IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CHRIS PURCELL, *et al.*	:	**CIVIL ACTION**
	:	
v.	:	**NO. 17-3523**
	:	
GILEAD SCIENCES, INC.	:	

MEMORANDUM

KEARNEY, J. **February 13, 2020**

Congress prohibits pharmaceutical companies from compensating healthcare providers to induce them to prescribe often more expensive drugs paid by federal and state treasuries. Mindful of this bar, marketing to persuade healthcare providers to prescribe new drugs created after significant research and development investment requires innovative approaches to bolster the merits of their new product. As recounted in numerous cases over the past several years, some pharmaceutical companies chose to invite busy doctors and physician assistants to speak at their sponsored conferences and serve on their internal advisory boards. The companies pay handsomely for the time; sometimes more than the prescriber makes from her practice. The issue for us is whether these arrangements are kickbacks to induce the reimbursed prescriptions prohibited by Congress. It can be a fact sensitive analysis. Under the False Claims Act, Congress allows private persons such as former pharmaceutical sales representatives to recover damages on behalf of government payors for induced prescriptions submitted or caused to be submitted to federal and state taxpayers. We today evaluate allegations challenging marketing of Hepatitis B Virus patented drugs Viread and Vemlidy through an "Opinion Leadership Program" involving speakers' programs and advisory boards targeted to the larger prescribers. After careful analysis of sixty pages of specific allegations, we today deny the company's motion to dismiss two of the sales representatives' claims but dismiss their redundant claim.

I. Alleged Facts[1]

Chris Purcell and Kimberly Groom once worked as regional sales directors for Gilead Sciences, Inc.[2] They sued Gilead under the False Claims Act for allegedly causing false payments to be submitted to federal and state healthcare payors by providing healthcare providers with thousands of dollars in speaker and advisor payments, travel, and other remuneration to induce them to prescribe Gilead's Hepatitis B Virus ("HBV") drugs Viread and Vemlidy. They claim Gilead's payments to healthcare providers under its "Opinion Leadership Program" violated the anti-kickback statute and tainted reimbursements under the False Claims Act.

Gilead created and now sells HBV drugs Viread and Vemlidy.

The Sales Directors allege Gilead paid to induce healthcare providers to prescribe its two patented drugs Viread and Vemlidy to treat Hepatitis B Virus.[3] Hepatitis B Virus is the most common liver disease in the world, with approximately two billion worldwide cases.[4] In the United States, approximately twelve million people are infected with HBV with many cases observed in high populous areas.[5] Gilead's Viread and Vemlidy generated over $2.5 Billion in sales since 2013.[6]

The Food and Drug Administration approved Viread in October 2001.[7] From 2014 to 2017, Viread recorded sales ranging between $484 Million and $514 Million.[8] Viread went off-patent on December 15, 2017.[9] In 2018, off-patent Viread sales dropped over $400 Million to approximately $50 Million.[10] Off-patent Viread faces competition from "multiple" generic HBV drugs and currently sells for around $41 for a month prescription.[11]

Vemlidy, approved by the FDA on November 10, 2016, still enjoys patent protection.[12] Vemlidy garnered $111 Million in sales in 2017 and $245 Million in 2018.[13] A month prescription of Vemlidy costs over $1,100.[14] The Sales Directors allege Gilead developed Vemlidy a number of years ago but waited to introduce Vemlidy until Viread neared off-patent status.[15]

Other pharmaceutical companies compete with Gilead in the HBV drug market. One competitor, Bristol Meyers Squibb, developed its own patented HBV drug Baraclude.[16] Baraclude lost its patent status in 2014 and, in the same year, Teva Pharmaceuticals introduced a generic Baraclude.[17] Baraclude now sells for $59.89 for a month supply.[18]

To market its HBV drugs to healthcare providers treating HBV infected patients, Gilead sales and marketing designed an "Opinion Leadership Program" initiative. The "Opinion Leadership Program" paid HBV healthcare providers to participate in speaker programs, advisory boards, and research grants.[19]

The Sales Directors allege Gilead's "Opinion Leadership Program" fostered a "scheme to maintain patent-level price and profit margins[.]"[20] In late 2013 and early 2014, when Gilead's Viread faced increased competition after entry of generic Baraclude, Gilead offered more paid programs to Viread's top prescription writers.[21] In 2016 and 2017, Gilead continued significant investments but pivoted to selling its newly-branded Vemlidy by "denigrat[ing] Viread's safety" and providing "monetary benefits to induce doctors to switch from Viread to Vemlidy."[22]

The Sales Directors allege Gilead's "Opinion Leadership Program" violated the anti-kickback statute in at least two ways. First, the Sales Directors allege Gilead offered excessive cumulative payments to healthcare providers to participate in "sham" speaker programs and advisory board meetings offering little educational value. Second, the Sales Directors allege Gilead's sales and marketing team selected paid invitees based on data about prescription writing volume and habits.

Gilead's use of speaker programs and advisory boards.

In pharmaceutical industry speaker programs, a healthcare provider is paid to educate other healthcare providers on the benefits of a drug.[23] "The purpose [is] to inform [the attending

healthcare providers] so that they might decide whether the drug in question would be right for their patient."[24] Pharmaceutical companies use advisory boards to gather information from its physician members.[25] While these programs can be legitimate educational programs for the medical community and the pharmaceutical companies, the Sales Directors allege Gilead's HBV speaker programs and advisory boards lacked educational merit and were instead conducted to confer payments and other benefits to providers prescribing their products.

The Sales Directors allege "the point of the Gilead [speaker] program is to pay the speaker the $3,000 honorarium[.]"[26] Paid speakers also used the program to invite other healthcare providers who formed part of their patient referral base.[27] Both speakers and the invited attendees enjoyed a dinner sponsored by Gilead.[28]

In 2017, Gilead maintained eighteen advisory boards with 450 paid advisors.[29] Many advisors attended more than one advisory board.[30] For a "typical" advisory board, "advisors arrived on Friday, were picked up at the airport by limousine, transported to their paid hotel, treated to drinks and dinner, received breakfast the next day, attended a four-hour presentation, and received a $3000.00" honoraria.[31]

Gilead's sales and marketing team "primarily" planned and ran the advisory boards.[32] Its sales staff accompanied advisors "to sell the Gilead product" throughout the advisory board weekend.[33] During the advisory board dinner and event, the sales team arranged the seating chart and placed providers who prescribed a high volume of Gilead drugs at every table.[34] The advisory board programs were "only four hours and Gilead staff did the majority of the speaking, touting the benefit of a prescription Gilead HBV drug over a generic."[35] At some meetings, Gilead's Associate Director of HBV Marketing "planted" certain providers to make pre-scripted remarks such as "I [have] switched all [of] my patients to Vemlidy, and I encourage everyone else to do

the same."[36] The Sales Directors question how much advising each of the forty advisors could accomplish "in this short time, especially since Gilead spent most of the program promoting the sale of Gilead's HBV drug."[37]

Gilead's programs offered significant monetary upside to participants. In 2014, Gilead paid some of the top Viread prescribers between $37,386 and $119,529 each for participating in Gilead programs.[38] In 2017, Gilead paid the top Vemlidy prescribers between $9,605 and $182,464 each.[39] Gilead paid one paid doctor $182,464 for participating in forty-four different Vemlidy programs.[40] Gilead paid another provider $45,694 for fifteen programs.[41] The Sales Directors allege one healthcare provider conducted twenty-six speaker programs in 2017 and Gilead paid it $78,000.[42] Gilead speaker payments represented the largest stream of revenue outside of practice for many healthcare providers.[43]

Gilead "touted the Vemlidy launch as the most successful launch of an HBV drug in history and noted that Vemlidy uptake was exceeding expectations."[44] But the Sales Directors claim Gilead's success is attributed to using "Opinion Leadership Program" dollars as an inducement citing statistics Gilead paid: each of the top ten Vemlidy writers;[45] sixty-two percent of the top fifty Vemlidy writers;[46] and, approximately 175 of the highest volume prescribers.[47]

Gilead's sales team selected healthcare providers to participate in the "Opinion Leadership Program."

The Sales Directors offer significant details about how Gilead's sales teams decided which healthcare providers to include in its "Opinion Leadership Program." As plead, Gilead's sales analytics team provided Gilead's sales team with "extensive data of the prescribing habits" of healthcare providers to include in paid programs.[48] The data included "local [versus] regional rating" (measuring the providers "span of influence") and the healthcare providers' "volume of

business in Viread, Vemlidy, and competitors."[49] The Sales Directors allege the sales team used this data "in making selections to receive Gilead money."[50]

The sales analytics team provided other data to the sales team. One Excel spreadsheet contained data showing advisory board attending providers: "(a) Previous[] [Advisory Board] engage[ments]; (b) Tier [c]lassification; (c) Vemlidy [s]cripts written; (d) Viread scripts written; (e) Baraclude (competitor) scripts written; (f) [S]pecialty; (g) Speaker Bureau participant[; and,] (h) [A]ttendance at [ ] previous Ad Board events."[51] The sales analytics team also provided "market mover" data to allow the sales team to target healthcare providers in high volume markets.[52] "Market mover" data attributed a decile rating (between one and ten) quantifying a healthcare provider by the volume of potential prescriptions.[53] Providers in deciles eight through ten wrote "exponentially more scripts" than deciles five through seven.[54] Gilead's Associate Director of Marketing circulated a spreadsheet with data about provider decile rating and business breakdown by product stating: "Attached is the Opinion Leader Engagement Spreadsheet that my team maintains for the purpose of knowing our customers better, having a readily available faculty for advisory boards and speaker related activities."[55] The Sales Directors allege Gilead's sales team used this data to target sales efforts at the 2,600 healthcare providers in the United States who treat HBV patients at the highest volume.[56]

The Gilead sales team tracked the prescription writing of paid speakers and advisors. The Gilead sales analytics team generated a list of the top fifty Vemlidy prescription writers and sent the list to the "Vice President, Senior Regional Director, and then to the Regional Directors" to ultimately share with sales representatives.[57] The Sales Directors claim those top fifty lists allowed the sales team to track the return of investment on speaker and advisory programs.[58]

Advisory board attendees "knew" Gilead's sales team tracked their prescription writing habits and invited them to advisory boards as an inducement to increase or maintain the prescriptions.[59] The Senior Director of HBV Sales and Marketing "often said to sales representatives when a high decile speaker started to slip" in prescription writing: "Well, have you given them talks? Give them more talks."[60] The Sales Directors identify a HBV prescription writer in the Northeast who "requested an annual West Coast [advisory board appearance or speaker program] around the Chinese New Year so he could travel from New York City to visit family;" even though the West Coast "did not need him," Gilead invited him, paid his expenses, and received an honorarium check of $3,000.[61] Another healthcare provider's wife told Gilead sales representatives to include her husband in more talks.[62]

Gilead's practices allegedly run afoul of its own business conduct code. For instance, Gilead's business conduct code states: "Advisors must be selected based on their knowledge, experience, patient demographic, size or type of practice, and other skill-based qualifications and not based on their history of or potential for purchasing or prescribing Gilead products. Gilead personnel may not conduct return on investment analyses of advisory programs; nor may they analyze the impact of advisory programs on [healthcare providers] prescribing practices with any Gilead-supported programs."[63] Gilead's code of conduct also states advisory boards "may not be used to promote Gilead products."[64]

Gilead's kickbacks tainted claims for reimbursement.

Gilead caused false claims to be submitted to the United States by inducing healthcare providers to prescribe Gilead HBV drugs for reimbursement from federal and state healthcare payors in violation of the anti-kickback statute. The Sales Directors specifically allege one Gilead paid healthcare provider prescribed Vemlidy ninety-two times for payment by Managed

Medicaid.[65] The Sales Directors allege another provider prescribed Viread and Vemlidy for payment by Medicare and Medicaid (Medical).[66]

The Sales Directors allege healthcare providers are required to comply with other federal laws when submitting claims to be paid by federal and state healthcare payors. "Government programs, including Medicare and Medicaid, do not cover claims for drugs when there is a kickback involved in the underlying transaction—including claims that were submitted for payment of a drug as a result of a kickback given to a [healthcare provider] to prescribe that drug."[67] To enroll and bill Medicare, providers must sign a "CMS Form 855" stating the provider will comply with the anti-kickback statute.[68] Providers must also agree to similar conditions to bill Medicaid programs.[69] The Sales Directors claim Gilead's anti-kickback statute violations caused "downstream entities to submit claims for reimbursement for Vemlidy and Viread."[70]

II. Analysis[71]

Gilead moves to dismiss the Sales Directors' Second Amended Complaint in its entirety arguing they: (1) fail to plead a False Claims Act claim with particularity; (2) present redundant False Claims Act claims; and, (3) do not adequately plead claims under state False Claims Act laws. After analysis, we find the Sales Directors plead claims under federal False Claims Act Sections 3729(a)(1)(A) and 3729(a)(1)(B) and under the state False Claims Acts of California, Illinois, New Jersey, New York, and Texas but dismiss the Sales Directors' federal Section 3729(a)(1)(G) claim.

A. The Sales Directors plead False Claims Act claims under Sections 3729(a)(1)(A) and 3729(a)(1)(B) with particularity.

Congress, through the False Claims Act, imposes liability on a person who knowingly: (1) "presents, or causes to be presented, a false or fraudulent claim for payment or approval"; (2) "makes, uses, or causes to be made or used, a false record or statement material to a false or

fraudulent claim"; (3) "makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government"; or (4) "conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[72]

To state a false claim cause of action under Sections 3729(a)(1)(A) and (a)(1)(B), the Sales Directors must allege "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent."[73] To assert a cause of action under Section 3729(a)(1)(G), the Sales Directors must plead Gilead owed an "obligation" to the United States."[74] The Sales Directors must plead False Claims Act claims with particularity under Federal Rule of Civil Procedure 9(b).[75]

Gilead moves to dismiss the Sales Directors' claims with prejudice arguing they fail to sufficiently plead the required elements to plead a cause of action under Sections 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G). We agree in part. The Sales Directors plead Sections 3729(a)(1)(A) and (a)(1)(B) False Claims Act claims with particularity but fail to state a claim under Section 3729(a)(1)(G).

1. The Sales Directors plead Gilead caused claims to be presented.

Gilead argues Sales Directors fail to sufficiently plead false claims actually submitted to the United States. Gilead argues the Sales Directors fail to allege a provider prescribed more Gilead products after serving as Gilead speakers or advisors.

Our Court of Appeals adopts the pleading standard detailed by the Court of Appeals for the Fifth Circuit for determining whether false claims have been submitted.[76] To survive a motion

to dismiss, the Sales Directors must plead "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."[77]

The Sales Directors plead particular details of a scheme—the "Opinion Leadership Program"—paired with reliable indicia—the prevalence of claims submitted to federal and state healthcare payors—showing a strong inference claims for reimbursements for Viread and Vemlidy were actually submitted. The Sales Directors plead several details of Gilead's "Opinion Leadership Program," including significant detail about the selection process, honorarium and other payments to participating providers. The Sales Directors plead paid participants included significant writers of Vilead and Vemlidy, and "[f]ederal, state, and local governments, through their Medicaid, Medicare, TRICARE, Veteran's Administration and other Government healthcare payors, are among the principal purchasers of Gilead's pharmaceutical products."[78] While these allegations alone offer a strong enough inference participating providers wrote Viread or Vemlidy prescriptions leading to claims for government payor reimbursement, the Sales Directors also provide specific examples of the billing from paid healthcare providers.[79] The Sales Directors do not need to show Gilead caused increased prescriptions to meet this element.[80] Sales Directors must only plead facts to allow as to plausibly infer claims were submitted. The Sales Directors meet the first element.

2. The Sales Directors plead false payments.

Gilead argues the Sales Directors fail to allege facts to establish claims submitted to government healthcare payors were false under the False Claims Act. A false claim can be factually or legally false.[81] A claim "is legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement."[82] The Sales Directors allege Gilead caused false claims to be submitted by causing actual violations of the anti-kickback statute. "[A]

claim that includes items and services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[83] Compliance with the anti-kickback statute is a material condition of payment under the False Claims Act.[84] If the Sales Directors sufficiently allege anti-kickback statute violations, then they sufficiently plead Gilead caused false claims to be submitted in violation of the False Claims Act.

Under the anti-kickback statute, it is illegal to "knowingly and willfully offer[ ] or pay[ ] 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, 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[.]"[85] It is sufficient at least "one purpose of the payment was to induce" Medicare purchases.[86]

Gilead explains its payments as routine in pharmaceutical marketing practices for a new product launch. Gilead may prove this to be true. But the Sales Directors plausibly plead Gilead's conduct fell outside of safe harbor provided 42 CFR § 1001.952(d)(5): "The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in armslength transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."[87] The Office of Inspector General of the United States Department of Health and Human Services instructs many factors—such as whether a product manufacturer considers the volume or value of business generated by a paid speaker or pays a speaker in excess of the fair market value the speaker offers to the product manufacturer—may be considered to

determine "whether any one purpose of the [payment] may be to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program."[88]

The Sales Directors plead particular facts showing one purpose of Gilead's remuneration could have been to induce Medicare purchases. The Sales Directors detail facts about Gilead sales team using data provided by Gilead's sales analytics team about high volume HBV prescribers to determine which healthcare providers to include in the advisory board and speaker programs. The Sales Directors plead extensive detail about Gilead's strategy of inviting "market movers" to participate in boards and programs. The Sales Directors excerpt an email from a marketing director attaching a spreadsheet with volume data stating they use the spreadsheet for "having a readily available faculty for advisory boards and speaker related activities."[89] Sales Directors allege facts showing Gilead's sales team weighed the number of prescriptions to determine who to elect as speakers and advisors.

The Sales Directors plead numbers showing a relationship between a healthcare provider's involvement in speaker and advisor programs and the number of prescriptions written by them. The Sales Directors allege each of the top ten Vemlidy prescription writers in the country for 2017 were program speakers. Eight of these top ten prescribers participated in over ten programs in 2017. Gilead paid at least six of the ten top Vemlidy prescribers over $30,000 in annual payments for participating in paid programs. Gilead paid one provider almost $200,000 for forty-four programs in one calendar year. The Sales Directors cite to one healthcare provider who Gilead hired to speak twenty-six times in 2017. The Sales Directors also point to healthcare providers (and spouses of providers) who were elected as speakers or advisors only after the provider specifically requested to participate in particular events for the monetary benefit because programs offered convenient free travel.[90] The Sales Directors allege payments—$3,000 honoraria for each

appearance—to induce providers to switch patients from off-patent Viread to patented Vemlidy. The timing of Viread's patent expiration and FDA-approval of branded Vemlidy matches the Sales Directors' alleged theories. The Sales Directors plausibly show one purpose of "Opinion Leadership Program" payment was to induce federal healthcare purchases of Gilead HBV prescription drugs.

The Sales Directors also plead facts demonstrating Gilead conducted "sham" advisory board and speaker programs.[91] Sales Directors allege Gilead sales and marketing teams primarily planned and ran advisory boards. Gilead's sales and marketing teams accompanied advisors throughout advisory board meetings to promote Gilead's products. Sales Directors allege Gilead "planted" advisors to make "pre-scripted remarks" such as "I [have] switched all [of] my patients to Vemlidy, and I encourage everyone else to do the same."[92] The Sales Directors question how much advising forty advisors could accomplish during four hour advisory board meetings. The Sales Directors also plead facts questioning the legitimacy of the speaker programs. These types of challenges are better suited for review after discovery. Drawing reasonable inferences in the Sales Directors' favor, they plead particular facts plausibly asserting the "sham" nature of advisory boards and speaker programs. If programs are conducted as "shams," and participating providers are paid even if failing to offer benefits consistent with their fair market values, the programs may violate the anti-kickback statute.

3. The Sales Directors plead Gilead's requisite intent.

Gilead argues the Sales Directors fail to sufficiently plead Gilead's knowledge of the alleged illegal kickback scheme. The Supreme Court explained in *Universal Health Services*: "The [False Claims Act's] scienter requirement defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or

falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'"[93] The Sales Directors are only required to allege scienter generally, and the anti-kickback statute does not require a specific intent.[94]

The Sales Directors plead facts to meet the *Universal Health Services* standard. The Sales Directors allege specific Gilead policies designed to deter practices of selecting participating healthcare providers based on volume or prescribing habits and to a policy stating advisory board sessions should not be used to sell Gilead products. And, despite the policies, Gilead's sales team used data from the sales analytics department to determine which speakers to include in the "Opinion Leadership Program." Sales Directors also allege particular facts about Gilead's sales team's involvement during advisory board programs. The policies reveal Gilead officials at least acted in deliberate indifference or in reckless disregard. But Sales Directors also plead specific directives provided by Gilead officials showing "actual knowledge." Sales Directors meet the third element.

4. The Section 3729(a)(1)(G) claim is redundant.

In addition to their claims under Sections 3729(a)(1)(A) and 3729(a)(1)(B), the Sales Directors also allege a reverse false claim under Section 3729(a)(1)(G).[95] "A reverse false claim requires the failure to pay money owed to the government."[96] Section 3729(a)(1)(G) creates liability for two categories: one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government" or one who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[97] Both of these prongs only apply where there is an obligation to pay the Government. An "obligation" is defined as an "established duty."[98] There must be "a 'clear' obligation or liability to the [G]overnment."[99]

Gilead moves to dismiss Sales Directors reverse false claim arguing the claim is redundant to Sales Directors' Section 3729(a)(1)(A) and Section 3729(a)(1)(B) claims. The Sales Directors predicate their claims on alleged violations of the anti-kickback statute. These claims uniformly follow the same theory: Gilead unlawfully induced healthcare providers to write Gilead prescriptions. This theory relates to issues with claims submitted to the United States. Section 3729(a)(1)(G) liability occurs when a defendant falsely avoids an obligation owed to the United States. Sales Directors do not plead Gilead owed an obligation to the United States but rather claim Gilead caused the United States to pay false claims. We agree with Gilead the Section 3729(a)(1)(G) claim is redundant.

B. The Sales Directors plead claims under the False Claims Act of California, Illinois, New Jersey, New York, and Texas.

The Sales Directors allege Gilead's "Opinion Leadership Program" inducing prescriptions by paying healthcare providers to participate in sham speaker programs and advisory boards violated state analogues of the False Claims Act in California, Illinois, New Jersey, New York, and Texas. Gilead argues we must dismiss these claims "for the same reason [we must dismiss] Sales Directors' federal [False Claims Act] claims."[100] Gilead offers no other reason state claims should be dismissed. We explained Sales Directors plead with sufficient particularity the necessary elements of establishing a claim under the federal False Claims Act. We cannot dismiss state claims "for the same reason as Sales Directors' federal claims."[101]

III. Conclusion

The Sales Directors plead facts with sufficient particularity to proceed into discovery under the False Claims Act Sections 3729(a)(1)(A) and 3729(a)(1)(B). The Sales Directors' claim under Section 3729(a)(1)(G) is redundant and dismissed without prejudice. The Sales Directors

sufficiently plead claims under the state False Claims Act of California, Illinois, New Jersey, New York, and Texas.

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[1] These facts are drawn from the Second Amended Complaint and, for purposes of Gilead's Motion to dismiss, are taken as true. *See Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). On August 7, 2017, the Sales Directors sued Gilead under seal and served its Complaint upon the United States. On July 12, 2018, the Sales Directors filed an Amended Complaint under seal and served its Amended Complaint upon the United States. The United States requested multiple extensions to extend the seal to allow it time to elect to intervene. On September 19, 2019, the Sales Directors filed their Second Amended Complaint under seal and served the Second Amended Complaint upon the United States. On October 7, 2019, the United States declined to intervene.[1] In the now unsealed Second Amended Complaint, the Sales Directors sue Gilead on behalf of the United States and the state governments of California, Illinois, New Jersey, New York, and Texas for violations of the False Claims Act.

[2] Chris Purcell worked for Gilead as a Regional Director (Midwest territory) of the HBV division from 2012 until 2017. ECF Doc. No. 21 at ¶ 21. Relator Kimberly Groom is a former Gilead Regional Director (West territory) of the HBV Division from 2013 until February 2018. *Id.* at ¶ 22.

[3] ECF Doc. No. 21 at ¶ 24.

[4] *Id.* at ¶ 26.

[5] *Id.* at ¶ 26.

[6] *Id.*

[7] Drug Approval Package, Viread (Tenofovir Disoproxil Fumarate) NDA #21-356, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/21-356_Viread.cfm (last visited Feb. 10, 2020). Viread's active ingredient is tenofovir disoproxil fumarate. ECF Doc. *Id.*

[8] ECF Doc. No. 21 at ¶ 35.

[9] *Id.*

[10] *Id.*

[11] *Id.* at ¶¶ 34-37.

[12] *Id.* at ¶ 31.

[13] *Id.* at ¶ 35. Vemlidy's active ingredient is tenofovir alafenanmide. *Id.* at ¶ 30.

[14] *Id.* at ¶ 34.

[15] *Id.* at ¶ 114.

[16] *Id.* at ¶ 32.

[17] *Id.* at ¶¶ 33-34.

[18] *Id.* at ¶ 76.

[19] *Id.* at ¶ 60.

[20] *Id.* at ¶ 114.

[21] *See id.* at ¶ 64. Sales Directors cite numbers demonstrating Gilead significantly increased payments to some HCPs, *i.e.*, from $55,374 in 2013 to $119,529 in 2014, "at a time when the industry knew its competitors' drug Baraclude was going generic, and Gilead would be the only HBV drug manufacturer that was offering HCPs significant money for [speaker programs and advisory boards]." *Id.* at ¶ 65.

[22] *Id.* at ¶ 117.

[23] *Id.* at ¶ 120.

[24] *Id.*

[25] *Id.* at ¶ 126.

[26] *Id.* at ¶¶ 121-122.

[27] *Id.* at ¶ 122.

[28] *Id.*

[29] *Id.* at ¶ 70.

[30] *Id.*

[31] *Id.* at ¶ 128.

[32] *Id.*

[33] *Id.* at ¶ 129; *see also id.* at ¶ 131 ("At these events Gilead's senior sales team had access to the [healthcare providers] throughout the [advisory board] pre-dinner and event.").

[34] *Id.* at ¶ 131.

[35] *Id.* at ¶ 71.

[36] *Id.* at ¶ 132.

[37] *Id.* at ¶ 136.

[38] *Id.* at ¶ 64.

[39] *Id.* at ¶ 107.

[40] *Id.*

[41] *Id.*

[42] *Id.* at ¶ 124.

[43] *Id.* at ¶ 123. The Sales Directors claim Gilead invested excessive amounts of money into HBV drug programs. Vemlidy (a $100 Million drug) had a comparable number of advisory boards to "the entire $6.5 [Billion] HIV drug franchise." *Id.* at ¶ 68. The Sales Directors also allege Gilead invested more money into HBV sales "than other larger products." *Id.* at ¶ 67.

[44] *Id.* at ¶ 145.

[45] *Id.* at ¶ 107.

[46] *Id.* at ¶ 104.

[47] *Id.* at ¶ 103.

[48] *Id.* at ¶¶ 80, 100.

[49] *Id.* at ¶ 101.

[50] *Id.*

[51] *Id.* at ¶ 102.

[52] *Id.* at ¶ 127.

[53] *Id.* at ¶ 102.

[54] *Id.* at ¶ 103.

[55] *Id.* at ¶ 105.

[56] *Id.* at ¶ 98.

[57] *Id.* at ¶ 119.

[58] *Id.* at ¶ 78.

[59] *Id.* at ¶ 130.

[60] *Id.* at ¶ 142.

[61] *Id.*

[62] *Id.* at ¶ 144.

[63] *Id.* at ¶ 173.

[64] *Id.* at ¶ 174.

[65] *Id.* at ¶ 184.

[66] *Id.*

[67] *Id.* at ¶ 194.

[68] *Id.* at ¶ 195.

[69] ECF Doc. No. 21 at ¶ 196 (citing California's Medicaid statute).

[70] ECF Doc. No. 21 at ¶ 202.

[71] When considering a motion to dismiss "[w]e accept as true all allegations in the plaintiff's complaint as well as all reasonable inferences that can be drawn from them, and we construe them in a light most favorable to the non-movant." *Tatis v. Allied Interstate, LLC*, 882 F.3d 422, 426 (3d Cir. 2018) (quoting *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010)). To survive dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Our Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal*, 556 U.S. at 675, 679).

[72] 31 U.S.C. § 3729(a)(1)(A), (B), (G).

[73] *United States ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 759 (3d Cir. 2011) (quoting *United States ex rel. Willis v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)); *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, No. 13-7547, 2018 WL 6300578, at *9 (E.D. Pa. Nov. 29, 2018), *clarified on denial of reconsideration*, 370 F. Supp. 3d 491 (E.D. Pa. 2019).

[74] *United States ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015), *aff'd on other grounds*, 855 F.3d 481 (3d Cir. 2017).

[75] *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004).

[76] *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014).

[77] *Id.* (quoting *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 190 (5th Cir.2009)).

[78] ECF Doc. No. 21 at ¶ 36.

[79] *Id.* at ¶¶ 183-184.

[80] *Cf. United States v. Teva Pharm. USA, Inc.*, No. 13-3702, 2016 WL 750720, at *15 (S.D.N.Y. Feb. 22, 2016) ("Sales Directors need not submit sample claims for *each government program* on behalf of which they have brought suit").

[81] *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018).

[82] *Id.*

[83] *Id.* at 95.

[84] *U.S. ex rel. Nevyas v. Allergan, Inc.,* No. 09-432, 2015 WL 4064629, at *4 (E.D. Pa. July 2, 2015).

[85] 42 U.S.C. § 1320a-7(b)(2)(B).

[86] *See United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985).

[87] 42 CFR § 1001.952(d)(5).

[88] *Compliance Program Guidance for Pharmaceutical Manufacturers*, U.S. Dep't of Health of Human Services Office of Inspector General (April 2003), https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (explaining factors to consider when arrangement falls out of safe harbor provisions of 42 CFR § 1001.952(d)).

[89] ECF Doc. No. 21 at ¶ 105.

[90] *Id.* at ¶ 144.

[91] *United States v. Teva Pharm. USA, Inc.*, No. 13-3702, 2019 WL 1245656, at *13 (S.D.N.Y. Feb. 27, 2019).

[92] ECF Doc. No. 21 at ¶ 132.

[93] *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016), (quoting 42 U.S.C. § 3729(b)(1)(A)).

[94] *See* Fed. R. Civ. P. 9(b); 42 U.S.C. § 1320a-7b(h).

[95] ECF Doc. No. 21 at p. 51.

[96] *United States ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015), *aff'd on other grounds*, 855 F.3d 481 (3d Cir. 2017).

[97] *Id.*

[98] 31 U.S.C. § 3729(b)(3).

[99] *United States ex rel. Thomas v. Siemens*, 708 F.Supp.2d 505, 514 (E.D.Pa. 2010) (citing *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 444 (3d Cir. 2004)).

[100] ECF Doc. No. 54 at p. 20.

[101] *Id.*

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CHRIS PURCELL, *et al.*	:	**CIVIL ACTION**
	:	
v.	:	**NO. 17-3523**
	:	
GILEAD SCIENCES, INC.	:	

ORDER

AND NOW, this 13th day of February 2020, upon considering the Defendant's Motion to dismiss (ECF Doc. No. 53), and for reasons in the accompanying Memorandum, it is **ORDERED** the Defendant's Motion (ECF Doc. No. 53) is **GRANTED in part** and **DENIED in part**:

1. Defendant's Motion (ECF Doc. No. 53) is **GRANTED** as to the redundant claims under Section 3729(a)(1)(G); and,

2. Defendant's Motion (ECF Doc. No. 53) is otherwise **DENIED** and it shall answer the second amended Complaint no later than **February 27, 2020**.

KEARNEY, J.