

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____	)	
UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-11548
	)	
TEVA PHARMACEUTICALS USA, INC., and	)	
TEVA NEUROSCIENCE, INC.,	)	
	)	
Defendants.	)	
_____	)	

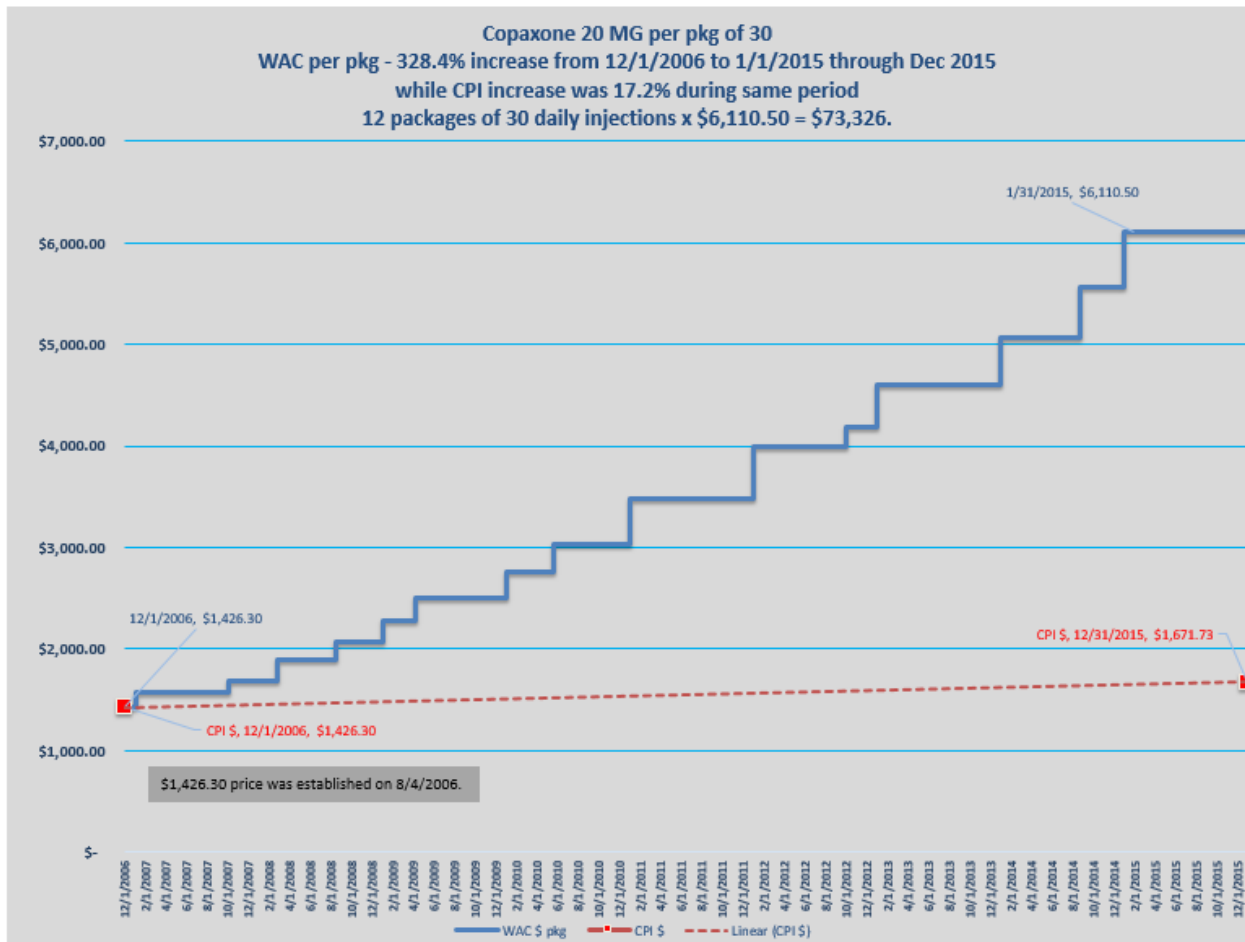
**COMPLAINT**

**Introduction**

1. This is an action against defendants Teva Pharmaceuticals USA, Inc., and Teva Neuroscience, Inc. (collectively, “Teva”), to recover treble damages, restitution, and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-33, and the common law for causing the submission of false claims to Medicare as a result of kickbacks that Teva paid in the form of illegal co-pay subsidies for its multiple sclerosis (“MS”) drug, Copaxone. During the period from late 2006 through at least 2015, Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over \$300 million to two third-party foundations, Chronic Disease Fund (“CDF”) and The Assistance Fund (“TAF”), to cover the Medicare co-pay obligations of Copaxone patients. This conduct generated hundreds of millions of dollars in false claims to Medicare and a corresponding amount of revenue for Teva.

2. Teva used CDF and TAF as conduits: it paid the foundations with the intent and understanding that, in violation of the anti-kickback statute, they would use Teva’s money to cover the co-pays of patients taking Copaxone. Teva intended the payments to ensure that

Copaxone patients never faced the steep prices that Teva charged for its drug, thus inducing the patients, including Medicare patients, to purchase the drug. As depicted in the graph below, during the period from late 2006 to 2015, while Teva was subsidizing Copaxone’s cost through CDF and TAF, Teva raised the price of Copaxone at a rate over 19 times the rate of inflation, from approximately \$17,000 per year to over \$73,000 per year.



3. Teva paid CDF and TAF tens of millions of dollars each year because it knew that the foundations would use Teva's money to cover Copaxone co-pays, thus increasing Copaxone sales and enriching Teva in amounts that far exceeded its payments to the foundations. (A list of payments from Teva to CDF and TAF during the period from December 2006 through 2015 is attached as Exhibit 1.) Ostensibly, CDF and TAF each operated a "MS" fund that covered co-pays for any of the many MS drugs on the market. In practice, however, Teva conspired with the foundations so that they operated their MS funds to maximize the proportion of Copaxone patients who benefited whenever Teva made a payment to the foundations.

4. Teva effectuated its scheme through a specialty pharmacy, Advanced Care Scripts, Inc. ("ACS"), to which Teva referred Copaxone patients who faced Medicare co-pays for the drug. ACS, in turn, arranged for the patients to obtain Medicare co-pay coverage, initially from CDF, and later, after TAF was established, from both CDF and TAF. ACS then reported back to Teva how many Copaxone patients were receiving co-pay coverage from each foundation. During its annual budgeting process, Teva used information from ACS and the foundations to determine how much money each foundation would need to cover the Medicare co-pays of existing Copaxone patients in the following year, and Teva paid each foundation accordingly. From the outset, ACS's founder, Edward Hensley "understood that Teva was purposefully utilizing ACS and structuring its donations to CDF in a manner that essentially ensured that such donations would benefit only Copaxone patients, and not patients who had

been prescribed competitor MS medications.” Affidavit of Edward Hensley (“Hensley Aff.”) ¶ 3 (attached as Exhibit 2). When Teva began paying TAF, in addition to CDF, Hensley ensured that Teva “understood that Teva effectively would be able to use TAF as it had CDF: essentially, as a ‘pass-through’ donation vehicle to get Teva monies into the hands of Copaxone patients.” *Id.* ¶ 10.

5. Teva and ACS also worked together to enable Teva to cover Medicare co-pays for Copaxone patients who started on the drug after the beginning of a year, when the TAF and CDF MS funds were often closed to new patients because the foundations had allocated all of their funding to existing patients. During the course of each year, ACS would provide periodic reports to Teva on the number of new Copaxone patients awaiting Medicare co-pay coverage. When an ACS report showed a substantial number of Copaxone patients waiting, Teva would multiply the number of waiting patients by the relevant foundation’s grant amount for Copaxone patients, add the foundation’s nine percent administrative fee, and then send a corresponding payment to the foundation. Just before sending the payment, Teva would notify ACS, which then would send a “batch file” of applications for all the waiting Copaxone patients to the foundation so that the foundation would act on those applications as soon as the fund re-opened. *See Hensley Aff.* ¶¶ 5-6. In this way, Teva and ACS ensured that the vast majority of Teva’s payments to the foundations went to cover the Medicare co-pays of Copaxone patients.

6. Thus, for Teva, both CDF and TAF functioned not as charities for MS patients, but as pass-through vehicles for money from Teva to Copaxone patients. Indeed, Teva had a special review process for charitable donations, but did not use that process when making its payments to CDF and TAF. Teva knew that, if it did not use CDF and TAF to subsidize Medicare patients' co-pays for Copaxone, substantially fewer patients would use Copaxone and Teva's revenues would suffer. As one Teva employee noted once when the company was considering whether to reduce funding for TAF, "[n]ot funding these patients has a direct and immediate impact on units [sold]." Teva avoided such lost sales by regularly paying CDF and TAF whatever it understood they needed to cover Medicare patients' co-pays for Copaxone.

7. Teva's scheme circumvented the congressional design of the Medicare system, which requires drug co-pays, in part, to act as a market constraint against increasing prices. Instead, unbound by any market check on pricing due to its payment of illegal kickbacks, Teva left American taxpayers to shoulder the high prices that Teva set for Copaxone, while Teva reaped for itself the resulting profits.

### **Jurisdiction and Venue**

8. This Court has subject matter jurisdiction under 28 U.S.C. § 1345. The Court has supplemental jurisdiction to entertain the common law cause of action under 28 U.S.C. § 1367(a). The Court may exercise personal jurisdiction over both Teva Pharmaceuticals USA,

Inc., and Teva Neuroscience, Inc., and venue is appropriate in this Court, under 31 U.S.C. § 3732(a), because both entities caused false claims to be submitted in this District.

**The Parties**

9. Plaintiff United States, acting through the Department of Health and Human Services (“HHS”), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (Medicare).

10. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”), is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), an Israeli business entity whose shares are publicly traded in the United States.

11. Defendant Teva Neuroscience, Inc. (“Teva Neuroscience”), is a Delaware corporation with its principal place of business in Overland Park, Kansas. It is a wholly-owned subsidiary of Teva USA.

12. Teva Neuroscience and Teva USA were individually and collectively involved in the schemes alleged herein. Personnel from both entities proposed, coordinated and approved the payments to CDF and TAF. In many instances, Teva USA was the source of Teva’s payments to the foundations. In other instances, Teva paid the foundations through Teva Neuroscience.

13. Teva Ltd. approved the Teva Neuroscience and Teva USA budgets for payments to CDF and TAF. Senior Teva Neuroscience management reported to Teva USA's senior management, who in turn reported to senior management at Teva Ltd. in Israel. Senior executives at Teva Ltd. directly approved some of the larger payments to TAF and CDF. As stated in a September 2015 e-mail regarding "Medicare Donations Process," the payments required approval from increasingly senior executives, up to Teva Ltd. Chief Executive Officer Erez Vigodman:

Approval Authority Levels

\$0.5M Sr. Director

\$1M VP

\$5M SVP (Larry Downey in the past)

\$15M TEC members (Rob Koremans)

\$25M CFO (Eyal Desheh)

>\$25M CEO (Erez Vigodman)

(A copy of this e-mail is attached as Exhibit 3.) Notably, Teva had a company process for making charitable donations. According to Teva's 2012 "Integrity Principles Policy" concerning charitable donations, "[t]he review and approval process, including all funding decisions for proposed donations, is the responsibility of the appropriate Review Committee (Corporate Responsibility, Medical Advocacy, Medical Affairs and/or Compliance) which is separate from Sales and Marketing." (A copy of the Teva Integrity Principles Policy is attached as Exhibit 4.) Teva did not follow this policy for payments to CDF and TAF; instead, Teva's marketing and patient services teams determined the timing and amounts of those payments, which came from

the Copaxone marketing budget, and senior Teva sales, marketing and finance executives then approved the payments.

### **Legal Background**

#### **I. The Medicare Part D Program And Co-Pays Under Medicare Part D**

##### **A. Medicare Part D**

14. Congress established Medicare in 1965 to provide health insurance coverage for people aged 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq.*

15. Medicare is funded by the federal government and administered by the Centers for Medicare and Medicaid Services (“CMS”), which is part of the United States Department of Health and Human Services (“HHS”).

16. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan Sponsors, to administer prescription drug plans. *See* 42 C.F.R. § 423.4.

17. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. CMS regulates and subsidizes the Part D Sponsors pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into



subcontracts with pharmacies, or other “downstream entities,” to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

18. These entities submit claims to Part D plans that pay for the drug using funds provided by CMS from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

B. Medicare Part D Co-Pay Obligations

19. By congressional design, under the Medicare statute, a Part D beneficiary may be required to make a partial payment for the cost of these prescription drugs in the form of a “co-payment,” “coinsurance,” or “deductible” (collectively “co-pays”). These co-pay obligations can be substantial for expensive medications and vary throughout the year, depending on the total Part D covered expenses the beneficiary has incurred in the year. *See* 42 U.S.C. § 1395w-102. For example, after meeting an annual deductible (originally \$250 in 2006), the standard Part D benefit requires a 25 percent patient co-pay up to an “initial coverage limit” (originally \$2,250 in 2006). *Id.* at b(1)-(2).

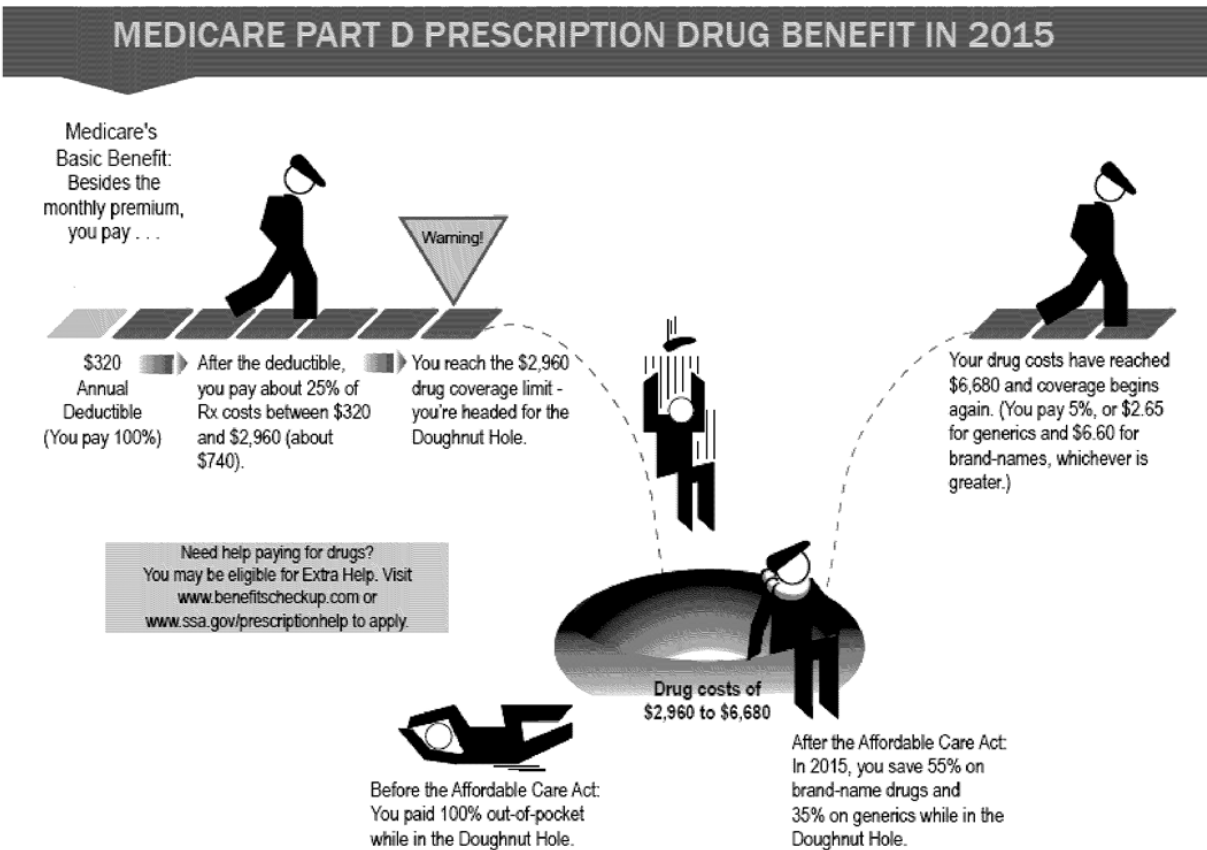
20. After meeting the “initial coverage limit,” there is a “coverage gap” during which patient co-pay obligations increase substantially until the patient meets an “annual out-of-pocket threshold” for the coverage year. *See* 42 U.S.C. § 1395w-102(b)(2)(D). For brand name drugs, the patient co-pay owed in the “coverage gap” was 100 percent through 2010, 50 percent in 2011 and 2012, 47.5 percent in 2013 and 2014, and 45 percent in 2015 and 2016.

21. The financial thresholds for the “deductible,” “initial coverage limit,” and annual “out-of-pocket threshold” have increased each year since 2006 pursuant to a statutory and regulatory formula (from \$250, \$2,250, and \$3,600, respectively, to \$360, \$3,310, and \$4,850, respectively, by 2016).

22. Medicare Part D coverage for costs incurred after the “coverage gap”, *i.e.*, on costs incurred for the remainder of the benefit year above the “annual out-of-pocket threshold” (originally \$3,600 in 2006), is commonly referred to as “catastrophic coverage.”

23. Congress determined that patients owe a co-pay obligation in the “catastrophic coverage” phase equaling the greater of: 1) five percent of the prescription drug costs; or 2) a small fixed dollar amount (originally \$5 for brand name drugs in 2006). 42 U.S.C. § 1395w-102(b)(4). As a practical matter, a patient will owe a five percent co-pay in the “catastrophic coverage” phase of Part D for any expensive, brand name drug. As described below, the remaining costs are paid by a “reinsurance subsidy” from CMS (80 percent) and by the Part D plans (15 percent).

24. In a July 2015 e-mail exchange, Teva employees shared the following visualization of the Medicare Part D co-pay structure:



(A copy of the e-mail exchange with this visual is attached as Exhibit 5.)

25. Congress intended these Medicare co-pays to encourage physicians and beneficiaries to be efficient consumers of federally-reimbursed health care products, and also to encourage those manufacturing such products to price them based on market forces such as consumer sensitivity and competition. Manufacturers paying the Medicare co-pays of those seeking to buy their drugs circumvent this congressionally-designed check on health care costs. As the United States Department of Health and Human Services, Office of the Inspector General

(“HHS-OIG”) has observed, drug manufacturers paying the Medicare Part D co-pays of patients taking their products “eliminat[e] a market safeguard against inflated prices.” HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005).

C. Medicare Payments For Prescription Drugs Under Medicare Part D

26. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, the patient can take the prescription to a pharmacy or submit it to a mail order specialty pharmacy to be filled.

27. When the patient submits the prescription, the Medicare co-pay is due from the patient to complete the purchase of the drug and have the pharmacy fill the prescription.

28. When the pharmacy dispenses a drug to a Part D beneficiary, the pharmacy submits a claim to the beneficiary’s Part D Sponsor, which, in turn, submits an electronic record of the claim, called a Prescription Drug Event (“PDE”), to CMS. After dispensing the drug, the pharmacy receives reimbursement from the CMS-funded Part D Sponsor for the drug cost less the co-pay for which the Part D beneficiary was responsible.

29. The PDE contains many specific representations regarding each Medicare prescription drug claim, including the patient’s name, service provider of the drug, the prescriber of the drug, the name of the drug, and the quantity dispensed to the patient. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing

event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

30. The creation and submission of PDE claims data is necessary for CMS to administer the Part D program and to reimburse Part D Plan Sponsors for qualified drug coverage that they provide to Medicare beneficiaries. Submitting the required information, which is contained in the PDE, is a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322.

31. CMS pays Part D Plan Sponsors based upon these PDEs in various ways. For example, CMS gives each Part D sponsor advance monthly payments to cover, among other things, the Part D Plan Sponsor's direct CMS subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor) and estimated reinsurance subsidies (to account for CMS's anticipated 80 percent subsidy of the "catastrophic coverage" costs that will be incurred for all enrollees). *See* 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Part D Sponsor with the actual costs the sponsor has incurred, as documented by PDE data. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D Sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D that year. In the case of the federal government's 80 percent reinsurance subsidy for catastrophic costs, for example, if CMS determines that it underpaid the sponsor, it will make

up the entire difference. The payments by CMS to the Part D sponsor — which in turn fund the provision of prescription drugs provided to beneficiaries at each drug dispensing event — come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

32. Part D Plan Sponsors must comply with “[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, et seq.), and the anti-kickback statute (§ 1128B(b) of the Act).” 42 C.F.R. § 423.505(h)(1). Any “first tier, downstream, and related entity” that Part D Plans subcontract with (including pharmacies dispensing medication) must also comply with these, and any other, contractual obligations of the Part D Plan, *see* 42 C.F.R. § 423.505(i)(3)(iii), and separately comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(3)(iv).

33. CMS regulations require Part D Plan Sponsors and related “downstream” entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the health care products or services reflected therein. 42 C.F.R. § 423.505(k).

34. Compliance with the regulatory requirement that claims data in the PDE record submitted to CMS be “true, accurate, and complete” is an express condition of payment under the Medicare Part D Program. 42 C.F.R. § 423.505(k).

35. The submission of PDEs is essential to the functioning of the Part D Program, the singular purpose of which is to provide coverage for drug products for the Medicare population. The accuracy of the information contained in each PDE for each patient determines how much payment will be made by Part D for that particular prescription.

## **II. The False Claims Act**

36. The False Claims Act provides, in pertinent part, 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 subparagraph (A) [or] (B),

. . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

37. For purposes of the False Claims Act, the terms “knowing” and “knowingly” mean that a person, with respect to information: (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. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

38. The False Claims Act defines the term “claim,” in pertinent part, as

any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

39. For purposes of the False Claims Act, the term “material” means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

### **III. The Anti-Kickback Statute**

40. The anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of Federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gives rise to overutilization, poor quality of care, or patient harm. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would “contribute significantly to the cost” of



Federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056. First enacted in 1972, Congress strengthened the anti-kickback statute in 1977, 1987, and 2010 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148.

41. The anti-kickback statute prohibits any person or entity from knowingly and willfully offering, making, soliciting, or accepting remuneration, in cash or in kind, directly or indirectly, to induce or reward any person for purchasing, ordering, or recommending or arranging for the purchasing or ordering of federally-funded medical goods or services:

(b) Illegal remunerations

\* \* \*

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than ten years, or both.

42 U.S.C. § 1320a-7b(b)(2). Violation of the anti-kickback statute also can subject the perpetrator to exclusion from participation in Federal health care programs and civil monetary penalties. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

42. The anti-kickback statute prohibits offering or paying anything of value, including “cash” and “in-kind” payments or rebates. 42 U.S.C. § 1320a-7b(b)(2). Money and other forms of financial subsidies that can be used to pay or waive Medicare co-pays constitute remuneration under the anti-kickback statute.

43. The anti-kickback statute defines a “Federal health care program” to mean “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,” except for the health insurance program for federal employees under 5 U.S.C. §§ 8901 *et seq.* 42 U.S.C. § 1320a-7b(f). Medicare is a “Federal health care program” for purposes of the anti-kickback statute.

44. The anti-kickback statute provides that, “[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” 42 U.S.C. § 1320a-7b(h).

45. In 2010, Congress amended the anti-kickback statute to include language that reaffirmed prior case law and provided that any Medicare claim “that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for

purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to Federal health care programs that result from violations of the anti-kickback statute are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a person violates the False Claims Act when he or she knowingly submits or causes to be submitted claims to Federal health care programs that result from violations of the anti-kickback statute.

46. Compliance with the anti-kickback statute is material to CMS’s decision to pay a Medicare claim.

### **Factual Allegations**

#### **I. Background**

##### **A. Teva And Copaxone**

47. Teva Ltd. licensed the rights to Copaxone from the Weizmann Institute of Science in 1987. The United States Food and Drug Administration approved Copaxone in 1996, and it subsequently became one of the best-selling drugs in the United States. For example, “[i]n 2015, Copaxone® revenues . . . amounted to \$3.2 billion in the U.S. (approximately 29% of Teva’s total 2015 U.S. revenues).” Teva Ltd., Annual Report (Form 20-k), Notes to Consolidated Financial Statements, F-64, *available at* <https://www.sec.gov/Archives/edgar/data/818686/000119312516459785/d120587d20f.htm>. In 2015, Medicare spent over \$1.1 billion on catastrophic coverage for Copaxone. *See* HHS-OIG, *High Price Drugs Are Increasing Federal Payments For Medicare Part D Catastrophic Coverage* (Jan. 2017), *available at* <https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf>.

B. Teva's "Shared Solutions" Program

48. For Copaxone patients, Teva provided a suite of services called "Shared Solutions." According to Teva, Shared Solutions was "dedicated to getting and keeping patients on" Copaxone. Through Shared Solutions, Teva offered free injection devices that patients could use to administer the drug, maintained a staff of nurses who provided patients with free injection training, and assigned case managers who worked with patients to obtain insurance coverage for the drug and helped them to identify means of covering the often substantial insurance co-pays for the drug. Physicians who prescribed Copaxone typically submitted an enrollment form directly to Shared Solutions for each new Copaxone patient. As a result, Shared Solutions established relationships with the vast majority of all Copaxone patients.

49. Teva explained the financial component of the Shared Solutions offering in a set of talking points for its Copaxone sales team:

- **Shared Solutions<sup>®</sup>** is committed to helping ensure that financial concerns do not come between patients and their treatment
- No patient should have to choose, interrupt, or discontinue therapy because of financial concerns, nor should a health care provider have to make clinical decisions based on cost
- **Shared Solutions<sup>®</sup>** is dedicated to finding the right assistance for both new and existing patients

- Affordable access is the reality for the majority of COPAXONE<sup>®</sup> (glatiramer acetate injection) patients
- **Shared Solutions<sup>®</sup>** supports 3 separate financial assistance programs for COPAXONE<sup>®</sup> patients
  - Free product
  - Medicare Part D assistance
  - Private co-pay assistance

Similarly, in a 2011 Work Plan for Teva Neuroscience, the company noted that “Copaxone Patient Assistance Programs remove prescribing barriers and drive[] adherence and compliance.” Thus, Shared Solutions served to assure both patients and their physicians that they need not worry about Copaxone’s substantial cost.

50. In October 2006, Teva entered into a contract with ACS, a specialty pharmacy that Hensley and Jeff Spafford had co-founded earlier that year. (A copy of this contract is attached as Exhibit 6.) Hensley had a prior business relationship with Denise Lynch, who at the time was Teva’s Director of Customer Resources and ran Teva’s Shared Solutions program. (Lynch’s title later changed to Vice President of Patient Services.) Pursuant to the contract, Shared Solutions referred to ACS patients who had been prescribed Copaxone and who either had or were eligible for Medicare Part D coverage. If a patient did not already have Medicare Part D coverage, ACS helped the patient sign up for coverage. If a patient was eligible for Medicare co-pay coverage from a foundation, ACS would gather the necessary information from the patient and submit an application for the patient to CDF.

51. ACS generated revenue on its work for Teva from service fees that Teva paid to ACS to facilitate foundation coverage for Medicare patients, and from dispensing Copaxone. ACS dispensed Copaxone to the vast majority of the Copaxone patients for whom it arranged co-pay coverage through its arrangement with Teva.

52. In 2008, Hensley and Spafford sold ACS to another pharmacy. They stayed on at ACS until late 2009. Meanwhile, during 2009, they founded TAF and a for-profit business called AssistRx. After TAF opened its MS fund in or about January 2010, ACS started helping Medicare patients obtain Copaxone co-pay coverage from both TAF and CDF. In September 2010, AssistRx started running Teva's free drug program for Copaxone patients who did not have insurance. As part of that program, AssistRx identified Medicare-eligible patients who were receiving free Copaxone from Teva. AssistRx arranged for those patients to obtain Medicare coverage, and referred them to ACS, which then would seek foundation co-pay funding for them. In February 2015, AssistRx also took over ACS's role of arranging Medicare co-pay funding for Copaxone patients referred by Shared Solutions.

53. Throughout the course of its work for Teva, ACS provided Teva with regular updates on the number of Copaxone patients receiving co-pay funding from CDF or TAF. In these updates, ACS told Teva how many Copaxone patients each foundation was funding and broke down the totals into patients receiving their drug from ACS or from another pharmacy.

TAF, meanwhile, reported that it approved over 99 percent of the co-pay coverage applications it received when funding was available.

## **II. Teva Paid Foundations To Generate Medicare Claims For Copaxone.**

54. Even before the start of the Medicare Part D program in 2006, Teva paid foundations to increase sales of Copaxone. In an article on December 1, 2005, the Wall Street Journal reported on an interview with Lynch:

‘Market research told us early on that we needed to do a patient support program’ because some people wouldn’t be able to afford their co-payments, says Denise Lynch . . . .

Ms. Lynch says Teva didn’t calculate the profit it could receive when making its donation, ‘but from a common-sense perspective, you can get there.’ . . .

Teva considered setting up a foundation on its own, she says, but concluded it was ‘cleaner from a regulatory point of view to work through a third party.’

Geeta Anand, *Through Charities, Drug Makers Help People—and Themselves*, Wall St. J. (Dec. 1, 2005). (A copy of this article is attached as Exhibit 7.)

55. Soon after Teva started working with ACS, Lynch told Hensley that she would not authorize payments to Patient Services, Inc. (“PSI”), another co-pay foundation, because PSI had “burned” her with respect to a prior payment from Teva. Hensley Aff. ¶ 4. Lynch explained to Hensley that a payment Teva had made to PSI had not been passed to Copaxone patients but rather had been used to cover the co-pays of patients on other drugs. *Id.* According to Hensley, Lynch said she was “‘tired’ of other pharmaceutical manufacturers ‘riding on [Teva’s]

coattails.” *Id.* Accordingly, as described further below, Teva financed the MS funds only at CDF and TAF, where it had assurance that its money would go to patients taking its drug, Copaxone.

56. ACS understood that Teva’s goal was to use the foundations as a “pass-through vehicle.” Hensley Aff. ¶ 10. In a February 2007 e-mail reflecting Hensley’s understanding of Teva’s goal, Hensley instructed his ACS colleagues that “particular manufacturer funds [should] go to their own drug as [that was] what was the intent of the project was originally.” (A copy of this e-mail is attached as Exhibit 8.)

57. Teva showed its intent to make money from its financing of CDF and TAF through its refusal to include Medicare patients in its charitable free drug program so long as foundation co-pay coverage was available. Teva generally excluded Medicare patients from its free drug program because foundation-assisted patients generated revenue from Medicare reimbursement, whereas free drug patients did not. At least as early as 2008, Teva instructed ACS not to refer Medicare patients to Teva’s Copaxone free drug program if foundations were accepting patients. Thus, in an August 2008 example of ACS implementing Teva’s instruction, Hensley told Lynch: “Just an FYI. Since we are getting no rejections yet from the non profit sources we are utilizing here at ACS, we have not started any Free Drug program. I will let you know the moment it kicks in.” (A copy of Hensley’s e-mail is attached as Exhibit 9.) Years later, Teva’s policy had not changed. In an April 2016 e-mail, a Shared Solutions supervisor



described the eligibility for the company's free Copaxone program and noted that "[p]atients with government funded plans are not eligible to apply." (A copy of this e-mail is attached as Exhibit 10.) Teva made an exception to this policy for Copaxone patients who obtained new Copaxone prescriptions or Medicare Part D coverage for the first time near the end of a calendar year when no foundation coverage was available. Teva, ACS, and the foundations then worked to move those patients onto foundation coverage at the beginning of the following year. As Hensley wrote in November 2007, "[t]he Copaxone Cares [*i.e.*, free drug] patients will transition to CDF Med D program in January." (A copy of this e-mail is attached as Exhibit 11.) Likewise, a Shared Solutions manager explained in an April 2016 e-mail that, "in the past when a new Med D patient needs assistance and at that time (usually close to the end of the calendar year) the Foundation has closed its funds[,] [i]f we want the patient to start drug we provide free product for the remainder of the calendar year and tee them up for Foundation Assistance for the following January when funds will be available." (A copy of this e-mail is attached as Exhibit 12.)

58. Teva knew that there was a direct correlation between its foundation funding and Copaxone sales. In December 2011, for example, Katie Hiatt, Teva Neuroscience's Director of Finance and Planning, and Felicia Ladin, Teva USA's Vice President of Finance, discussed the possibility of reducing Teva's planned 2011 fourth quarter payment to TAF from \$10 million to \$5 million. Hiatt warned Ladin against such a cut: "Not funding these patients has a direct and

immediate impact on units.” (A copy of this e-mail is attached as Exhibit 13.) A week later, Teva paid TAF \$10 million, just as it had planned.

59. A year later, in December 2012, Mike Sheehy, a Teva marketing director, told his boss, John Hassler, that he had conferred with Lynch regarding the need for “patient assistance funding,” and that Teva needed to pay about \$15 million more in 2013 than Teva had planned. Sheehy further reported that he had “provided Denise [Lynch] the direction to move forward because *not doing so directly impacts the topline with existing patients.*” (A copy of this e-mail is attached as Exhibit 14.) (Emphasis added.)

60. Similarly, in early 2015, as Teva again was considering whether to pay TAF less than it had planned, the company ended up paying the planned amount because it knew that paying less would reduce sales. In an e-mail dated January 9, 2015, Jennifer Clark, an Associate Director in Teva’s Patient Services department, warned that, if Teva cut its foundation payments, the company’s sales forecasts would be “overstated”: “They still have Medicare revenue in [the forecast] which is highly unlikely if the donations are no longer made.” (A copy of this e-mail is attached as Exhibit 15.) A few weeks later, in an e-mail dated February 2, 2015, Alejandro Castro, a Teva financial analyst, advised David Loughery, Teva’s Vice President of Finance, that “Patient access has also mentioned that they will need between **\$5M and \$8M in donations** soon to avoid losing an estimated 1,500 Medicare Patients.” (A copy of this e-mail is attached as Exhibit 16.) (Emphasis in original.) Castro then quantified the dollar value of losing those

patients: “There is about \$6.3M in donations budget that are the target of possible cost reductions but there may be a risk to Net Sales of approximately \$5.8M per month associated with reducing donations.” Shortly thereafter, instead of cutting the “donations budget,” Teva agreed to pay TAF \$8.5 million, which was over \$2 million more than Teva previously had planned to pay at that time.

61. In August 2015, in another discussion about potentially reducing Teva’s future financial support of TAF, Clark reiterated her earlier warning, this time to Ryan Sloss, a Teva finance manager: “it’s clear that if the \$10M gets removed, the sales will decrease as well, as there will be Medicare patients out there that won’t be able to fill.” (A copy of this e-mail is attached as Exhibit 17.) Sloss concurred: “we either pay it and go over budget or we don’t make our sales numbers.”

62. Meanwhile, Teva consistently raised the price of Copaxone, and paid CDF and TAF to eliminate the bite of those increases on patients and their physicians, but not on the taxpayers who fund Medicare. Thus, for example in an e-mail on November 15, 2011, Katie Hiett forwarded Felicia Ladin a discussion of a potential price increase and wrote: “I discussed the need for Patient Assistance with Denise [Lynch] and incremental price increases of 9.9%/5% over planned amount of 8.9% would cause a potential patient assistance increase of \$4M-\$5M across all of the Copaxone patient assistance programs.” (A copy of this e-mail is attached as

Exhibit 18.) As Ms. Hiatt later explained in testimony: “Well, if you raise the price of your product, the patient’s coinsurance for out of pocket goes up as well.”

63. Because Teva intended its payments to CDF and TAF to generate Copaxone sales, Teva’s Tax department wrote that the company should treat those payments as business expenses rather than charitable donations. In a July 2013 memorandum, a manager in Teva’s Tax department reviewed Teva’s recent payments to CDF and TAF and concluded that “[t]he payments . . . are made with the expectation of financial return commensurate with the amount donated and should therefore be deducted as business expense.” (A copy of this memorandum is attached as Exhibit 19.)

64. Tellingly, even though Teva’s payments to CDF and TAF were ostensibly for the foundations’ MS funds, which theoretically could assist patients on any MS drug, senior Teva executives commonly referred to those payments as “Copaxone donations.” Examples of such references include the following:

- A December 2014 e-mail from a Teva Senior Vice President directing her subordinate to “release \$25M of *Copaxone donations* to be mailed on Dec 29<sup>th</sup>.” (A copy of this e-mail is attached as Exhibit 20.) (Emphasis added.)
- A January 2015 e-mail from Eyal Desheh, the Chief Financial Officer of Teva Ltd., approving a “*Copaxone Donation* payment.” (A copy of this e-mail is attached as Exhibit 21.) (Emphasis added.)
- A February 2015 e-mail from a Teva Associate Director of Finance to Larry Downey, the President of Teva’s North America Specialty Medicines (“NASM”) unit, with the subject “Response requested: Approval for *Copaxone donation* payment.” Downey approved, and forwarded the e-mail to Rob Koremans,

President and CEO Global Specialty Medicines at Teva Ltd., who approved as well. (A copy of this e-mail chain is attached as Exhibit 22.) (Emphasis added.)

- An April 2015 e-mail from Jan Jones, Teva’s Director of Patient Services and Support, approving a “*Copaxone Donation.*” (A copy of this e-mail is attached as Exhibit 23.) (Emphasis added.)
- A January 2017 e-mail from a Teva NASM VP of Finance to Koremans, President and CEO Global Specialty Medicines at Teva Ltd., regarding “*Copaxone donations approval.*” (A copy of this e-mail is attached as Exhibit 24.) (Emphasis added.)

65. Although Teva made its substantial payments to CDF and TAF in order to generate revenue from Copaxone sales to Medicare patients, Teva generally avoided conducting formal return on investment (“ROI”) analyses of its foundation support, for fear of creating an obvious compliance issue. One former Patient Services manager, Jenny Jackson, testified that “it was very clear that there was never to be any kind of ROI analysis on Medicare. That was widely known.” Still, Jackson’s handwritten notes from a January 2010 meeting show that the company did in fact calculate ROI from its payments to Medicare patients through TAF and CDF. The notes, which are entitled “Medicare” and are in a folder also entitled “Medicare,” reflect Teva’s understanding that a \$28 million “expense” would support over 4,800 Copaxone patients and generate over \$114 million in net revenue. In other words, Teva knew that foundation support generated substantial ROI, which is why Teva paid CDF and TAF hundreds of millions of dollars. An image of Jackson’s notes is below:

Medicare  
1/21/10

AKS  
4900 x 12 = 57,600  
comp. 90 = 51,840

4900  
x 1650  
-----  
6,450  
6500 x 12 = 78,000  
comp. 90 = 70,200

59,670  
+ 27,500  
-----  
164,092  
114,064  
-----  
50,028  
28M expense  
-----  
20.5

discount 85 = 59,670

annual doses  
70 (margin)

**III. Teva Understood That It Should Not Use Foundations As Conduits To Cover Copaxone Patients' Medicare Co-Pays.**

66. Teva knew that federal law prohibited it from covering a Medicare patient's co-pay directly. Thus, while it operated a program to cover Copaxone co-pays for patients with private insurance, that program did not cover patients with government insurance.

67. Teva further knew that federal law did not permit it to cover a Medicare patient's co-pay indirectly by using a foundation as a pass-through vehicle. Lynch and other Teva employees knew that the AKS prohibited Teva from earmarking its money to patients on its drug, Copaxone. They were aware of HHS-OIG's 2005 Special Advisory Bulletin on Patient

Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), and HHS-OIG’s 2014 Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014). In the 2005 Special Advisory Bulletin, HHS-OIG advised that, notwithstanding the facial applicability of the anti-kickback statute to payments by pharmaceutical manufacturers to patients via foundations, “pharmaceutical manufacturers can donate to *bona fide* independent charity PAPs, provided appropriate safeguards exist.” 70 Fed. Reg. at 70625. The 2005 Special Advisory Bulletin spelled out these “safeguards,” including that a foundation “must not function as a conduit for payments by the pharmaceutical manufacturer to patients,” and that a pharmaceutical manufacturer should not “solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.” *Id.* at 70626, 70627. The 2014 Supplemental Special Advisory Bulletin reiterated these warnings and concluded with this specific caution:

These opinions do not address actions by donors to correlate their funding of [co-pay foundations] with support for their own products. Such actions may be indicative of a donor’s intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.

79 Fed. Reg. at 31123.

68. Thus, not only did Teva know that it should not create bad appearances by performing ROI analyses on its payments to co-pay foundations, it knew that the AKS prohibited

it from using the foundations as conduits for payments to patients on its drug, and it further knew that HHS-OIG had similarly warned pharmaceutical manufacturers and co-pay foundations.

69. Teva's first contract with CDF, which both Lynch and Larry Downey, the CEO of Teva Neuroscience, signed in 2006, provided that CDF "shall be [] a *bona fide*, independent charity as described by the [2005 HHS-OIG Special Advisory Bulletin]. Further, the Foundation has received a favorable OIG opinion . . . as documented in OIG Opinion 06-10." (A copy of this contract is attached as Exhibit 25.) Consistent with the 2005 Special Advisory Bulletin, CDF's OIG Opinion relied on CDF's representation that its "reports to donors do not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number . . . of patients that use its products." HHS-OIG, Advisory Opinion 06-10 at 5, available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-10A.pdf>. The CDF Advisory Opinion further noted that "Donors are not assured that the amount of financial assistance their patients . . . receive will bear any relationship to the amount of their donations. Indeed, donors are not guaranteed that any of their patients . . . will receive any financial assistance whatsoever from [CDF]." Teva, however, knew and intended that CDF would use Teva's money to cover Medicare co-pays for the vast majority of the Copaxone patients Teva referred to CDF through ACS.

70. In December 2010, after Teva began paying TAF, Hensley e-mailed Lynch with a copy of the advisory opinion TAF had obtained from HHS-OIG earlier that year. (A copy of



Hensley's e-mail, with its attachments, is attached as Exhibit 26.) Like the CDF Advisory Opinion, the Advisory Opinion for TAF noted that the foundation's conduct would be low risk under the anti-kickback statute so long as it did "not provide Donors with any data that would facilitate the Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services," and "Donors would not be permitted to earmark contributions for specific Specialty Medications." The opinion emphasized that anti-kickback statute concerns would dissipate only if "Donors would not be assured that the amount of financial assistance their patients . . . receive would bear any relationship to the amount of their donations," and "Donors would not be guaranteed that any of their patients . . . would receive any financial assistance whatsoever from [TAF]." Teva, however, knew and intended that TAF would use Teva's money to cover Medicare co-pays for the Copaxone patients Teva referred to TAF through ACS.

71. In December 2011, three Teva employees – Lynch, Clark, and Katie Hiett, Teva's Director of Finance and Planning – exchanged e-mails about information they would like from CDF. (A copy of their e-mail exchange is attached as Exhibit 27.) In one of these e-mails, Lynch wrote: "Is there a way to get to total patients in the fund (what % of the fund is made up of Copaxone patients[.])...I don't believe they can provide this directly but is there some way you can back in to the answer?"

72. In May 2012, a Teva employee circulated a 2008 PowerPoint presentation from a law firm, Sidley Austin, on “Legal Considerations in Developing Patient Assistance Programs.” The presentation summarized the anti-kickback statute and noted that, according to HHS-OIG:

PAPs present “all of the usual risks of fraud and abuse associated with kickbacks”

- Steering patients to particular drugs
- Increasing costs to Medicare
- Providing financial incentives over competing drugs
- Reducing enrollees’ incentives to locate and use less expensive, equally effective drugs[.]

The presentation then reiterated HHS-OIG’s warning that “the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients.” (A copy of this presentation is attached as Exhibit 28.)

73. In May 2014, Hensley e-mailed Lynch a copy of HHS-OIG’s recently-issued 2014 Special Advisory Bulletin. (A copy of Hensley’s e-mail is attached as Exhibit 29.)

74. Lynch testified that she knew she “wasn’t supposed to” obtain Copaxone numbers directly from a foundation. She said that she had that “understanding . . . as a result of training that we received regarding anti-kickback.”

75. In addition, according to Hensley, after Lynch retired from Teva, she told Hensley that “she had warned Teva’s senior leadership years before that Teva should ‘take a reserve’ to cover False Claims Act liabilities associated with Teva’s donations to CDF and TAF ‘in the event’ that the donations came under government scrutiny.” Hensley Aff. ¶ 18.

**IV. In Coordination With ACS, Teva Used CDF And TAF As Conduits To Cover Copaxone Patients' Medicare Co-Pays**

76. As noted above, from the outset, Teva made clear to ACS that it wanted its foundation support to go to Copaxone patients. In a February 2007 e-mail reflecting Hensley's understanding of Teva's goal, Hensley instructed his colleagues that "particular manufacturer funds [should] go to their own drug as [that was] what was the intent of the project was originally." (A copy of this e-mail is attached as Exhibit 8.)

77. The mechanics of Teva's arrangements with ACS, CDF and TAF enabled it to ensure that its payments to the foundations went to Copaxone patients. Unlike other foundations, CDF was willing to accept batch files from ACS, facilitating the mass enrollment of Copaxone patients whenever Teva made a payment to CDF. TAF later accepted ACS's Copaxone batch files, too. By timing its payments to TAF and CDF with ACS's submission of batch files of applications, Teva was able to ensure that each foundation would cover Copaxone patients whenever Teva provided funding.

78. Knowing that CDF and TAF paid at least lip service to the HHS-OIG guidelines and were generally reluctant to provide Teva with precise data on the number of Copaxone patients they were assisting, Teva nonetheless obtained substantially the same information from ACS, which, as Teva knew, got its information from CDF and TAF. At the end of each year, Teva used that information to correlate its funding of CDF and TAF with their anticipated spending on Copaxone patients' Medicare co-pays in the following year. Teva performed

similar correlations during the course of each year when ACS told Teva how many new Copaxone patients were awaiting Medicare co-pay coverage; Teva used the information from ACS to calculate how much and when to pay CDF and TAF, and ACS then arranged for batch enrollment of Copaxone patients into the funds. Teva thus achieved its goal of using CDF and TAF as pass-through vehicles to funnel money to Copaxone patients who otherwise would have faced cost-prohibitive Medicare co-pays for Teva's expensive drug.

A. Teva's Receipt Of The Data Necessary For Its End-Of-Year Correlations

79. Teva needed three data points to calculate how much to pay CDF and TAF at the end of each year to ensure that each foundation's MS fund would continue to cover Copaxone patients' Medicare co-pays in the following year: (1) the number of Copaxone patients enrolled in each fund, (2) each fund's annual per-patient grant amount; and (3) each fund's administrative fee, which was generally 9 percent during the relevant time period.

80. Teva regularly received, from both CDF and TAF, the per-patient grant amount that each foundation provided to Copaxone patients at any given time. For example, the following series of e-mails shows how CDF conveyed per-patient grant amounts to Teva:

- On October 28, 2010, CDF's President, Michael Banigan, sent an e-mail to Lynch: "We are estimating the per-patient grant amount of \$3,950 next year. Math is simple. Number of patients times the grant amount divided by .91. We can chat at your convenience." (A copy of this e-mail is attached as Exhibit 30.) Banigan's e-mail presumed that Lynch knew the "[n]umber of patients," and, in fact, Lynch could get that from ACS. Banigan suggested the factor of .91 to take into account CDF's nine percent fee.

- On September 15, 2011, Banigan wrote to Lynch: “Do you have time for a call tomorrow? I have preliminary numbers for you.” (A copy of this e-mail is attached as Exhibit 31.)
- On November 7, 2012, Lynch sent Banigan an e-mail asking for the “2013 patient contribution,” and Banigan responded: “Everything is the same as last year. \$3750 per patient [and] \$1500 for [low-income subsidy]. Admin is 9%, but in reality we paid out 92% last year across all funds.” (A copy of this e-mail chain is attached as Exhibit 31.) Later that day, Walley sent Lynch an e-mail clarifying that “the 2012 per patient allocation for the MS program is \$4750. . . . The allocations will remain the same for the 2013 calendar year.” (A copy of this e-mail is attached as Exhibit 33.)
- On December 20, 2013, Lynch asked Walley for the “per patient donation estimate for the MS fund for 2014,” and Walley responded: “Initial allocation is \$5000.” (A copy of this e-mail is attached as Exhibit 34.)

Further, Lynch testified that CDF provided her with per-patient grant amounts.

81. Teva received similar information from TAF on a quarterly basis. Hensley often provided this information to Lynch over the phone or in person, but sometimes he provided it in writing. For example, on September 27, 2011, Hensley sent Lynch an e-mail that included the following:

The allocation per patient for 2012 is \$4,600. To give you a historical number of what it has been in the past:

2012 - \$4,600

2011 - \$4,400

2010 - \$5,600

(A copy of this e-mail is attached as Exhibit 35.) *See also* Hensley Aff. ¶ 13 (“I would regularly provide either Ms. Lynch or Mr. Blanc (or both) the “per-patient allocation” that TAF was using

for its MS Fund at any given time. I sometimes did this proactively, but usually did this in response to a specific request by Ms. Lynch.”).

82. With the per-patient grant amounts readily available directly from the foundations, Teva then obtained from ACS the number of Copaxone patients who were receiving co-pay coverage from each foundation. ACS provided this information in writing and over the telephone. The following e-mails exemplify ACS’s provision of such information to Teva for budgeting purposes:

- On August 7, 2007, Teva sent ACS an e-mail noting that it had received a file from ACS. Included within that file was a list of 1,082 Copaxone patients who were “Approved for Assistance” with CDF. (A copy of the cover e-mail is attached as Exhibit 36. The accompanying file is not attached because it contains protected health information.)
- On December 23, 2008, ACS sent Teva an e-mail reporting that a total of 2,499 Copaxone patients were receiving co-pay coverage from CDF at that time. (A copy of this e-mail is attached as Exhibit 37.)
- On November 30, 2009, ACS sent Teva an e-mail reporting that a total of 3,230 Copaxone patients were receiving co-pay coverage from CDF at that time. (A copy of this e-mail is attached as Exhibit 38.)
- On December 14, 2010, ACS sent Teva an e-mail reporting that, at that time, a total of 2,008 Copaxone patients were receiving co-pay coverage from CDF and a total of 2,714 Copaxone patients were receiving co-pay coverage from TAF. (A copy of this e-mail is attached as Exhibit 39.)
- On August 30, 2011, Teva’s Jennifer Clark sent an e-mail asking one of her colleagues, Barb Ross, to tell her the “Estimated # of Medicare Patients rcvg full/partial assistance by year-end.” Ross responded that “David and Zach [of ACS] will be getting numbers first thing in the morning, they are checking with CDF for total numbers.” (A copy of this e-mail is attached as Exhibit 40.) A

week later, Ross was able to report to Clark: “There are 83 partial assistance with CDF, 153 partial assistance with TAF. Full assistance with CDF 1896 and full assistance with TAF 3440.” The resulting totals were 1979 at CDF and 3593 at TAF. Ross also reported that there were 525 Copaxone patients who were receiving free product but were eligible for Medicare. (A copy of this e-mail is attached as Exhibit 41.)

- On August 27, 2012, ACS’s Blanc sent an e-mail to Lynch with the “current numbers,” as follows:

AF	4747
CDF	1456
PAN	2
Total of 6205 assisted via 501c3	

(A copy of this e-mail is attached as Exhibit 42.) (“PAN” was another co-pay foundation that Teva did not support at that time.)

- On December 5, 2013, Blanc sent Lynch the latest numbers again:

Hey Denise –
Great catching up with you yesterday!
As requested, numbers:
TAF 5614
CDF 1188
LIS 3543
Let me know if you need anything further.
Thank you for the partnership –

(A copy of this e-mail is attached as Exhibit 43.)

**B. *Teva's Use Of Data From CDF, TAF, And ACS To Determine How Much To Pay CDF And TAF For Existing Copaxone Patients Each Year***

83. For each year from 2008 through at least 2014, Teva used data reflecting per-patient grant amounts and numbers of Copaxone patients CDF and TAF were assisting to determine how much Teva would pay the foundations to cover existing Copaxone patients in the next year. As Hensley explained, Teva's receipt of information from TAF and ACS "would be sufficient to enable her [Lynch] to determine how much Teva should donate at the start of the year." Hensley Aff. ¶ 14.

84. Jennifer Clark, who in 2011 took over the process of preparing Teva's budgets for foundation payments, explained the process as follows:

So, I would take an estimated number of Medicare patients, apply that towards what the typical average Medicare cost per patient might be for a calendar year, and then multiply that times those patients to determine what that might look like. And then I understood the administration fees for foundations were typically somewhere in the nine percent range, so I would do that calculation to determine how much we would need for the upcoming year.

Clark further explained that the "Medicare patients" she referenced were Copaxone patients.

85. For example, in September 2011, after having just learned from her colleague, Barb Ross, that ACS was estimating 5,572 Copaxone patients would be receiving foundation co-



pay coverage by the end of that year, Clark put together the following budget spreadsheet:

	A	D	E	F	G	H	I
		2011	2012	2013	2014		*2013 is first year
2	501c Funding per pt		4771	5004	5280		
3	Katie's portion		1867	1900	1900		*patient picks up more than p
4	<b>Govt Portion</b>						
5	Medicare Funding per pt.	\$ 6,250	\$ 6,638	\$ 6,904	\$ 7,180		
6	Qual-new Medicare pt.	\$ 150	\$ 150	\$ 150	\$ 150		
7	Requal-Medicare pt.	\$ 125	\$ 125	\$ 125	\$ 125		
8	Adherence rate	88%	88%	88%	88%		
9	Admin fee	9%	9%	9%	9%		
10	Additional factor for	120%	120%	120%	120%		
11	Estimated Fund Carryover						
12	COGS & Shipping & Handling - Med D Free - per month (\$60+\$70)	\$ 190	\$ 130	\$ 130	\$ 130		
13	Average # of Med D Free dispenses per pt	4	3	3	3		
14							
15							
16	Beginning of Year		6300	5988	5330		
17	Additional new pts - assistance donated		500	506	473		
18	Med Free Roll-over	525	525	483	452		
19	Retention - Patients at year-end (full funding & partial LIS)	5775	5984	5715	5107	Per Zach, 8/31	
20	Full LIS	2475	2723	2995	2750	Per Zach, 8/31	
21	Total Patient Count	8775	9232	9193	8308		
22							
23							
24	Qualification-new pts.	\$ 94,500.00	\$ 184,500.00	\$ 178,020.00	\$ 166,410.00		
25	Qualification-existing pts.	\$ 78,750.00	\$ 1,098,750.00	\$ 1,046,592.00	\$ 938,212.67		
26	TN 50% portion on assisted pts						
27	Donut Hole Funding	\$ -	\$ 32,442,800.00	\$ 32,494,259.87	\$ 30,639,197.37		
28	Total Donation	\$ -	\$ 35,651,428.57	\$ 35,707,977.87	\$ 33,669,447.66		
29	Admin fee	\$ -	\$ 3,208,628.57	\$ 3,213,718.01	\$ 3,030,250.29		
30	Estimated Fund Carryover	\$ -	\$ -	\$ -	\$ -		
31	<b>TOTAL Medicare - excl</b>	<b>\$ 173,250.00</b>	<b>\$ 36,934,678.57</b>	<b>\$ 36,932,589.87</b>	<b>\$ 34,774,070.32</b>		\$5.5M donation made 12/31/2009

(A full copy of this spreadsheet is attached as Exhibit 44. Other iterations from other years are attached as Exhibits 45, 46, 47, and 48.) The number “5775” on line 19 of this spreadsheet was a rounding of the number Clark had received from ACS via Ross, as indicated by the note “Per Zach [Gammage at ACS], 8/31” in column H of line 19. See Exhibits 40 and 41. The figure immediately above that, 525 “Med Free Roll-over,” also had come from ACS via Ross and reflected the number of Copaxone patients on Medicare who were then receiving free drug but for whom ACS would obtain foundation coverage in 2012. *Id.* The formula metadata in the

spreadsheet shows that Clark added 5,775 and 525 to get 6,300, which is the number that appears on line 16, the “Beginning of Year” patients for 2012. According to line 17 of the spreadsheet, Clark estimated that 500 additional Copaxone patients would need Medicare co-pay coverage in 2012. The spreadsheet formula metadata further shows that Clark added 6,300 to 500 and then multiplied the sum by 4,771, the “501c Funding per pt” on line 2, to get the “Donut Hole Funding” amount of \$32,442,800 on line 27. (“501c Funding per pt” was the amount that Teva calculated it needed to fund per patient based on a standard Medicare Part D plan and the cost of Copaxone; “Donut Hole Funding” was a term that Teva used to describe the total amount it planned to pay for Medicare co-pays for Copaxone patients.) Teva added the foundations’ 9 percent administrative fee to generate the “Total Donation” budget amount on Line 28.

86. During the last week of December 2011 and the first week of January 2012, Teva paid CDF and TAF a total of \$33,200,000 from its foundation budget. Using data received from CDF and TAF via ACS, Teva paid the foundations what it understood they needed to cover co-pays for Copaxone patients in the upcoming year.

87. During each of the years from 2007 through at least 2014, Teva consistently followed this practice of using data from the foundations (via ACS) to calculate its budgets for TAF and CDF and to pay them what they needed to cover co-pays for Copaxone patients in the following year. After Teva made these payments, it then received confirmation from the

foundations (via ACS) that they had covered the Copaxone patients who had sought to renew their annual Medicare co-pay grants.

C. Teva's Correlations For Payments To TAF During The Course Of The Year

88. As soon as TAF's MS fund started accepting patients in January 2010, Teva, ACS and TAF engaged in schemes to enroll Copaxone patients into TAF's MS fund using Teva's payments. Teva's use of TAF as a conduit started with Medicare patients on Teva's free drug program at ACS. As an ACS vice president explained in an e-mail dated January 4, 2010, "Teva has funded all their Free drug patients through a new foundation called 'The Assistance fund.'" (A copy of this e-mail, with the subject "The Assistance Fund - A new copay foundation for Copaxone MS patients," is attached as Exhibit 49.) Teva paid TAF \$15.7 million in four payments between December 30, 2009, and January 25, 2010, during which time approximately 99.9% of the payments from TAF's MS fund went to Copaxone patients. By February 4, 2010, ACS reported to Teva that TAF was covering Medicare co-pays for 2,322 Copaxone patients. (A copy of this e-mail is attached as Exhibit 50.) The close cooperation between Teva, ACS, and TAF continued at least into 2015.

89. Shortly after the beginning of each year, TAF generally closed its MS fund because it had committed all of its funding to existing patients who had just renewed their annual co-pay grants. With TAF's MS fund closed and with CDF also generally not providing new grants after the beginning of a year, but with new MS patients still being prescribed Copaxone

and seeking Medicare co-pay coverage, Teva worked with ACS and TAF to ensure that these new Copaxone patients, too, would not have to pay co-pays for the drug. In doing so, Teva again sought to correlate its payments to TAF with TAF's anticipated spending on Copaxone patients.

90. To achieve this goal, Teva, ACS, and TAF engaged in a coordinated multi-step process. First, ACS told Teva how many new Copaxone patients were awaiting Medicare co-pay coverage at a particular time. Second, TAF told Teva the average Medicare co-pay grant amount for a Copaxone patient at that time. Third, Teva multiplied those two figures together and added an amount for TAF's administrative fee to determine how much to pay TAF. Fourth, Teva told ACS how much and when it planned to pay TAF. Fifth, ACS sent a "batch file" of Copaxone co-pay coverage applications to TAF as soon as TAF's MS fund opened upon receipt of Teva's payment. Finally, TAF provided co-pay grants to the Copaxone patients in ACS's batch file, which eliminated the backlog of Copaxone patients awaiting Medicare co-pay coverage. Lynch testified that this "was the normal way it was done." Likewise, Hensley described this same process. *See Hensley Aff.* ¶¶ 13-14. The following examples show how this process worked in practice.

91. On February 9, 2011, ACS sent Teva an e-mail showing, among other things, that there were 320 Copaxone patients awaiting Medicare co-pay assistance. (A copy of this e-mail is attached as Exhibit 51. 320 is the sum of the 155 patients "waiting paperwork return" and the 165 patients "pending new assistance.") At that time, the per-patient allocation in TAF's MS

Fund was \$4,400, and TAF's administrative fee was 9 percent. Factoring those figures results in the following calculation:  $320 \times \$4,400 \times 1.09 = \$1,534,720$ . On February 10, 2011, Lynch e-mailed Jon Congleton, then the general manager of Teva's Neuroscience division, and asked "Are you OK with a \$1.5MM Medicare contribution to AF (this is a little less than what I had though[t] when we talked on [February 8, 2011].)" Congleton replied with his approval. (A copy of this e-mail exchange is attached as Exhibit 52.) The next day, February 11, 2011, Teva paid TAF \$1.5 million. *See* Exhibit 1.

92. On the morning of June 30, 2011, Teva's Barb Ross, a Medicare Specialist in Teva's Patient Services department, sent Lynch an e-mail stating: "I just spoke with David [Blanc] and Zach [Gammage] @ ACS. We figure around 200. This includes the 100 they already have, in addition to the 50 I am getting ready to send over July 5<sup>th</sup> as July eligible and we estimated about another 120 for the 4 weeks in July. David thinks he can maybe count on 50 of those for funds. . . ." (A copy of this e-mail is attached as Exhibit 53.) At that time, the per-patient allocation in TAF's MS fund was \$4,400, and TAF's administrative fee was 9 percent. Factoring those figures results in the following calculation:  $200 \times \$4,400 \times 1.09 = \$959,200$ . Later that day, Teva paid TAF \$1 million. *See* Exhibit 1. On July 5, 2011, Blanc reported to his supervisors that, as to Teva, ACS had "[s]ecured additional funding for up to 200 patients." (A copy of this e-mail is attached as Exhibit 54.) On July 8, 2011, TAF's Maureen Boyd sent

Hensley and Spafford an e-mail reporting that, of 100 new patients TAF had approved on July 1, 2011, 94 were Copaxone patients. (A copy of this e-mail is attached as Exhibit 55.)

93. On January 23, 2012, Kristin Wright, a Senior Supervisor in Teva's Patient Services department, sent an e-mail to Jennifer Clark stating: "I know funds are closed and AssistRx [the TAF affiliate that handled the Copaxone free drug program and referred Medicare-eligible Copaxone patients to ACS for co-pay coverage] will keep this patient on their list for when funds open back up." Clark forwarded this e-mail to Lynch, stating: "I know we're talking to Edward [Hensley] tomorrow night, this may be a topic of discussion." Lynch replied: "I agree...I talked with him today and learned that we will need to make a contribution. I will talk to David [Blanc at ACS] in the morning to understand how many patients they have in queue and then we can discuss the contribution amount!" (A copy of this e-mail exchange is attached as Exhibit 56.) On January 24, 2012, Blanc sent Lynch an e-mail reporting that 538 Copaxone patients were "pending [paperwork]" at TAF. (A copy of this e-mail is attached as Exhibit 57.) At that time, the per-patient allocation in TAF's MS fund was \$4,600, and TAF's administrative fee was 9 percent. Factoring those figures results in the following calculation:  $538 \times \$4,600 \times 1.09 = \$2,697,532$ . On January 30, 2012, Teva paid TAF \$2.75 million. *See* Exhibit 1.

94. On June 25, 2012, Barb Ross sent Clark and Lynch an e-mail stating: "Holding as of 06-25-12: 215. . . . Estimate for the rest of this month 32 + July eligible so far this month

35[.] Total to fund for to date would be 282. I called Idy [Moeller of ACS] and confirmed actual amounts. . . . Hope that gives you some idea of what we are needing.” (A copy of this e-mail is attached as Exhibit 58.) At that time, the per-patient allocation for TAF’s MS fund was \$4,600, and TAF’s administrative fee was 9 percent. Factoring those figures results in the following calculation:  $282 \times \$4,600 \times 1.09 = \$1,413,949$ . On June 27, 2012, Teva paid TAF \$1.4 million. *See* Exhibit 1. That same day, David Blanc of ACS sent his colleague, Idy Moeller, an e-mail with the subject “Copaxone TAF referral” and the following request: “Can you prepare the list of patients for referral?” (A copy of this e-mail is attached as Exhibit 59.)

95. On August 22, 2012, Blanc sent Lynch an e-mail stating that “we currently have 165 patients in wait.” (A copy of this e-mail is attached as Exhibit 60.) At that time, TAF’s average grant amount for a Copaxone patient was \$3,200, and TAF’s administrative fee was 9 percent. Factoring those figures results in the following calculation:  $165 \times \$3,200 \times 1.09 = \$575,520$ . On August 24, 2012, Teva paid TAF \$575,000. On August 27, 2012, Blanc sent Lynch an e-mail stating: “Below are the current numbers – the AF numbers do not include approx. 164 patients who should be approved today.” (A copy of this e-mail is attached as Exhibit 42.)

96. On September 19, 2012, Blanc sent Lynch an e-mail stating, “At this time we have 168 and 18 that we are still attempting to reach. (A copy of this e-mail is attached as Exhibit 61.) That same day, Lynch sent Hensley an e-mail stating: “Need to talk with you about

another donation.” (A copy of this e-mail is attached as Exhibit 62.) Hensley forwarded Lynch’s email to TAF executives, including Boyd, and wrote: “What number should I give her? She intends to donate at the end of September. This would be only for patients till the end of the year of course. It’s a couple hundred patients, I believe.” *Id.* Boyd responded: “Good Morning Edward, The Allocation Amount was reduced from \$4600 to **\$3200** effective August 2012. If it was for 200 new patients the total ask will need to be \$703,500.00 (which includes the 9% admin fee).” *Id.* (emphasis in original). On September 20, 2012, Blanc sent Lynch an e-mail stating that “[t]he up to the minute number is 197.” (A copy of this e-mail is attached as Exhibit 63.) TAF’s administrative fee at that time was 9 percent. Factoring those figures results in the following calculation:  $197 \times \$3,200 \times 1.09 = \$687,136$ . On September 21, 2012, Teva paid TAF \$700,000. On September 26, 2012, TAF’s Maureen Boyd wrote to Hensley that TAF had “processed 202 new Copaxone patients from the ACS referral file.” (A copy of this e-mail is attached as Exhibit 64.) On September 28, 2012, Hensley asked Boyd for an update on the same e-mail chain: “Can you please update the numbers below for me this morning, please. I am mtg with Denise [Lynch] at 2 at the hotel.” *Id.* Boyd responded: “the final number of new patients created from September 24<sup>th</sup>, 2012: . . . Copaxone = 234.” *Id.*

97. On May 7, 2013, Blanc sent Lynch an e-mail stating that ACS had 176 Copaxone patients “ready for referral” and another 30 “pending contact.” (A copy of this e-mail is attached as Exhibit 65.) At that time, TAF’s per-patient allocation for its MS fund was \$4,300, and



TAF's administrative fee was 9 percent. (A copy of an e-mail from Hensley to Lynch reflecting the \$4,300 average grant amount as of that time is attached as Exhibit 66.) Factoring those figures results in the following calculation:  $206 \times \$4,300 \times 1.09 = \$965,522$ . On May 8, 2013, Teva paid TAF \$925,000. (A copy of an e-mail confirming this payment is attached as Exhibit 67.) That same day, Lynch told Blanc that she was "just advised that the wire transfer was completed a few minutes ago." (A copy of this e-mail is attached as Exhibit 65.) Blanc wrote back: "Terrific! We are ready." *Id.*

98. On August 27, 2013, Blanc sent Lynch an e-mail stating: "We are at 196 with 14 pending contact at this time." (A copy of this e-mail is attached as Exhibit 68.) The previous day, Lynch had asked Spafford of TAF for the "Q3 patient donation," and Stafford had responded "\$3,700." (A copy of this e-mail exchange is attached as Exhibit 69.) At that time, TAF's administrative fee was 9 percent. Factoring those figures results in the following calculation:  $210 \times \$3,700 \times 1.09 = \$846,930$ . On August 27, 2013, Teva paid TAF \$850,000. On the evening of August 27, 2013, Blanc sent an e-mail to his ACS colleagues stating: "Please prep the file for referral to TAF ASAP!!" (A copy of this e-mail is attached as Exhibit 70.) On the morning of August 28, 2013, an ACS employee sent TAF the following question: "David sent a file over with 200+ patients, he is wondering if we can have an update[] on it today?" Later that day, TAF responded: "The file has been processed. 199 patients. 1 duplicate." (A copy of this e-mail exchange is attached as Exhibit 71.)

99. On March 11, 2014, Blanc sent Lynch an e-mail stating: “this morning’s count is 162 queued up; 30 in process; received 9 new this morning.” (A copy of this e-mail is attached as Exhibit 72.) At that time, TAF’s per-patient allocation for its MS fund was \$5,100, and TAF’s administrative fee was 9 percent. Factoring those figures results in the following calculation:  $201 \times \$5,100 \times 1.09 = \$1,117,359$ . On March 11, 2014, Teva paid TAF \$1,100,000. On March 13, 2014, Blanc reported to Lynch that there had been “189 Conditional Approvals this morning.” (A copy of this e-mail is attached as Exhibit 73.)

100. On the morning of April 22, 2014, Lynch asked her Teva colleague, Barb Ross, for “the number of patients we have ready to go at ACS, May eligible and approx. how many we are sending over a day.” (A copy of this e-mail is attached as Exhibit 74.) That afternoon, ACS sent Ross an e-mail with the subject line “CPA numbers” and a report that ACS had “approx. 187 and 27 pending interviews.” (A copy of this e-mail is attached as Exhibit 75.) Shortly thereafter, Ross reported the following to Lynch: “Looks like we have 187 ready to go, 27 that still need financial assessments, and 40 for May eligible.” (A copy of this e-mail is attached as Exhibit 76.) At that time, TAF’s per-patient allocation for its MS fund was \$4,500, and TAF’s administrative fee was 9 percent. Factoring those figures results in the following calculation:  $254 \times \$4,500 \times 1.09 = \$1,245,870$ . On April 24, 2014, Teva paid TAF \$1,275,000. (A copy of an e-mail confirming this payment is attached as Exhibit 77.) Hours later, Blanc sent an e-mail

to his ACS colleagues directing them “to prepare a file for referral to TAF for Copaxone in the morning tomorrow.” (A copy of this e-mail is attached as Exhibit 78.)

**V. Teva Caused The Submission of Materially False Claims to Medicare**

101. Teva’s conduct caused the submission of false claims to Medicare as a result of its violations of the anti-kickback statute.

A. Teva’s Violations Were Material To Payment Decisions.

102. Compliance with the anti-kickback statute is a material condition of payment by Medicare.

103. Congress reaffirmed the centrality of the anti-kickback statute to the claims payment decision in amending the anti-kickback statute to provide that any Medicare claim “that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act].” 42 U.S.C. § 1320a-7b(g).

104. Entities submitting claims to Medicare are subject to mandatory exclusion from Federal health care programs by HHS-OIG if criminally convicted of an anti-kickback statute violation, *see, e.g.*, 42 U.S.C. § 1320a-7(a)(1), and subject to permissive exclusion if HHS-OIG determines that the entity “has committed an act” described in the anti-kickback statute, 42 U.S.C. § 1320a-7(b)(7).

105. The United States regularly enforces the anti-kickback statute and pursues False Claims Act liability based on underlying violations of the anti-kickback statute. In particular, it has pursued matters against drug companies like Teva for conduct like that alleged here.

106. The conduct by Teva undermined the core concerns of the anti-kickback statute — in particular, preventing excessive costs to Medicare resulting from illegal co-pay subsidies that facilitate high drug costs and push the financial burden of those costs to Medicare and the American taxpayer.

107. Compliance with the regulatory requirement that the claims data in the PDE record submitted to CMS be “true, accurate, and complete” is an express condition of payment under the Medicare Part D Program.

108. The submission of PDEs is essential to the functioning of the Part D Program, the singular purpose of which is to provide coverage for drug products for the Medicare population. The accuracy of the information contained in each PDE for each patient determines how much payment will be made by Part D for that particular prescription.

109. The scheme that Teva spearheaded resulted in third parties’ submissions of thousands of false PDEs to Part D over a period of multiple years, resulting in hundreds of millions of dollars of damage to Medicare.

B. Sample False Copaxone Claims

110. Throughout the time period in which Teva used CDF and TAF as conduits to pay illegal Copaxone co-pay subsidies, patients used these subsidies at pharmacies to purchase Copaxone prescriptions, and the pharmacies submitted claims to Medicare Part D sponsors seeking Medicare reimbursement for those prescriptions. These false claims are documented in PDE data. Moreover, Part D Plan Sponsors, in turn, submitted this false PDE data to CMS in

order to obtain payment from the federal government for expenses incurred for the illegally subsidized Copaxone prescriptions.

111. Prescription Drug Event data attached as Exhibit 79 includes representative examples of false claims for Copaxone prescriptions that resulted from Teva's kickbacks and were reimbursed by Medicare. Each line on Exhibit 79 represents a distinct Prescription Drug Event reflecting a false Medicare claim for Copaxone (*i.e.*, a Medicare-reimbursed purchase of Copaxone by a Medicare beneficiary to fill a Copaxone prescription using an illegal co-pay subsidy from Teva via CDF or TAF). In each line item, the PDE data also shows the Medicare Part D Beneficiary who received the drug, reported here in the "CMS Beneficiary Name" field (using a de-identified value for purposes of the exhibit).

112. For each line item, the "Date of Service" shows the date the pharmacy indicated as the date of service in its claim to CMS, *i.e.*, when the beneficiary purchased the Medicare-covered Copaxone prescription using the co-pay subsidy. The reported Medicare cost of the prescription is reflected in the following PDE data fields: Amount Below Out-Of-Pocket Threshold ("AMT Below OOPT") and Amount Above Out-Of-Pocket Threshold ("AMT Above OOPT"). "AMT Below OOPT" refers to total costs for that prescription considered to be below the "catastrophic coverage" threshold for that benefit year. "AMT Above OOPT" represents the portion of the drug cost considered to be in the "catastrophic coverage" benefit phase, and subject to the Medicare Part D reinsurance subsidy.

113. Exhibit 79 shows the illegal co-pay subsidy amounts that Teva paid for each sample false claim identified in Exhibit 79. Teva paid, via CDF and TAF, the co-pay subsidy amounts reflected in the “Payment Amount” column for each claim, on the indicated date to induce each Medicare reimbursed-purchase of Copaxone. CDF or TAF, in turn, covered the beneficiary’s Medicare co-pay for Copaxone on the date identified in the “Date of Foundation Payment” column.

114. The claims did not disclose that the patients received illegal remuneration to induce their purchases of Copaxone in violation of the anti-kickback statute.

C. The Copaxone Claims That Teva Subsidized Through CDF And TAF Were False Claims.

115. Teva knowingly and willfully paid remuneration to Medicare patients to induce the patients to purchase Copaxone by providing them with financial subsidies to satisfy the co-pay obligations necessary to buy the drug.

116. Teva knowingly caused the submission of false claims for reimbursement to Medicare in each instance in which it provided a patient with a co-pay subsidy for Copaxone through CDF or TAF.

117. The claims were per se false or fraudulent as a matter of law. 42 U.S.C. § 1320a-7b(g).

118. The claims were also false because the PDE data and the specific representations therein failed to disclose a violation of a requirement material to the agency's payment decision, namely compliance with the anti-kickback statute.

119. The PDE data was not true, accurate, and complete because it did not disclose a violation of the anti-kickback statute. The PDE data for each claim was a false record that Teva caused to be used to pay the false claims alleged herein.

120. The representations of compliance with the anti-kickback statute made by the Part D Sponsors and downstream entities were false because the claims resulted from illegal kickbacks that Teva paid. The representations were false records that Teva caused to be used for payment of the false claims alleged herein.

**COUNT I**  
**(False Claims Act: Presentation Of False Claims)**  
**(31 U.S.C. § 3729(a)(1)(A) (2009), formerly 31 U.S.C. § 3729(a)(1))**

121. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

122. By virtue of the acts described above, Teva knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) (2009), formerly 31 U.S.C. § 3729(a)(1); that is, Teva knowingly made or presented, or caused to be made or presented, to the United States claims for payment for Copaxone that were tainted by illegal kickbacks.

123. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Teva's conduct.

124. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

## **COUNT II**

### **(False Claims Act: False Records Material To A False Or Fraudulent Claim) (31 U.S.C. § 3729(a)(1)(B) (2009), formerly 31 U.S.C. § 3729(a)(2))**

125. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

126. By virtue of the acts described above, Teva knowingly made, used, or caused to be made or used, false records or statements, namely, false claims, false statements in PDEs, and false statements about compliance with the anti-kickback statute, all of which were material to false or fraudulent claims for Copaxone that were submitted to the United States, paid and approved by the Medicare program, and tainted by illegal kickbacks, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009), formerly 31 U.S.C. § 3729(a)(2).

127. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of Teva's statements and actions.



128. By reason of the false or fraudulent records or statements, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

**COUNT III**  
**(False Claims Act: Conspiracy to Violate the False Claims Act)**  
**(31 U.S.C. § 3729(a)(1)(C) (2009), formerly 31 U.S.C. § 3729(a)(3))**

129. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

130. By virtue of the acts described above, Teva, and known and unknown employees of Teva, conspired with ACS, CDF, and TAF, and known and unknown individuals at those entities, knowingly to present or to cause to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C) (2009), formerly 31 U.S.C. § 3729(a)(3); that is, Teva, and known and unknown employees of Teva, conspired with ACS, CDF, and TAF, and known and unknown individuals at those entities, knowingly to make or present, or to cause to be made or presented, to the United States claims for payment for Copaxone that were tainted by illegal kickbacks.

131. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the conspiracy between and among (i) Teva, CDF, and ACS, and (ii) Teva, TAF, and ACS, and known and unknown individuals at those entities.

132. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

**COUNT IV  
(Unjust Enrichment)**

133. Plaintiff the United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

134. The United States claims the recovery of all monies by which Teva has been unjustly enriched, including profits Teva earned because of illegal inducements Teva paid to Medicare patients via CDF and TAF.

135. By obtaining monies as a result of its violations of federal and state law, Teva was unjustly enriched, and is liable to account and pay such amounts, which are to be determined at trial, to the United States.

136. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Teva on sales to Medicare patients who received Copaxone co-pay coverage via CDF or TAF, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

- I. On Counts I, II, and III under the False Claims Act against Teva, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.
- II. On Count IV for unjust enrichment, for the damages sustained and/or amounts by which Teva retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.
- III. All other and further relief as the Court deems just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Respectfully submitted,

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