UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, et al.

ex rel.

OMNI HEALTHCARE, INC.

Plaintiffs,

v.

MCKESSON CORPORATION, et al.,

Defendants.

Civil Action No. 1:12-CV-06440 (NG)(ST)

MEMORANDUM OF LAW IN SUPPORT OF NON-PARTY FOOD AND DRUG ADMINISTRATION'S MOTION TO QUASH SUBPOENAS PURSUANT TO FED. R. CIV. P. 45(d)(3)

JACQUELYN M. KASULIS
Acting United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201

Deborah B. Zwany
Matthew Silverman
Assistant U.S. Attorneys

Jamie A. Yavelberg
Edward Crooke
Sanjay M. Bhambhani
U.S. Department of Justice
Civil Division, Frauds Section

Kelsey Schaefer, Associate Chief Counsel for Enforcement
Food and Drug Administration
Food & Drug Division, OGC HHS
Office of Chief Counsel, FDA

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INTRODUCTION

The United States respectfully submits this Memorandum in Support of its Motion to Quash two third-party subpoenas that defendants McKesson Corporation and its related entity, Oncology Therapeutics Network (OTN) (collectively "McKesson"), served on the Food and Drug Administration (FDA), a non-party to this action. (Addenda 1 and 2).[1] At issue in this declined False Claims Act (FCA) case is whether McKesson knowingly caused the submission of false or fraudulent claims to the Centers for Medicare and Medicaid Services (CMS) for reimbursement of overfill in pre-filled syringes that lacked FDA approval or that were produced in violation of the Food Drug and Cosmetic Act (FDCA) and FDA regulations.[2] McKesson claims it needs discovery from FDA to show that the violations alleged in the complaint are not material under *Universal Health Servs., v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (*Escobar*), and that FDA laws and enforcement authority were ambiguous, negating its scienter under the FCA. (ECF No. 136 at 1-2). McKesson now demands that FDA produce within 90 days over 40,000 pages of documents, relating almost entirely to entities other than McKesson.

McKesson's discovery demands from FDA are irrelevant to the arguments it has asserted and disproportional to the needs of the case. In addition, they are overbroad, unduly burdensome, and require FDA to divert critical resources away from its primary public health mission. The discovery McKesson seeks has no bearing on whether CMS – the payor agency – continued to pay claims for oncology drugs despite having "actual knowledge that certain requirements were violated." *Escobar*, 136 S. Ct. at 2003-04. McKesson has already served extensive subpoenas on CMS, among its other demands. In addition, whether the relevant statute or regulations are

[1] The motion is supported by the declarations of Howard Philips (Philips Decl.), and Douglas Weinfield (Weinfield Decl.).

[2] The Second Amended Complaint also contains an Average Sales Price claim not relevant to this motion.

"ambiguous," and whether McKesson held an "objectively reasonable" interpretation of the law are "legal questions" that do not necessitate any fact discovery from FDA.

FDA has now spent approximately one thousand hours and had over sixty (60) conferences and substantive exchanges with McKesson's counsel in a good faith attempt to respond to its discovery demands. FDA has produced over 15,000 pages of documents and provided links to thousands of additional pages of publicly available information on its website, responsive to McKesson's requests, though not relevant to its defenses. Throughout the discovery process, however, McKesson has continually shifted its demands, preventing FDA from completing its production under the subpoenas. It appears that McKesson is misusing discovery as a cudgel to extract from the government a dismissal of Relator's FCA claims pursuant to 31 U.S.C. § 3730(c)(2)(A). McKesson's actions leave FDA with no choice but to seek relief from the Court and move to quash its subpoenas to FDA pursuant to Fed. R. Civ. P. 45(d)(3).

FACTUAL AND PROCEDURAL BACKGROUND

I. Procedural History of this Qui Tam Action

Relator, Omni Healthcare, Inc., (Omni or Relator) filed this action under seal in March 2012, against AmerisourceBergen Corporation (ABC) and three affiliated ABC companies pursuant to the *qui tam* provisions of the FCA.[3] *See* 31 U.S.C. § 3729 *et seq.* Relator filed an amended complaint in October 2012, adding as defendants McKesson Corporation, OTN and US Oncology, Inc. On April 3, 2018, Relator filed a Second Amended Complaint against the

[3] The FCA permits either the Attorney General or a private party, known as a relator, to initiate a civil action alleging fraud on the Government. Under the statute, if the United States intervenes and proceeds with the action, it acquires "the primary responsibility for prosecuting the action." 31 U.S.C. § 3730(c)(1). If, however, the United States declines to intervene, the relator may proceed with the action.

McKesson entities (SAC) (ECF No. 33), and on April 16, 2018, the United States declined to intervene as to the claims against the McKesson entities. (ECF No. 34).[4]

In its SAC, Relator alleged, among other things, that from 2001 until at least 2010, defendants harvested the "overfill"[5] in certain oncology drugs into pre-filled syringes and sold those pre-filled syringes, which lacked FDA approval, to providers, resulting in the submission of false claims to various federal and state healthcare programs. *See* SAC ¶¶ 6-7, 27-28. In particular, Relator alleged that "[p]roviders are not allowed to bill for any excess drug, such as overfill, for which the drug manufacturer does not charge." (Overfill claim) *Id.* ¶8. Relator further alleged that defendants are prohibited from submitting claims for unapproved new drugs[6] (Unapproved New Drug claim) and that in creating pre-filled syringes, defendants violated the FDCA and associated

[4] The United States later intervened with respect to certain claims against the ABC defendants, but not the McKesson defendants. At Relator Omni's request, on March 28, 2018, the Court severed this action (relating to the McKesson defendants) from the ABC action.

[5] The term "overfill" generally refers to the excess volume of an injectable product included in a vial above and beyond the content indicated in the FDA-approved label. Manufacturers include a certain amount of overfill in each vial of injectable product to ensure that the health care provider will be able to extract the full labeled volume from the vial to allow for correct dosing. See, e.g., 75 Fed. Reg. 73170, 73466-67 (Nov. 29, 2010). For example, a vial of drug that is labeled with a volume of 100 milliliters (mL) may in fact contain 110 mL. The additional 10 mL is overfill. The amount of overfill is determined by the manufacturer, in compliance with 21 CFR 201.51, which requires compliance with U.S. Pharmacopeia or the National Formulary and varies from drug to drug. "[P]roviders may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider." *Id*. at 73466–67.

[6] Under the Medicare program, unapproved new drugs are not deemed reasonable and necessary and, therefore, ineligible for reimbursement. 42 U.S.C. § 1395x(t)(2)(A) and (B); Medicare Benefit Policy Manual Chapter (MBPM) 15 § 50.4.1. *See Vitreo Retinal Consultants of the Palm Beaches, P.A. v. U.S. Dep't of Health & Human Servs.,* 649 Fed.App'x. 684 (11th Cir. 2016) (holding that CMS's decision to deny reimbursement as medically unreasonable based on FDA-approved labeling allowing for only a single dose from a single vial was reasonable.).

regulations (FDCA claim) *Id.* ¶¶ 8, 197-199.[7] Relator also alleged that McKesson caused artificial inflation of the Average Sales Price (ASP) because of overfill billing (ASP Claim).[8] *See id.* ¶ 7.

On October 15, 2018, McKesson filed a motion to dismiss Relator's SAC on several grounds, including the FCA's first-to-file bar, *see* 31 U.S.C. § 3730(b)(5), and Rules 9(b) and 12(b)(6). (ECF No. 55-1). McKesson argued, among other things, that Relator's Overfill and ASP claims failed to state a claim under the FCA. *See id.* 18-22. Neither McKesson nor Relator addressed the Unapproved New Drug or FDCA claims. *See* ECF No. 55-8, at 21. On February 4, 2019, Judge Gershon issued an Opinion and Order dismissing all defendants except McKesson Corporation and OTN. *United States ex rel. Omni v. McKesson Corp.,* Civ. No. 12-06440, 2019 WL 438357, at *12 (E.D.N.Y. Feb. 4, 2019) (ECF No. 66).

II. McKesson's Rule 45 Subpoenas to FDA

On November 11, 2019, McKesson served a subpoena under Rule 45 on FDA with twelve exceedingly broad, vague, and burdensome requests, many with multiple subparts. *See* Addendum 1. Among other requests, McKesson's subpoena demanded production of all documents referring to FDA policies, procedures, and practices relating to overfill, and the creation and approval of injectable Products, and all documents relating to FDA's knowledge of practices relating to overfill and the creation of injectable products. McKesson also sought all documents concerning FDA "Regulatory and Enforcement Actions" from 2005 through 2010 "potentially applicable . . . to the

[7] As a general matter, merely demonstrating lack of compliance with the FDCA or FDA regulations is insufficient to establish FCA liability. As *Escobar* held, "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002. Here, where McKesson never sought approval for its prefilled syringes and was not issued any warning letters relating to its prefilled syringes, (Philips Decl. ¶¶ 42, 43) FDA can only produce discovery regarding non-McKesson entities, which is irrelevant to allegations concerning McKesson.

[8] Because the motion to compel did not seek documents relating to the ASP Claim, we do not address it here. In any event, ASP is a pricing issue that is within the purview of CMS and not FDA.

type of conduct alleged in the complaint," and seven other broad categories. *Id.* On May 28, 2020, McKesson served a second subpoena under Rule 45 on FDA with thirteen additional broad and burdensome requests. (Addendum 2). FDA timely objected to both subpoenas but committed to working with McKesson to provide reasonably accessible information.

As detailed in the Philips declaration, even though FDA viewed McKesson's requests to be irrelevant to any of its defenses, overbroad, vague, and unduly burdensome, FDA sought to comply with the subpoenas. FDA has had over sixty (60) conferences and substantive exchanges with McKesson's counsel on its two subpoenas. FDA has searched multiple internal components for responsive material and has made seven separate productions totaling over 15,000 pages of responsive (although not relevant) documents. In addition, FDA has provided links to thousands of additional pages of publicly available material on FDA's website including: (1) warning and untitled letters; (2) weekly enforcement reports; (3) recalls, market withdrawals, and safety alerts; (4) pharmacy inspections and related records; (5) compounding inspections, recalls, and other actions; (6) various presentation materials; (7) FDA regulations; (8) FDA Guidance documents; (9) FDA Compliance Program Guidance Manuals; (10) FDA Manual of Compliance Policy Guides; and (11) FDA's Regulatory Procedures Manual. *See* FDA Letter Dated May 22, 2020 (ECF No. 109-1). FDA has also suggested that McKesson seek information about third parties from those parties directly, rather than from FDA.

Because McKesson's requests are so vague and broadly worded, the substance and scope of each request is unclear. FDA has repeatedly asked McKesson to identify with particularity the documents or types of documents it seeks, as required by Rule 34(b)(1)(A) (requiring that each request "must describe with particularity each item or category of items to be inspected"). (Addendum 3). McKesson has refused to do so. Instead, it has demanded that FDA produce

hundreds of thousands of pages of documents regarding other entities and topics unrelated to the issues in this case. McKesson has also repeatedly demanded that FDA conduct searches of numerous custodians' emails based on broad search terms that are over-inclusive. (Addendum 4).

On November 2, 2020, without a Meet and Confer with FDA, McKesson filed its first motion to compel, which FDA opposed. ECF Nos. 105, 109, 110. On November 18, 2020, following a hearing, this Court issued an order incorporating FDA's offer during the hearing to complete its response to McKesson's subpoenas by conducting certain email searches on a limited number of custodians and to work with McKesson "in order to obtain the most useful results." ECF No. 112. The Court stated that it would "consider cost shifting to alleviate the burden on FDA depending on the size of the requested production." *Id.*

After FDA provided data from the results of the agreed-upon email searches, McKesson filed a second motion to compel on April 28, 2021, again without a Meet and Confer with FDA. FDA once again opposed the motion, and the Court directed the parties to meet and confer and file status reports on progress. *See* ECF Nos. 136-140. Although FDA initially believed that progress was being made on a defined and narrow production that would conclude its production under the subpoenas, by letter dated June 3, 2021, McKesson demanded that FDA produce almost 42,000 pages of documents comprised of 1,990 emails and attachments (40,054 pages), 30 Establishment Inspection Reports (EIRs), and 1,758 pages of documents FDA had previously provided to the Senate and House Committees relating to the New England Compounding Center (NECC). In addition, McKesson demanded that production be completed within 90 days and reserved the right to seek an additional approximately 460,000 pages of emails and attachments, and an additional approximately 27,000 pages of documents relating to NECC.

ARGUMENT

I. The United States Is Not a Party For Purposes of Discovery

Because the United States declined to intervene in this case, it is not a party to the case for purposes of discovery. *See U.S. ex rel. Eisenstein v. City of N.Y.*, 556 U.S. 928 (2009). In *Eisenstein*, the Supreme Court considered whether the United States is a "party" in a declined *qui tam* action even though it is the real party in interest. The Court explained that Congress gave the United States "discretion to intervene in FCA actions – a decision that requires consideration of the costs and benefits of party status." *Id.* In fact, the Court specifically identified party discovery under Fed. R. Civ. P. 26, 34, and 37, among the various "burdens" and "obligations" that the United States would assume if it chose to intervene. *See id.* at 933-34. Accordingly, the *Eisenstein* Court concluded that "[t]he United States . . . is a 'party' to a privately filed FCA action only if it intervenes in accordance with the procedures established by federal law." *Id.* at 933. Thus, "when, as here, a real party in interest has declined to bring the action or intervene, there is no basis for deeming it a 'party' for purposes of Rule 4(a)(1)(B)." *Id.* at 935. The rules for discovery from non-parties therefore apply to McKesson's subpoenas served upon FDA.

II. Non-Party Discovery Must be Relevant, Proportional and not Unduly Burdensome

A subpoena to a non-party under Rule 45 must conform to the requirements of Fed. R. Civ. P. 26(b)(1), meaning it must be both relevant to a party's claims or defenses and proportional to the needs of the case. *See S.E.C. v. Laura*, 18 Civ. 5075, 2020 WL 5152873, at *2 (E.D.N.Y. Aug. 31, 2020). When discovery is sought from non-parties, "the Court should be particularly sensitive to weighing the probative value of the information sought against the burden of production on the nonparty." *Cohen v. City of N.Y.*, 255 F.R.D. 110, 117 (S.D.N.Y. 2008) (quotations omitted). A party issuing a subpoena under Rule 45 must "take reasonable steps to avoid imposing undue

burden or expense" on the non-party. *See* Fed. R. Civ. P. 45(d)(1); *Strike 3 Holdings, LLC v. Doe*, 331 F.R.D. 14, 17 (E.D.N.Y. 2019). A court "*must* enforce this duty and impose an appropriate sanction . . . on a party or attorney who fails to comply." Fed. R. Civ. P. 45(d)(1); *Saint-Jean v. Emigrant Mortg. Co.*, 11-CV-2122, 2015 WL 13735434, at *3 (E.D.N.Y. Oct. 7, 2015).

Fed. R. Civ. P. 45(d)(3)(A)(iv) provides that "the court . . . must quash or modify a subpoena that . . . subjects a person to undue burden." In determining whether a subpoena presents an undue burden, the court may consider "relevance, the need of the party for the documents, the breadth of the document requests, the time period covered by it, the particularity with which the documents are described, and the burden imposed." *Libaire v. Kaplan*, 760 F. Supp. 2d 288, 293-94 (E.D.N.Y. 2011) (quotations omitted). That discovery is sought from a non-party is a significant factor weighing in favor of finding a discovery request unduly burdensome. *Solarex Corp. v. Arco Solar, Inc.*, 121 F.R.D. 163, 179 (E.D.N.Y. 1988) *aff'd*, 870 F.2d 642 (Fed.Cir.1989).

Any court order for production or inspection must also protect the non-party "from significant expenses resulting from compliance." Fed. R. Civ. P. 45(d)(2)(B)(ii). Under this rule, fee shifting to protect a non-party from significant expense imposed by a subpoena is mandatory. *Linder v. Calero-Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001) ("Rule 45 requires [mandatory fee shifting] – the district court 'shall protect' a non-party from 'significant expense.'"); *Legal Voice v. Stormans Inc.*, 738 F.3d 1178, 1184 (9th Cir. 2013) (same); *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 F. App'x 880, 882 (3d Cir. 2002).

Finally, "discovery under Rules 26 and 45 must properly accommodate 'the government's serious and legitimate concern that its employee resources not be commandeered into service by private litigants to the detriment of the smooth functioning of government operations." *Watts v. S.E.C.*, 482 F.3d 501, 509 (D.C. Cir. 2007) (quoting *Exxon Shipping Co. v. Dep't of Interior*, 34

F.3d 774, 776 (9th Cir. 1994)); *United States ex rel. Conroy v. Select Med. Corp.*, 307 F. Supp. 3d 896, 902 (S.D. Ind. 2018).

III. McKesson's Subpoenas Are Not Relevant or Proportional and are Unduly Burdensome

McKesson's motion to compel (ECF No. 143-1) focuses on three broad categories of documents, (emails/attachments, EIRs for non-McKesson entities, and NECC documents). The Court should grant FDA's motion to quash considering the lack of "relevance, [and] need of [McKesson] for the documents, the breadth of [McKesson's] requests, the time period covered by it, the [lack of] particularity with which the documents are described, and the burden imposed [on FDA]." *Libaire*, 760 F. Supp. 2d at 293-94.

A. McKesson's Discovery from FDA is Irrelevant to Materiality Under Escobar

McKesson attempts to justify its discovery from FDA by citing *Escobar* and arguing that "FDA documents showing that the Government was aware that entities created pre-filled syringes, and yet continued to pay claims for such syringes, will prove fatal to Omni's case." *See* ECF Nos. 136 at 1-2; 105 at 1. McKesson misreads *Escobar.*

In *Escobar*, the Supreme Court identified several factors as relevant to the materiality analysis under the FCA, but rejected the notion that any single factor is dispositive. *Escobar*, 136 S. Ct. at 2001 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27,39 (2011)). As one of several non-dispositive factors, the government's continued payment of claims is relevant to the materiality inquiry only when "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated[.]" *Escobar*, 136 S. Ct. at 2003, 2004. The "actual knowledge" standard under *Escobar* thus focuses on whether a violation is actually known to the payor agency and impacts its "payment decision." *Escobar*, 136 S. Ct. at

2002 (noting that "the Medicaid program would not have paid those claims had it known of those violations").[9]

In this case the government agency that pays Medicare claims is CMS. Under the Medicare Act, "[t]he Secretary has the authority "to determine what claims are covered by the Act 'in accordance with the regulations'[.]" *Heckler v. Ringer,* 104 S. Ct. 2013, 2016 (1984) (citing 42 U.S.C. § 1395ff(a)). This authority is in turn delegated to CMS.[10] FDA has an altogether different public health mission, which is to protect the public health by ensuring the safety, efficacy, and security of drugs, vaccines, biological products, and medical devices. FDA does not process or pay Medicare claims for reimbursement, nor does it promulgate Medicare payment rules. Thus, FDA does not make Medicare "payment decisions." The relevant inquiry when evaluating the continued payment of claims under *Escobar* is whether CMS, the payor, had "actual knowledge that certain requirements were violated" and, nevertheless, paid claims despite that "actual knowledge."

B. None of the Cases Cited by McKesson Support the Discovery It Seeks From FDA

McKesson elides the fact that FDA does not make Medicare payment decisions by arguing broadly that courts routinely require the government to participate in discovery. *See* ECF No. 136

[9] The relevant agency's awareness of *allegations* of violations is insufficient to demonstrate "actual knowledge that certain requirements were violated." *See e.g., United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("mere awareness of allegations concerning non-compliance is different from knowledge of actual non-compliance"); *United States ex rel. Rahimi v. Rite-Aid Corp.*, 2019 WL 1426333, at *8 (E.D. Mich. Mar. 30, 2019) ("Rite-Aid's argument conflates 'actual knowledge that certain requirements were violated' with actual knowledge of allegations that certain requirements were violated"); *United States ex rel. Brown v. Pfizer*, 2017 WL 1344365, at *11 (E.D. Pa. Apr. 17, 2017) ("mere knowledge of allegations regarding non-compliance is insufficient to prove actual knowledge of noncompliance").

[10] *See e.g.*, Social Security Act § 1842 (42 U.S.C. § 1395u); 42 C.F.R. Part 421.

at 2. However, the issue is not the government's participation in discovery (which both FDA and CMS have done extensively in this case).[11] Rather, the issue is whether McKesson may, for purposes of the materiality issue, demand overbroad and burdensome discovery from FDA when FDA plays no role in processing Medicare claims for payment. Neither *Escobar* nor any other case cited by McKesson suggests that a defendant in a declined FCA case may make such a misdirected demand on government resources. In fact, in each case cited by McKesson, the court assessed the import of the government's continued payment of claims from the standpoint of the agency that made the payment decision and whether it had "actual knowledge" of violations. *See e.g., United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764-65 (3d Cir. 2017)(assessing materiality from the standpoint of CMS, the payor in a Medicare case); *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F. 3d 645, 668 (5th Cir. 2017)(determining materiality based on the payor Federal Highway Administration's payment decisions); *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1033 (D.C. Cir. 2017)(assessing materiality based on the payor Army's payment decisions). *See* ECF No. 136, at 2. At bottom, McKesson's discovery from FDA is an erroneous effort to impute knowledge to CMS based on information contained within FDA files – an effort that is fundamentally incompatible with *Escobar's* "actual knowledge" standard.

C. McKesson's Discovery Demands from FDA are Irrelevant to its Defenses and Overinclusive

The discovery McKesson demands from FDA is irrelevant to Relator's Overfill claim – that McKesson knowingly caused CMS to pay for excess drug or overfill in violation of Medicare

[11] As indicated above, McKesson has served extensive subpoenas on CMS, which has produced thousands of pages of documents and referred McKesson to tens of thousands of pages of additional publicly available documents.

payment rules. McKesson's insistence that FDA produce documents based on search terms such as "overfill" and "pre-filled syringe" is overinclusive and captures documents that have nothing to do with whether CMS had "actual knowledge" that it was paying claims for overfill in violation of Medicare payment rules. *Escobar*, 136 S. Ct. at 2003. Most containers of injectable products contain a certain amount of overfill, but that does not mean that FDA documents with search hits show that CMS made "payment decisions" with "actual knowledge" that a particular claim or type of claim was for overfill. Instead, the mention of overfill can simply be to note the amount of overfill the manufacturer included in a vial. Furthermore, FDA regularly reviews New Drug Applications (NDA) or Biologics License Applications (BLA), *see* 21 U.S.C. §§ 355(b)(1) and 42 U.S.C. § 262(a)(2)(C), for injectable products in pre-filled syringes and other containers, and regularly receives adverse event reports, annual reports, and supplements relating to those applications. (Philips Decl. ¶ 44). These types of documents have no probative value as to the Overfill claim. The irrelevance and overbreadth of McKesson's search terms is underscored by the fact that FDA ran searches within these 40,054 pages for the terms "McKesson" or "Medicare" and each term appears in a mere one-half of one (0.5%) percent of the 40,054 pages. (Weinfield Decl. ¶ 6). This strongly suggests that these 40,054 pages are substantially over-inclusive and capture documents having nothing to do with the Overfill claim.

As to Relator's Unapproved New Drug Claim, McKesson does not need any discovery from FDA to know whether it submitted the necessary applications and obtained the necessary approvals from FDA to market new oncology drugs in pre-filled syringes. FDA has no record of an NDA or BLA from McKesson or any approval of such application. (Philips Decl. ¶ 43). If McKesson has such an approved application, it needs no discovery from FDA in defense of the Unapproved New Drug claim. Moreover, to the extent FDA has approved or otherwise acted on

applications from other entities for approval of pharmaceutical products in pre-filled syringes, the details of those applications are wholly irrelevant to a defense to the allegation that McKesson failed to file its own application. As to positions taken by FDA with respect to repackaging of drugs into pre-filled syringes generally, FDA's public statements (if any) provide McKesson with FDA's position. (*See e.g.,* Philips Decl. ¶¶ 2, 24, 27, 44).

With respect to the FDCA Claim, Relator appears to assert that McKesson's alleged violations of the FDCA create a separate basis for violating the FCA.[12] McKesson seeks numerous EIRs relating to non-McKesson entities. However, FDA has already provided McKesson with EIRs, Reports of Inspectional Observations, and Warning Letters as well as certain materials relating to specific Congressional Committees investigating NECC, all relating to non-McKesson entities. FDA has also provided McKesson with links to extensive additional information regarding FDA enforcement activities that are publicly available on the FDA website.

Nevertheless, McKesson now insists that FDA produce more of the same, which is "unreasonably cumulative or duplicative." Fed. R. Civ. P. 26(b)(2)(C). Significantly, FDA has no EIRs, Reports of Inspectional Observations, or Warning Letters for McKesson or OTN relating to pre-filled syringes. (Philips Decl. ¶¶ 41, 42). Nor would FDA documents show that CMS had "actual knowledge" of FDCA violations by McKesson yet paid Medicare claims despite "actual knowledge" of those violations. Therefore, McKesson's demand for FDA discovery regarding non-McKesson entities is an irrelevant fishing expedition that should be rejected by this Court, as did the Court in a related subpoena enforcement action. *See United States v. McKesson Corp.,* Case No. 21-mc-80065-JCS, 2021 WL 2037965, at *17 (N.D. Cal. May 21, 2021).

[12] The United States takes no position as to whether Relator's SAC plausibly alleges sufficient facts to state a violation of the FCA based on alleged violations of the FDCA or FDA regulations.

In that related matter, which is connected to this action, the Relator in this action, Omni, issued a broad subpoena under Fed. R. Civ. P. 45 to the California Board of Pharmacy (the Board) for "documents and communications that relate to the activities of non-McKesson entities who may have engaged in conduct similar to that which is alleged as to McKesson." *Id.* at *17. Like FDA here, the Board objected to the subpoena and Omni filed a motion to compel in the Northern District of California. In its motion to compel, Omni argued that "activities by non-McKesson entities could demonstrate materiality by showing that the Board believed such activities to be unlawful and therefore, that Medi-Cal would not have paid McKesson's claims." *Id.*[13] The Northern District of California rejected Omni's materiality argument as "far-fetched," sharply limited the scope of Omni's subpoena, and disallowed discovery of non-McKesson entities as overbroad and unduly burdensome. *Id.* at 18. In reaching its decision, the Court noted that "the Board has no involvement in Medi-Cal payments," and that Omni had failed to demonstrate any "connection between the Board's activities and Medi-Cal payment decisions."

The California court further explained that:

> To the extent the Board may have taken any positions on the legal requirements governing prefilled syringes, *they are only likely to be relevant if they were made public* – for example, in the educational materials that are available on its website or in the published disciplinary decisions that are also available on its website. Therefore, Omni has not demonstrated that it needs the documents and information that are sought in these Requests.

[13] McKesson argues that further discovery of non-McKesson entities will reveal "FDA had extensive knowledge of the type of conduct at issue in this case and that it made a conscious decision not to take action to stop the conduct. FDA's decision had the effect of allowing payment of resulting claims for reimbursement to Government healthcare programs." ECF No. 136 at 5. McKesson's argument that FDA's failure to take enforcement action effectively converts a non-payable claim into a payable claim is inconsistent with Supreme Court precedent. *See OPM v. Richmond*, 496 U.S. 414, 424 (1990) ("no money can be paid out of the Treasury unless it has been appropriated by an act of Congress"); *Heckler v. Comm'n Health Servs.,* 467 U.S. 51, 60 (1984) (declining to estop the government from recouping funds provided to a recipient based on erroneous government advice).

Id. at *17 (emphasis added). Here, like the California Board, FDA has already provided links to publicly available information on FDA's website, including FDA EIRs, Warning Letters and Guidance documents. McKesson is free to conduct whatever research it deems relevant to its scienter defense from these publicly available documents. *See In re Ampal-American Israel Corp.*, No. 12-13689-SMB, 2019 WL 3756728, at *7 (S.D.N.Y. 2019) (discovery does not extend to information that is publicly available and equally accessible to all parties) (citing *SEC v. Samuel H. Sloan & Co.*, 369 F. Supp. 994, 995-96 (S.D.N.Y. 1973)) ("It is well-established that discovery need not be required of documents of public record which are equally accessible to all parties."). FDA should not be required to provide irrelevant non-public information concerning non-McKesson entities. Accordingly, this Court should endorse the well-reasoned decision of its sister court, which would also serve to level the playing field in terms of the proper scope of discovery that Relator and McKesson are entitled to receive from third parties.

D. Discovery from FDA is Irrelevant to McKesson's Scienter

McKesson contends that "documents showing FDA knew that its regulations and enforcement authority were ambiguous will negate any finding that Defendants acted with scienter." ECF No. 136 at 2. This justification for broad discovery on FDA is incorrect for several reasons. First, whether a statue, regulation or rule is "ambiguous" is a "legal question" to be decided by a court, not a factual question necessitating discovery. *See Firstland Int'l, Inc. v. INS*, 264 F. App'x 22, 24 (2d Cir. 2008) (summary order) (whether a statute is ambiguous is a question of law); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) (whether a regulation "is ambiguous and whether [defendant's] interpretation is objectively reasonable are legal questions"); *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018) (whether the particular provision at issue was ambiguous "is a question of statutory interpretation"); *Humanoids Group v. Rogan*, 375 F.3d 301, 306 (4th Cir. 2004) ("whether a

regulation or statute is ambiguous presents a legal question"). To the extent McKesson argues that it held an "objectively reasonable" interpretation of the law, whether such interpretation is "objectively reasonable" is also a "legal question." *See Purcell*, 807 F.3d at 288. Moreover, whether McKesson actually held such an interpretation, as opposed to manufacturing such an interpretation *post hoc,* is a fact within McKesson's own possession. Indeed, information regarding McKesson's scienter or state of mind will be found in McKesson's own documents and files, not by rummaging through non-public FDA emails, inspection reports, or other FDA records.

To the extent McKesson attempts to argue ambiguity concerning FDA's enforcement authority over McKesson's alleged conduct, *see* ECF No. 136 at 5 ("FDA's 'authority over compounding [was] limited, unclear, and contested),"[14] it may do so from information in the public record and case law. The evolution of caselaw and enforcement of 21 U.S.C. § 353a is a matter of public record and does not require discovery from FDA. A detailed history of the regulatory framework for compounding in the United States until 2013 is available at: https://fas.org/sgp/crs/misc/R43038.pdf. Nothing in FDA's files beyond the public pronouncements on this statute has bearing on McKesson's scienter argument.

Finally, none of the cases cited by McKesson support the proposition that mere ambiguity in a statute, regulation, or "enforcement authority" (even if it were determined to exist) negates scienter under the FCA. In fact, numerous courts have recognized that a defendant can act with "knowledge" under the FCA even when a regulatory requirement is ambiguous. *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("Although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter.");

[14] McKesson cites to FDA Commissioner Margaret A. Hamburg's testimony before the Senate Committee investigating the NECC 2012 meningitis outbreak contained in its November 15, 2012 Hearing Report. (ECF No. 136-10). This is an example of the type of public information readily available to McKesson.

see also United States ex rel. Walker v. R&F Props., Inc., 433 F.3d 1349, 1358 (11th Cir. 2005) (same); *United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002). In sum, whether the relevant provision of the FDCA, 21 U.S.C. § 353a, is ambiguous is a legal question. How any such ambiguity, even if it were determined to exist, impacted McKesson's state of mind involves facts within McKesson's own possession. Neither issue warrants discovery from FDA.[15]

IV. The Extreme Burden and Expense of a Page by Page Review of Tens of Thousands of Pages is Not Proportional to the Needs of the Case

To date, FDA has spent approximately one thousand hours complying with McKesson's overbroad and unduly burdensome subpoenas. FDA has searched multiple components for responsive documents and has attempted to meet McKesson's priorities with seven separate productions totaling over 15,000 pages of documents plus links to thousands of pages of additional records on FDA's website. (Philips Decl. ¶¶ 14-32) McKesson now demands that FDA review and produce an additional 42,000 pages of documents that do not relate to McKesson and have no bearing on whether CMS continued to pay claims despite its "actual knowledge" of violations. Furthermore, McKesson has reserved the right to demand that FDA produce an additional 487,000 pages of irrelevant records.

[15] McKesson characterizes certain internal FDA documents as "exculpatory" and "required to be produced under the principles of *Brady v. Maryland*, 373 U.S. 83 (1963)." ECF No. 136 at 3. Contrary to McKesson's argument, however, courts have rejected the application of *Brady* in the civil context, except in sharply limited circumstances when someone's liberty is at stake. *See e.g., United States ex rel. [Redacted] v. [Redacted]*, 209 F.R.D. 475 (D. Utah 2001) (reviewing the case law and rejecting the application of *Brady* to a civil FCA action); *United States v. Project on Gov't Oversight*, 839 F.Supp.2d 330, 342 (D.D.C. 2012) ("courts have found that *Brady* is not applicable in civil proceedings"); *Brodie v. Dep't of Health & Human Servs.*, 951 F.Supp.108, 118 (D.D.C. 2013) ("*Brady* does not apply in civil cases except in rare situations, such as when a person's liberty is at stake.").

As set forth in the Philips declaration, McKesson's demands pose an extreme and unjustified burden on FDA that is impossible to meet within McKesson's timeframe. McKesson's demands would require FDA to conduct a line-by-line, page-by-page review of 42,000 pages of irrelevant documents, which would take a minimum of 2,100 hours of FDA personnel time (323 days or approximately 1.35 years) at a cost of $96,600. (Philips Decl. ¶¶ 33-40) Moreover, these are conservative estimates because a significant portion of the 42,000 pages will involve Trade Secret (TS) or Confidential Commercial Information (CCI) of third parties. The Trade Secrets Act prohibits the release of TS/CCI unless otherwise authorized by law, and there are potential civil and criminal penalties for federal employees who violate the Trade Secrets Act. *See* 18 U.S.C. § 1905. The FDCA also prohibits the release of TS information to persons other than Department of Health and Human Services employees, to Congress, or to the courts in cases brought under the Act. *See* 21 U.S.C. § 331(j). Additionally, FDA regulations provide that TS/CCI is not available for public disclosure. *See* 21 C.F.R. § 20.61. (Philips Decl. ¶¶ 20, 34). Thus, these documents will need to be reviewed for TS/CCI in addition to other privileges and protections, including the deliberative process privilege, attorney-client privilege, work product protection, law enforcement privilege, and Personal Privacy Information. FDA anticipates that it may have to reach out to third-party owners of TS/CCI to obtain their views regarding the potential release of their TS/CCI, which may lead to additional delays, further highlighting the conservative nature of the time estimates. (Philips Decl. ¶ 34, 35)

The diversion of FDA personnel and resources from its public health mission to such an unnecessary task is wholly disproportional to the needs of the case and would pose an extreme and unjustifiable burden on FDA. (Philips Decl. ¶ 40) The unjustified nature of this burden is underscored by McKesson's unwillingness to pay for any of the costs associated with the

production it demands and refusal to come to any agreement regarding the completion of FDA's obligations under its subpoenas. Under Rule 45(d)(1), a party issuing a subpoena "must take reasonable steps to avoid imposing undue burden and expense" on the recipient of a subpoena. McKesson has breached its mandatory duty in this case and should not be allowed to use discovery in this declined *qui tam* action to commandeer FDA into the service of its own litigation interests to the detriment of FDA's vital public health mission. *See, e.g., Watts* 482 F.3d 501, 509.

V. McKesson is Attempting to Use Broad and Burdensome Discovery to Extract a Dismissal

As noted above, the FCA authorizes a private individual or relator to proceed with the action if the United States declines to intervene. The FCA, however, does not leave such suits entirely in the hands of the relator, who may not always make litigation choices that are in the best interests of the United States. Rather, under the statute, Congress reserves to the Attorney General several important powers, including broad authority to "dismiss the action notwithstanding the objections" of the relator. 31 U.S.C. § 3730(c)(2)(A). The United States has exercised this authority sparingly but has done so on occasion to avoid the burdens and costs of litigation. *See e.g., United States ex rel. Borzilleri v. AbbVie, Inc.*, No. 15-CV-7881 (JMF), 2019 WL 3203000, *2 (S.D.N.Y. July 16, 2019), *aff'd*, 837 F. App'x 813 (2d Cir. 2020).

The United States is now experiencing what appears to be an increasing effort by defense counsel to induce the Government into exercising its dismissal authority under 31 U.S.C. § 3730(c)(2)(A) by propounding burdensome and irrelevant discovery demands on government agencies in declined cases. *See e.g., United States ex rel. Simpson v. Bayer*, Civ. No. 05-3895, Slip Op. (D.N.J. March 26, 2020)(Special Master opinion and order granting government's motion to quash defendant's third party subpoena seeking 230 million pages of aged paper records sought by defendant for the claimed purpose of contesting materiality) (Addendum 5). The United States

believes that the discovery McKesson seeks from FDA in this case is designed to pressure the Government into exercising its dismissal authority. McKesson has propounded vague and overbroad requests that do not describe with "reasonable particularity each item or category of items" to be produced, as required by Fed. R. Civ. P. 34(b)(1)(A). McKesson has refused to narrow any of its requests, only agreeing to prioritize portions of the production. Throughout the multiple Meet and Confers, McKesson has continually shifted the goal posts in a manner that prevents FDA from completing production under the subpoena. And in response to the Government's repeated concerns over the breadth, burden, and diversion of resources necessary to comply with McKesson's subpoenas, McKesson's counsel has suggested that the Government exercise its dismissal authority. McKesson appears to be using burdensome discovery to extract a dismissal of Relator's FCA claims pursuant to 31 U.S.C. § 3730(c)(2)(A). The United States respectfully submits such abusive discovery practices should not be countenanced by the Court.

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court grant FDA's motion to quash the two subpoenas served on FDA in their entirety and deny McKesson's motion to compel.

Dated: Brooklyn, New York
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Respectfully submitted,

JACQUELYN M. KASULIS
ACTING UNITED STATES ATTORNEY
Eastern District of New York

By /s/Deborah B.Zwany/Matthew Silverman
Deborah B. Zwany/Matthew Silverman
Assistant United States Attorneys
718-254-6010/6049