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.)))

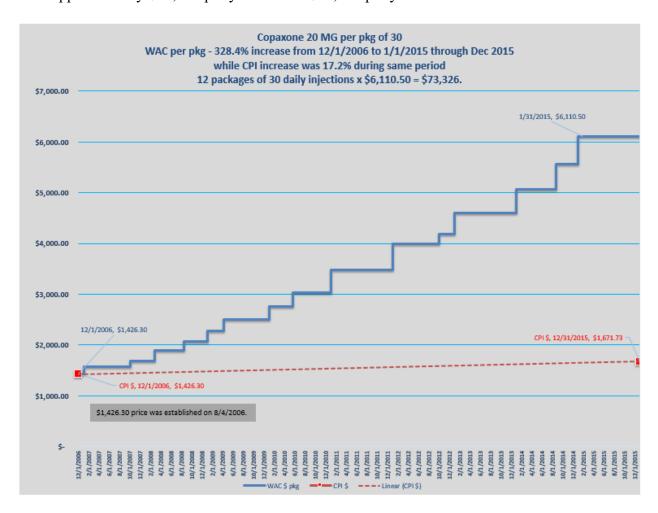
COMPLAINT

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 copays 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,





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