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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA and STATE)		
OF NEW YORK, ex rel. SUSAN)		
VIERCZHALEK, M.D., et al.,)		
)		
Plaintiffs,)	Case No. 09-CIV-3919 (RJS)	
)		
against)		
)		
MEDIMMUNE, INC., et al.)	JURY TRIAL DEMANDED	
)		
Defendants.)		
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)		
THE STATE OF NEW YORK,)		
)		
Plaintiff,)	Case No. 09-CIV-3919 (RJS)	
against)		
)		
)		
MEDIMMUNE, INC.,)		
)		
Defendant.)		
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**COMPLAINT IN INTERVENTION OF THE STATE OF NEW YORK
AGAINST MEDIMMUNE, INC.**

For its Complaint in Intervention against Defendant MedImmune, Inc., the State of New York, by its attorney Eric T. Schneiderman, Attorney General for the State of New York, alleges as follows upon information and belief:

I. NATURE OF THE ACTION

1. The State of New York (the “State”) brings this action against MedImmune, Inc., (“MedImmune”), the manufacturer of the drug Synagis (Palivizumab), to recover treble damages and civil penalties under the New York State False Claims Act, N.Y. State Finance Law §§ 187-190, damages and other monetary relief under N.Y. Social Services Law § 145-b, N.Y. Executive Law § 63(12), N.Y. Executive Law § 63-c, and to recover amounts by which MedImmune was unjustly enriched.

2. In particular, the State seeks to recover from MedImmune millions of dollars of damages incurred by the New York State Medical Assistance Program (“Medicaid”) as a result of MedImmune’s kickback scheme with Trinity Homecare LLC pharmacy concerning MedImmune’s biggest moneymaking drug, Synagis. MedImmune is the sole manufacturer of Synagis, an expensive brand name injectable drug for infants for which there is no generic substitute.

3. As set forth below, to increase its sales of and profits from Synagis, through its kickback scheme with Trinity pharmacy (which was acquired by successor parent entities: Option Care Inc., and later Walgreen Co., collectively “Trinity”), and MedImmune’s causing of Trinity’s presentment of false claims to Medicaid for Synagis from January 2007 through March 2011 (the “relevant time period”), MedImmune violated New York State Medicaid regulations, 18 N.Y.C.R.R. §§ 515.2(b), and 518.1(c); the New York State False Claims Act, State Fin. Law § 189; and the New York State Anti-Kickback Statute, New York Social Services Law § 366-f and the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2).

4. MedImmune’s illegal kickback scheme with Trinity was based on a cynical and profitable arrangement, with several facets. In furtherance of its scheme, MedImmune provided

remuneration to Trinity by working aggressively with Trinity to penetrate hospital Neo-Natal Intensive Care Units (“NICU”) in predominantly in New York City public hospitals, and mine them for confidential patient information, and by providing other valuable information and assistance to Trinity to increase its Synagis sales paid for by Medicaid. Along with Trinity, MedImmune became generally known to hospital staff as the “Synagis people.”

5. By engaging in this conduct, MedImmune orchestrated an opportunity to increase its profit by elevating sales of its most profitable drug, Synagis, by improperly assisting Trinity in joint efforts to exploit the confidential identifying information of one of the State’s most vulnerable populations – formerly hospitalized infants insured by Medicaid.

6. Trinity dispenses and delivers drugs to patient homes, provides or arranges for homecare services, and does not service retail walk-in customers. During the relevant time period, Trinity presented claims for reimbursement for Synagis to the State’s Medicaid program. During this period, Synagis cost New York Medicaid, on average statewide, \$814.51 per 50mg vial and \$1910.32 per 100mg vial with some infants requiring more than one monthly vial. In fact, Trinity received as much as \$1,082 for a 50 mg vial of Synagis and \$2,041 for a 100 mg vial of Synagis.

7. MedImmune knew that Trinity predominately concentrated on a New York State Medicaid population for Synagis, and MedImmune sought an opportunity to profit. It increased its sales of Synagis through its illegal kickback scheme with Trinity, by having MedImmune employees work illegally with Trinity to cultivate Medicaid claims for Synagis.

8. Without having written business associate privacy agreements (“BAA”) with Trinity or such hospitals, and without parental consent, MedImmune obtained confidential personal information about specific babies from NICU logbooks and hospital records to obtain

birth certificate information for potential Synagis outpatient treatment. Medimmune then provided that information to Trinity to use as “leads” to obtain Synagis prescriptions Trinity could then dispense for these babies on an outpatient basis. Among other things, this information included: name, gender, date of birth, mother’s name, medical record number, gestational birth weight, address, insurance, phone number, and notes. MedImmune engaged in this conduct to identify babies both during the Synagis season and during the off-season. (The off-season concerned babies who had been discharged from NICUs principally between April and September.)

9. MedImmune also obtained referrals from licensed professionals who may or may not have continued to care for the babies and provided them to Trinity.

10. As to the baby leads and referrals MedImmune provided to Trinity, most of these infant patients had not been prescribed Synagis in the hospital nor were they discharged with a prescription for Synagis, or with prescriber instructions to obtain a Synagis prescription during the next applicable Synagis season.

11. MedImmune’s deceptive practices to assist Trinity also included MedImmune staff gathering additional personal information to provide to Trinity from other sources to help turn leads and referrals, outpatient babies, into Synagis customers. Thereafter, MedImmune assisted Trinity when a baby began receiving Synagis by improperly initiating communications, on Trinity’s behalf, with a specific prescriber’s office so that Trinity and, ultimately MedImmune, could profit from Synagis refills.

12. Principally, MedImmune’s illegal kickbacks to Trinity included: a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing

personnel assistance and protected health information (“PHI”) to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills. MedImmune engaged in this unlawful conduct for the purpose of increasing sales of Synagis, by working with Trinity to increase Synagis claims Trinity presented to Medicaid.

13. The practices identified above, and described in detail below, were conducted with the knowledge and approval of MedImmune management and employee supervisors. The information MedImmune shared with Trinity about babies who were insured by Medicaid, who were potential “customers” for Trinity, ultimately resulted in increased sales of Synagis for MedImmune, increased Medicaid proceeds to Trinity, and rebates paid by MedImmune to Trinity. The profits reaped by both MedImmune and Trinity were the intended result of the illegal kickback scheme, as were the illicit funds obtained from Medicaid reimbursements that resulted from the false and fraudulent claims that MedImmune caused Trinity to present to Medicaid.

14. Indeed, MedImmune’s Associate Director of Sales, Training, and Development and thereafter, Compliance Director of AstraZeneca North America 2007 through the relevant time period and thereafter (“Medi/AstraZeneca Compliance Director”) admitted that if MedImmune employees provide assistance to pharmacies by providing them with names of babies that could lead to the pharmacy obtaining prescriptions of Synagis for those babies, this would be conduct that could be considered added value or a kickback.

15. The State’s single damages resulting from the false and fraudulent claims MedImmune caused Trinity to present to Medicaid during the period January 2007 through March 2011, are currently assessed at over \$7.3 million dollars for more than 600 babies. These claims were false in a material respect. Had the State known these Synagis Medicaid claims

were the result of an illegal kickback arrangement between MedImmune and Trinity, the State would not have reimbursed Trinity for these claims.

16. By providing kickbacks to Trinity through several forms of remuneration, MedImmune knowingly caused the presentment of false Synagis claims for payment to the Medicaid program. Accordingly, MedImmune is also liable under the New York False Claims Act, N.Y. State Fin. Law §§ 187 - 190, for treble damages and penalties for these claims for reimbursement for Synagis, as discussed in detail below.

II. JURISDICTION AND VENUE

17. Eric T. Schneiderman is the Attorney General of the State of New York. He is authorized to recover three times the amount of damages sustained by the State on account of defendant's false and fraudulent claims and statements along with civil penalties of between \$6,000 and \$12,000 per violation pursuant to the New York State False Claims Act, N.Y. State Fin. Law §§ 189, 190(1), to recover treble damages for overpayments of public funds obtained by means of false statements or other fraudulent schemes, N.Y. Social Services Law § 145-b(2), to prosecute and institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1), and to seek restitution for repeated or persistent fraudulent or illegal business acts or practices, N.Y. Executive Law § 63(12).

18. This Court has subject matter jurisdiction to entertain the original action filed by Relator under 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action arises from the same transaction or occurrence as an action brought under 31 U.S.C. § 3730.

19. The Court has supplemental jurisdiction to entertain the state statutory, common law, and equitable causes of action pursuant to 28 U.S.C. § 1367(a). Federal district courts have

supplemental jurisdiction over state law claims that “are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy.” 28 U.S.C. § 1367(a).

20. This Court also has diversity jurisdiction pursuant to 28 U.S.C § 1332(c) because the matter in controversy exceeds the sum or value of \$75,000 and the parties are citizens of different states. There is complete diversity.

21. Further, jurisdiction in this Court is appropriate because this Court has overseen this action including, the \$22.4 million dollar settlement between the State and Trinity in July 2015. The Court should exercise its discretion to continue to oversee this matter, as district courts must balance the values of judicial economy, convenience, fairness, and comity.

22. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because MedImmune does business in this District and false or fraudulent acts occurred in this District.

III. PARTIES

A. Named Parties

23. Plaintiff, the State of New York, was and is at all relevant times to this action a sovereign state of the United States of America.

24. Defendant MedImmune is an American drug manufacturer and a wholly-owned subsidiary of AstraZeneca PLC (“AstraZeneca”), an international biopharmaceutical company which is headquartered in London, England. Defendant MedImmune is incorporated in Delaware and its principal place of business is located at 1 MedImmune Way in Gaithersburg, Maryland 20878. Defendant MedImmune does business throughout the United States, including in the Southern District of New York.

25. In 2006, Synagis accounted for approximately \$1.1 billion dollars of MedImmune's \$1.2 billion dollars in annual sales.

26. In April 2007, AstraZeneca announced its intentions to acquire MedImmune, and the acquisition was completed in June 2007.

B. Relevant Non-Parties

27. Non-party Trinity Homecare was a named defendant in the original action filed by the relator and is a limited liability company organized under the laws of New Jersey with its principal place of business located at 114-02 15th Avenue, College Point, New York 11356. Trinity became a wholly owned subsidiary of Walgreen Co. as part of Walgreen Co.'s acquisition of Option Care, Inc. in August 2007. (Prior to that acquisition, in March 2006, Option Care of New York Inc. entered into a purchase agreement to acquire Trinity. The transaction formally closed on June 4, 2007).

28. Trinity's Medicaid provider number is 01858951 and its National Provider Identifier number is 1518036458. Throughout the acquisitions, Option Care of New York Inc. and Walgreen Co. continued to present Medicaid claims under the name and provider number of Trinity.

29. Trinity operates a pharmacy specializing in dispensing expensive home delivered drugs, including Synagis during the relevant period.

30. Trinity also coordinates home care for Synagis patients. It also provides nursing and clinical support, infusion therapy, respiratory care, medical equipment and supplies. Trinity also operates a home health care service in New York. The majority of its revenues during the relevant period came from the State's reimbursement of its Medicaid claims.

31. For the majority of the relevant time period, 2007-2010, Trinity was the top Synagis Medicaid biller in the State and received over \$108 million dollars in reimbursement, for its Medicaid claims for Synagis compared to \$112.9 million dollars Medicaid paid to 58 other Medicaid pharmacy providers in the State during the same time frame. The closest competitor pharmacy dispensing Synagis to the Medicaid population only billed the State more than \$18.1 million dollars, during this same time period.

32. Relator Dr. Susan Vierczhalek (“Relator”) is a resident of the State of New York. She is a licensed pediatrician and, at all relevant times, served as the Director of the outpatient Newborn Nursery at Bellevue Hospital Center (“BHC”) in New York. At all relevant times, as part of her duties at BHC, Dr. Vierczhalek operated the “PINK Program,” a follow-up clinic for high-risk newborns and prescribed Synagis where appropriate. Many of the PINK Program patients had previously been hospitalized at BHC’s NICU.

33. Relator filed a complaint on behalf of herself, the United States, and several states on April 20, 2009, alleging violations of the federal and state False Claims Acts against MedImmune, Trinity and Option Care, Inc. related to Trinity’s Synagis Medicaid claims. Among other allegations, Relator alleged that Defendants and/or their agents caused false or fraudulent claims to be submitted to the government for Synagis. Relator also alleged that, “[i]n order to increase the number of patients it serves, Trinity obtained access to hospital logbooks or surreptitiously obtained patient records located in the NICU at Bellevue in violation of Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).” With such access, Trinity was then able to contact the parents of NICU patients, post-hospital discharge, in an effort to secure them as clients. The Relator’s claim against Trinity also related to the unauthorized use

of her name and medical license number, in the fall of 2008, on an alleged Synagis prescription Trinity dispensed for a baby she did not care for in the BHC outpatient clinic.

C. In July 2015, Trinity Entered into a Settlement with the State Regarding Synagis

34. In July 2015, following the State's investigation of Relator's allegations, Trinity agreed to pay the State \$22.4 million dollars in settlement of the State's and Relator's claims. The State's investigation determined that Trinity engaged in improper conduct and presented false Medicaid billings for the period 2007 through September 2011. The State further found and determined that Trinity lacked basic required documentation for certain of the Medicaid claims it presented, including proof that it had delivered Synagis to homes of Synagis Medicaid recipients.

35. The State's investigation also found and determined that Trinity used the names of certain New York prescribers on alleged Synagis prescriptions and on Medicaid claims without authorization, and thereby presented Medicaid claims for Synagis for babies even when no prescriber had determined that the baby qualified to receive the drug.

IV. THE LAW

A. New York's Prohibitions on Kickbacks

36. The State has an anti-kickback statute, regulations, and requirements that apply to its Medicaid program. Compliance with these statutes, regulations, and requirements are conditions of payment under the State Medicaid program, and the State will not knowingly pay for Medicaid claims tainted by kickbacks. These statutes, regulations, and requirements include: New York, 18 N.Y.C.R.R. § 515.2(b), § 518.1(c), Soc. Serv. Law § 366-f, and the N.Y.S. Medicaid Provider Manual, Information for All Providers – General Policy. Further,

reimbursement by the government is only made when providers execute a Medicaid claims Certification Statement as to the propriety of their claims and compliance with law.

37. MedImmune violated the law by engaging in the kickback scheme with Trinity and by knowingly causing Trinity to present false claims for reimbursement to Medicaid, which rendered Trinity's Certification Statements, described herein, false.

B. The New York State False Claims Act

38. The New York State False Claims Act, State Fin. Law §§ 187-194, is modeled on the federal False Claims Act, 31, U.S.C. §§ 3729-33.

39. The New York False Claims Act provides that any person who:

- a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
- b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
- c) conspires to commit a violation of [paragraphs (a) or (b)] of this subdivision;

* * *

shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

N.Y. State Fin. Law § 189(1).

40. "Knowing and knowingly"

(a) means that with respect to information, a person:

- (i) has actual knowledge of the information;
- (ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(b) require no proof of specific intent to defraud, provided, however that acts occurring by mistake or as a result of mere negligence are not covered by this article.

N.Y. State Fin. Law § 188(3).

41. Under the New York False Claims Act, a "claim":

(a) means any request or demand, whether under a contract or otherwise, for money or property that:

(i) is presented to an officer, employee or agent of the state or a local government; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state or a local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded; or (B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

N.Y. State Fin. Law § 188(1).

42. "Material" means:

Having a natural tendency to influence, or be capable of influencing the payment or receipt of money or property.

N.Y. State Fin. Law § 188(5).

43. The State also has statutes that allow it to recover monies for goods or services that were tainted by kickbacks, as stated below.

C. The New York State Anti-Kickback Statute

44. The New York State Anti-Kickback Statute provides, in pertinent part, that:

No person acting in concert with a medical assistance provider shall, with intent to defraud:

(a) solicit, receive, accept or agree to receive or accept any payment or other consideration in any form from another person to the extent such payment or other consideration is given (i) for the referral of services for which payment is made under this title or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under this title; or

(b) offer, agree to give or give any payment or other consideration in any form to another person to the extent such payment or other consideration is given (i) for the referral of services for which payment is made under this title; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under this title;

New York Social Services Law § 366-f

45. Violation of the New York Anti-Kickback Statute can subject the perpetrator to criminal prosecution, fines of between \$500 and \$10,000, and, if the perpetrator has obtained money or property through the violation, a fine not to exceed double the amount of the gain from the violation. N.Y. Social Services Law § 366-d(3)(c).

D. New York Social Services Law § 145-b

46. N.Y. Social Services Law § 145-b(1)(a) provides, in pertinent part, that:

It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

47. “Statement or representation,” as used within Social Services Law 145-b(1)(a) includes, but is not limited to, a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the qualifications of a person that is or has rendered health care services. N.Y. Social Services Law § 145-b(1)(b).

E. New York Executive Law § 63(12)

48. New York Executive Law § 63(12) provides, in pertinent part, that:

Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages

F. New York Executive Law § 63-c

49. New York Executive Law § 63-c(1) provides, in relevant part, that:

Where any money, funds, credits, or other property, held or owned by the state, or held or owned officially or otherwise for or in behalf of a governmental or other public interest, . . . has heretofore been . . . without right obtained . . . an action to recover the same, or to recover damages or other compensation for so obtaining . . . of the same, or both, may be maintained by the state in any court of the state, or before any court or tribunal of the United States, or of any other state, or of any territory of the United States, or of any foreign country, having jurisdiction. . . .

G. The Medicaid Program – Federal Participation

50. Medicaid is a joint federal-state program that provides health care benefits for certain vulnerable populations, primarily the poor and disabled. The federal involvement in Medicaid includes providing matching federal funds and ensuring that states comply with minimum standards in the administration of the program.

51. The federal Medicaid statute sets the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. § 1396, *et seq.*

52. At all times relevant hereto, the United States provided funds to New York State for its Medicaid program, which is administered by the New York State Department of Health. The State pays its fee-for-service health care providers, including pharmacies and physicians, according to established rates, and the federal government then pays a statutorily established

share of "the total amount expended . . . as medical assistance under the State plan." See 42 U.S.C. §§ 1396b(a)(1).

H. The Federal Anti-Kickback Statute

53. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect patients and federal healthcare programs, including Medicare and Medicaid, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

54. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the Federal False Claims Act]."

55. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

56. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federally funded health care programs, including the Medicaid program of the State of New York. Thus, the State will not pay for Medicaid claims tainted by kickbacks.

57. Violation of the AKS is a felony punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

I. New York State Medicaid Regulations and Requirements

58. New York's Medicaid program covers prescription medications for its beneficiaries. 18 N.Y.C.R.R. § 505.3. Prescription medications, including Synagis, are dispensed and provided to Medicaid recipients by pharmacies pursuant to a written or verbal prescription ordered by a physician or other licensed healthcare professional authorized to prescribe medications in New York State. Pharmacies dispense the prescription and for non-managed care enrolled patients, present fee-for-service claims to Medicaid, and are reimbursed for the prescription medications assuming receipt by the patient. Pharmacies are required to maintain documentation that the patient either picks up or receives delivery of the medication.

59. Before presenting claims for payment to the New York State Medicaid program, whether in paper or electronic form, enrolled fee-for-service providers, including physicians and pharmacies, such as Trinity, are required to first execute before a Notary a Certification Statement for Provider Billing Medicaid (hereinafter, "Certification Statement"). See New York State EMedNY Billing Guidelines-Pharmacy, Versions 2007-01 - 2011-01, at p. 5. In the Certification Statement, the provider certifies that, for all claims submitted to Medicaid, "I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

60. Trinity was an enrolled Medicaid provider. Medicaid regulations require that “[a]ny person who furnishes medical care, services or supplies for which payments under the [Medicaid] program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care or supplies.” 18 NYCRR § 504.1(b)(1).

61. Trinity executed such Certification Statements during the relevant period and provided these documents to the State.

62. As a condition of enrollment and as a condition of payment of claims presented to Medicaid, providers must affirmatively certify, compliance with applicable federal and state laws and regulations.

63. A provider must renew the Certification Statement, periodically by signing a new Certification Statement. The Certification Statement last signed by the provider remains in effect for all claims until a new Certification Statement is signed by the provider.

64. Since in or about 2007, the Certification Statement requirement has applied to all claims presented to Medicaid, whether submitted electronically or on paper. Prior to 2007, for paper claims the provider’s certification statement was included on the paper claim form submitted to Medicaid, and the provider certified that the care, services or supplies listed on the claim form were “furnished in accordance with applicable Federal and State laws and regulations” when submitting the claim form for payment.

65. 18 N.Y.C.R.R. § 515.2(b) specifically prohibits as an “unacceptable practice”:

(5) Bribes and Kickbacks . . .

(ii) soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program;

* * *

(iv) offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program

* * *

66. 18 N.Y.C.R.R. § 515.2(a) also specifically prohibits as an “unacceptable practice” conduct that is contrary to:

(3) the official rules and regulations of the Departments of Health, Education and Mental Hygiene, including the latter department’s offices and division, relating to standards for medical care and services under the [Medicaid] program; or

(4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.

67. Pursuant to 18 N.Y.C.R.R. § 518.1(c) “overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake.”

68. Title 18 provides further that “[n]o payments will be made to or on behalf of any person for the medical care, services or supplies furnished . . . in violation of any condition of participation in the program,” nor will payments be made for “for any medical care, services or supplies ordered or prescribed in violation of any condition of participation in the program.” 18 N.Y.C.R.R. § 515.5(a), (b). Accordingly, all claims for payment to Medicaid resulting from kickbacks are in violation of a material condition of payment of the New York State Medicaid Program.

V. FACTUAL ALLEGATIONS

A. Indicated Use of Synagis

69. Synagis was approved by the FDA in 1998, “for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤ 35 weeks gestational age), and children with hemodynamically significant heart disease (CHD).” (Synagis label)

70. The American Academy of Pediatrics (“AAP”) provides guidance as to risk factors, in addition to premature birth, that make a baby a candidate for Synagis. Premature birth, in and of itself, is not the sole criterion for prescribing Synagis. Further, the New York State Department of Health (“NYSDOH”) issued general guidelines for identifying infants and children who should be considered for RSV prophylaxis in State Medicaid Updates. The Medicaid program relies on its Medicaid updates to reimburse providers.

71. Synagis is a refrigerated, weight-based, injectable drug the MedImmune manufactures in 50mg and 100mg vials. The amount of Synagis to be dispensed and administered is based on the baby’s weight, properly determined right before injection, based on a formula - 15mg of Synagis per kilogram of patient weight. Depending on the baby’s weight, some babies require less than the amount contained in a vial, while other babies might require injections of two or more vials per month during Synagis season in varying sizes. Synagis is administered once a month during certain months of the year when RSV is most prevalent, the so-called Synagis season.

72. Prior to Synagis administration, the baby is weighed so that only the amount from a 50mg or 100mg vial that corresponds to the baby’s weight, based on the formula, is

administered. Synagis vials may be used only once. Thus, if excess quantity remains in the vial after the proper dosage is removed for administration, the excess must be discarded. It is wasteful to present claims to the Medicaid program for more vials or a larger size vial than needed.

B. Medicaid Reimbursement for Synagis

73. New York's Medicaid program reimburses pharmacies for certain prescription drugs dispensed to Medicaid beneficiaries. For a pharmacy to be paid for dispensing a prescription drug to a Medicaid recipient, the pharmacy must be enrolled in Medicaid and must present a claim for payment. New York's Medicaid program reimbursed Trinity for its claims relating to Synagis.

74. During the period, January 2007 through March 2011, Medicaid's reimbursement costs per Synagis vial increased. For a 50mg vial, Trinity presented Medicaid claims to the State and received in the range of \$771 to \$1,082 per vial. For a 100mg vial, reimbursement was in the range of \$1,423 to \$2,041 per vial.

75. Medicaid reimbursed Trinity at least \$7.3 million dollars for false claims which MedImmune knowingly caused Trinity to present, due to its illegal conduct. The State expects this amount will increase as discovery is taken of MedImmune employees and management. However, certain evidence will not be uncovered due to Medimmune's failure to uniformly require retention of documents during the relevant period and an April 2011 MedImmune document destruction directive concerning PHI about babies that MedImmune sales representatives and management may have possessed..

C. How Trinity Obtained Its Synagis Business

76. Trinity was required to have a valid prescription for Synagis before dispensing the drug and presenting claims for reimbursement to Medicaid. Thereafter, the need for a monthly refill during Synagis season had to be confirmed by a pharmacy. Prescriptions for Synagis were required to be written on a valid prescription form or properly documented by Trinity for a telephone order from a prescriber.

77. RSV is often treated with five doses of Synagis and a prescription might allow for five refills. However, the pharmacy was not permitted to automatically dispense the drug and present claims to Medicaid for refills. Rather, the pharmacy had to contact either a parent and/or a physician to determine whether the next dose was needed, the baby still resided at its current address, and further, the baby's weight was required to be known at the time of dispensing the drug, as Synagis is a weight-based drug.

78. With regard to written prescriptions, beginning in April 2006 in New York State, with certain hospital exemptions, a written prescription was only valid if it was written on an official serialized prescription form. Additionally, as of April 1, 2008, under federal law, paper prescriptions were required to be on a tamper resistant proof prescription form. Therefore, for Synagis to be dispensed legally, a valid written prescription on a serialized, tamper resistant proof prescription form or documented verbal order, as indicated below, had to be obtained from a prescriber.

79. In New York, verbal order prescriptions can also be accepted by a pharmacy from a prescriber. The pharmacy is required to contemporaneously document all necessary information about verbal orders including the identity of the person providing the order, the time and date of the call, the initials of the person taking the call and the dispenser, prior to dispensing the drug.

80. Trinity also obtained Synagis prescriptions by using information it received about babies who might be candidates for Synagis pursuant to its receipt of a referral form. The referral form was not a legal substitute for a valid New York State written prescription or verbal order. The form was known under various names, including as the “Trinity Homecare Referral Form Statement of Medical Necessity for RSV Prophylaxis,” the “NICU Prophylaxis Assessment Form”, the “Hospital RSV Patient Assessment Form” and informally, as the “4 Part Form”. (The “Referral Form” or the “4 Part Form”). The Referral Form was supposed to be completed by a prescriber or the prescriber’s staff. The form included information about the baby and parent/guardian, referral information and clinical information as to the baby’s birth and current weight, medical conditions and risk factors. The Referral Form was also supposed to include information as to whether the baby had received a dose of Synagis. (A sample Referral Form is attached as Exhibit A).

81. Trinity also increased its Synagis business by presenting claims to Medicaid which resulted from MedImmune’s illegal assistance. This included: a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and PHI to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills.

82. MedImmune’s primary New York Area Business Manager, (“Medi Manager 1”), knew that his staff sometimes secured information for the Referral Forms and provided that information, acting as a “conduit for the information to flow to a pharmacy”.

D. MedImmune’s New York Biotech Sales Specialists & Clinical Marketing Managers Engaged in Illegal Conduct

83. MedImmune had a network of employee sales representatives who promoted Synagis. Initially, MedImmune Biotech Sales Specialists (“BSS”) were responsible for sales of Synagis, primarily for patients who had previously been in New York hospital NICUs. Later, the position of BSS was adjusted at MedImmune and Clinical Marketing Managers (“CMM”) assumed their job responsibilities. MedImmune CMMs were senior to BSSs, and were responsible for promoting Synagis to out-patient prescribers, as well as to physicians in hospitals.

84. CMM responsibilities included serving as hospital sales specialists and disease state/product experts of area sales teams. CMMs could educate providers and their office staff about the Synagis referral process, which included, trouble-shooting a particular case, when asked and where appropriate. The decision as to whether an individual baby should be identified as a candidate for Synagis, whether any risk factors were present and issues of medical necessity, was always to be made by the prescriber alone. However, MedImmune knew that at least one CMM identified babies as candidates for Synagis and then communicated this information to Trinity or to certain potential prescribers who he then encouraged to provide Synagis prescriptions to Trinity.

85. As alleged herein, MedImmune CMMs, who were compensated and incentivized by meeting sales goals, engaged in improper conduct that included: a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and PHI to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills. This conduct benefited MedImmune; it profited from greater Medicaid sales of Synagis and its employees received additional compensation based upon sales for their regions.

E. MedImmune Knew Trinity Controlled New York's Synagis Market

86. At all times relevant to the Complaint, MedImmune was acutely aware of Trinity's New York Synagis market coverage and its aggressive efforts to market Synagis. Trinity was the principal pharmacy dispensing Synagis on an outpatient basis to New York State Medicaid infant recipients, primarily within the five boroughs of New York City.

87. Both MedImmune and Trinity viewed Trinity as a pharmacy that would "accept a referral on the back of a napkin" for Synagis.

88. On October 4, 2006, MedImmune CMM 1 ("CMM 1"), e-mailed a MedImmune Executive Manager of National Accounts ("Medi Manager 2") and several other MedImmune employees, including Medi Manager 1, CMM 1's Area Business Manager, and explained that, "Trinity is a small pharmacy who handles approximately 80% of [Synagis] business" in Brooklyn, the Bronx, and Manhattan. He explained that Trinity's strength was in "getting a little information and then digging to find the rest. [MedImmune] need[s] [its] nationals to have a fraction of that ambition. They need to understand that the info. that gets triaged is all Trinity had in the first place."

89. During the relevant period, MedImmune management remained aware that Trinity controlled the Medicaid business for Synagis in New York. This is evidenced by an email, dated March 31, 2009, forwarded from MedImmune Regional Account Manager, ("Medi Manager 3") to MedImmune Vice President of Managed Care Markets, ("Medi Manager 4") titled, "NY Medicaid data". Attached to the email is a MedImmune authored slide deck titled, "New York Medicaid PA Analysis." wherein MedImmune acknowledged that "[c]urrently Walgreens/Option Care [formerly Trinity] has 64% of the NY Medicaid business; There are only 2 other

distributors with >10%: Regioncare (12.3%) and Omnicare (10.5%)”. (New York Medicaid PA Analysis p. 11/34) (This information reflects data from the 2008-2009 Synagis season).

VI. THE SYNAGIS KICKBACK SCHEME

A. MedImmune Provided Remuneration to Trinity in Various Ways for Participating In the Illegal Synagis Scheme

90. Remuneration provided by MedImmune to Trinity was the basis for an improper business relationship between MedImmune and Trinity, a lucrative kickback scheme that benefited both the drug manufacturer and the pharmacy. The monies received by both entities were illicit funds obtained from Medicaid reimbursements to Trinity from claims that MedImmune knowingly caused Trinity to present.

91. Specifically, MedImmune provided remuneration to Trinity in the following forms: a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and PHI to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills.

92. Among other things, by selectively providing baby lead and referral information to Trinity, MedImmune supplied Trinity with a thing of value, a kickback. Because MedImmune provided this remuneration to Trinity, to induce referrals of Synagis, the parties violated the anti-kickback statutes. In fact, MedImmune supplied more than 1250 baby leads and/or referrals, during the relevant time period, to Trinity that resulted in millions of dollars in Synagis Medicaid claims that MedImmune caused to be presented.

93. MedImmune sought an opportunity to make a profit on Synagis by assisting Trinity in its aggressive baby lead and referral identification practices in hospital NICUs.

94. As stated above, MedImmune was aware of Trinity's relationships with NICU prescribers and Trinity's access to NICU logbooks and information contained therein. MedImmune schemed to expedite and expand Trinity's purchases of Synagis resulting in MedImmune selling more Synagis paid for with public funds. MedImmune's conduct included assisting Trinity in acquiring names of potential Synagis customers as leads for Trinity to pursue to try to obtain a New York State prescription for a future outpatient Synagis dose(s). Leads initially required follow-up on missing personal and demographic information which required contact with the baby's future pediatrician, upon discharge from the NICU, prior to the next Synagis season and ultimately a prescription of 50mg and/or 100mg that was based on the baby's weight. Sometimes, MedImmune also tried to obtain lead information and prescriptions from NICU prescribers for former NICU patients even if they had no current relationship with the baby.

95. Walgreen's corporate Synagis Coordinator stated that, "Most of the "referrals" that come from the NICU aren't true referrals. They are more like leads."

96. MedImmune's primary objective in acquiring leads and referrals, and providing them to Trinity was to turn those leads and referrals into Trinity customers for outpatient Synagis prescriptions. Trinity could then present claims for reimbursement, largely to the Medicaid program.

i. MedImmune Infiltrated New York Hospital NICUs, Obtained, and Provided Patient Leads to Trinity from NICU Logbooks

97. At all times relevant to the Complaint, as part of the scheme to increase outpatient Synagis sales, MedImmune worked as Trinity's agent obtaining leads and referrals for potential outpatients from hospital NICU logbooks and/or staff to provide to Trinity.

98. Millions of dollars of the outpatient Medicaid Synagis business that Trinity obtained through referrals and leads from hospital records was obtained with the assistance of MedImmune employees. MedImmune employees often worked with Trinity employees, and/or on their own infiltrated New York hospital NICUs, without MedImmune having any BAAs with these hospitals and parental consent to obtain PHI of former or current NICU babies to provide for Trinity's use.

99. MedImmune then compiled information including from NICU logbooks and from hospital staff to give to Trinity lists of baby names and demographic information, which were things of value, to both MedImmune and Trinity. MedImmune went to great lengths to try to obtain missing personal and demographic information for these potential Trinity Synagis customers. This information was collected and transmitted by MedImmune and sent to Trinity for further efforts to try to obtain prescriptions. Trinity then dispensed the drug, purportedly had proof of a prescription and delivery, and presented claims to Medicaid for reimbursement which MedImmune caused to be presented. MedImmune's kickbacks to Trinity made these claims false and fraudulent.

100. There were also times that MedImmune went to hospital NICUs to capture leads and referrals to assist Trinity because Trinity employees were too busy visiting other hospital NICUs to try to obtain outpatient Synagis business.

101. Medi Manager 1 knew that certain members of his sales team took information from NICU logbooks including taking "down patient names for every baby born 35 weeks or less gestational age." MedImmune would "then convey the information over to a pharmacy, and in most cases it was Trinity because Trinity had a lion's share of NICU coverage in the area."

102. MedImmune memorialized a component of its plan to assist Trinity in obtaining additional Synagis business in a February 8, 2007 email in which a MedImmune BSS, (“BSS 1”), summarized to her supervisor, Medi Manger 1, and colleagues including CMM 1. The email titled, “Notes from Biz Unit Meeting,” states, “Here are the notes that I took on Tuesday regarding our plan of action for the remainder of the season: We have two goals at this point 1) Recover lost patients 2) Activate new patients... Breaking it down into hospitals... The next step is confirming these numbers with Trinity. [CMM 1] is going to try to obtain the lists from Trinity and give them to us. We are hopefully going to get the lists/referrals from all hospitals because there may be some overlapping between territories. Once we have this information we are going to do the following: Take referrals to WIC coordinators to see if we can locate babies[,] [a]ppeal to them on clinical grounds[,] [m]aybe take [] with us...”

103. Soon after, on February 12, 2007, CMM 1 followed-up and wrote an email titled, “Lists of Inactives” to Trinity’s former RSV Program Manager/Account Executive and later the Director of Business Development (“Trinity’s Synagis Director”), referencing babies for whom Trinity was not dispensing Synagis. The email states, “I wanted to send you a reminder that we need to get those lists together. You have told me it’s easy and I believe you. So please, pretty please with sugar on top, could you please bring the lists for SUNY, Kings, Brookdale, Wyckoff, and Woodhull. I will have B.A. agreements in tow with me this week. And if you are still uncomfortable with me handling this info I will gladly escort you to any and all facilities to get these in the right hands. If you do not think this is a worthy pursuit please tell me and just let me then run with the info. This as well as April dosing are of my top priorities right now. This would mean a lot to me.”

104. In an email dated July 2, 2007, MedImmune CMM 1 wrote to a New York hospital NICU physician describing his collaboration with Trinity and his typical process for gathering Synagis leads at a NICU. This included, “making contact with the [baby’s] family to verify all info. as well as send them educational/premium items i.e. soap in order to prevent the spread of RSV, preemie magazine. Trinity then makes regular follow up calls/mailers until the season begins. The real motivation behind this program is simple. Medicaid patients tend to have inconsistent living conditions as you know. Typically, [Trinity’s Synagis Director] will receive a list from a NICU in August and several patients (about 50%) will have non working/disconnected phone numbers, wrong address, different names etc. and unfortunately, go without therapy. *Our efforts are geared toward contacting these patients before these changes take place. All of that being said, I was hoping we could meet at the hospital and go through the log book. I’m happy to sit (out of everyone’s way) and compile the data myself as I do in many other hospitals...*” (Emphasis added).

105. Significantly, CMM 1 would take baby names from the logbooks, transfer the information to spreadsheets, and then send that information to Trinity for follow-up.

106. Trinity’s Synagis Director received these lists of leads on spreadsheets from CMM 1. Using the information on the spreadsheets, Trinity’s Synagis Director and Trinity employees contacted the babies’ families and prescribers to try to obtain Synagis prescriptions for those babies. Trinity’s Synagis Director sometimes accompanied CMM 1 to hospital NICUs and observed him writing down names of babies who were possible candidates for Synagis, in order to assist Trinity in trying to increase its Medicaid Synagis sales.

107. During the relevant time period, CMM 1 sent Trinity lists of baby leads or referrals he obtained who had been patients in the following non-exhaustive list of New York

hospitals: Brookdale Hospital, Coney Island Hospital, Jamaica Hospital Medical Center, Kings County Hospital, The Brooklyn Hospital Center, Woodhull Medical Center, New York Methodist Hospital, SUNY Downstate Medical Center, and Long Island College Hospital - SUNY Downstate to Trinity. Many of these leads and referrals resulted in Synagis Medicaid claims by Trinity.

108. For example, on July 16, 2008, CMM 1 sent an email to Trinity's Synagis Director and cc'd ("Trinity's Synagis Coordinator") titled, "New Tracking and New Contact Info. (Coney Island, LICH, Woodhull, Kings, SUNY)." The email stated, "Hey guys, here are some attachments with new tracking and the other is updated info from SUNY and Kings. [Trinity Synagis Director], could you go ahead and send me the new Kings tracking when you have a moment? And I counted about 12-14 patients from our last round at Methodist. Can you verify that number? Oh, and the updates are in yellow when you scroll to the left. Let me know if you have any questions. Thanks! [CMM 1]." The information provided by MedImmune and sent to Trinity included: baby name, date of birth, gender, record number, name of hospital baby was treated in, guardian/parent names, addresses and telephone contact information.

109. MedImmune continued this process on August 14, 2008. CMM 1 emailed Trinity's Synagis Coordinator and cc'd Trinity's Synagis Director attaching names of patients from SUNY Downstate and Kings County Hospital ("KCH") and asked them to check, "that I picked up where [Trinity's Synagis Director] left off at Kings." This referenced CMM 1 retrieving names of babies from the KCH NICU logbook.

110. Similarly, in an email dated August 17, 2008, titled, "new Jamaica," CMM 1 sent to Trinity's Synagis Coordinator and cc'd Trinity's Synagis Director; he attached a spreadsheet containing baby names he obtained from Jamaica Hospital NICU tracking, which he sent to

Trinity for follow-up. The email stated, “Here are the new Jamaica patients I tracked on Friday. Talk soon!”

111. MedImmune could have stopped the above conduct from occurring if it had enforced its instruction that its employees were not to transmit or receive PHI through email or had otherwise monitored whether its employees were doing so.

112. MedImmune also encouraged the sharing of leads with Trinity. A document prepared for a meeting between MedImmune and Trinity titled, “MedImmune/Trinity Partnership Meeting Monday April 23, 2007 College Point, NY,” discussed, “Daily Email Reports... Referrals/Leads” and further referenced the following, “Patient Identification Program (Tracking)...Share all referral data.”

113. In May 2007, MedImmune and Trinity were scheduled to meet at Trinity’s College Point Office to discuss, among other topics, early referrals. A MedImmune document, authored by Medi Manager 1, referenced a “Trinity SDN Partnership Meeting for May 30, 2007. “Points for Discussion” included, “Early Referrals” including “Excel Spreadsheets ([CMM 1]) and Excel Spreadsheet Data Merge with Referral Forms...” Further, Compliance/Communication included, “Timely Information Share with MedImmune Sales Personnel”.

114. In September 2008, CMM 1 sought to assist Trinity by inputting baby lead and referral information and data merging onto Trinity’s referral form, as previously referenced above.

115. On September 13, 2008, CMM 1 wrote an email to Trinity’s Synagis Director titled, “New Methodist and LICH patients.” The email also contained a request. CMM 1 asked, “...Could you send me a copy of the Trinity form as a word document so I can mail merge them

and send you spreadsheets as well as the spreadsheets? I am doing a ton of tracking next week and I hope the mail merge thing could make things easier for you...”

116. On September 17, 2008, Trinity’s Synagis Director emailed CMM 1 “The internal NICU Trinity referral form.” Trinity’s Synagis Director emailed the July 2007 version which, as attached in paragraph 78 herein, required information as to the identity of the referral/physician information and the identity and phone number of the person who made the referral.

117. Later, that same day, September 17, 2008, CMM 1 stated in an email to Trinity’s Synagis Director, “I can mail merge onto Trinity’s form but doesn’t save so I’ll be happy to walk you through it.”

118. In MedImmune’s, *Synagis Referral Process: Provider Level Do’s & Don’ts*, MedImmune compliance knew that it was a “don’t” to “complete any portion of the referral form as this is the provider’s responsibility.” (Also previously alleged herein , Medi Manager 1 knew that his staff sometimes secured information for the Referral Forms and provided that information, acting as a “conduit for the information to flow to a pharmacy”).

119. Medi/AstraZeneca’s Compliance Director admitted that if MedImmune employees provide assistance to pharmacies by providing them with names of babies that could lead to the pharmacy obtaining prescriptions of Synagis for those babies, this would be conduct that could be considered added value or a kickback.

120. MedImmune’s provision of leads and its other improper assistance resulted in millions of dollars of Synagis Medicaid claims presented by Trinity, at times even when Trinity had no prescription. This conduct yielded additional Medicaid revenue for Trinity, the payment of rebates by MedImmune to Trinity’s parent entities, and increased sales of Synagis for MedImmune paid for with public funds.

ii. MedImmune Obtained and Provided Leads and/or Referrals to Trinity from Licensed Medical Professionals

121. CMM 1 frequently exchanged emails with NICU staff containing names and information about babies who did not have Synagis prescriptions and then provided information about the babies to Trinity, including in spreadsheet format. Some examples follow.

122. In the fall of 2006, CMM 1 sent a spreadsheet to Trinity's Synagis Director with names of babies who were leads, who CMM 1 claimed had been obtained from a physician at LICH (Long Island College Hospital). Trinity then modified that spreadsheet.

123. On September 4, 2007, CMM 1 sent an email titled, "Synagis Patients," with an attachment to a physician's assistant at KCH ("KCH PA"). The email stated, "Attached are all of the patients I pulled from the [KCH] NICU logs today..." The attachment contained a list of 54 leads that CMM 1 provided to the KCH PA, seeking updated information and approval for prescriptions of Synagis for these leads. No prescriptions accompanied the email, but many of the names on the list resulted in claims presented by Trinity to the Medicaid program.

124. On September 8, 2007, that same KCH PA emailed CMM 1, "Synagis Update, September Part 2," which contained updated information. CMM 1 forwarded this information to Trinity for follow-up for Trinity to try to obtain prescriptions for Synagis for these leads. Many of the names on the list resulted in claims presented by Trinity to the Medicaid program, for which Trinity received reimbursement from Medicaid.

125. Also, on at least one occasion, CMM 1 met with a prescriber at Queens Hospital Center who provided him "with names and other personal information concerning babies," which CMM 1 then provided to Trinity's Synagis Director Trinity's Synagis Director. Other Trinity personnel then used this information to try to contact families of the babies and their current physicians in an effort to obtain Synagis prescriptions for them.

126. An example of another MedImmune employee obtaining PHI and referrals and providing that information to Trinity occurred at a diner in the Bronx. MedImmune CMM 2 met with Trinity's Synagis Director in a diner, during the relevant period, and provided her with information about babies he obtained from Bronx Lebanon Hospital.

127. At the diner, CMM 2 provided Trinity's Synagis Director with referral forms for babies who might be eligible for Synagis and/or a list of potential referrals from the Bronx Lebanon Hospital NICU. This information included PHI about the babies. Trinity's Synagis Director then provided this information to other Trinity personnel to contact the babies' families. Trinity had not received Synagis prescriptions for any of these babies and was hoping that the families of these babies would inform Trinity of the names of the babies' physicians so that Trinity could try to obtain prescriptions for Synagis.

128. MedImmune also engaged in specifically providing Synagis leads and referrals to Trinity despite the fact that in 2008, MedImmune established what was known as the RSV Connection, an allegedly independent referral source or clearinghouse for prescribers, with the purported intention of directing these referrals to indiscriminate pharmacies enrolled in the network. However, by sending leads and referrals directly to Trinity, MedImmune employees circumvented the RSV Connection, and confirmed the intrinsic financial value of the confidential infant PHI that MedImmune was regularly providing to Trinity.

129. Upon receiving leads from MedImmune and others, Trinity typically sent form letters to potential prescribers suggesting that a baby qualified for Synagis without disclosing that in some cases, an unlicensed medical professional, a MedImmune employee, had identified information about a baby and provided that information to Trinity or had determined to give referrals from providers without prescriptions selectively to Trinity. MedImmune's NICU

tracking and providing names and PHI to Trinity knowingly caused the presentment of false claims to Medicaid, which resulted in increased sales of Synagis ultimately paid for from public funds to MedImmune.

130. MedImmune management, including Medi/AstaZeneca's Compliance Director, knew that MedImmune should not have been providing PHI to a pharmacy even if the parent/guardian "of these vulnerable babies would sign off and say, we agree that Medimmune may take our child's name... along with where we will be taking them for their pediatric visit, and hand it [the 4 Part form] from the NICU provider to the next caregiver." This handing over of the form was for "the sole purpose... so the pediatrician could do his or her self-evaluation of whether this baby was a candidate for Synagis or not." Medi/AstraZeneca's Compliance Director admitted that, under the circumstances, it would be improper for a MedImmune employee to assist a pharmacy by providing it with the names of patient baby leads that it obtained at a NICU. Further, "the next caregiver" was not supposed to be a pharmacy without a prescription.

131. In any event, MedImmune failed to produce or otherwise identify any 4 Part Forms, in response to the New York State Attorney General's subpoena, any 4 Part Forms containing parental consent for any of the babies for whom MedImmune assisted in arranging for services, or other types of remuneration MedImmune provided to Trinity to increase Synagis sales for which Trinity presented Medicaid claims for.

iii. MedImmune Provided Personnel Assistance and PHI to Increase Its Sales of Synagis

132. MedImmune also provided other illegal assistance to Trinity by way of joint MedImmune/Trinity presentations to NICUs in various hospitals in New York City. The "Synagis People", promoted their pre-outpatient prescription collaboration. For example, CMM

1 and Trinity's Synagis Director gave a joint presentation titled, "Kings County Synagis Program, 2007-2008 RSV Season" to the Kings County Hospital NICU. Their joint document included information under the heading, "Communication/Data Management" that states, "Unable to Locate, Trinity/MedImmune will communicate with Kings NICU." Vague as to any separation of roles between the drug manufacturer and the pharmacy, the "Synagis People" would then follow-up with NICU staff and potential prescribers to obtain babies' missing personal and demographic information and leads to try to obtain Synagis prescriptions.

133. Medi Manager 1 was aware of occasions when MedImmune helped collect additional information about the baby that would allow the pharmacy to contact the patient. And, Medi Manager 5 knew that a MedImmune representative should not be working in conjunction with a pharmacy representative to obtain a lead and/or a referral for a prescription. "Such conduct should not occur."

134. A Trinity employee described MedImmune's assistance in trying to obtain Synagis prescriptions for Trinity as, "[y]ou let them [MedImmune,] know who the baby is. Who the doctor is. Then they go in and I guess talk to the doctor and let them know why Trinity is trying to reach them."

135. In pursuit of an opportunity for MedImmune to profit, CMM 1 went so far as to improperly gather PHI by going to hospital birth certificate offices to obtain current phone numbers and addresses of babies that CMM 1 then provided to Trinity. Medi Manager 1 knew that CMM 1 was doing this to turn leads into referrals. He would "use the birth certificate office as a vehicle to get current phone numbers and home address and feed that information back to Trinity for them to contact the parent."

136. Medi/Astra Zeneca's Compliance Director admitted, "Our employees should never have had access to [birth certificate information or records]." As a result of such fishing expeditions, Trinity could contact the parents/guardians of those babies or have the parents/guardians contact physicians to try to turn MedImmune leads into Synagis prescriptions.

137. MedImmune provided other personnel assistance to Trinity, some of which was documented in Trinity's CPR and clinical notes, internal electronic record keeping systems implemented by Trinity to maintain data including that of potential Synagis customers as well as Trinity's active Synagis customers. These notes documented that MedImmune employees provided information to Trinity about a baby's medical eligibility regarding recent and future dosing for current Synagis customers, as well as providing Medicaid ID numbers, dates of birth, and addresses. This was done so that Trinity could allegedly dispense Synagis to babies and present claims to Medicaid.

138. For example, the following notes represent how MedImmune provided remuneration to Trinity via personnel assistance:

1) 03/21/07, "As per [BSS 1] from MedImmune, Mom has re-applied for caid + should have card shortly; will meds ASAP". To be billed as caid pending as MD needs meds". (Baby 76 on Exhibit C1).

2) 08/17/07, "Confirmed all info w/aunt (mom does not speak English); she will c/m/b w/caid #'s and name of PCP (new info. given to me by [CMM1])". (Baby 85 on Exhibit C2). 3) 02/19/08, "Rec'd caid # for twins from [BSS 2] at MedImmune 03/13/08, As per [BSS 2] at MedImmune, baby was dosed 02/23/08 (WT=9lbs)". (Baby 42 on Exhibit C1).

4) 04/14/09, "Rec'd new caid # from [BSS 3] (MedImmune)." (Baby 328 on Exhibit C1).

139. Certain notes demonstrate that MedImmune provided personal information to Trinity about babies who had already received Synagis injections on an outpatient basis, at home, and Trinity then used this information to refill another seasonal monthly dose of Synagis.

140. MedImmune also arranged for Trinity's services, such as for Synagis to be delivered often to a medical facility, as it was faster than delivering it to the baby's home. However, arranging for services was not the responsibility of MedImmune, the delivery of Synagis to a specific location, medical facility or home, was Trinity's responsibility.

141. For example, the following CPR notes represent how MedImmune provided remuneration to Trinity by arranging for services:

1) 10/10/06, "As per Ida at MD office mom wants homecare; however, as per [Medi employee 1], Dr. Tapia wants MD office del (it is quicker to get meds)". (Baby 108 on Exhibit C1).

2) 10/29/07, "As per [Medi employee 2] at MedImmune, of to del meds to MD office w/out contacting parents". (Baby 474 on Exhibit C1).

3) 11/20/07, "[Medi employee 2] from MedImmune will have MD fax Rx today". (Baby 500 on Exhibit C1).

4) 03/24/08, "As per [BSS 3] from MedImmune, Baby showed up in Dr. Chong-Gayle's office in Suffolk county w/the meds (del'ed to home in Nov; S/H/B given at BFCC); faxed referral form to new MD; will send new meds to MD office when new ref + Rx rec'd". (Baby 405 on Exhibit C2).

5) 11/11/08, "As per [BSS 2] from MedImmune, ok to del meds to MD office". (Baby 451 on Exhibit C1).

B. MedImmune Recommended Trinity to Bellevue for Outpatient Synagis, Although Other Pharmacies Were Already Dispensing Synagis to the Hospital's Former Inpatients and Current Outpatients

142. In April 2008, Trinity hired a former MedImmune employee as an account manager ("Trinity Account Manager"), at the recommendation of a MedImmune CMM ("CMM 3"). Thereafter, Trinity's Account Manager attended a meeting at Bellevue Hospital Center ("BHC") arranged by and attended by CMM 3, a BHC neonatologist and BHC NICU Director ("BHC NICU Director"), and the Director of Social Work at BHC.

143. The purpose of the meeting was to discuss a proposed Synagis tracking program by Trinity that would follow former patients of the NICU. Some of these patients were being seen by the outpatient clinic and others were not. These babies had not received a prescription for Synagis before they were discharged from BHC.

144. CMM 3 recommended Trinity to BHC for Synagis outpatient purposes. Trinity's Account Manager stated that, "this was a hospital that was targeted for me to work with. The MedImmune rep contacted me. I have a contact there. I have a relationship with the director; did I want to go in." Trinity's Account Manager further stated, "Everything I did mostly with this account for the time that I worked with them was through [CMM 3]." This introduction and ongoing assistance by MedImmune presented an opportunity for Trinity to increase its Medicaid reimbursement for Synagis and for MedImmune to make sales. Trinity's Account Manager understood the power of MedImmune's assistance and CMM 3 was the "mechanism" by which Trinity's Account Manager gained access to the BHC NICU for outpatient purposes. Trinity's Account Manager stated that, "[CMM 3] was the one who brought me into that NICU..."

145. Trinity's Account Manager also generally stated that, "Often times, it was the MedImmune rep who would have the contact [at the NICU], and would say, hello, this is

[Trinity's Account Manager], she will assist you in identifying those babies at high risk for Synagis prophylaxis."

146. Trinity's Account Manager obtained information about babies from visiting the BHC NICU. Trinity's Account Manager stated her usual "vehicle" for getting in touch with the BHC NICU Director was through the MedImmune rep.

147. On May 31, 2011, when CMM 3 departed from MedImmune, her secretary wiped-out her laptop hard drive and sent the laptop back to MedImmune.

148. Trinity increased its Synagis Medicaid reimbursement as a result of MedImmune recommending it. Medi Manger 1 also knew that recommendations of pharmacies that dispensed outpatient Synagis were provided by MedImmune to hospitals.

C. MedImmune Recommended Trinity to Bellevue Resulting in a Baby Receiving Synagis with the Relator Being Identified on Two Medicaid Claims as the Prescriber, Even Though She Did Not Prescribe Synagis for the Baby

149. MedImmune's recommendation that Trinity be the pharmacy to provide BHC's outpatients with Synagis resulted in at least one baby receiving Synagis without a prescription from the prescriber identified on the Medicaid claims. In October and November of 2008, Trinity presented claims to the Medicaid program identifying Relator as the prescriber, even though the Relator, had not prescribed Synagis for the baby. After Relator learned about the unauthorized use of her name by Trinity, she reported the incident to BHC.

150. MedImmune also became aware of the unauthorized use of the Relator's name and Trinity provided MedImmune with information identifying the baby. CMM 3 approached Trinity's Account Manager and Trinity's Account Manager stated that, "[CMM 3] is the one who asked me about this child... maybe I felt she should be the first to get an answer."

151. Thereafter, a letter dated March 3, 2009, from BHC's Director of Network Contracts, to the Visiting Nurse Service that Trinity had referred the baby to, and on which Trinity was copied stated, "Please be advised that Trinity Representatives should not be on Bellevue Hospital Center Premises except in instances coordinated by the Bellevue Hospital Center Social Work Department. And even in those instances, Trinity Representatives should not be acquiring personal and confidential patient information. These activities must cease immediately. Furthermore, Trinity Representatives shall not use any information gathered while on Bellevue Hospital Premises for any marketing purposes whatsoever."

D. Kings County Hospital Barred MedImmune from Its NICU

152. During the relevant period, MedImmune failed to take steps to ensure that its employees were not engaging in prohibited conduct. MedImmune knew that one of its employees had been reviewing and taking PHI from the KCH NICU logbooks and was stopped from doing so. Prior to CMM 1 engaging in this conduct, Medi Manager 1 knew that another MedImmune employee, CMM 4, also obtained "access to the logbook." Specifically, in the summer of 2009, CMM 1 was barred from retrieving information from the NICU logbooks at KCH. His supervisor, Medi Manager 1, knew that the KCH NICU Director had "put a stop to it".

153. In an email dated October 13, 2009, to the KCH NICU Director, CMM 1 tried to regain access to the KCH NICU. CMM 1 stated, "I think it would be great for us to have a very candid conversation regarding what has gone on and what Kings County will do moving forward." CMM 1 admitted that he had independently taken information from the KCH logbooks. The email stated, "First, my fear is that I give the wrong impression of myself in the hospital due to the fact that I am a sales representative. I'd like to clarify that the criteria I've

used with regard to logbooks have never differed from the AAP guidelines. Gestational age was not documented in the logbooks for some time, and I would refer less than 2500-gram patients, as that is what other institutions do when information is unavailable in the logbooks... Another concern I have is logistics. That is why I urge you to allow me in to the process... We haven't tracked patients in the NICU this summer as well, which makes patients harder to find, as this is a very transient community..." Without access to the NICU, MedImmune was no longer able to send Trinity leads. Trinity was also no longer permitted in the NICU.

154. On December 5, 2010, CMM 1 sent an email to Medi Manager 1 and MedImmune's Northeast Senior Government Affairs Manager, referencing MedImmune knowledge of a New York governmental investigation concerning Synagis stating, "Apparently, one of the attending neonatologists was questioned by NY Medicaid for a lengthy session, so I'm told. I don't have the details but I do know that Kings is a huge NICU and haven't properly kicked off their Synagis season, at least partly due to this issue."

E. In 2011, MedImmune Ordered Its Employees to Sign a Certification of Destruction Policy Regarding PHI

155. By April 14, 2011, with the aforementioned knowledge of a governmental investigation, MedImmune's compliance department determined to make sure its employees ceased obtaining access to and retaining PHI and providing "limited assistance with a specific patient case at the request of a provider, institution or office," in limited areas, as long as a BAA was in place. In April 2011, MedImmune also announced it was terminating its CMM program. MedImmune employees were directed to review their materials and records to destroy any paper and electronically saved PHI in their possession by: shredding it, depositing it in confidential waste bins, or by completely electronically deleting it. Among others, BSS 3, BSS 4, and Medi Manager 1, executed the Certification of Destruction by April 30, 2011.

156. MedImmune should not have removed and retained PHI from any medical facility to provide to Trinity as a lead or as a referral, thus creating a need to destroy it. Significantly, if MedImmune had not ordered PHI it improperly possessed destroyed, this additional PHI would have shown an increased number of improper claims presented to Medicaid by Trinity resulting from MedImmune's assistance. During the relevant period, MedImmune did not maintain uniform record-keeping retention policies or policies that ensured records were kept of CMM activities. For example, after MedImmune terminated CMM 1 for what MedImmune considered a sales force restructuring, the standard practice was for his laptop and others to be returned, the data erased and the laptop issued to another Medimmune employee. CMM 3 also had her laptop wiped. The data on such laptops was not otherwise available for MedImmune to search when the State served it and AstraZeneca with subpoenas dated July 1, 2011.

157. Indeed, MedImmune was acting as an agent of Trinity, with regard to trying to obtain outpatient Synagis prescriptions which would increase both Trinity's and MedImmune's receipt of money from governmental funds.

F. MedImmune Supervisors Were Aware of and Applauded the Aggressive Practices of Its CMMs Who Sought an Opportunity for MedImmune to Profit by Illegally Assisting Trinity

158. MedImmune employees engaged in illegal conduct and MedImmune supervisors condoned such practices to increase Synagis sales and earn a profit, at the cost of harming the Medicaid program and causing improper claims to be presented for payment by Trinity. Some examples follow.

159. On February 6, 2007, a former MedImmune BSS, ("BSS 4"), emailed her regional supervisor, Medi Manager 1, highlights from her week. The email states, "I had a lunch meeting with Brookdale @ New Lots to review their referrals with [Trinity's Synagis Director] from

Trinity. Trinity's Synagis Director went through their referrals that she had on file with their office, there were some discrepancies but overall it was a good meeting. *We were able to capture three babies and get their drug shipped to the office.* As mentioned before I implemented my new binder and we wrote down each baby and the date dose. In addition, any subsequent referrals that go to Trinity will be copied and placed in my binder for tracking purposes." (Emphasis added)

160. Medi Manager 1 responded on February 8, 2007 and complemented BSS 4 for "taking more accountability at New Lots."

161. In an email dated October 9, 2007, written by CMM 1 to MedImmune management, Medi Manager 1 and Medi Manager 5, titled, "NICU Update", CMM 1 boasted about his access to and use of personal baby information that he provided to Trinity. He stated, "Last year the info would flow from- the NICU to Trinity to Me (only in numbers). Now I do 100% of the tracking and the info flows from the NICU to Me to Trinity and then back to me again so I can note patient status as well as dig deeper for better quality of info. As it stands, our growth is right in front of us within our books"

162. Medi Manager 1 also responded on October 9, 2007, with kudos, "This is absolutely terrific work!!! When I look at the amount of control and accountability you have taken on with your accounts I am very impressed! Keep this same level of intensity throughout the entire season and success will be yours!"

163. Medi Manager 1's superior, Medi Manager 5 echoed Medi Manager 1's praise, "...Thanks again for the efforts! I know that this work takes extraordinary effort and finesse." Medi Manager 5 further responded to CMM 1's email, "[CMM 1], Thanks for the perspective. Congratulations and great job in taking control of the process this summer."

164. On November 22, 2008, Medi Manager 1 emailed CMM 1. The email stated “[CMM 1]: Thanks for a very productive day at Kings County Hospital. You truly performed some true hospital salesmanship. Your NICU protocol produced another 21 babies identified for Synagis administration in the last (3 weeks) 126 to date...”

165. When MedImmune’s access to certain NICUs was restricted, MedImmune managers acknowledged the impact on Synagis sales. For example, a June 2009, Medi Manager 1 authored PowerPoint, “ID103 Manhattan-Long Island 2009-2010 Business Plan,” contained a section titled “Puts & Takes”: Synagis. “Puts” is defined as “opportunities” and “Takes” is defined as “threats”. In the takes or threats column, Medi Manager 1 identified his managerial concern, “NICU’s restricting CMM/distributor access to birthing Log Book → decrease in patient ID expected.”

166. Medi/AstraZeneca’s Compliance Director admitted that CMM 1 was not “allowed to track patients generally in NICUs.”

167. Medi/AstraZeneca’s Compliance Director also admitted, “I’m not aware of a circumstance that it would be consistent with policy for an employee to obtain PHI from a logbook, create a document and maintain it.” “Our employees are not allowed to access patient information. The 4-Part Form does not allow employees to access patient information.” And further, CMM 1 “should not take data off of that form and create, using PHI, his own individual tracking form or provide that to any other third-party.” He also confirmed that MedImmune employees, “should not, on their own, be in the NICU and creating their own list of particular babies with particular baby information, to then keep and/or transfer to a pharmacy.”

168. Also, MedImmune supervisors and employees had knowledge of New York’s Medicaid guidelines as they pertained to Synagis. MedImmune acknowledged updated, stricter

NYSDOH guidelines as to the number of Synagis refills that were seasonally appropriate for a baby which would result in a decline in Synagis sales but MedImmune still hoped to get away with sales for an April dose.

169. For example, in September of 2008, a New York Medicaid Update was issued by NYSDOH concerning “Synagis Medicaid Coverage for Children at Risk for Respiratory Syncytial Virus Infection.” The Update stated that the number of monthly doses of Synagis was five throughout the RSV season, typically beginning in November in New York. MedImmune employees and supervisors, upon becoming aware of this update, commented in an email thread dated October 16, 2008. In this email, CMM 1 referenced the update to Medi Manager 1, and attached a link to the Medicaid Update. CMM 1 stated, “Did you already see this or was this what you were referring to this morning? Yikes. Anyway I am banking on the slow movement of the Medicaid employees to get through the season...” Medi Manager 1 responded to CMM 1 in an email, also dated October 16, 2008. He confirmed what CMM 1 had stated, “Yes... the policy is exactly what I was referring to this AM... Note, they mention starts of season in November with (5) doses. Sounds very commercial, does it not? No mention of April. The statement is a departure from last season.”

G. MedImmune Violated Its Obligations to Comply with Anti-Kickback Laws and Similar State Prohibitions

170. Despite its knowledge and issuance of materials that recognized legal requirements and specified appropriate practices, as alleged below, MedImmune knowingly allowed its employees to violate the law. This conduct caused Trinity to present false claims to the Medicaid program.

171. MedImmune knew that it was required to comply with anti-kickback laws with regard to Synagis, but it nevertheless acted in direct contravention of the law and its own policies

and procedures. As a matter of written policy, and noted in several iterations, in a document authored by MedImmune's corporate compliance department titled, *MedImmune, Responsible Entrepreneurs: The Synagis Referral Process*, MedImmune knew that "educating and troubleshooting around Synagis logistics and coverage issues raises real and serious risks if done inappropriately: Anti-kickback Act: providing inappropriate added value/kickback (e.g. doing office work for the office)."

172. In a similar document titled, *MedImmune Providing Assistance*, which was created as an E-module that ran on MedImmune's learning management system for employees to complete, there is a section titled, "Laws and Regulations", specifically on the Medicare/Medicaid anti-kickback laws. It states, "[t]he AKA prohibits offering or giving anything of value to anyone to induce the use, purchase, prescription or recommendation of products reimbursed by government healthcare payers. For example, doing general office work, such as completing or faxing in referral forms for an office may be seen as providing a valuable service for which the office would otherwise need to pay. This act could be seen as a kickback, which could qualify as a felony."

173. Despite its awareness of the anti-kickback laws, MedImmune engaged in its illegal kickback arrangement with Trinity and knowingly caused Trinity to present false claims to Medicaid for Synagis.

H. MedImmune Increased Sales of Synagis by Violating Terms of the Assignment of Benefit Agreements with Trinity and the Anti-Kickback Statutes

174. MedImmune and Trinity entered into AOBs with defined terms and conditions, which were required for Trinity to try to obtain drug manufacturer rebates. (A "rebate" is any discount, the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of the sale.

(1001.952(h)(B)(4)). However, a critical term of the AOBs concerning anti-kickback statutes and regulations was violated.

175. MedImmune and Trinity agreed not to violate the federal and state anti-kickback statutes, as stated in the AOBs section 3.1(d) (2006-2007 AOB). This section states, “It is the intent of the parties to establish a business relationship which complies with the anti-kickback statute applicable to federal healthcare programs set forth at 42 USC 1320a-7(b).” By a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and PHI to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills, MedImmune violated terms of the AOBs and in turn violated the anti-kickback statutes and regulations.

176. Further, even if this conduct had been disclosed in the rebate agreements, such conduct would not be legal as it violated anti-kickback statutes and regulations, which resulted in the presentment of false claims to Medicaid by Trinity, caused by MedImmune.

177. Further, as a result of the conduct, Trinity and its successor parents received rebates from MedImmune and a portion of that rebate was inevitably the result of improper Medicaid claims that Trinity presented to the State which were tainted by MedImmune’s illegal conduct. This additional remuneration to Trinity was another form of an illegal kickback.

178. The business generated by the symbiotic relationship, between MedImmune and Trinity was the result of a kickback scheme. MedImmune provided baby leads, potential outpatient Synagis business, to Trinity as well as other assistance and, in exchange, Trinity received payment in the form of a rebate and obtained increased Medicaid revenues. As a result

of the relationship, MedImmune also obtained increased Synagis sales. Any claim presented to Medicaid as the result of a kickback is false and fraudulent.

I. The Synagis Kickback Scheme Was Very Profitable for MedImmune and Trinity

179. The Synagis kickback scheme was highly profitable for MedImmune. As Trinity profited, MedImmune profited, both at the expense of the Medicaid program.

180. As Trinity and MedImmune became aware of the Attorney General's Synagis investigation, Trinity's Synagis Medicaid business decreased and it ultimately terminated its Synagis program in April, 2011. Significantly, the rest of the New York Medicaid market dispensing Synagis remained relatively unchanged and unaffected. Meaning, no other New York pharmacy that dispensed Synagis picked up Trinity's business. Thus, when the kickback conduct ended, and when Trinity terminated its Synagis program, utilization of Synagis declined statewide in subsequent years.

181. MedImmune caused the presentment of thousands of false claims for payment to the New York State Medicaid program during the period January 2007 through March 2011. Accordingly, MedImmune is liable under the New York False Claims Act for treble damages and penalties for these claims for reimbursement for Synagis.

VII. MedImmune's Synagis Kickback Scheme Caused the Presentment of Thousands of False Claims to New York's Medicaid Program

182. As MedImmune benefited from their Synagis kickback scheme through higher sales associated with profiting from baby leads and referrals sent to Trinity and other assistance it afforded Trinity, the State's Medicaid program unknowingly assumed the financial cost of this corrupt scheme.

183. Throughout the Synagis kickback scheme, *i.e.*, from January 2007 through March 2011, Trinity presented claims to the State's Medicaid program seeking reimbursement for

Synagis. Certain of these claims were false and ineligible for reimbursement because they had been tainted by the kickback relationship with MedImmune. Such claims further violated Trinity's Certification Statement submitted to the New York Medicaid program.

184. In order to dispense and present claims to Medicaid for prescription medications, fee for service pharmacy Medicaid providers are required to sign a Medicaid Certification Statement (referenced in the preceding paragraph and earlier in paragraphs 59-64), attesting that the care, services or supplies for which claims to Medicaid are submitted were furnished "in accordance with applicable federal and state laws and regulations."

185. Attached as Exhibit B to this Complaint are copies of Trinity's Certification Statements effective from 2007 through 2011.

186. The Certification Statements are representations of compliance with a material condition of payment, namely that MedImmune's manufactured drug, Synagis, for which claims for payment were made to Medicaid by Trinity, were in accordance with all applicable Federal and State laws and regulations regarding the provision of health care services. (This includes the Federal and New York Anti-Kickback Statutes and regulations.) Claims that MedImmune caused to be presented to Medicaid, alleged herein, render those certifications false.

187. In addition, the Certification Statements are representations of compliance with another material condition of payment, namely the prohibition against "offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program." 18 N.Y.C.R.R. § 515.2(b)(5)(iv). Claims that MedImmune caused to be presented to

Medicaid, by seeking an opportunity for profit in providing remuneration to Trinity, alleged herein, render those certifications false.

188. In short, by engaging in the Synagis kickback scheme, MedImmune caused the presentment of thousands of false claims to Medicaid. The scheme, in turn, caused Medicaid to pay out millions of dollars based on the kickback-tainted false Synagis claims. In total, the New York's Medicaid program paid more than \$7.3 million dollars for the kickback-tainted false claims.

189. Claims for payment to Trinity whereby MedImmune caused those claims to be presented, pursuant to a false certification, and as alleged herein, expressly and impliedly misrepresent compliance with multiple material conditions of payment of the New York State Medicaid program.

190. By providing remuneration to Trinity, MedImmune intended to induce Trinity to present claims for Synagis to Medicaid for reimbursement. MedImmune knew that the majority of New York Synagis sales were for Medicaid enrollees for Synagis and were made by Trinity.

191. MedImmune caused the presentment of false claims to the New York State Medicaid program, including, but not limited to, the claims listed on Exhibit C1 and C2 to this Complaint.

192. MedImmune is therefore liable to the State of New York for damages based upon payment of the claims for MedImmune's prescription drug, Synagis, listed on Exhibit C1 and C2 to this Complaint.

FIRST COUNT

New York False Claims Act, N.Y. State Fin. Law § 189(1)(b)

193. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

194. As a result of MedImmune's kickbacks and offers of kickbacks to induce Trinity to purchase, to order, and to recommend Synagis in violation of the New York Anti-Kickback Statute, New York Social Services Law § 366-f, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R. § 515.2(b), and the laws, rules and regulations of the New York State Medicaid program, including its Medicaid updates and provider manuals, MedImmune knowingly caused Trinity to make false records or statements or omissions that were material to false or fraudulent claims for payment presented to the State of New York, in violation of N.Y. State Fin. Law § 189(1)(b). The false records or statements or omissions were Trinity's false certifications, representations, or omissions that the services were provided in compliance with all applicable State and Federal laws and regulations, including but not limited to, State and Federal anti-kickback statutes and regulations, and the laws, rules and regulations of the New York State Medicaid program, including its Medicaid updates and provider manuals.

195. Had Medicaid known these Synagis claims were the result of improper conduct, the State would not have reimbursed Trinity.

196. By reason of the false records or statements, the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of \$6,000 to \$12,000 for each violation.

SECOND COUNT

New York False Claims Act, N.Y. State Fin. Law § 189(1)(c)

197. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

198. As set forth above, from January 2007 to March 2011, MedImmune conspired with Trinity by offering and paying Trinity kickbacks in exchange for, or to induce, Trinity to purchase, to order, or to recommend Synagis in violation of the federal Anti-Kickback Statute,

42 U.S.C. § 1320a-7b(b)(2), 18 N.Y.C.R.R. § 515.2(b), the New York Anti-Kickback Statute, New York Social Services Law § 366-f, and the laws, rules and regulations of the New York State Medicaid program, including its provider manuals, thereby causing Trinity to present false and fraudulent claims to the State of New York and causing Trinity to make false records or statements or omissions that were material to false or fraudulent claims for payment submitted to the State of New York.

199. Had Medicaid known these Synagis claims were the result of improper conduct, the State would not have reimbursed Trinity.

200. By virtue of the false or fraudulent claims MedImmune and Trinity conspired to present and allowed or paid or by reasons of their conspiracy to violate N.Y. State Fin. Law § 189(1)(a) and N.Y. State Fin. Law § 189(1)(b), the State of New York has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty of \$6,000 to \$12,000 for each violation.

THIRD COUNT
New York Social Services Law § 145-b

201. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

202. As set forth above, MedImmune knowingly, or acting in deliberate ignorance or in reckless disregard for the truth, caused to be presented to the State of New York false or fraudulent claims for payment.

203. The State of New York paid such false or fraudulent claims because of the acts of MedImmune.

204. By reason of MedImmune's conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

205. By reason of the foregoing, MedImmune is liable, pursuant to N.Y. Social Services Law §145-b, to the State of New York for treble damages, penalties, costs, and interest at the highest legal rate.

FOURTH COUNT
New York Executive Law § 63(12)

206. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

207. N.Y. Executive Law § 63(12) makes "repeated fraudulent . . . acts of . . . persistent fraud . . . in the carrying on, conducting or transaction of business actionable by the Attorney General."

208. By engaging in the acts and practices described above, MedImmune has engaged in repeated fraudulent acts or persistent fraud in violation of N.Y. Executive Law § 63(12).

209. By reason of the foregoing, MedImmune is liable to the State of New York for damages, in an amount to be determined at trial, for the economic injuries suffered by the State of New York.

FIFTH COUNT
New York Executive Law § 63-c

210. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

211. The acts and practices of MedImmune complained of herein constitute a misappropriation of public property, in violation of N.Y. Executive Law § 63-c. By reason of the foregoing, the State of New York is entitled to restitution from MedImmune in an amount yet to be determined, plus costs, expenses, and the maximum amount of interest available under law.

SIXTH COUNT
Unjust Enrichment

212. New York repeats and realleges each of the preceding paragraphs as if fully set forth herein.

213. This is a claim for the recovery of monies by which MedImmune has been unjustly enriched.

214. By directly or indirectly obtaining funds from the State of New York to which it was not entitled, MedImmune has been unjustly enriched, and is liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the State of New York, plus costs, expenses, and the maximum amount of interest available under law.

PRAYER FOR RELIEF

WHEREFORE, The State demands and prays that judgment be entered in its favor against Defendants as follows:

a) On the First and Second Counts under the New York State False Claims Act, for the amount of the State's damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief, as may be just and proper.

b) On the Third Count under New York Social Services Law § 145-b, for the amount of the State's damages, trebled, plus interest at the highest legal rate.

c) On the Fourth Count under New York Executive Law § 63(12), for restitution to the State based on MedImmune's repeated or persistent fraudulent and illegal practices, for the economic injuries suffered by the State.

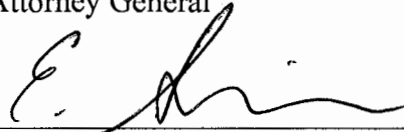
d) On the Fifth and Sixth Counts, for the damages sustained and/or amounts by which MedImmune was unjustly enriched or by which MedImmune retained illegally obtained monies, plus interest, costs, and expenses, and all such further relief as may be just and proper.

Dated: March 31, 2017
New York, New York

Respectfully submitted,

THE STATE OF NEW YORK
By its attorney,
ERIC T. SCHNEIDERMAN
Attorney General

By:

A handwritten signature in black ink, appearing to be 'E. Silverman', written over a horizontal line.

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