UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

UNITED STATES OF AMERICA, *et al.* *ex rel*. HEALTH CHOICE GROUP, LLC, Plaintiffs, v. BAYER CORPORATION, ONYX PHARMACEUTICALS, INC., AMERISOURCEBERGEN CORPORATION, & LASH GROUP Defendants.	)	No. 5:17-CV-126-RWS-CMC

THE UNITED STATES'
MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

Pursuant to 31 U.S.C. §3730(c)(2)(A), the United States of America ("United States" or "Government") hereby moves to dismiss this *qui tam* action brought on behalf of the United States by Health Choice Group, LLC under the False Claims Act, 31 U.S.C. §3729, *et seq.* ("FCA").[1] As discussed more fully below, this action was brought by a professional relator who has filed eleven *qui tam* actions throughout seven judicial districts, each raising substantially the same allegations under the FCA. Having completed its investigation, and finding the allegations to lack sufficient merit to justify the cost of investigation and prosecution and otherwise be

[1] Relators have brought claims on behalf of certain Medicaid-participating states under their respective state false claim statutes. Undersigned counsel does not represent the named state plaintiffs; however, Kerry Muldowney Ascher, counsel for the state of Texas and representative of the National Association of Medicaid Fraud Control Units, has represented to the United States that all named plaintiff states consent to the United States' motion to dismiss so long as it is without prejudice as to the states, with the exception of New Jersey, which takes no position on the motion.

contrary to the public interest, the United States now seeks to dismiss these actions. Accordingly, the United States requests that this action be dismissed with prejudice as to Health Choice Group, LLC, and without prejudice as to the United States.

I. BACKGROUND AND PROCEDURAL HISTORY

A. The NHCA Group *Qui Tam* Actions

This *qui tam* action was filed on June 19, 2017, by Health Choice Group, LLC, a limited liability company established for the sole purpose of serving as the named relator in this action. Health Choice Group LLC was established by National Health Care Analysis Group ("NHCA Group"), which is itself a pseudonym for a partnership comprised of limited liability companies set up by investors and former Wall Street investment bankers. *See* accompanying Declaration of Brian J. McCabe ("McCabe Decl."), ¶¶ 2-3 and Exhibit A (email from attorney Marc Mukasey, counsel for NHCA Group, describing corporate structure of NCHA Group); and Exhibit B (visual aid depicting NHCA Group relators and corporate organization).

The partnership, acting through shell company relators, has filed eleven *qui tam* complaints against a total of thirty-eight different defendants for essentially the same alleged conduct. In addition to this action, the other complaints include:

- *U.S. ex rel. SAPF, LLC, v. Amgen, Inc.,* No. 16-cv-5203 (E.D. Pa.)
- *U.S. ex rel. SMSPF, LLC v. EMD Serono, Inc.*, No. 16-cv-5594 (E.D. Pa.)
- *U.S. ex rel. SMSF, LLC v. Biogen, Inc.,* No 1:16-cv-11379-IT (D. Mass.)
- *U.S. ex rel. NHCA-TEV, LLC v. Teva Pharms.*, No. 17-cv-2040 (E.D. Pa.)
- *U.S. ex rel. SCEF, LLC v. Astra Zeneca PLC,* No. 17-cv-1328 (W.D. Wash.)
- *U.S. ex rel. Miller, v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.)
- *U.S. ex rel. Carle, v. Otsuka Holdings Co.*, No. 17-cv-966 (N.D. Ill.)
- *U.S. ex rel. CIMZNHCA v. UCB, Inc*., No. 3:17-cv-00765 (S.D. Ill.)
- *U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.,* No. 5:17-cv-123 (E.D. Tex.)
- *U.S. ex rel. Health Choice Advocates, LLC v. Gilead, et al.,* No. 5:17-cv-121 (E.D. Tex.)[2]

[2] Relators voluntarily dismissed the *Gilead* action on July 23, 2018. The United States consented to the dismissal "based on its determination that under the circumstances such a

All of these cases present essentially the same theories of FCA liability – that pharmaceutical companies and commercial outsourcing vendors violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), by engaging in so-called "white coat marketing" and by providing free "nurse services" and "reimbursement support services." *See generally* Second Amended Complaint (SAC), Dkt. 102, at ¶¶ 2-7. First, the complaints allege that the defendants provided illegal remuneration in the form of "free nurse services," such as visiting patients at home to provide instruction on how to properly administer their newly-prescribed medications. *See id.* ¶¶ 94-152. Second, according to NHCA Group, the defendants allegedly engaged in improper "white coat marketing" by hiring independent contractor nurses to act as "undercover sales representatives," who engage in impermissible promotional activity. *See id*. ¶¶ 153-99. Third, the complaints allege that the pharmaceutical companies violated the AKS by helping physicians complete insurance documents, such as benefit verifications and prior authorization forms. *See id.* ¶¶ 200-59.

In preparing its numerous complaints, NHCA Group appears to have utilized the same model or template, resulting in what are essentially cloned complaints. When viewed side-by-side, it is apparent that certain allegations are repeated from one complaint to the next, including seemingly particularized allegations. For example, the relator in this case alleges that Bayer employees "emphasized" a specific marketing message regarding reimbursement support, *see* SAC at ¶ 214; notably, the other complaints attribute the exact same message to the other defendants as well:

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dismissal is commensurate with the public interest and that the matter does not warrant the continued expenditure of government resources to pursue or monitor the action[.]"

> **Biogen First Amended Compl. ¶ 202:** "Biogen sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Biogen, thereby increasing the Prescriber's bottom line."
>
> **Gilead First Amended Compl. ¶ 133:** "Gilead sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Gilead, thereby increasing the Prescriber's bottom line."
>
> **Eli Lilly Second Amended Compl. ¶ 227:** "Lilly sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Lilly, thereby increasing the Prescriber's bottom line."

Similarly, the relator in this case specifically alleges that Bayer personnel utilized this "value proposition" messaging to influence prescribing physicians. *See* SAC at ¶ 215. Yet again this same allegation is repeated nearly verbatim in the other *qui tam* actions:

> **Biogen First Amended Compl. ¶ 203:** "This value proposition was a powerful tool in the hands of the Biogen drug representatives, and it was used to induce Prescribers to recommend Avonex, Plegridy and Tysabri."
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> **Amgen Compl. ¶ 99:** "This value proposition was a powerful tool in the hands of Amgen's drug reps and used to influence providers to recommend Amgen Covered Drugs."
>
> **Eli Lilly Second Amended Compl. ¶ 228:** "This value proposition was a powerful tool in the hands of Lilly drug representatives, and used to induce Prescribers to recommend Forteo."
>
> **UCB Compl. ¶ 74:** "This value proposition was a powerful tool in the hands of UCB's drug representatives and used to influence providers to recommend UCB's Cimzia."
>
> **Gilead First Amended Compl. ¶ 134:** "This value proposition was a powerful tool in the hands of Gilead's drug reps and Covance's field reps, and was used to induce Prescribers to recommend Gilead drugs."
>
> **Teva First Amended Compl. ¶ 124:** "This value proposition was a powerful tool in the hands of Teva's sales representatives and was used to influence providers to recommend its drug Copaxone over its competitors."

These are just a few examples of particularized allegations that are copied nearly verbatim across other NHCA complaints.

B. The NHCA Group *Qui Tam* Business Model

Shortly before the first of these actions was filed, the managing agent for NHCA Group, one of its investors, John Mininno, spoke to the media and explained NHCA Group's business model. *See* J.C. Herz, *Medicare Scammers Steal $60 Billion a Year. This Man is Hunting Them.*, Wired, March 7, 2016, available at https://www.wired.com/2016/03/john-mininno-medicare/ (last visited November 26, 2018). Described as a "big-data entrepreneur," Mr. Mininno recalled that when the Centers for Medicare and Medicaid Services (CMS) made available to the public vast amounts of Medicare claims data, he viewed it as "a massive business opportunity," specifically with regard to *qui tam* suits. *Id.* Backed by a "Wall Street angel investor," NHCA Group was established. *Id.*

In order to obtain information for its *qui tam* business, NHCA Group created a database of resumes, "scraped and extracted from publicly-available sources," which the organization uses to identify "potential informants." *Id.* NHCA Group then contacts these individuals under the guise of conducting a "research study" of the pharmaceutical industry. More specifically, NHCA Group offers to pay these individuals to participate in what it calls a "qualitative research study;" however, the information is actually being collected for use in *qui tam* complaints filed by the NHCA Group through its pseudonymous limited liability companies.[3]

On its website, NHCA Group makes no mention of its role behind dozens of *qui tam* actions, instead holding itself out to the public as a "healthcare research company that engages in

[3] All eleven of NHCA Group's *qui tam* actions referenced herein was brought by a corporate relator; however, at least 4 of the cases also included an individual co-relator alongside the LLC relator when originally filed. NHCA Group has attempted to add individual co-relators to a number of the other cases at the time of subsequent amendments, albeit with limited success. *See, e.g.*, Dkt No. 98 (dismissing individual co-relator added to amended complaint because her claims "are barred by the False Claims Act's first-to-file rule.").

qualitative research of pharmaceutical and other healthcare-related industries." National Healthcare Analysis Group, http://www.nhcagroup.com (last visited November 26, 2018). Although it collects information to use in *qui tam* actions against pharmaceutical companies, NHCA Group states prominently on its website that it has "no particular bias one way or the other about the industry." *Id.*

The transcripts of NHCA Group witness interviews reveals the false pretenses NHCA Group uses to obtain information from witnesses. *See* McCabe Decl., ¶ 5, Exhibits C-1 – C-3. For instance, when explaining the purpose of the interview, NHCA Group representatives repeatedly tell the witnesses that the organization is conducting a "research study," and underscore that "they have no bias one way or the other" regarding the pharmaceutical industry. *Id*. The witnesses are not told that the interviewer is acting at the direction of attorneys to collect information that will be used in lawsuits involving the witnesses' current or former employers, nor are they told that they will be named as corroborating "witnesses" in those lawsuits. *See Id.*[4]

By utilizing cloned complaints and information gleaned from its fictitious "research study," NHCA Group advances sweeping allegations of nationwide misconduct by thirty-eight different defendants – allegations that, for Medicare Part D alone, implicate more than 73 million prescriptions written by hundreds of thousands of different physicians for millions of different Medicare beneficiaries. Due to the expansive scope of the allegations, the Department of Justice has expended substantial resources investigating the NHCA Group matters.

[4] In *United States ex rel. Leysock v. Forest Labs., et al.*, No. 1:12-cv-11354-FDS, 2017 WL 1591833 (D. Mass. April 28, 2017), relator's counsel interviewed witnesses as part of a fictitious "research study" that the court found to be part of "an elaborate scheme of deceptive conduct" designed to obtain specific details to satisfy *qui tam* pleading requirements. *Id*. at *1 The court concluded that such conduct violated several Massachusetts rules of professional conduct and, as a sanction, struck from the complaint all particularized details obtained through the fictitious "research study," and dismissed the complaint. *Id.* at *9-10.

After concluding that relator's allegations in this case lacked sufficient factual and legal support, as in the other actions, the United States notified the Court on October 30, 2017 that it was declining to intervene. Dkt. 7. The case was thereafter unsealed, and relator filed an Amended Complaint on January 12, 2018, Dkt. 32, which was dismissed without prejudice on July 31, 2018. Dkt. 98. Relator filed a Second Amended Complaint (SAC) on August 15, 2018. Dkt. 102. The United States now respectfully requests that this action be dismissed pursuant to 31 U.S.C. § 3730(c)(2)(A), for the reasons discussed below.

II. ARGUMENT

A. The FCA Statutory Framework

The FCA enables the United States to recover monies lost due to the submission of false claims. 31 U.S.C. § 3729. Among the unique features of the FCA is that it allows private parties, known as relators, to bring an action on behalf of the United States through the filing of a *qui tam* action. The *qui tam* provisions of the FCA provide a special means for the United States to recover damages suffered as a result of fraud or false claims, through the assistance of relators, who file suit "for the person and for the United States Government." *Id.* § 3730(b). Although a *qui tam* suit is brought in the name of the United States, a relator has a right to a share of the recovery, plus attorneys' fees and costs. *Id.* § 3730(b), (d).

Among other things, the FCA directs that the relator must file his or her complaint under seal and serve it, along with a written disclosure of evidence, on the United States. *Id.* §§ 3730(b)(1) and (2). The United States has 60 days (and any extensions granted by the district court) to investigate the allegations and elect whether or not to intervene in the litigation. *Id.* §§ 3730(b)(2) and (3). If the United States intervenes in the case, "the action shall be conducted by the Government," and the Government assumes "the primary responsibility for prosecuting

the action" and is not bound by an act of the relator. *Id.* §§ 3730(b)(4)(A) and (c)(1). The relator remains a party to the suit, but the Government may settle the case over his objection (*Id.* § 3730(c)(2)(B)) or may seek to limit his participation in the litigation. *Id.* § 3730(c)(2)(C).

If the United States declines to intervene in the case, the relator has the right to proceed with the action. *Id.* § 3730(c)(3). However, that right is *not* absolute; rather, it is circumscribed by a number of limitations designed to ensure that the United States retains control over the declined action. For example, the relator cannot dismiss the action without the written consent of the Attorney General. *Id.* § 3730(b)(1). The court may stay discovery in the *qui tam* action if it would interfere with the Government's investigation or prosecution of another matter. *Id.* § 3730(c)(4). Moreover, even when the Attorney General initially declines to intervene in the suit, the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." *Id.* § 3730(c)(3).

Most importantly for purposes of this motion, the FCA authorizes the Attorney General to dismiss a *qui tam* action over a relator's objection:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

Id. § 3730(c)(2)(A). The United States is authorized to dismiss even where it has opted not to intervene. *See United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 753 n.10 (9th Cir. 1993), *cert. denied*, 510 U.S. 1140 (1994), *citing Juliano v. Fed. Asset Disposition Ass'n*, 736 F. Supp. 348 (D.D.C. 1990), *aff'd*, 959 F.2d 1101 (D.C. Cir. 1992) (table).

B. <u>Standard of Review</u>

The Government possesses broad authority to dismiss *qui tam* actions under Section 3730(c)(2)(A). Two different standards have been adopted by appellate courts to guide the application of the government's dismissal authority. In *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003), the Court of Appeals for the District of Columbia interpreted the FCA to grant the Government "an unfettered right to dismiss" a *qui tam* action. The Ninth Circuit has applied a "rational relationship test" for dismissal but has also recognized that the United States has broad prosecutorial discretion to dismiss even meritorious *qui tam* cases where the reasons for dismissal are rationally related to a legitimate Government interest. *See United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). Building on *Sequoia Orange*, the Tenth Circuit has concluded that "it is enough that there are plausible, or arguable, reasons supporting the agency decision [to move for dismissal]." *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 937 (10th Cir. 2005) (citing the district court decision in *Sequoia Orange*, 912 F. Supp. 1325, 1341 (E.D. Cal. 1995)).

The Fifth Circuit has yet to adopt a standard for dismissal under Section 3730(c)(2)(A), although it has indicated that the United States retains unilateral authority to seek dismissal in a declined *qui tam* action. *See Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749 (5th Cir. 2001) ("[T]he government retains the unilateral power to dismiss an action notwithstanding the objections of the [relator]." (citations and internal quotation marks omitted)); *see also United States ex rel. Gal-Or v. Northrup Gruman*, No. 4:17-cv-00139-O (N.D. Tex. Oct. 26, 2017) (following *Swift* and explaining that "[n]othing in the language of 3730(c)(2)(A) suggests anything less than affording the Executive the historical prerogative to decide which cases are prosecuted in the name of the United States."); *United States ex rel. May v. City of Dallas*, No. 3:13-cv-4194, 2014 WL 5454819, at *3 (N.D. Tex. Oct. 27, 2014) ("The *Swift* court makes a

compelling case that the United States should not be compelled to permit a relator to sue on its behalf and that the statutory language does not require—or even permit—judicial review of this discretionary decision."). The government agrees that the more recent *Swift* standard better comports with the FCA's statutory text and framework, as well as the well-established deference to the government's exercise of prosecutorial discretion. Under either standard, however, dismissal is warranted in this case.

C. Dismissal is Warranted Under the *Swift* Standard of Unfettered Discretion

Consistent with *Swift*, this Court should find that the United States has an unfettered right to dismiss a *qui tam* suit and defer to the United States' decision to dismiss this action.

As the *Swift* court explained, the FCA operates against the backdrop of the general principle of separation of powers, in which the Executive Branch exercises control over whether to pursue litigation for the United States. *Swift*, 318 F.3d at 251-52. The court concluded that full deference to the Executive Branch is particularly appropriate, observing that "we cannot see how § 3730(c)(2)(A) gives the judiciary general oversight of the Executive´s judgment in this regard," given that "'[t]he Government'—meaning the Executive Branch, not the Judicial—'may dismiss the action,' which at least suggests the absence of judicial constraint." 318 F.3d at 252. The *Swift* court further held that the Government's decision not to prosecute a case that is brought in its name is "unreviewable," including decisions to dismiss under section 3730(c)(2)(A). *Id.*

As the D.C. Circuit concluded in *Swift*, imposing judicial review on the Executive's litigation determinations is inconsistent with the general principle of separation of powers: "decisions not the prosecute, which is what the government's judgment in this case amounts to, are unreviewable." *Id.* Thus, the appellate court concluded, under § 3730(c)(2)(A), the

Attorney General has an "unfettered right to dismiss an action" *Id.*; *see also id.* at 253 ("The decision whether to bring an action on behalf of the United States is therefore 'a decision generally committed to [the Government's] absolute discretion' for the reasons spelled out in *Heckler v. Chaney*, 470 U.S. at 831").

The *Swift* court also rejected the notion that a relator's right to a hearing, as provided in section 3730(c)(2)(A), was intended to confer authority on the court to review the Government's reasons for dismissal. *Id.* at 253. It explained that nothing in the FCA "purports to deprive the Executive Branch of its historical prerogative to decide which cases should go forward in the name of the United States." *Id.* Instead, the *Swift* court concluded that the function of a hearing, if requested by relator, "is simply to give the relator a formal opportunity to convince the government not to end the case." *Id.*

The *Swift* standard is also more consistent with the plain language of section 3730(c)(2)(A), which differs markedly from the provision in the statute authorizing the Attorney General to settle a *qui tam* case over a relator's objection: "The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, *that the proposed settlement is fair, adequate, and reasonable under all the circumstances.*" 31 U.S.C. § 3730(c)(2)(B) (emphasis added). Significantly, section 3730(c)(2)(A) imposes no similar limitation on the Attorney General's authority to dismiss a *qui tam* case.

The Attorney General's broad dismissal authority in the statute also sharply contrasts with the ability of a relator to dismiss a *qui tam* case. The FCA specifically states that the relator has no such power unless "the court and the Attorney General give written consent to the

dismissal and their reasons for consenting." *Id.* at § 3730(b)(1). Once again, no such restrictions appear in section 3730(c)(2)(A).

It is not surprising that Congress gave unfettered discretion to the Attorney General to determine whether a *qui tam* case should be prosecuted. A *qui tam* relator has been authorized by Congress to sue solely to seek recovery of injuries suffered by the United States, not by the relator. As the Supreme Court made clear in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), a relator has Article III standing because she can be regarded as having received a "partial assignment from Congress of the Government's damages." *Id*. at 773, 772-774. Specifically, a relator has standing "to assert the injury in fact suffered by the assignor [United States]." *Id*. Thus, a relator herself has suffered no cognizable injury warranting the continuation of a suit opposed by the United States. *See id*. at 773.

D. Dismissal is Warranted Under *Sequoia Orange's* Rational Relationship Test

While the United States submits that *Swift's* unfettered discretion reflects the appropriate construction of 3730(c)(2)(A), the court need not resolve that issue, because dismissal is also warranted under the rational relationship test articulated in *Sequoia Orange*. Under this standard, the United States need only (1) identify a "valid government purpose" for dismissing the case, and (2) show a "rational relationship between dismissal and accomplishment of the purpose." *Id*. (quotations omitted). If the United States satisfies this two-step test, "the burden switches to the relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Id*.

In developing this test, the Ninth Circuit observed that "the decision to dismiss has been likened to a matter within the government's prosecutorial discretion in enforcing federal laws," and the dismissal provision in the FCA should not be construed to grant the Judiciary an

impermissible power to approve or disapprove the Executive's exercise of prosecutorial discretion. *Id*. at 1143. Consequently, the Ninth Circuit reasoned that when a court considers a motion by the government to dismiss a *qui tam* case, it should "respect[] the Executive Branch's prosecutorial authority by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself." *Id.* at 1146. As a result, even where the *Sequoia* standard is applied, courts are careful not to create barriers to the Government's exercise of prosecutorial discretion.

As the District of Massachusetts has noted, "the Government's quest to dismiss an action under the *Sequoia* standard" should not be "particularly arduous." *United States ex rel. Nasuti v. Savage Farms, Inc.*, No. 12-30121, 2014 WL 1327015, at *10 (D. Mass. Mar. 27, 2014). In *Nasuti*, the court held:

> [D]espite not intervening in the action, the Government clearly has standing and is entitled to seek dismissal under 3730(c)(2)(A). As discussed, even if the Government does not intervene in a FCA *qui tam* action, it retains significant control over the litigation and is still considered the 'real party in interest.'

Id. at *9. The court further explained:

> [L]imiting the Government's role in any significant way in *qui tam* actions, including its ability to accomplish dismissal under section 3730(c)(2)(A), could bring the constitutionality of the FCA into question. After all, a *qui tam* action is brought in the Government's name and, as the real party in interest, it should have broad discretion to determine its fate.

Id. at *10. The court went on to hold that dismissal was appropriate under either standard because the Government articulated a concern that "were this case to continue, it would incur substantial costs in monitoring the litigation . . . , responding to discovery requests, and clarifying relator's misstatements of the law." *Id.* at *11. The court acknowledged that "litigation costs represent a valid government interest" and the Government may therefore rationally seek dismissal of an action even where the allegations may have merit. *Id. See also*

Sequoia Orange, 151 F.3d at 1146 (approving of district court's consideration of "the burden imposed on the taxpayers by its litigation" and "internal staff costs" the government would occur with relator's litigation); *Swift*, 318 F.3d at 254 ("[T]he government's goal of minimizing its expenses is still a legitimate objective, and dismissal of the suit furthered that objective."); *United States ex rel. Stovall v. Webster Univ.*, Civil Action No. 3:15-cv-03530 2018 WL 3756888 *3 (D.S.C., Aug. 8, 2018) (granting the government's motion to dismiss because "dismissal will further its interest in preserving scarce resources by avoiding the time and expense necessary to monitor this action."); *see United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17, 2015 WL 1499519, at *5 (E.D. Ky. Apr. 1, 2015) (same); *United States ex rel. Nicholson v. Spigelman*, No. 10-cv-3361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (same).

In this case dismissal is appropriate because it is rationally related to the valid governmental purposes of preserving scarce government resources and protecting important policy prerogatives of the federal government's healthcare programs. As an initial matter, based on its extensive investigation of all of the various Venari Partner complaints, the government has concluded that the relators' allegations lack sufficient factual and legal support. The government's investigations included, among other things, the collection and review of tens of thousands documents from the defendants and third parties and interviews of numerous witnesses, including prescribing physicians. The government also has had extensive discussions with relators' counsel and has reviewed various information that they have provided. In addition, the government has consulted with subject-matter experts at HHS-OIG about the

relators' allegations and the applicability of regulatory safe harbors and government-issued industry guidance.[5]

As a result, the government has concluded that further expenditure of government resources is not justified. Because relator alleges nationwide misconduct involving Medicare, Medicaid, and TRICARE over at least a six-year period, the government will incur substantial costs in monitoring the litigation and responding to discovery requests. For Medicare Part D alone in this period, there were nearly 500,000 prescriptions for the Bayer drugs at issue, written by more than 10,000 physicians treating tens of thousands of Medicare beneficiaries. The vast scope of the allegations will necessarily yield substantial litigation burdens for the United States. These burdens include the expense of collecting, reviewing, processing, and producing documents from among multiple federal healthcare programs, as well as voluminous prescription drug event data and patient health information for potentially thousands of beneficiaries, which, due to its sensitive nature, may require additional (and costly) screening and redaction. Moreover, the government will also have to spend considerable time preparing numerous agency witnesses for depositions and filing statements of interest relating to a variety of legal issues, including the potential need to address Relator's interpretation of the AKS, statutory safe harbors, and HHS-OIG Advisory Opinions.[6] The government has rationally concluded based on its extensive investigation of relators' various cases that the relators' sweeping allegations lack

[5] To date, Department attorneys in the Civil Division's Fraud Section have collectively spent more than 1,500 hours on the eleven NHCA Group matters referenced herein. This figure does *not* include the substantial time spent by numerous Assistant U.S. Attorneys and attorneys from the Department of Health and Human Services Office of Counsel to the Inspector General, nor does it include the time spent by law enforcement agents, investigators, or auditors.

[6] The expansive scope of the allegations in this case will also impose substantial burdens on the court, the defendants, and potentially thousands of third-party healthcare providers who are not named as defendants but may get dragged into the case by one or both parties.

adequate support and are unlikely to yield any recovery sufficient to justify the significant costs and burdens that the government will incur if the cases proceed and the resulting diversion of the government's limited resources away from other more meritorious matters.

In addition, the government has concluded that the specific allegations in this case conflict with important policy and enforcement prerogatives of the federal government's healthcare programs. For instance, relators allege that the provision of educational information and instruction to patients constitutes illegal kickbacks to physicians. But given the vast sums the government spends on the medications at issue, federal healthcare programs have a strong interest in ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medication. In another context, HHS-OIG has advised that the provision of educational materials or informational programs to patients, without more, does not constitute "remuneration" *See* 81 Fed. Reg. 88368-01 at 88396 (Dec. 7, 2016). These relators should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry that would undermine common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal healthcare programs and their beneficiaries.

III. CONCLUSION

For the reasons set forth above, this Court should dismiss all claims brought on behalf of the United States by Health Choice Group, LLC under the FCA with prejudice as to Relator and without prejudice as to the United States pursuant to 31 U.S.C. § 3730(c)(2)(A).

Respectfully submitted,

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Dated: December 17, 2018

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CERTIFICATE OF SERVICE

I certify that on this 17th day of December 2018, I caused this document filed through the ECF system to be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants.

/s/ *James G. Gillingham*
JAMES G. GILLINGHAM