

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

| | Page |
|---|------|
| TABLE OF AUTHORITIES..... | ii |
| I. INTRODUCTION..... | 1 |
| II. BACKGROUND | 4 |
| A. Medicare Part D Created the Need for Charitable Assistance..... | 5 |
| B. The Alleged Charitable Support..... | 8 |
| 1. Teva's Copaxone Treats Multiple Sclerosis, A Life-Altering Disease..... | 8 |
| 2. Teva's Shared Solutions Program Helps Copaxone Patients Investigate Benefits and Refers Patients to Third-Party Patient Assistance Hubs..... | 9 |
| C. The Charitable Foundations, CDF and TAF, Operated Independently of Teva | 10 |
| III. LEGAL STANDARD | 13 |
| IV. ARGUMENT..... | 15 |
| A. The Government Fails to Allege a Violation of the Anti-Kickback Statute. | 15 |
| 1. The Government Fails to Allege That Teva Had the Requisite Intent to Induce or Reward Medicare Purchases..... | 15 |
| a. The Government Must Allege Facts That Plausibly Show that Teva Controlled the Charities' Use of Their Funds. | 15 |
| b. The Government's Factual Allegations Demonstrate that Teva Did Not Have Control Over The Charities..... | 19 |
| c. The Government's Reliance On Teva's Alleged Usage of Data Is Unavailing and Is Inconsistent With DOJ Policy. | 21 |
| 2. The Government Fails to Allege That Teva Improperly Induced Doctors or Patients to Use Copaxone..... | 25 |
| 3. The Government Fails to Allege That Teva Improperly Rewarded Patients for Using Copaxone. | 28 |
| B. The Government Fails to Allege a Violation of the False Claims Act. | 30 |
| C. The Government Fails to Allege a Conspiracy to Violate the False Claims Act. | 34 |
| D. The Government's Unjust Enrichment Claim Should Be Dismissed..... | 35 |
| E. Teva's Communications with TAF and CDF are Protected Under the First Amendment as "Charitable Solicitations." | 37 |
| V. CONCLUSION..... | 38 |

TABLE OF AUTHORITIES

| | Page(s) |
|---|----------------|
| CASES | |
| <i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009)..... | 13 |
| <i>Bank of New York Mellon Tr. Co. v. Morgan Stanley Mortg. Capital, Inc.</i> , No. 11 Civ. 0505, 2011 WL 2610661 (S.D.N.Y. June 27, 2011)..... | 20 |
| <i>Barr v. Am. Ass'n of Political Consultants</i> , 140 S. Ct. 2335 (2020)..... | 39 |
| <i>Bd. of Trustees of State Univ. of N.Y. v. Fox</i> , 492 U.S. 469 (1989)..... | 38 |
| <i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)..... | 13 |
| <i>Clifton v. Fed. Election Comm'n</i> , 114 F.3d 1309 (1st Cir. 1997)..... | 39 |
| <i>Cmty. Builders, Inc. v. Indian Motocycle Assocs., Inc.</i> , 692 N.E.2d 964 (Ma. 1998)..... | 38 |
| <i>Decovich v. Anthem Life Ins. Co.</i> , 744 F. App'x 466 (9th Cir. 2018) | 9 |
| <i>g., United States ex rel. Kasowitz Benson Torres LLP v. BASF Corp.</i> , 285 F. Supp. 3d 44, 56 (D.D.C. 2017), <i>aff'd</i> , 929 F.3d 721 (D.C. Cir. 2019) | 36 |
| <i>Guilfoile v. Shields</i> , 913 F.3d 178 (1st Cir. 2019)..... | 15, 26, 31, 32 |
| <i>Hagerty ex rel. United States v. Cyberonics, Inc.</i> , 844 F.3d 26 (1st Cir. 2016) | 14 |
| <i>Hanlester Network v. Shalala</i> , 51 F.3d 1390 (9th Cir. 1995) | 26 |
| <i>Humana Inc. v. Mallinckrodt ARD LLC</i> , No. CV1906926DSFMRW, 2020 WL 3041309 (C.D. Cal. Mar. 9, 2020) | 7, 19 |
| <i>Jones-McNamara v. Holzer Health Sys.</i> , 630 F. App'x 394 (6th Cir. 2015) | 7, 22 |

TABLE OF CONTENTS

| | Page |
|--|--------|
| <i>Koufos v. US Bank, N.A.</i> , 939 F. Supp. 2d 40 (D. Mass 2013) | 37 |
| <i>Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.</i> , 842 F.3d 125 (1st Cir. 2016)..... | 14, 15 |
| <i>Lyman v. Baker</i> , 954 F.3d 351 (1st Cir. 2020)..... | 13 |
| <i>Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.</i> , 552 F.3d 47 (1st Cir. 2009) | 37 |
| <i>N. Heel Corp. v. Compo Indus., Inc.</i> , 851 F.2d 456 (1st Cir. 1988)..... | 7 |
| <i>R.A.V. v. City of St. Paul</i> , 505 U.S. 377 (1992)..... | 39 |
| <i>Riley v. Nat'l Fed'n of the Blind of N. C., Inc.</i> , 487 U.S. 781 (1988)..... | 38 |
| <i>Sorrell v. IMS Health, Inc.</i> , 564 U.S. 552 (2011)..... | 39 |
| <i>Speet v. Schuette</i> , 726 F.3d 867 (6th Cir. 2013) | 38 |
| <i>Taylor v. Moskow</i> , No. CIV.A. 13-12675-FDS, 2014 WL 2573990 (D. Mass. June 6, 2014) | 37 |
| <i>United States el rel. Strunck v. Mallinckrodt Ard LLC</i> , No. 12-175, 2020 U.S. Dist. LEXIS 10191 (E.D. Pa. Jan. 21, 2020) | passim |
| <i>United States ex rel. Atkinson v. Pa. Shipbuilding Co.</i> , No. 94-7316, 2004 U.S. Dist. LEXIS 14532 (E.D. Pa. July 28, 2004) | 34 |
| <i>United States ex rel. Booker v. Pfizer, Inc.</i> , 847 F.3d 52 (1st Cir. 2017) | 31, 33 |
| <i>United States ex rel. Brown v. Pfizer, Inc.</i> , No. CV 05-6795, 2017 WL 1344365 (E.D. Pa. Apr. 12, 2017) | 28 |
| <i>United States ex rel. Clausen v. Lab. Corp. of America, Inc.</i> , 290 F.3d 1301 (11th Cir. 2002) | 32, 33 |

TABLE OF CONTENTS

| | Page |
|--|----------------|
| <i>United States ex rel. D'Agostino v. EV3, Inc.,</i> 153 F. Supp. 3d 519, 530 (D. Mass. 2015), <i>aff'd sub nom. D'Agostino v. ev3, Inc.</i> , 845 F.3d 1 (1st Cir. 2016)..... | 14 |
| <i>United States ex rel. Emerson Park v. Legacy Heart Care, LLC,</i> No. 3:16-CV-0803-S, 2019 WL 4450371 (N.D. Tex. Sept. 17, 2019) (N.D. Texas 2019)..... | 26 |
| <i>United States ex rel. Gagne v. City of Worcester,</i> 565 F.3d 40 (1st Cir. 2009) | 34 |
| <i>United States ex rel. Ge v. Takeda Pharm. Co.,</i> 737 F.3d 116 (1st Cir. 2013)..... | 14 |
| <i>United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.,</i> No. CV 02-2964, 2020 WL 4260797 (E.D. Pa. July 24, 2020) | 7, 22 |
| <i>United States ex rel. Goodman v. Arriva Med., LLC,</i> No. 3:13-CV-0760, 2020 WL 3840446 (M.D. Tenn. July 8, 2020)..... | 29, 30 |
| <i>United States ex rel. Greenfield v. Medco Health Sols., Inc.,</i> 880 F. 3d 89 (3d Cir. 2011) | 27, 32, 33, 34 |
| <i>United States ex rel. McGee v. IBM Corp.,</i> 81 F. Supp. 3d 643, 666 (N.D. Ill. 2015)..... | 35 |
| <i>United States ex rel. Osheroff v. Tenet Healthcare Corp.,</i> No. 09-22253-CIV, 2012 WL 2871264 (S.D. Fla. July 12, 2012)..... | 28 |
| <i>United States ex rel. Ruscher v. Omnicare, Inc.,</i> 663 F. App'x 368 (5th Cir. 2016) | 15 |
| <i>United States ex rel. Vitale v. MiMedx Group, Inc.,</i> 381 F. Supp. 3d 647 (D.S.C. 2019) | 27, 29 |
| <i>United States v. Celgene Corp.,</i> 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016)..... | passim |
| <i>United States v. Job Res. For Disabled,</i> No. 97 C 3904, 2000 WL 562444 (N.D. Ill. May 9, 2000) | 36 |
| <i>United States v. Krikheli,</i> 461 F. App'x 7 (2d Cir. 2012) | 26 |

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.