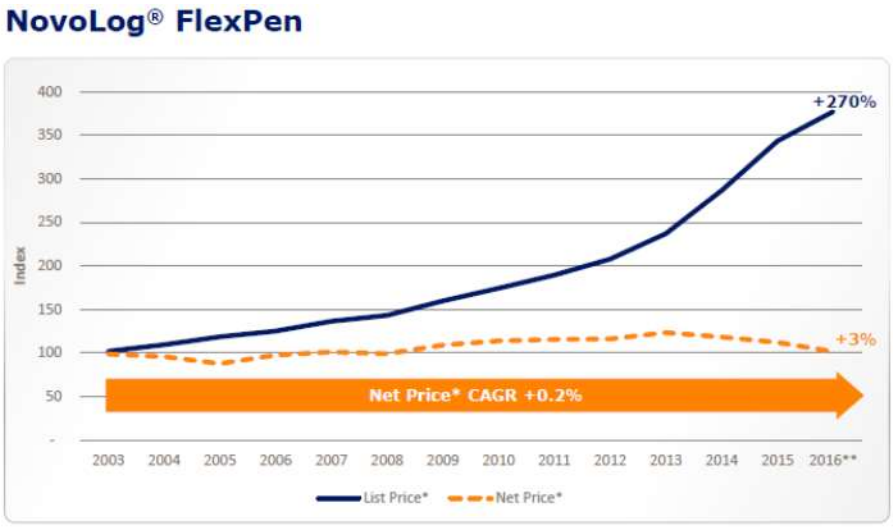
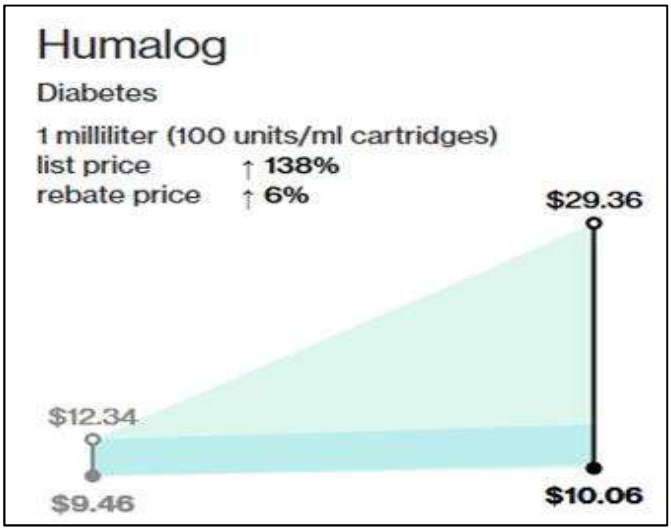


Figure 13: Net prices versus reported prices of NovoLog pens



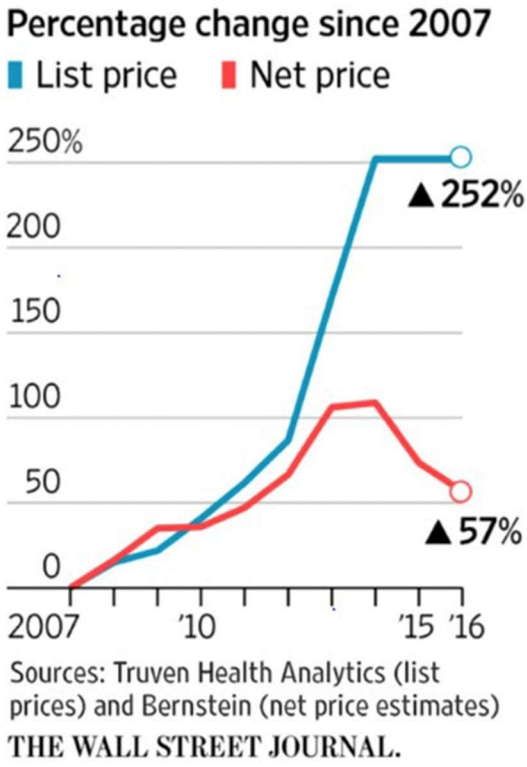
259. Figure 14 shows the widening gap between Eli Lilly's reported price and the net price of Humalog.

Figure 14: Net prices versus reported prices of Eli Lilly's Humalog



260. Sanofi's manipulation of its spreads is visible in Figure 15:

Figure 15: Sanofi's net prices versus reported prices of Lantus



261. Thus, Manufacturer Defendants admit—and the data corroborates—both their role and PBM Defendants' role in the Insulin Pricing Scheme.

PBMs Profit Off the Insulin Pricing Scheme

262. PBM Defendants and Manufacturer Defendants have conspired to artificially inflate the reported price of diabetes medications to exploit profits from health plans like Harris County.

263. For Manufacturer Defendants their artificially inflated prices allow them to make large secret payments back to PBM Defendants in order to buy formulary position, which leads to increased sales and profits.

264. PBM Defendants profit off the Insulin Pricing Scheme by: (1) pocketing significant portions of the payments made paid by Manufacturer Defendants ("Secret Payment Game"); (2) charging health plans, such as Harris County, based on the inflated prices and then reimbursing pharmacies a lower price for the same product ("Pharmacy Spread") and (3) using the inflated price to increase their margins on diabetes medications sold through their own mail order pharmacies.

265. With respect to (1), the Secret Payment Game, the rate of increase in payments by Manufacturer Defendants has accelerated to represent more than half of the list price of diabetes medications.[83]

266. When PBMs contract with health plans, the contract allows the PBM to keep all or at least some of these payments, rather than pass them along to the health plan. In fact, a recent study showed that most employers report that they do not receive the total share of the rebates that PBMs claim to pass on to them.[84]

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[83] Langreth R, Keller M, Cannon C. Decoding big pharma's secret drug pricing practices [article online]. Bloomberg, 29 June 2016. Available from https://www.bloomberg.com/graphics/2016-drug-prices/. Accessed 5 March 2018

[84] Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices Controversies, and What Lies Ahead, The Commonwealth Fund*, March 26, 2019, available at https://www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead.

267. Since payments are kept confidential between Manufacturer Defendants and PBM Defendants, health plans are unable to determine how much PBMs are keeping for themselves.

268. Over time, health plans, including Harris County, have secured contract provisions guaranteeing them all or some portion of the "rebates" paid by drug manufacturers to PBMs. But—critically—"rebates" are only a portion of the total secret payments paid.

269. In this regard, PBM and Manufacturer Defendants have created a "hide-the-ball" system where the consideration exchanged between them (and not shared with health plans) is labeled and relabeled. As more health plans moved to contracts that required PBMs to pass a majority of the manufacturer "rebates" through to the health plan, PBMs have begun relabeling these payments in order to keep a more substantial portion of this money. Payments once known as "rebates" are now called administrative fees, volume discounts, service fees, price or margin guarantees, or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

270. And the secret payments are indeed substantial. A recent heavily redacted complaint filed by Defendant Express Scripts revealed that *Express Scripts now retains up to 13 times more in "administrative fees" than it passes through to health plans in "rebates."*[85]

271. With respect to the second way that PBM Defendants profit off the Insulin Pricing Scheme—the Pharmacy Spread—PBM Defendants decide which pharmacies are

[85] *Express Scripts, Inc., et al. v. kaleo, Inc.*, Case No. 4:17-cv-01520-RLW (E.D.Mo 2017).

included in a prescription drug plan and how much they will reimburse pharmacies for each drug dispensed.

272. PBM Defendants do not specifically disclose to the health plan how much the PBM is reimbursing the pharmacies for the drugs dispensed or vice versa.

273. The price that the health plan pays for diabetes medications is directly tied to the artificially inflated reported price, while the price the pharmacy is reimbursed for the drug often is not.

274. This allows PBM Defendants to charge the health plan significantly more than what the PBM is reimbursing the pharmacy for the same drug and the PBM pockets the difference.

275. Spread pricing, like secret payment negotiation, happens behind closed doors. There is no transparency, no commitment from PBM Defendants to take into account the cost effectiveness of a drug, and no communication with the health plans to let them know if they are getting a fair deal.

276. While some spread pricing can be expected even in a fair market, the opacity of the profit stream of the Insulin Pricing Scheme masks the allegedly low costs PBM Defendants tout to health plans to get them to sign up and demonstrates the strong financial incentive PBMs have to drive up the reported price.

277. With respect to the third way PBMs profit off the Insulin Pricing Scheme—PBM Defendants all operate their own highly profitable mail order pharmacies. The higher the price that PBM Defendants are able to get their customers, such as health plans like Harris County, to pay for diabetes medications, the higher the profit PBM Defendants realize through their own mail order pharmacies.

E. The Insulin Pricing Scheme Deceived and Harmed Harris County and the Insulin Market

278. Harris County has been deceived by Defendants' Insulin Pricing Scheme and it has cost the County millions of dollars.

279. The Harris County government serves its almost 5 million residents providing public safety, emergency management, and health services just to name a few of its vital roles. As more federal and state responsibilities are mandated to local government, Harris County has to meet a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Harris County's overall budget and, in turn, negatively impact its ability to provide necessary services to the community or force the County to raise taxes to compensate for the losses.

280. As a large government employer, Harris County provides health benefits to 38,000 Beneficiaries.

281. One of the benefits that Harris County offers its Beneficiaries is paying a significant portion of the cost of their healthcare.

282. Harris County is what is known as a self-funded health plan—meaning Harris County provides health benefits using its own funds, including funds contributed by its Beneficiaries. As part of this health plan, Harris County subsidizes its health plan's Beneficiaries' prescription drug purchases.

283. Harris County also spends millions of dollars a year purchasing pharmaceutical drugs, including diabetes medications, that are administered to inmates in the Harris County jails.

284. To administer its health plan, Harris County contracts with insurance companies. For the alleged purposes of limiting administrative burden and controlling pharmaceutical drugs costs, these insurance companies then contract with PBMs to administer Harris County's pharmacy benefits.

285. As detailed in Appendix A, as part of its pharmaceutical drug spend, Harris County spends millions of dollars every year on the at issue drugs.

286. At different periods during the relevant times, Defendants Aetna Rx, CVS Caremark, OptumRx and Express Scripts provided PBM services to Plaintiff Harris County.

287. Unfortunately, PBMs have not helped control the cost of Harris County's diabetes medication purchases as promised. To the contrary, as a direct result of Defendants' Insulin Pricing Scheme, the amount that Harris County pays for diabetes medications has increased significantly in the last ten years.

Defendants Deceived Harris County

288. Defendants deceived Harris County into paying significantly inflated prices for diabetes medications.

289. PBM Defendants falsely represent that they negotiate with Manufacturer Defendants in good faith and for the benefit of health plans, that the "rebates" PBM Defendants received from Manufacturer Defendants lowered the price Harris County paid for diabetes medications and that PBM Defendants were transparent with health plans regarding these "rebates." [86]

[86] *See e.g* Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices, CBS News, February 7, 2017, available at https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/ ("we negotiate with drug companies to get

290. This is yet another example of Defendants' "hide-the-ball" system. PBM executives represented to Congress that they are passing along all "rebates" to plans when in reality "rebates" are today a small fraction of the total payments PBMs receive from manufacturers in exchange for formulary placement.

291. When testifying before Congress earlier this year, Amy Bricker, Senior Vice President of Defendant Express Scripts had the following exchange with Representative John Sarbanes of Maryland regarding the transparency (and lack thereof) of the Rebate Game:

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . [However] the reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> Mr. Sarbanes. What about if we made it completely transparent? Who would be for that?
>
> Ms. Bricker. Absolutely not . . . it will hurt the consumer.
>
> Mr. Sarbanes. I don't buy it.
>
> Ms. Bricker – prices will be held high.
>
> Mr. Sarbanes. I am not buying it. I think a system has been built that allows for gaming to go on and you have all got your talking points. Ms. Tregoning [of Sanofi], you have said you want to guarantee patient access and affordability at least ten times, which is great, but there is a collaboration going on here . . . the system is working for both of you at the expense of the patient. Now I reserve most of my frustration for the moment in this setting for the PBMs, because I think the lack of transparency is allowing for a lot of manipulation. I think the rebate system is totally screwed up, that without transparency there is opportunity for a lot of hocus-pocus to go on with the rebates. Because the list price ends up being unreal in certain ways except to the extent that it leaves certain patients holding the bag, then the rebate is negotiated, but we don't know exactly what happens when the

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the prices down;" "the rebates flow through us, 100 percent of the time our client determines where it goes;" we support "absolute transparency" regarding rebates, etc); *see also* Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017); CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2017); OptumRx, Annual Report (Form 10-K) (Dec. 31, 2017).

> rebate is exchanged in terms of who ultimately benefits from that. And I think we need more transparency and I do not buy the argument that the patient is going to be worse off, the consumer is going to be worse off if we have absolute transparency . . . I know when you started out, I understand what the mission was originally with the PBMs . . . But now things have gotten out of control. You are too big and the lack of transparency allows you to manipulate the system at the expense of the patients. So I don't buy the argument that the patient and consumer is going to get hurt if we have absolute transparency.[87]

292. Manufacturer Defendants and PBM Defendants also falsely represent that the formulary status of diabetes medications reflects the drugs' safety, efficacy, and cost-effectiveness, as determined by PBM Defendants' formulary committees.[88]

293. PBM Defendants have repeatedly made these false representations not only through public statements and disclosures, but also through direct marketing and solicitation material to Harris County.

294. For example, Harris County received marketing and solicitation material from PBM Defendants that represented that their formulary programs promoted cost effective drugs and the drugs selected for preferred positions were based on safety and efficacy.

295. Harris County also received direct solicitations from several health plan administrators that represented that PBM Defendants' formularies managed to lower

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[87] *See supra* note 69.

[88] *See, e.g,* Express Scripts, Annual Report (Form 10-K) (Dec. 31, 2017) ("In making formulary recommendations, [our Pharmacy & Therapeutics Committee] considers the drug's safety and efficacy, without any information on or consideration of the cost of the drug, including any discount or rebate arrangement we might negotiate with the manufacturer. . . We fully comply with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy"); CVS Caremark, Annual Report (Form 10-K) (Dec. 31, 2017) ("We utilize an independent panel of doctors, pharmacists and other medical experts. . . to review and approve the selection of drugs that meet our high standards of safety and efficacy for inclusion on one of our template formularies. Our formularies . . . help[] to drive the lowest net cost for our clients. . ."); OptumRx, Annual Report (Form 10-K) (Dec. 31, 2017)(we "promote lower costs by using formulary programs to produce better unit costs, encouraging consumers to use drugs that offer improved value.")

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drug cost, that rebate contracting is one way that PBM Defendants lower the cost of prescription medications and that the rebates PBM Defendants' negotiated with manufacturers would save Harris County tax-payers millions of dollars.

296. Manufacturer Defendants and PBM Defendants also falsely represented to Harris County—through publicly reporting their prices and basing the price Harris County paid for diabetes medications on their reported prices—that the reported price of diabetes medications bears a reasonable relationship to the drug's ingredient cost and is a reasonable approximation of the net price realized by Defendants.

297. Harris County did not know that the prices it was being charged for diabetes medications did not result from transparent and competitive market forces, but rather from Defendants' Insulin Pricing Scheme that was designed to maximize profits at Harris County's expense.

298. In particular, Harris had no knowledge that the reported prices were artificially inflated solely for the purpose of increasing Defendants' profit margins and were completely untethered from the cost of the drugs or the price realized by Defendants.

299. Harris County also had no knowledge that the "rebates" and formularies that were allegedly saving Harris County money were an integral part of the scheme that was responsible for the skyrocketing prices of diabetes medications.

300. Defendants concealed their Insulin Pricing Scheme by closely guarding their pricing structures, agreements and sales figures.

301. Manufacturer Defendants do not disclose to health plans or the public the net prices or rebates or other payments they offer to PBM Defendants.

302. PBM Defendants do not disclose the details of their agreements with drug manufacturers, and the payments they receive from them—as well as their agreements with insurers, health plans and pharmacies.

303. PBM Defendants have gone as far as suing governmental entities to block the release of details on their pricing agreements with manufacturers and pharmacies.[89]

304. Even when audited by health plans, PBM Defendants often still refuse to disclose their agreements with manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets and other unnecessary restrictions.

305. In a previous lawsuit involving the manipulation of drug pricing spreads, evidence came forth explicitly demonstrating this deceit:

> Because these PBMs benefited from the increased spreads perpetuated by the Scheme, Plaintiffs argue that they had no incentive to inform [third party payors or health plans] of the inflated AWP, let alone fiercely compete to mitigate any damage. As proof, Plaintiffs quote an April 26, 2002 internal [PBM] e-mail . . . that states that "the AWP increases being pushed through by First Data Bank [are] having a very favorable impact on our mail margins." The e-mail goes on to state, "Our clients (health plans and insurers) will not be sympathetic to our financial situation since we [will have benefited] from the AWP increase in the mail and they hired us to control drug trend." The e-mail includes a handwritten note, in response, "Let's put a lid on it and not make it a big deal."[90]

306. Defendants knew that Harris County considered the price that it paid for diabetes medications, which was directly tied to Manufacturer Defendants' reported price, a reasonable approximation of the net price realized by Defendants and a price that resulted from competitive and transparent market forces. Consequently, PBM Defendants were able to use reported prices as a basis for the price Harris County paid.

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[89] Catherine Candisky, "CVS Sues State To Block Release of Report On Its Drug Pricing," The Columbus Dispatch July 16, 2018, available at https://gatehousenews.com/sideeffects/cvs-sues-state-block-release-report-drug-pricing/site/dispatch.com/

[90] *New England Carpenters Health Benefits Fund v. First Data Bank, Inc.*, 248 F.R.D. 363, 367 (D. Mass 2008) (internal citations omitted).

307. The Insulin Pricing Scheme enabled Manufacturer Defendants to offer something of value to the PBM Defendants—inflated prices and payments—in exchange for preferred formulary status.

308. PBM Defendants were able to use the inflated prices to create significant profit streams.

309. Without the Insulin Pricing Scheme and its secret payment and pricing system, Defendants would have been forced to compete for market share in the way competitors do in a healthy market: by offering lower actual prices that are available and transparent to the participants in the market.

310. In sum, each Defendant affirmatively misrepresented that: (i) the reported prices for diabetes medications were a reasonable approximation of the net price realized by Defendants and a price that resulted from competitive and transparent market forces, (ii) that the payments PBM Defendants received from Manufacturer Defendants were for the benefit of health plans, and (iii) that preferred formulary status of diabetes medications reflected the drugs' safety, efficacy, and cost-effectiveness.

311. Harris County relied on Defendants' representations and paid for diabetes medications based on these artificially inflated prices to its detriment. Harris County, unaware of the fact that the pricing and selection of the diabetes medications it pays for are the result of the Insulin Pricing Scheme, continues to pay for the medicines based on their reported prices.

Defendants' Insulin Pricing Scheme Damaged Harris County

312. Harris County was and is damaged as a direct result of Defendants' Insulin Pricing Scheme.

313. Harris County spends millions of dollars each year on the at issue drugs.[91] The price that Harris County paid for these drugs was directly tied to Manufacturer Defendants' reported price. Thus, because Defendants' Insulin Pricing Scheme caused the reported prices to fraudulently and substantially increase, Defendants' pattern of fraudulent conduct directly and proximately caused Harris County to substantially overpay for diabetes medications.

314. The amount it has overpaid is the difference between the price that Harris County paid for these drugs and what it would have paid absent the Insulin Pricing Scheme. Factors to be considered include: the cost to manufacture the at issue drugs; a reasonable profit margin; the payments that Manufacturer Defendants made to PBM Defendants that were not passed through to Harris County; the amount that PBM Defendants pocketed from the fraudulent Pharmacy Spread; and PBM Defendants' additional undisclosed profit margins on diabetes medications purchased for and dispensed through their own mail order pharmacies.

Defendants' Insulin Pricing Scheme has Damaged Competition and Consumers

315. Defendants' Insulin Pricing Scheme has also harmed competition and other consumers within the insulin market by anticompetitively and artificially inflating the price of insulin.

316. As a result of years of market concentration, as detailed above, PBM Defendants have a dominant market share in controlling the pricing and administration of the prescription drug market in the Texas. To further exacerbate this market saturation, PBM Defendants carve up the market geographically, effectively not

[91] *See* Appendix A.

competing in certain regions of the country.[92] Amid such concentration, consumers in the insulin market, such as health plans like Harris County, have little ability to select the best PBM on price or quality.

317. Equally concentrated is the insulin product market, with Manufacturer Defendants representing 99% of all insulin products sold.[93]

318. Manufacturer Defendants have taken numerous steps to ensure that they maintain their dominant market share.

319. For example, Manufacturer Defendants engage in a practice known as "evergreening." In a competitive drug market, manufacturers are granted a short period of market exclusivity prior to the expiration of their patent in order to increase profits to offset the substantial cost of bringing a new drug to the market. Once the patent expires, generics (in the case of insulin, biosimilars) enter the market at a substantially lower price.

320. Here, however, Manufacturer Defendants have engaged in the repatenting tactic called "evergreening," in which a series of extra patents on incremental variations of the original drug are sought solely for the purposes of extending the life of a patent after initial expiration. Defendant Sanofi, for example, has applied for 69 different patents on Lantus in the U.S. *after* the drug was approved in 2000.[94] Evergreening prevents generics/biosimiliars from entering the market, even though the patented "improvements" are often inconsequential and do not produce better clinical results.

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[92] David Dayen, The Hidden Monopolies That Raise Drug Prices, The American Prospect, Spring 2017, available at https://prospect.org/health/hidden-monopolies-raise-drug-prices/.
[93] Beran, supra note 48.
[94] I-MAK Report, Lantus (Insulin Glargine) Overpatented, Overpriced, October 2018, available at: http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf

321. In addition to "evergreening," Manufacturer Defendants have also engaged in "pay for delay," where a generic/biosimilar manufacturer acknowledges the original patent of a pharmaceutical company and agrees to refrain from marketing its product for a specific period of time in return for payment.

322. One example of this occurred a few years ago when the drug company Merck announced plans to sell a biosimilar version of Sanofi's Lantus. Sanofi sued, and eventually Merck announced that it was no longer pursuing it's biosimilar due to payments from Sanofi to stay off the market.

323. As a result of their "evergreening" and "pay for delay" strategies, Manufacturer Defendants have eliminated competition for their insulins in order to maintain their dominant control over the U.S. insulin market.

324. Because of the market domination of both PBM Defendants and Manufacturer Defendants, consumers in this market, including health plans, often have little or no choice as to which insulin drugs that they are able to purchase.

325. The insulins that are available to the consumer are directly determined by which insulin drugs PBM Defendants place on their formularies. And rather than allowing competition and lower actual prices determine which insulins receive preferred status, PBM Defendants have agreed to grant formulary positions to Manufacturer Defendants based on which drug's price is the most inflated and which manufacturer makes the largest payments to them.

326. Thus, consumers in the insulin market are left with no reasonable substitutes—Manufacturer Defendants make nearly all of the insulin on the market and agreed in lockstep to increase the prices of these insulins. And PBM Defendants control which insulin products are available to consumers.

327. Consequently, consumers in this market, such as Harris County, are stuck in the Insulin Pricing Scheme, forced to pay the skyrocketing prices of insulin.

F. Tolling of Statute of Limitations

328. Harris County, as a county government, is a political subdivision of the state. Thus, pursuant to the common law and TEX. CIV. PRAC. & REM CODE 16.061, Harris County is not subject to any applicable statute of limitations.

329. Even assuming, *arguendo*, that Harris County was subject to applicable statutes of limitations, in the alternative Harris County asserts that it diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, Harris County did not receive inquiry notice nor learn of the factual basis for its claims in this Complaint and the injuries suffered therefrom until recently. Consequently, the following tolling doctrines apply.

Discovery Rule Tolling

330. Harris County had no way of knowing about the scheme and deception with respect to Insulin Pricing Scheme.

331. As discussed above, PBM and Manufacturer Defendants refused to disclose the net prices of diabetes medications realized by Defendants, labeling them trade secrets and protecting them with confidentiality agreements. Each Defendant group also affirmatively blamed the other for the price increase described herein, both during their congressional testimonies and through the media. Hence, a reasonable plaintiff and consumer could not discover the truth.

332. Within the period of any applicable statutes of limitation, Harris County could not have discovered, through the exercise of reasonable diligence, that Defendants were concealing the conduct complained of herein.

333. Harris County did not discover, and did not know of facts that would have caused a reasonable person to suspect, that Defendants were engaged in the scheme, nor would a reasonable and diligent investigation have disclosed the true facts.

334. Even today, lack of transparency in insulin pricing and the arrangements, relationships, and agreements between and among Manufacturer Defendants and PBM Defendants that result in the Insulin Pricing Scheme continue to hide Defendants' unlawful conduct from Harris County.

335. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to claims identified herein.

Fraudulent Concealment Tolling

336. As detailed above, all applicable statutes of limitation have also been tolled by the Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

Estoppel

337. Defendants were under a continuous duty to disclose to Harris County the true character, quality, and nature of the reported prices upon which their payments for insulin were based, and the true nature of the services being provided.

338. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

Continuing Violations

339. All applicable statutes of limitations are also tolled because Defendants' fraudulent activities have not ceased and still continue to this day and thus any causes of action are not complete and do not accrue until the tortious and anticompetitive acts have ceased.

VI. CLAIMS FOR RELIEF

COUNT ONE

Violations of the Texas Free Enterprise and Antitrust Act ("TFEAA") (Against Defendants)[95]

340. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

341. Each Defendant has combined, conspired, or attempted to combine or conspire to unreasonably restrain trade and commerce in the insulin market in violation of the Texas Free Enterprise and Antitrust Act, by engaging in a price fixing conspiracy between competitor PBMs and competitor drug manufacturers to artificially raise prices for the purposes of securing preferential formulary placement and maximizing profits.

Defendants had a Conscious Commitment to the Insulin Pricing Scheme

342. Each Defendant had a conscious commitment to participate in the Insulin Pricing Scheme. As detailed in paragraphs 244-255, Defendants explicitly admitted that they agreed to and did participate in the Insulin Pricing Scheme.

343. As detailed in paragraphs 176-195, Manufacturer Defendants' agreed with each other to increase, in lockstep, the reported price of their insulins in order to participate in the Insulin Pricing Scheme.

344. This agreement between Manufacturer Defendants was necessary because their insulins have similar efficacy and risk profiles and thus purchasers choose whose product to buy based primarily on price. In a competitive insulin market unilateral price

[95] Count One, Violations of the Texas Free Enterprise and Antitrust Act, applies only to the insulin products at issue in this case: Eli Lilly's Humulin N, Humilin R, Humalog and Basaglar; Sanofi's Lantus, Toujeo, Soliqua and Apidra and Novo Nordisk's Novolog, Levemir and Tresiba. Count One does not apply to the at issue non-insulin drugs Trulicity, Victoza and Ozempic.

increases would result in loss of market share and removal from preferred positions on PBM Defendants' formularies. Thus, it would have been economically irrational for any one Manufacturer Defendant to raise its prices without assurance that its competitors would also increase prices and assurance from PBM Defendants that it would receive preferred formulary positions in exchange for these inflated prices.

345. As detailed paragraphs 176-195 and 235-261, Manufacturer Defendants agreed with PBM Defendants to intentionally and artificially raise their reported insulin prices and then "rebate" back to PBM Defendants a significant portion of those prices.

346. As detailed paragraphs 235-255, in exchange for Manufacturer Defendants' inflating their prices and making large secret payments, PBM Defendants agreed to and did grant preferred formulary status to Manufacturer Defendants' insulins.

347. In a competitive PBM market, PBM Defendants would have granted formulary position based on lower reported prices, rather than inflated prices and secret payments.

348. In a competitive market the non-transparent and convoluted secret payment system devised by Defendants would have been unnecessary.

349. In a competitive market, if PBM Defendant acted unilaterally to grant formulary position based upon higher reported prices and non-transparent payments, the services and formularies that PBM made available to health plans, such as Harris County, would be less competitive compared to those of ostensibly competing PBMs granting formulary position on lower, transparent prices.

350. Each Defendant shares a common purpose of perpetuating the Insulin Pricing Scheme and neither PBM Defendants nor Manufacturer Defendants alone could have accomplished the Insulin Pricing Scheme without their co-conspirators.

351. PBM Defendants need Manufacturer Defendants to artificially inflate the reported price of their insulins and to make secret payments back to PBM Defendants in order for PBM Defendants to profit off the Insulin Pricing Scheme.

352. Manufacturer Defendants need PBM Defendants to grant their insulins preferred formulary placement and to bind health plans, such as Harris County, to pay for drugs based on the inflated reported prices.

353. In furtherance of the Insulin Pricing Scheme, PBM Defendants and Manufacturer Defendants made joint decisions, were in regular communication, and met on a regular basis regarding artificially inflating the reported price of insulin and the regular flow of payments from Manufacturer Defendants to PBM Defendants for formulary placement including: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants in an effort to promote products.

354. In addition to other allegations contained in this Petition, Defendants' agreement and conscious commitment to the Insulin Pricing Scheme is also demonstrated by:

a. As detailed in paragraphs 266-275, 289-291 and 300-305, Defendants refusal to disclose the details of their pricing structures, agreements and sales figures in order maintain the secrecy of the Insulin Pricing Scheme;

b. Numerous ongoing government investigations, hearings and inquiries targeting the Insulin Pricing Scheme and the collusion and anticompetitive behavior of Defendants, including:

- In 2016, Manufacturer Defendants received civil investigative demands from the State of Washington and the State of New Mexico relating to the pricing of their insulin products and their relationships with PBM Defendants;

- In 2017, Manufacturer Defendants received civil investigation demands from the States of Minnesota, California and Florida related to the pricing of their insulin products;

- Letters from numerous senators and representatives in recent years, including Senator Bernie Sanders (D-VT), Representative Elijah Cummings (D-MD), and Representative Tim Burchett (TN-02) to the Justice Department and the Federal Trade Commission asking them to investigate potential collusion and anticompetitive behavior among Defendants;

- A 2017 House Oversight committee investigation into the corporate strategies of drug companies, including Manufacturer Defendants, seeking information on the increasing price of drugs and manufacturers efforts to preserve market share and pricing power;

- A 2018 report issued by Tom Reed (R-NY) and Diana DeGette (D-CO) titled "Insulin: A Lifesaving Drug Too Often Out Of Reach" aimed addressing the dramatic increase in the price of insulin; and

- Several 2019 hearings before both the Senate Financing Committee and the House Oversight and Reform Committees on the Insulin Pricing Scheme;

c. the fact that the astronomical rise in the price of insulins coincided with PBM Defendants rise to power within the pharmaceutical pricing system starting in 2003.

The Insulin Pricing Scheme Unreasonably Restrained Trade and Commerce

355. The Insulin Pricing Scheme has harmed competition and caused prices for insulins to be higher than they would have been absent the fraudulent scheme. These price increases were not the result of independent decision making by Defendants engaged in economic self-interest or free and fair competition.

356. As demonstrated by paragraphs 227-230 and 244-255, Defendants' admitted that the exponential increase in the reported price of insulin is unrelated to competitive factors such as increased production or research costs or improved clinical benefit.

357. The inflated reported price upon which governmental entities, like Harris County, pay for insulin bears no relationship to the price realized by Defendants or that which would be charged absent the Insulin Pricing Scheme.

358. In a fair competitive market, Manufacturers Defendants would have competed by lowering their reported prices of insulin. PBM Defendants would have granted formulary status based on this lower reported price and then used this lower reported price to set the price that governmental entities, like Harris County, paid for insulins. Defendants also would have been transparent about their arrangements and pricing structures to ensure a fair, competitive market.

359. Instead, Defendants conspired together to create the Insulin Pricing Scheme where they secretly negotiated between themselves based on artificially raised reported prices and undisclosed "rebate" payments in order to extract large profits from the insulin market.

360. Both Manufacturer Defendants and PBM Defendants have dominant market shares. Consequently, consumers in the insulin market are left with no reasonable substitutes—Manufacturer Defendants make nearly all of the insulin on the market and PBM Defendants control the manner in which insulin products are available to consumers.

361. As a direct result of the Insulin Pricing Scheme consumers, such as Harris County, in the insulin market were forced to pay higher prices.

362. The Insulin Pricing Scheme constitutes a restraint of trade that is unlawful under all three applicable standards of review: (1) the *per se* standard, which governs price-fixing and the allocation of markets; (2) the "quick-look" standard, which governs apparently anticompetitive schemes with which the courts lack familiarity; and (3) the rule-of- reason standard (the "Rule of Reason"), which governs all other challenged restraints of trade.

363. Plaintiff Harris County respectfully submits that the Court should apply well-recognized *per se* rules to condemn the challenged price fixing conspiracy, but in an abundance of caution pleads this claim in the alternative so that it is raised not only under the *per se* rules, but also under the "quick-look" standard and the rule of reason.

Relevant Geographic and Product Markets

364. Assuming, *arguendo*, that a relevant product market needs to be defined, the relevant product market is the market for insulin.

365. There are no reasonable product substitutes for insulins in this market and Manufacturer Defendants make over 99% of the insulins in the relevant market. Thus, in the insulin market, the demand is highly inelastic, the market for the sale of insulin is extremely concentrated and there are high regulatory, legal and cost barriers to enter the market. These economic conditions make the market for the manufacture and sale of insulins conducive to anticompetitive conspiracies.

366. The relevant geographic market is Texas.

Harris County was Harmed as a Direct Result of Defendants' Anticompetitive Acts

367. Defendants anticompetitive acts in violation of the Texas Free Enterprise and Antitrust Act have directly and proximately caused Plaintiff Harris County to be injured in its business or property.

368. Harris County pays for insulin directly to a PBM Defendant, at a rate which is based on Manufacturer Defendants' artificially inflated AWP reported prices.

369. Each Defendant agreed to and did participate in the Insulin Pricing Scheme that was directly responsible for these artificially inflated reported prices.

370. As an integral part of the Insulin Pricing Scheme, Defendants specifically intended on deceiving Harris County and other health plans into paying these artificially inflated prices in order to profit off the Insulin Pricing Scheme.

371. No other intermediary in the supply chain has control over or is responsible for the reported prices on which Harris County's payments for insulin are based or the contracted rate Harris County paid for insulins other than Defendants.

372. Harris County's damages are separate and distinct from any other victim that was harmed by Defendants' Insulin Pricing Scheme.

373. Harris County damages are the difference between the price it paid for insulin and the price that it would have paid absent the Insulin Pricing Scheme.

374. In sum, Harris County was damaged as a result of the Insulin Pricing Scheme. But for the misrepresentations and inflated prices created by the Insulin Pricing Scheme, Harris County would have paid less for insulins.

375. As a direct and proximate result of Defendants' past and continuing violations of the Texas Free Enterprise and Antitrust Act, Plaintiff Harris County has suffered injury and damages in an amount to be proved at trial. These actual damages should be trebled under Section 15.21 of the Texas Free Enterprise and Antitrust Act.

376. Plaintiff Harris County also seeks injunctive relief. The violations set forth above are continuing, are causing irreparable harm, and will continue unless injunctive relief is granted.

377. Plaintiff Harris County also seeks recovery of its attorneys' fees and costs under Section 15.21 of the Texas Free Enterprise and Antitrust Act as a remedy for the costs they have incurred as a result of Defendants' conduct.

COUNT TWO

Common Law Fraud
(Against Defendants)

378. Plaintiff Harris County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

379. As alleged extensively above, Defendants affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the actual cost and/or price of the diabetes medications realized by Defendants; (b) the inflated and/or fraudulent nature of the reported price(s) set and/or charged by Defendants for the diabetes medications described herein; (c) the existence, amount, and/or purpose(s) of discounts and/or payments offered and/or negotiated by Defendants for those products; and (d) the role that Defendants' played in the price paid for the diabetes medications described herein, including but not limited to marketing material averring that Defendants decrease the price of prescription drugs for health plans and insurers.

380. In fact, PBM Defendants base their entire business model around representing—directly and indirectly—to health plans, including Harris County, that they negotiate with Manufacturer Defendants, through rebates and formulary decisions, to lower the actual price that Harris County pays for diabetes medications.

381. PBM Defendants make these misrepresentations for the sole purpose of inducing reliance by health plans, including Harris County, into purchasing diabetes medications through PBM Defendants.

382. Defendants knew that the representations described above were false when they made the representations—the rebates and formulary positions agreed upon between Defendants did not lower the price Harris County paid for insulin, but rather were primary factors driving the exponential increase in the amount that Harris County paid for insulins over the last fifteen years.

383. Defendants made these false representations directly to Harris County through marketing materials, presentations, the inclusion of the reported price in Harris County's contract as a determinant of the price for diabetes medications, publications of the artificially inflated reported price and public statements and testimonies in the media, on various websites, in Defendants' governmental filings and at Congressional hearings.

384. Defendants' false representations and omissions were material to Plaintiff Harris County.

385. Plaintiff Harris County reasonably relied on Defendants' deception in paying for diabetes medications at inflated prices. Plaintiff Harris County had no way of discerning that Defendants were, in fact, deceiving it because Defendants possessed exclusive knowledge regarding the nature of the pricing of diabetes medications; intentionally concealed the foregoing from Plaintiff Harris County; and made incomplete or negligent representations about the pricing of the diabetes medications and the Defendants' role in that pricing, while purposefully withholding material facts from Plaintiff Harris County that contradicted these representations.

386. Defendants' actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health.

387. As a direct and proximate result of Defendants' fraudulent Insulin Pricing Scheme, Harris County sustained damages, including but not limited to paying excessive and inflated prices for diabetes medications described herein.

388. Defendants are liable to Plaintiff Harris County for damages in an amount to be proven at trial. Moreover, because Defendants acted wantonly, maliciously, recklessly, deliberately, and with intent to defraud Plaintiff Harris County for the purpose of enriching themselves at Plaintiff's detriment, Defendants' conduct warrants substantial punitive and exemplary damages in an amount to be determined at trial.

COUNT THREE

Money Had and Received
(Against Defendants)

389. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

390. Defendants have benefitted from and hold money for selling, setting prices for and negotiating discounts for diabetes medications marketed and sold at an artificially inflated price.

391. PBM Defendants have received and retained money and unjust benefits from Plaintiff Harris County in the form of excess payments paid by Plaintiff Harris County to PBM Defendants for diabetes medications. PBM Defendants also have received and retained the proceeds from the Pharmacy Spread discussed above. In addition, PBM Defendants have received and retained secret payments paid by Manufacturer Defendants to PBM Defendants to which Plaintiff Harris County is entitled.

392. Manufacturer Defendants have received and retained money and unjust benefits using the artificially inflated reported prices paid by Harris County to incentivize

Manufacturer Defendants into giving their diabetes medications preferred formulary placement. This fraudulent scheme also allowed Manufacturer Defendants to increase the amount of "rebates" that they paid to PBM Defendants in exchange for preferred formulary placement without having to compromise their own profit margins.

393. As a result of Defendants' Insulin Pricing Scheme inequity has resulted and it would be unconscionable for Defendants to retain these monies and benefits.

394. Because Defendants concealed their fraud and deception, Plaintiff Harris County was not aware of the true facts concerning the Insulin Pricing Scheme described herein and did not benefit from Defendants' misconduct.

395. Defendants knowingly accepted the money and unjust benefits of its fraudulent conduct.

396. As a result of Defendants' misconduct, an amount of money and Defendants' unjust enrichment should be disgorged and returned to Plaintiff Harris County in an amount to be proven at trial.

COUNT FOUR

Unjust Enrichment
(Against Defendants)

397. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

398. Defendants have benefitted from the Insulin Pricing Schemes by selling, setting prices for and negotiating discounts for diabetes medications marketed and sold at an artificially inflated price.

399. Defendants wrongfully secured and retained unjust benefits from the Plaintiff Harris County, in the form of amounts paid for diabetes medications based on fraudulently inflated prices, and inequity has resulted.

400. It is inequitable and unconscionable for Defendants to retain these benefits.

401. Defendants knowingly accepted the unjust benefits of its fraudulent conduct.

402. As a result of Defendants' misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiff Harris County, in an amount to be proven at trial.

COUNT FIVE

Civil Conspiracy
(Against Defendants)

403. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

404. Defendants' conduct described herein constitutes a civil conspiracy and aiding and abetting each other to violate the Texas Free Enterprise and Antitrust Act and to commit the torts of fraud, unjust enrichment and money had and received. In furtherance of their conspiracy, Defendants have undertaken efforts to eliminate competition in the insulin market. As a direct result of the overt acts taken in furtherance of Defendants' conspiracy, Harris County has suffered damages in an amount to be proven at trial. Defendants are all jointly and severally liable for the actions taken in furtherance of their joint conduct.

VII. APPLICATION FOR TEMPORARY AND PERMANENT INJUNCTION

405. Plaintiff re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

406. Due to Defendants' conduct, Plaintiff did and will suffer irreparable injury and has no adequate remedy at law.

407. After Defendants have been cited to appear and answer, Plaintiff requests the Court to enter a temporary injunction to enjoin Defendants, their agents, employees, and attorneys, together with all persons in concert with them, from engaging in anticompetitive and unlawful conduct, including continuing to report artificially inflated prices for diabetes medications.

408. If such relief is not granted, Plaintiff will suffer irreparable harm before a trial on the merits of this case can be conducted.

409. Plaintiff further requests that, following a trial on the merits in this case, the Court enter a permanent injunction enjoining Defendants from their unlawful scheme.

VIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff Harris County respectfully demand that this Court:

A. Enter judgments against Defendants and in favor of Plaintiff Harris County for violations of state laws and legal standards invoked herein;

B. Order Defendants to pay pre-judgment and post-judgment interest as provided for by law or allowed in equity;

C. Award damages for economic and actual damages in an amount to be determined at trial; to be trebled with interest and all exemplary and/or punitive damages that may be awarded.

D. That the Court issue a preliminary and permanent injunction enjoining Defendants from continuing to report artificially inflated prices.

E. Plaintiffs further pray that the Court enter judgment also finding that Defendants are additionally liable to Plaintiffs for:

1. Costs of suit;
2. Prejudgment and post-judgment interest;
3. Attorney's fees; and
4. All other relief the Court deems appropriate.

IX. CONDITIONS PRECEDENT

All conditions precedent have been performed, have occurred, or have been excused.

X. JURY DEMAND

Pursuant to TEX. R. CIV. P 216, Plaintiffs respectfully demand a trial by jury on all issues so triable.

Dated: November 21, 2019

Respectfully submitted,

OFFICE OF HARRIS COUNTY ATTORNEY, VINCE RYAN

/s/ Vince Ryan
Vince Ryan
Harris County Attorney
Texas Bar No. 17489500
Robert Soard
First Assistant Harris County Attorney
Texas Bar No. 18819100
Terence L. O'Rourke
Special Assistant Harris County Attorney
Texas Bar No. 15311000
Pegi S. Block
Assistant Harris County Attorney
Texas Bar No. 02498250
1019 Congress, 15th Floor
Houston, Texas 77002
Telephone: (713) 274-5121
Facsimile: (713) 437-4211
Vince.Ryan@cao.hctx.net
Robert.Soard@cao.hctx.net
Terence.ORourke@cao.hctx.net
Pegi.Block@cao.hctx.net

LAW OFFICE OF RICHARD SCHECHTER, P.C.

/s/ Richard Schechter
Richard Schechter
Texas Bar No. 17735500
1 Greenway Plaza, Suite 740
Houston TX 77046-0102
Telephone: 713-623-8919
Facsimile: 713-622-1680
richard@rs-law.com

THE CICALA LAW FIRM PLLC

/s/ Joanne Cicala
Joanne Cicala
Texas Bar No. 24052632
Joshua T. Wackerly
Texas Bar No. 24093311

101 College Street
Dripping Springs, Texas 78620
Telephone: (512) 275-6550
Facsimile: (512) 858-1801
joanne@cicalapllc.com
josh@cicalapllc.com

BAKER • WOTRING LLP

/s/ Debra Tsuchiyama Baker
Debra Tsuchiyama Baker
Texas Bar No. 15089600
Earnest W. Wotring
Texas Bar No. 22012400
John Muir
Texas Bar No. 14630477
David George
Texas Bar No. 00793212
700 JPMorgan Chase Tower
600 Travis Street
Houston, Texas 77002
Telephone: (713) 980-1700
Facsimile: (713) 980-1701
dbaker@bakerwotring.com
ewotring@bakerwotring.com
jmuir@bakerwotring.com
dgeorge@bakerwotring.com

HOLLINS LAW GROUP PLLC

/s/ Christopher G. Hollins
Christopher G. Hollins
Texas Bar No. 24090168
Aysia N. Mayo-Gray
Texas Bar No. 24109256
5832 Highway 6 North
Houston, Texas 77084
Telephone: 346.980.4600
Facsimile: 346.980.4610
c.hollins@hollinslawgroup.com
a.mayo-gray@hollinslawgroup.com

ATTORNEYS FOR PLAINTIFF