SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among (1) the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") and the United States Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program, and the TRICARE Management Activity ("TMA"), through its General Counsel (collectively, the "United States"), (2) sanofi-aventis U.S., Inc., now Sanofi US Services Inc., and sanofi-aventis U.S., LLC (collectively, "Sanofi US"), and (3) Mark Giddarie ("Relator") (hereinafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. At all relevant times, Sanofi US marketed and sold pharmaceutical products in the United States.


C. Sanofi US has entered or will be entering into a separate settlement agreement, described in Paragraph 1.b below (the “Medicaid State Settlement Agreement”) with certain states and the District of Columbia (the “Medicaid States”) in settlement of the Covered Conduct, defined below.
D. The United States contends that Sanofi US submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1, the Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5, the Federal Employees Health Benefit Program ("FEHBP"), 5 U.S.C. §§ 8901-14, and the TRICARE Program, 10 U.S.C. §§ 1071-1110a (collectively, the "Federal Health Care Programs").

E. The United States contends that it has certain civil claims against Sanofi US for engaging in the alleged conduct described in the United States’ Statement of Facts set forth in Attachment A and as follows (hereinafter collectively referred to as the "Covered Conduct"):  

1. During the period 2005 through 2009, Sanofi US knowingly caused false or fraudulent claims for Hyalgan to be submitted to the Federal Health Care Programs by offering and providing illegal remuneration to physicians to induce the physicians to purchase and to prescribe Hyalgan, in violation of the federal anti-kickback statute, 42 U.S.C. § 1320a–7b(b)(2), by offering and providing them “free” Hyalgan units for which Sanofi US knew physicians could obtain reimbursement from the Federal Health Care Programs and/or that were not in fact “free” because the units were offered only in exchange for purchasing Hyalgan.

2. During the period from 2005 through 2009, Sanofi US knowingly made and used false statements to the Centers for Medicare and Medicaid Services ("CMS") concerning Hyalgan’s Average Sales Price ("ASP"). Sanofi US’s ASP reports were false because they did not take into account the value of the free Hyalgan that Sanofi US provided to physicians contingent on the physicians’ purchases of Hyalgan. The false ASP reports caused the reimbursement amounts for Hyalgan and for a competing product, Supartz, to be inflated, thus rendering false all claims to the Federal Health Care Programs for Hyalgan and Supartz during the period from 2005 through 2009.
F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

**TERMS AND CONDITIONS**

1. No later than seven days after the Effective Date of this Agreement, Sanofi US shall pay to the United States and the Medicaid States, collectively, $109,000,000, plus interest at a rate of 1.375% from July 24, 2012, through the day before full payment (the “Settlement Amount”). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid States, under the following terms and conditions:

   a. Sanofi US shall pay to the United States the sum of $108,716,070, plus accrued interest as set forth above (“Federal Settlement Amount”). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) days after the Effective Date of this Agreement.

   b. Sanofi US shall deposit the sum of $283,930, plus accrued interest as set forth above into one or more interest-bearing money market or bank accounts that are held in the name of Sanofi US, but segregated from other Sanofi US accounts (the “State Settlement Accounts”), and make payment from the State Settlement Accounts to the Medicaid States pursuant to the terms of the Medicaid State Settlement Agreement that Sanofi US has entered or will enter into with the Medicaid States.
2. Conditioned upon the United States receiving the Settlement Amount from Sanofi US and as soon as feasible after receipt, the United States shall pay $18,500,000, plus interest at a rate of 1.375% from July 24, 2012, through the day before Sanofi US’s full payment of the Federal Settlement Amount, to Relator by electronic funds transfer.

3. Sanofi US agrees to pay Relator’s attorneys’ fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in a separate agreement being entered into simultaneously with the execution of this Settlement Agreement.

4. Subject to the exceptions in Paragraph 9 (concerning excluded claims) below, and conditioned upon Sanofi US’s full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) releases Sanofi US, together with its predecessors, and its current and former divisions, parents, affiliates, subsidiaries, successors and assigns, their current and former directors and officers, and their current employees (except for current employees referenced in the United States’ Statement of Facts), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or under the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Conditioned upon Sanofi US’s full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, assigns, and any other person acting on his behalf or asserting his rights, releases Sanofi US, its predecessors, and its current and former divisions, parents, affiliates, subsidiaries, successors and assigns, and their current and former directors, officers and employees, from any civil monetary claim the relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C.
§§ 3729-33, for the Covered Conduct, and from any and all liability, claims, allegations, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or under common law or that he or they otherwise may have had or may now have from the beginning of the world, including, without limitation, any claim that the Relator asserted or could have asserted in the Civil Action, and, conditioned upon receipt of payment contemplated in Paragraph 3, any claims asserted for expenses, attorneys’ fees, and costs under 31 U.S.C. § 3730(d).

6. OIG-HHS expressly reserves all rights to institute, to direct, or to maintain any administrative action seeking exclusion against Sanofi US and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

7. In consideration of the obligations of Sanofi US set forth in this Agreement, conditioned upon Sanofi US’s full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Sanofi US under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 9 (concerning excluded claims), below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude Sanofi US from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below.
8. In consideration of the obligations of Sanofi US in this Agreement, conditioned upon Sanofi US's full payment of the Settlement Amount, and further conditioned on Sanofi US entering into a Corporate Integrity Agreement ("CIA") with HHS-OIG before January 1, 2014, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from the FEHBP against Sanofi US under 5 U.S.C. § 8902a or 5 C.F.R. Part 919 for the Covered Conduct, except as reserved in Paragraph 9 (concerning excluded claims), below and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below.

9. Notwithstanding the releases given in paragraphs 4, 6, 7, and 8 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

   a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
   b. Any criminal liability;
   c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
   d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
   e. Any liability based upon obligations created by this Agreement;
   f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
   g. Any liability for failure to deliver goods or services due;
h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or


10. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator’s receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

11. Sanofi US waives and shall not assert any defenses Sanofi US may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

12. Sanofi US fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney’s fees, costs, and expenses of every kind and however denominated) that Sanofi US has asserted, could have asserted, or
may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States’ investigation and prosecution thereof.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by, TRICARE, FEHBP, or any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and Sanofi US agrees not to resubmit to TRICARE, FEHBP, or any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

14. Sanofi US agrees to the following:
   a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Sanofi US, its present or former officers, directors, employees, shareholders, and agents in connection with:
      (1) the matters covered by this Agreement;
      (2) the United States’ audit(s) and civil investigation(s) of the matters covered by this Agreement;
      (3) Sanofi US’s investigation, defense, and corrective actions undertaken in response to the United States’ audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney’s fees);
      (4) the negotiation and performance of this Agreement; and
(5) the payment Sanofi US makes to the United States pursuant to this Agreement and any payments that Sanofi US may make to Relator, including costs and attorneys fees.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Sanofi US, and Sanofi US shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Sanofi US or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Sanofi US further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Sanofi US or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Sanofi US agrees that the United States, at a minimum, shall be entitled to recoup from Sanofi US any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.
Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Sanofi US or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Sanofi US or any of its subsidiaries or affiliates’ cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Sanofi US’s books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

15. Sanofi US agrees to cooperate fully and truthfully with the United States’ investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Sanofi US shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Sanofi US further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

16. This Agreement is intended to be for the benefit of the Parties only; it does not create any rights or benefits as to third parties. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 17 (waiver for beneficiaries paragraph), below.
17. Sanofi US agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file a joint Stipulation of Dismissal, in the form attached hereto as Attachment B, of the Civil Action pursuant to Rule 41(a)(1).

19. With exception of the payment described in Paragraph 3, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

20. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

21. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

22. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

23. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
25. This Agreement is binding on Sanofi US’s successors, transferees, heirs, and assigns.

26. This Agreement is binding on Relator’s successors, transferees, heirs, and assigns.

27. All parties consent to the United States’ disclosure of this Agreement, and information about this Agreement, to the public.

28. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.
THE UNITED STATES OF AMERICA

DATED: 12/18/12

BY: [Signature]
GREGG SHAPIRO
Assistant United States Attorney
United States Attorney’s Office
District of Massachusetts

DATED: 12/14/12

BY: [Signature]
JAMIL ANN YAVELBERG
DOUGLAS ROSENTHAL
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: [Blank]

BY: [Signature]
ROBERT DeCONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
United States Department of
Health and Human Services

DATED: [Blank]

BY: [Signature]
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: [Blank]

BY: [Signature]
SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance
Operations
United States Office of Personnel Management

Settlement Agreement between
the United States and Sanofi US

13
THE UNITED STATES OF AMERICA

DATED:_________  BY:  

GREGG SHAPIRO  
Assistant United States Attorney  
United States Attorney’s Office  
District of Massachusetts

DATED:_________  BY:  

JAMIE ANN YAVELBERG  
DOUGLAS ROSENTHAL  
Attorneys  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 12/12/12  BY:  

ROBERT DeCONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
United States Department of  
Health and Human Services

DATED:_________  BY:  

PAUL J. HUTTER  
General Counsel  
TRICARE Management Activity  
United States Department of Defense

DATED:_________  BY:  

SHIRLEY R. PATTERSON  
Assistant Director for Federal Employee Insurance  
Operations  
United States Office of Personnel Management

Settlement Agreement between the United States and Sanofi US
THE UNITED STATES OF AMERICA

DATED: __________  BY: ______________________
GREGG SHAPIRO
Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED: __________  BY: ______________________
JAMIE ANN YAVELBERG
DOUGLAS ROSENTHAL
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: __________  BY: ______________________
ROBERT DeCONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
United States Department of Health and Human Services

DATED: 12/12/12  BY: ______________________
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: __________  BY: ______________________
SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance Operations
United States Office of Personnel Management
THE UNITED STATES OF AMERICA

DATED:_______ BY: ____________________________
GREGG SHAPIRO
Assistant United States Attorney
United States Attorney’s Office
District of Massachusetts

DATED:_______ BY: ____________________________
JAMIE ANN YAVELBERG
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Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED:_______ BY: ____________________________
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Office of Inspector General
United States Department of
Health and Human Services

DATED:_______ BY: ____________________________
PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 12/12/12 BY: ____________________________
SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance
Operations
United States Office of Personnel Management

Settlement Agreement between
the United States and Sanofi US
DATED: 12/12/2012

BY:  

DAVID COPE
Debarring Official
Office of the Assistant Inspector General
for Legal Affairs
United States Office of Personnel Management

Settlement Agreement between the United States and Sanofi US
SANOFI US SERVICES INC. & SANOFI-AVENTIS U.S., LLC – DEFENDANTS

DATED: 12/17/12

BY: ____________________________
THOMAS J. DESROSIER
North America General Counsel
Sanofi US
55 Corporate Drive
Bridgewater, NJ 08807

DATED: 12/17/12

BY: ____________________________
ROBERT F. SHERMAN
BROOKS A. AMES
DLA Piper LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110-1447

Settlement Agreement between the United States and Sanofi US
Attachment A: United States’ Statement of Facts

Hyalgan is an injectable product, sold in a syringe or vial, that the Food and Drug Administration (“FDA”) has approved as a device for treatment of osteoarthritis pain in the knee. It is in a class of products called viscosupplements, or hyaluronic acids. The FDA has approved five viscosupplements: Hyalgan, Synvisc, Supartz, Orthovisc, and Euflexxa.

Sanofi US licensed the right to market Hyalgan in the United States from Fidia Farmaceutici S.p.A., an Italian company. Sanofi US began selling Hyalgan in the United States in the late 1990s. During the period from 2005 to 2009, Sanofi US’s annual net sales of Hyalgan in the United States averaged slightly more than $80 million. Approximately 60 percent of these sales were reimbursed by federal health care programs (primarily Medicare).

During the period from 2005 to 2009, reimbursement for physician-administered drugs (and for certain devices, including Hyalgan) was based on the reported Average Sales Price (“ASP”). Under the ASP system, within 30 days after the close of each quarter, a drug manufacturer must report to the Centers for Medicare & Medicaid Services (“CMS”) the ASP for each of its drugs. See 42 U.S.C. § 1396r–8(b)(3)(a)(iii). ASP means the manufacturer’s average sales price “to all purchasers,” with certain exceptions. See 42 U.S.C. § 1395w–3a(c)(1). The ASP statute further specifies that, “[i]n calculating the manufacturer’s average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, [and] free goods that are contingent on any purchase requirement.” 42 U.S.C. § 1395w–3a(c)(3) (emphasis added). Under the “free goods” provision, for example, if a manufacturer offers to provide one free unit for every 10 purchased at a unit price of $100 (for a total price of $1000), then the reportable ASP per unit is not $100 ($1000/10 units), but $90.91 ($1000/11 units).

For products like Hyalgan, a physician typically buys the product from the manufacturer or a distributor and maintains it as inventory in his or her office. Each time the physician administers the product to a federal health care patient in his or her office, the physician then typically submits a claim to the federal health care program seeking reimbursement for the product. This is commonly known as a “buy and bill” arrangement. When a physician submits a Medicare claim for a drug or device for which payment is made under the ASP system, Medicare reimburses the physician based on the product’s Healthcare Common Procedure Coding System (“HCPCS”) code. The amount of reimbursement for a particular HCPCS code typically is 106% of the volume-weighted average of the reported ASPs for the products in the code for the quarter two quarters prior to the administration. See 42 U.S.C. § 1395w–3a(b)(1). Consequently, if a manufacturer reports an inflated ASP – e.g., an ASP that does not take into account the price-reducing effect of providing free goods contingent on a purchase – the HCPCS amount will be inflated and Medicare will pay an excessive amount of reimbursement.

For much of the period from 2005 to 2009, Hyalgan and Supartz shared a HCPCS code: the reimbursement amount for each product was based on the aggregate volume-weighted average ASP of Hyalgan and Supartz. This grouping of Hyalgan and Supartz meant that, if one of the products had a lower price, that product would offer a greater reimbursement “spread,” or
net revenue, to a health care provider. Supartz, which was a relatively late entrant to the market, was typically priced lower than Hyalgan and thus offered physicians a bigger spread.

From 2005 until at least early 2008, Sanofi US’s Hyalgan marketing team chose not to compete with Supartz by lowering prices across the board for fear of setting off a price war and creating a “downward spiral” in the price and reimbursement for Hyalgan. At the same time, Sanofi US provided its sales representatives with large numbers of Hyalgan “samples.” During the period from 2005 to 2009, Sanofi US sales representatives distributed over 168,000 samples of Hyalgan. Notwithstanding the large number of Hyalgan samples that Sanofi US provided to its sales representatives, Sanofi US took no steps prior to 2009 to track or limit the way in which the company’s sales force used samples or the number of samples provided to particular accounts.

During the period from 2005 through 2009, Sanofi US marketed samples as a “value add” that Sanofi US provided with Hyalgan. For example, Sanofi US field sales management observed that the “Best reps ... Articulate the value of samples (left 50 samples; equivalent to $5K...).” In promoting Hyalgan to health care providers, some Sanofi US sales representatives articulated the “value add” of samples in monetary terms. Sanofi US also encouraged Hyalgan sales representatives to “leverage” the samples that Sanofi US provided to them. For example, one Sanofi US sales manager directed a Sanofi US sales representative to “use samples as a negotiating tool.” In practice, “leveraging” samples often meant using samples to lower the effective price of Hyalgan to compete with Supartz.

During the 2005-2009 period, the Sanofi US sales force’s illegal use of samples included the following arrangements:

• A Southern California-based sales representative initially promised 25 Hyalgan samples to Physician Practice A for every 100 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. When Sanofi US reduced the invoice price of Hyalgan, the sales representative reduced the number of samples he promised to 15 for every 100 Hyalgan units that Physician Practice A purchased. The sales representative explained this change in an e-mail to Physician Practice A: “orders @ 93 you get 25 samples. Orders at $77 you get 15.” The sales representative supplemented these kickbacks via samples by regularly taking all of the office personnel at Physician Practice A office to lavish dinners at Morton’s restaurant, all at Sanofi US’s expense and with Sanofi US’s approval. The same sales representative also promised 20 Hyalgan samples to Physician Practice B for every 100 Hyalgan units that this practice purchased, in order to reduce the effective unit price of Hyalgan. When Sanofi US promoted this sales representative to district sales manager in 2008, he directed other Sanofi US sales representatives to continue the illegal arrangements he had in place with Physician Practice A and Physician Practice B. During the period from 2005 to 2009, various Sanofi US employees delivered over 1500 Hyalgan samples to Physician Practice A and Physician Practice B pursuant to these illegal arrangements.
• A New York-based Sanofi US sales representative promised 12 Hyalgan samples to Physician Practice C for every 50 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2005 to 2009, the sales representative delivered over 900 Hyalgan samples to Physician Practice C pursuant to this illegal arrangement. A Sanofi US district sales manager supplemented these kickbacks via samples by taking all of the personnel in Physician Practice C, along with several of their friends and family members, to a lavish dinner at Megu restaurant in Manhattan, all at Sanofi US’s expense and with Sanofi US’s approval.

• Another New York-based Sanofi US sales representative promised specific quantities of Hyalgan samples to various physician practices in exchange for purchases of Hyalgan, in order to reduce the effective unit price of Hyalgan. Sanofi US managers directed and condoned these arrangements, which involved the delivery of hundreds of samples.

• In 2007, a Central Texas-based Sanofi US sales representative promised Physician Practice D that Sanofi US would deliver 125 free Hyalgan syringes if the practice made a single purchase of 500 Hyalgan units, in order to reduce the effective unit price of Hyalgan. After the practice placed the order for 500 units, the sales representative actually delivered 150 free Hyalgan syringes. After the sales representative struck this deal, Sanofi US’s Texas sales team lauded him for “[u]tiliz[ing] samples to provide value for the office.”

• A Rhode-Island-based Sanofi US sales representative promised 10 Hyalgan samples to Physician Practice E for every 50 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2007 to 2008, the sales representative delivered over 150 Hyalgan samples to Physician Practice E pursuant to this illegal arrangement.

• A North Carolina-based Sanofi US sales representative promised 25 free Hyalgan units to Physician Practice F for every 100 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2008 to 2009, the sales representative delivered over 200 Hyalgan samples to Physician Practice F pursuant to this illegal arrangement.

• A Northern California-based Sanofi US sales representative promised 12 Hyalgan samples to Physician Practice G for every 60 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. The sales representative separately promised 5 Hyalgan samples to Physician Practice H for every 20 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2006 to 2009, the sales representative delivered over 125 Hyalgan samples to these physician practices pursuant to these illegal arrangements.
• Two Indiana-based Sanofi US sales representatives promised 30 Hyalgan samples to Physician Practice I for every 100 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2005 to 2008, the sales representatives delivered over 400 Hyalgan samples to Physician Practice I pursuant to this illegal arrangement, which Sanofi US managers expressly condoned.

• A South-Florida based Sanofi US sales representative promised 15 Hyalgan samples to Physician Practice J for every 50 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2007 to 2008, the sales representative delivered over 200 Hyalgan samples to Physician Practice J pursuant to this illegal arrangement.

• A Georgia-based Sanofi US sales representative promised 10 Hyalgan samples to Physician Practice K for every 100 Hyalgan units that the practice purchased, in order to reduce the effective unit price of Hyalgan. During the period from 2006 to 2008, the sales representative delivered over 200 Hyalgan samples to Physician Practice J pursuant to this illegal arrangement.
ATTACHMENT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al.
ex rel. MARK GIDDARIE,

Plaintiffs,

v.

SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Civil Action No. 10-10070-NMG

FILED UNDER SEAL

STIPULATION OF DISMISSAL


Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure and the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b)(1), and in accordance with and subject to the terms of the settlement agreement among the United States, Sanofi US, and the Relator (the “Settlement Agreement”), the parties hereby stipulate, through their undersigned counsel, to the entry of an order (1) dismissing with prejudice all claims asserted on behalf of the United States against Sanofi US in the Civil Action concerning the Covered Conduct as defined in Paragraph E of the Settlement Agreement, and (2) dismissing with prejudice to the Relator and without prejudice to the United States all remaining claims against Sanofi US in the Civil Action.
The Relator, on behalf of himself, his heirs, successors, attorneys, agents, and assigns, stipulates that the Settlement Amount set forth in the Settlement Agreement and the terms and conditions described therein are fair, adequate, and reasonable under all the circumstances, that he will not challenge the settlement pursuant to 31 U.S.C. § 3730(c)(2)(B), and that he expressly waives the opportunity for a hearing on any objection to the settlement pursuant to 31 U.S.C. § 3730(c)(2)(B).

The parties respectfully request that the Court enter an order in the form of the attached proposed order.

Respectfully submitted,

STUART F. DELERY
Principal Deputy Assistant Attorney General

CARMEN M. ORTIZ
United States Attorney

Dated: ______, 2012

By: ____________________________

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SANOFI-AVENTIS U.S., LLC

Dated: ___________ 2012  By:

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MARK GIDDARIE

Dated: ___________ 2012  By:

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Boston, MA 02114
ORDER OF DISMISSAL


IT IS HEREBY ORDERED that,

Consistent with, and subject to, the terms of the Settlement Agreement executed by the United States, Sanofi US, and the Relator, all claims asserted on behalf of the United States against Sanofi US in this action concerning the Covered Conduct as defined in Paragraphs E of the Settlement Agreement shall be dismissed with prejudice, and all remaining claims asserted against Sanofi US in this action shall be dismissed with prejudice to the Relator and without prejudice to the United States.

Dated: ____________________________

NATHANIEL M. GORTON
UNITED STATES DISTRICT JUDGE