

United States District Court
District of Massachusetts

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| United States of America, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Civil Action No. |
| |) | 20-11548-NMG |
| Teva Pharmaceuticals USA, Inc., |) | |
| and Teva Neuroscience, Inc., |) | |
| |) | |
| Defendants. |) | |
| |) | |

MEMORANDUM & ORDER

GORTON, J.

This case arises out of purported violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), and the False Claims Act, 31 U.S.C. §§ 3729 et seq. ("FCA"), by a pharmaceutical company. The government alleges that Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Neuroscience, Inc. ("Teva Neuroscience") (collectively, "Teva" or "defendants") improperly paid millions of dollars to charitable foundations with the intent and understanding that the money would be used to subsidize patients' out-of-pocket expenses for a drug manufactured by Teva, violating the AKS and causing the submission of false claims for payment to Medicare.

Pending before the court is Teva's motion to dismiss the complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). For the reasons that follow, that motion will be allowed, in part, and denied, in part.

I. Background

The following facts are as alleged in the complaint.

A. The Parties & Medicare Part D's Cost-Sharing Structure

Plaintiff, the government, 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"). Teva is a pharmaceutical company which manufactures Copaxone, an injectable drug used to treat multiple sclerosis ("MS"), a disease of the central nervous system. The annual per patient cost of Copaxone has increased from approximately \$17,000 in 2006 to more than \$73,000 by 2015.

Medicare Part D, which provides prescription drug coverage for Medicare beneficiaries, became effective in 2006. That coverage is not comprehensive, however, and Medicare patients may need to pay for part of the cost of the prescription drugs provided under Part D. Those partial payments ("copays") are intended to encourage physicians and beneficiaries to be efficient consumers of federally-reimbursed health care products

and to encourage drug manufacturers to price their products based upon market forces.

After paying an annual deductible, Medicare Part D beneficiaries are responsible for a 25% copay up to an "initial coverage limit." Once that limit is reached, there is a "coverage gap" in which patients must pay a high percentage of brand name prescription drugs until they reach an "annual out-of-pocket threshold" for the coverage year. For brand name drugs like Copaxone, the copay during the coverage gap was 100% through 2010, 50% in 2011 and 2012, 47.5% in 2013 and 2014 and 45% in 2015 and 2016. Once that annual threshold is met, Medicare's "catastrophic coverage" begins and the patient's copay is only 5% of the cost of the drug.

In 2015, Medicare spent over \$1.1 billion on catastrophic coverage for Copaxone.

B. Teva's Charitable Donations & Alleged Misconduct

Teva administers a program known as "Shared Solutions" which provides Copaxone patients with services including educational resources, injection training and financial assistance. Beginning in 2006, Shared Solutions referred Medicare and Medicare-eligible Copaxone patients to specialty

pharmacy Advanced Care Scripts, Inc. ("ACS") to help them obtain Medicare Part D coverage and copay assistance.

The Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF") are charitable foundations. During the period of time relevant to the instant action, each operated a fund for MS patients to cover the copays for a number of available MS medications ("MS funds"). Once the MS funds at CDF and TAF allocated all of their funds to existing patients, they would temporarily close to new patients. They did not create wait lists for those who applied for coverage while the funds were closed. When the funds received new donations, they would open on a "first come, first served" basis, meaning that only the most recent applicants would receive grants.

The government alleges that Teva worked with ACS to ensure that its donations to CDF and TAF were used solely for Copaxone copay assistance. ACS would purportedly provide periodic reports to Teva regarding the number of new Copaxone patients waiting for Medicare copay coverage. When ACS possessed a substantial number of Copaxone patient grant applications, Teva would multiply that number of patients by the foundation's average grant for Copaxone patients, add the foundation's administrative fee and send a corresponding donation to the

foundation. After receiving notice from Teva that the donation had been made, ACS would send a "batch file" of Copaxone patient applications to the relevant foundation for coverage as soon as the MS fund reopened, ensuring that most, if not all, of Teva's donations covered Copaxone patients specifically.

Between December, 2006 and December, 2015, Teva donated to CDF and TAF more than \$328 million in 66 payments. The complaint alleges that those contributions were intended to increase sales of and generate Medicare claims for Copaxone. Although Teva avoided conducting a formal return on investment ("ROI") analysis of its foundation support, handwritten notes from a meeting held in January, 2010, purportedly indicate that the company informally calculated that its donations to CDF and TAF generated substantial ROI.

The government alleges that Teva knew that CDF and TAF used its donations almost exclusively for Copaxone patients rather than for MS patients in general. As a result, the government contends that Teva effectively used those contributions to subsidize its own drug at the expense of Medicare.

C. Procedural History

The government filed suit in this Court in August, 2020. In the complaint, it claims that Teva 1) made materially false

or fraudulent claims for payment or approval to Medicare in violation of the FCA (Count I); 2) used false or fraudulent records or statements in connection with the purportedly false claims (Count II); 3) conspired with ACS, CDF and TAF to violate the FCA (Count III); and 4) was unjustly enriched as a result of sales made to Medicare patients who received copay assistance from CDF or TAF (Count IV).

Defendants filed a motion to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) in October, 2020, which the government timely opposed.

II. Motion to Dismiss

A. Legal Standard

To survive a motion to dismiss, a claim must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In considering the merits of a motion to dismiss, the Court may only look to the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference and matters of which judicial notice can be taken. Nollet v. Justices of Trial Court of Mass., 83 F. Supp. 2d 204, 208 (D. Mass. 2000), aff'd, 228 F.3d 1127 (1st Cir. 2000).

Furthermore, the Court must accept all factual allegations in the claim as true and draw all reasonable inferences in the claimant's favor. Langadinos v. Am. Airlines, Inc., 199 F.3d 68, 69 (1st Cir. 2000). If the facts in the claim are sufficient to state a cause of action, a motion to dismiss must be denied. See Nollet, 83 F. Supp. 2d at 208.

Although a court must accept as true all the factual allegations in a claim, that doctrine is not applicable to legal conclusions. Ashcroft v. Iqbal, 556 U.S. 662 (2009). Threadbare recitals of legal elements which are supported by mere conclusory statements do not suffice to state a cause of action. Id.

Under Rule 9(b), allegations of fraud are held to a higher pleading standard. To survive a motion to dismiss, a complaint alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

B. Regulatory Framework

The FCA imposes civil liability for anyone who

knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). A "claim" is "any request or demand . . . for money or property" presented to an officer, employee or agent of the United States. 31 U.S.C. § 3729(b)(2).

The AKS imposes criminal liability on anyone who

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 . . . to purchase . . . or arrange for or recommend purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7b(b)(2). A violation of the AKS which results in a federal health care payment is a "per se false claim under the FCA." United States v. Regeneron Pharms., Inc., 2020 U.S. Dist. LEXIS 227643, at *43 (D. Mass. Dec. 4, 2020) (quoting Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019)).

Under that regulatory framework, the government alleges that Teva violated the AKS through its payments to CDF and TAF and that the resulting claims submitted to Medicare were per se false in violation of the FCA. Teva urges dismissal of the complaint because the government has failed to allege sufficiently a violation of either the AKS or the FCA.

C. Violation of the Anti-Kickback Statute

1. Remuneration

First, the complaint clearly and plausibly alleges that Teva provided remuneration within the meaning of the AKS. Remuneration is defined broadly, see Regeneron, 2020 U.S. Dist. LEXIS 227643, at *29-30 & n.7, and includes payments made both directly and indirectly. See 42 U.S.C. § 1320a-7b(b)(2); United States ex rel. Banigan v. Organon USA Inc., No. CV 07-12153-RWZ, 2016 WL 10704126, at *3 n.8 (D. Mass. Aug. 23, 2016) (“[T]he AKS prohibits even the indirect receipt of prohibited remuneration.”).

Here, the government alleges that Teva indirectly provided remuneration to patients prescribed Copaxone through donations to CDF and TAF which were used to cover the copays of those patients. Several courts have recently found similar indirect payments to patients through charities to constitute remunerations sufficient to state a claim under the AKS. See, e.g., Regeneron, 2020 U.S. Dist. LEXIS 227643, at *29 (“[D]efendant indirectly provided remuneration to patients prescribed Eylea, by making donations to CDF that offset patients’ copays.”); United States ex rel. Strunck v. Mallinckrodt Ard LLC, Nos. 12-175 and 13-1776, 2020 U.S. Dist.

LEXIS 10191, at *13 (E.D. Pa. Jan. 21, 2020) (holding that the complaint alleged facts sufficient to plead violations of the AKS where it stated that the defendant "indirectly paid remuneration to . . . patients in the form of copay subsidies funneled through CDF").

2. Intent to Induce Purchases of Copaxone by Medicare Patients

a. Whether the Complaint Must Allege Control over CDF and TAF Funds

Because the parties dispute whether the requisite intent can be established absent allegations that Teva controlled the charities' ultimate expenditure of funds, the Court finds it prudent to address the nature of allegations sufficient to demonstrate intent under the AKS.

The intent of the person or company providing remuneration is "critical to proving an AKS violation." Regeneron, 2020 U.S. Dist. LEXIS 227643, at *24. Courts have held that liability under the AKS generally requires intent to influence physicians to prescribe care reimbursable by the federal government. See, e.g., Guilfoile, 913 F.3d at 192-93 ("[T]he heartland of what the AKS is intended to prevent [is] the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs."). The AKS has also been interpreted to prohibit the

waiver or payment of patients' copays by companies in order to induce such patients to purchase their products. See Regeneron, 2020 U.S. Dist. LEXIS 227643, at *25 ("[C]ompanies' practices of waiving copays or making donations to offset the cost of copays may violate the AKS."). The intent requirement may be satisfied as long as "at least one purpose of the remuneration was to induce Medicare purchases." Mallinckrodt, 2020 U.S. Dist. LEXIS 10191, at *13.

Teva asserts that donations made to independent charities rather than to patients directly "sever[] any link between the pharmaceutical manufacturer's funding and the beneficiary," 70 Fed. Reg. 70626 (Nov. 22, 2005), thereby rendering the AKS prohibitions inapplicable to its conduct with respect to CDF and TAF. It cites United States v. Celgene Corp., 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016) for the proposition that a drug manufacturer "cannot be liable for giving money to co-pay foundations" absent evidence that the donations were

contingent on the foundation's agreement to purchase or recommend [the manufacturer's] drugs.

Because it had no control over how CDF and TAF distributed its donations, Teva contends the government cannot demonstrate that it intended to induce patients to purchase Copaxone.

That interpretation of the AKS has no clear legal support. The Celgene court cited no authority favoring such a proposition and the decision is "of course not binding upon this Court." Regeneron, 2020 U.S. Dist. LEXIS 227643, at *35. Furthermore, the plain text of the AKS reveals no requirement that a manufacturer have control of or an agreement with a third-party foundation for liability to attach. See 42 U.S.C. § 1320a-7b(b) (2) (imposing liability whenever an entity "pays any remuneration . . . indirectly . . . to any person to induce such person . . . to purchase" a product reimbursable by Medicare).

Instead, substantial caselaw and guidance from the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG") make it clear that AKS liability hinges upon the intent of the donating party regardless of whether it had control over the ultimate disposition of the donated funds. See 70 Fed. Reg. 70627 ("Simply put, the independent charity . . . must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices."); Regeneron, 2020 U.S. Dist. LEXIS 227643, at *35 (stating that "improperly structured donations to copay-assistance charities may violate the AKS if they are made with the intent to induce

Medicare-funded referrals or drug purchases” and collecting cases in support).

Teva insists that, without the limiting principle articulated in Celgene, virtually every donation from a pharmaceutical company to a third-party foundation offering copay assistance would violate the AKS. This Court disagrees. As other courts have held, the AKS is not violated where a company hopes or expects that “referrals may ensue from remuneration that was designed wholly for other purposes.” United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000). Rather, liability attaches only when the statements and actions of a pharmaceutical company reveal an intent beyond a “collateral hope or expectation,” id. at 835 n.7, such that it is clear that the remunerations were designed specifically to encourage claims to Medicare.

Accordingly, the complaint need not allege that Teva’s donations were contingent upon the agreement of CDF and TAF to promote Copaxone in order to state a claim under the AKS.

**b. Whether the Complaint Alleges that Teva
Intended to Induce Purchases of Copaxone by
Medicare Patients**

Teva contends that it merely hoped and expected that its donations would be used to cover the copays of Copaxone and

therefore did not possess the requisite intent under the AKS. The complaint plausibly alleges, however, that Teva did far more than "hope and expect." Rather, the government asserts that Teva specifically intended its donations to CDF and TAF to induce purchases of Copaxone by Medicare patients. Such allegations are supported with claims sufficient to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b).

First, the complaint alleges that Teva structured its donations to ensure that they would be used exclusively to generate sales of Copaxone. Teva worked closely with ACS to calculate the precise amount necessary to cover the copays of a specific number of Copaxone patients. Then it coordinated the timing of its donations with the submission of batch files of applications by ACS shortly thereafter, maximizing the likelihood that Teva's donations would be disbursed to Copaxone patients. The complaint also alleges that Teva refused to authorize payments to at least one foundation because it could not guarantee that the donations would be used on Copaxone patients.

The facts alleged in the complaint further demonstrate that Teva understood and intended that its donations would result in increased revenue from Medicare claims. The government asserts

that, although Teva avoided conducting formal ROI analyses of its foundation support, a former employee's handwritten notes from a meeting in January, 2010, indicate that the company had determined that \$28 million of donations would generate over \$114 million in new revenue from Medicare patients. The complaint also recounts a warning from Jennifer Clark, an Associate Director in Teva's Patient Services Department, that a reduction in the amount provided to TAF would

decrease [sales] as well, as there will be Medicare patients out there that won't be able to fill [their prescriptions of Copaxone].

Such allegations, if proved, demonstrate that Teva understood that its donations to CDF and TAF led to an increase in Medicare claims for Copaxone.

The instant action presents facts nearly identical to those in United States ex rel. Vitale v. MiMedx Grp, Inc., 381 F. Supp. 3d 647 (D.S.C. 2019). The Court in MiMedx concluded that the complaint stated a plausible AKS violation where the defendant drug manufacturer made donations to a copay-assistance charity in an amount correlated with the number of patients who were seeking funding for the defendant's drug. The complaint also alleged that the defendant held applications for copay assistance until just after the charity received its

contributions, ensuring that the payments would be spent on the company's products. The only significant difference between the allegations in MiMedx and the instant action is that Teva used ACS to compile and submit patient applications while the defendant in MiMedx used its own employees. That distinction does not render the allegations against Teva insufficient.

Because the government has adequately alleged that Teva intended to induce purchases of Copaxone and the resulting Medicare claims, the complaint plausibly states that Teva possessed the requisite intent under the AKS.

3. Knowing and Willful Violation

Finally, the government plausibly alleges that Teva acted in a knowingly and willful manner when it purportedly violated the AKS.

To establish a knowing violation, the complaint must demonstrate that Teva acted voluntarily and deliberately rather than by accident or mistake. See United States v. Bay State Ambulance & Hosp. Rental Serv., 874 F.2d 20, 33 (1st Cir. 1989). The government alleges throughout the complaint that Teva acted voluntarily and deliberately in donating to CDF and TAF and in coordinating with ACS to maximize the likelihood that its payments would be used on Copaxone patients.

Next, to establish a willful violation, the complaint must allege that Teva acted with knowledge that its conduct was unlawful. See In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, (D. Mass. 2007). The government has met this bar because it alleges that Teva knew that federal law prohibited the indirect payment of Medicare patients' copays using foundations as pass-through vehicles but that it nonetheless engaged in such conduct. It highlights the fact that, in 2012, a Teva employee circulated a law firm presentation warning of the risks associated with donations to copay assistance charities.

Teva responds that its charitable activity was not clearly unlawful and that it was "explicitly approved" by guidance issued by the HHS-OIG. It observes that the guidance approves of donations from drug manufacturers to copay assistance charities in certain circumstances and, because donations to charities which fund only a single drug do not necessarily violate the AKS, Teva contends that the HHS-OIG recognizes that drug manufacturers may lawfully benefit their own products.

Teva's reliance on that guidance is unavailing. Although the HHS-OIG does indicate that donations from drug manufacturers to charities "should raise few, if any, anti-kickback statute

concerns," it goes on to list several safeguards which must be in place for that to be true, including that the manufacturer may not solicit or receive data from the charity to correlate its donations with the payments to be used on its products. See 70 Fed. Reg. 70626. The guidance also cautions against the use of such charities "as a conduit" for payments to patients. Id. at 70627. Here, the government alleges that Teva flouted such guidance and therefore acted willfully.

Accordingly, the government has plausibly stated a knowing and willful violation of the AKS.

D. Violation of the False Claims Act

Teva contends that the government fails to allege a violation of the FCA because it cannot establish that Teva caused the submission of any false claim to Medicare. Specifically, defendants assert that, because several pharmaceutical companies contributed to the MS funds at CDF and TAF, it is impossible for the government to demonstrate that the donations from Teva, specifically, led to the purportedly false claims.

A claim is false within the meaning of the FCA if there is a "sufficient causal connection between an AKS violation and [the] claim submitted to the federal government." Guilfoile, 913

F.3d at 190. To establish that there has been a violation of the FCA, the government must demonstrate that

at least one of [the] claims sought reimbursement for medical care that was provided in violation of the [AKS].

United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 98 (3d Cir. 2018).

Teva's assertion that the government cannot link its donations to specific false claims because other donors contributed to the relevant MS funds is unpersuasive. See Regeneron, 2020 U.S. Dist. LEXIS 227643, at *35 (rejecting an argument identical to Teva's, finding that the defendant read into the FCA "a specificity . . . that is unsupported by the text of the statute or case law"). The government has alleged, in sufficient detail, a scheme by which Teva practically guaranteed that its own donations would result in the submission of Medicare claims for Copaxone.

To wit, the complaint identifies 30 examples of payments made by either CDF or TAF to cover the copays of Copaxone patients who later submitted claims to Medicare for their prescriptions. It links those payments to the purported scheme in which Teva contributed to MS funds devoid of funding so that the applications submitted by ACS for Copaxone patients would be first in line to benefit from the new funding. Those

allegations, which this Court must accept as true, raise a reasonable inference that the 30 foundation payments identified by the government “result[ed] in a federal health care payment [which] is per se false under the FCA.” Guilfoile, 913 F.3d at 190.

The complaint, therefore, states a plausible violation of the FCA.

E. False Claims Act Conspiracy

Teva seeks dismissal of the FCA conspiracy claim on the ground that the complaint fails to allege that either CDF or TAF agreed with ACS or Teva to submit false claims to Medicare for reimbursement.

Conspiracy liability under the FCA requires only that

(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; and (2) one or more conspirators performed any act to effect the object of the conspiracy.

United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267, 280 (D. Mass. 2010) (quoting United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 196 (D. Mass. 2004)). The first element requires an agreement between the relevant parties to commit fraud within the meaning of the FCA. See Harvard Coll., 323 F. Supp. 2d at 198 (finding a FCA

conspiracy where defendants "acted in agreement, explicit or implicit" to cause the submission of false claims); United States ex rel. Atkinson v. Pa. Shipbuilding Co., No. 94-7316, 2004 U.S. Dist. LEXIS 14532, at *15 (E.D. Pa. July 28, 2004) (FCA conspiracy claim requires a "meeting of the minds").

Here, the complaint plausibly pleads that Teva, ACS and the copay assistance charities conspired to channel Teva's donations to Copaxone patients, thereby causing the submission of claims to Medicare. The government details the close relationship between Teva and ACS and how the two companies agreed to work in concert to submit patient applications and donations in a manner virtually ensuring that Copaxone patients exclusively would benefit. The complaint also references conversations between top executives at CDF and TAF, on the one hand, and employees at Teva or ACS, on the other hand, in which the foundations appear to assist Teva in correlating its donations with the number of grants to be provided to Copaxone patients.

Although CDF and TAF may not have been as involved in the purported conspiracy as Teva and ACS, the facts alleged allow one reasonably to infer that the foundations agreed, at least implicitly, to assist in the scheme to direct Teva's donations to Medicare patients taking Copaxone. As a result, dismissal of

the government's FCA conspiracy claim is unwarranted at this early stage in the litigation.

F. Unjust Enrichment

Teva also seeks the dismissal of the government's unjust enrichment claim. It submits that the government should not be permitted to seek such equitable relief where it has an adequate remedy at law under the FCA and that, in any event, the complaint does not allege any unlawful or unjust conduct.

It is unnecessary to address the merits of the second of Teva's assertions because "courts do dismiss unjust enrichment claims where an adequate remedy at law is available." United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs., No. 15-cv-13065, 2021 U.S. Dist. LEXIS 95932, at *60 (D. Mass. May 19, 2021) (citing A.J. Props., LLC v. Stanley Black & Decker, Inc., 972 F. Supp. 2d 68, 79-80 (D. Mass. 2013)). Because an adequate remedy at law exists in the government's FCA claims, see id., Count IV will be dismissed.

G. First Amendment Claim by Teva

Finally, Teva asserts that the instant action restricts speech between Teva and charitable foundations in violation of the First Amendment to the United States Constitution. Specifically, Teva argues that the government's theory of

liability under the AKS would criminalize speech incident to charitable giving, thereby impermissibly restricting speech based upon the identity of the speaker and the content of the speech.

Teva's contention is without merit. The complaint is clear that it is Teva's conduct and not its speech which purportedly violates the AKS. Several courts confronted with similar First Amendment challenges to allegations of AKS violations have "rejected them on the basis that the AKS criminalizes conduct (remunerations), not speech." Regeneron, 2020 U.S. Dist. LEXIS 227643, at *35 (collecting cases). Furthermore, the First Amendment

does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.

United States v. Facticeau, No. 15-cr-10076, 2020 U.S. Dist. LEXIS 167169, at *32 (D. Mass. Sept. 14, 2020) (quoting Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993)). The speech referenced in the complaint is presented as evidence of Teva's intent to violate the AKS rather than a violation of the AKS in and of itself.

Accordingly, the instant action will not be dismissed on First Amendment grounds.

ORDER

For the foregoing reasons, the motion of Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively, "Teva") to dismiss plaintiff's complaint (Docket No. 22) is, with respect to Count IV, **ALLOWED**, but otherwise, **DENIED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated September 9, 2021