

UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

_____)	
SECURITIES AND EXCHANGE)	
COMMISSION,)	
Plaintiff,)	
)	Miscellaneous 05-00506 (RWR/AK)
v.)	
)	
BIOPURE CORPORATION, <i>et al.</i> ,)	
Defendants.)	
_____)	

MEMORANDUM OPINION

Pending before the Court is Defendant Biopure Corporation’s Motion to Compel FDA Compliance with Federal Subpoenas (“Motion to Compel”) [1]; Plaintiff Securities and Exchange Commission’s (“SEC”) Response thereto (“Response”)[4]; Non-Party Respondent United States Food and Drug Administration’s (hereinafter “Respondent” or “FDA”) [consolidated] Motion to Quash Subpoenas Duces Tecum and Opposition to Motion to Compel (“Motion to Quash”) [5/6]; Defendant Biopure Corporation’s Reply Memorandum of Law in Further Support of the Motion to Compel and in Opposition to the Motion to Quash (“Opposition”) [7/8]; the SEC’s Surreply [no docket number assigned]; and the Reply by the Food and Drug Administration (“Reply”) [11].¹ Defendant Biopure Corporation (“Defendant” or

¹Biopure Corporation contests the Securities and Exchange Commission’s standing to challenge the Motion to Compel or enforcement of the subpoenas, on grounds that the SEC “claims no interest or privilege in the FDA documents at issue” Motion to Compel at 16 (emphasis in original). *See Washington v. Thurgood Marshall Acad.*, 230 F.R.D. 18, 21 (D.D.C. 2005)(“A party generally lacks standing to challenge a subpoena issued to a third-party absent a claim of privilege, proprietary interests, or personal interest in the subpoenaed matter.”) (citations omitted). The Court notes that this dispute centers around the arguments made by Biopure Corporation in its Motion to Compel and by the FDA in its Motion to Quash. The arguments in the SEC’s Response and its Surreply are encompassed within the FDA’s pleadings and thus, the Court permitted the filing of

“Biopure”) moves to compel the FDA to comply with three subpoenas served on the FDA by Biopure. *See* Motion to Compel Exhibits A-C (copies of the three subpoenas). The subpoenaed discovery is sought in connection with Biopure’s defense in a federal, civil enforcement action pending in the United States District Court for the District of Massachusetts.² For the reasons set forth herein, Defendant’s Motion to Compel is denied and Respondent FDA’s Motion to Quash is granted. An appropriate Order accompanies this Memorandum Opinion.

I. Background

_____ On November 4, 2005, Biopure served upon the FDA and one of its divisions, the Center for Biologics Evaluation and Review (“CBER”), three subpoenas seeking the production of business records and the depositions of the FDA and CBER record-keepers, as well as the deposition of Lawrence Landow, an employee of CBER. By Letter dated November 15, 2005, counsel for the FDA objected to the Biopure subpoenas on grounds that the subpoenas:

(1) could not be used to obtain discovery from FDA because the United States is not a person within the meaning of Rule 45 and cannot be served with a third- party subpoena; (2) did not comply with the FDA’s *Touhy* regulations governing requests for FDA testimony; (3) requested documents containing “proprietary, trade secret, . . . and/or agency deliberative process information” that is not subject to release; (4) were unduly burdensome, over[ly] broad, and would require an unreasonable commitment of agency resources; (5) were unduly burdensome in that they requested documents that may be maintained by agencies other than the FDA; (6) were unduly burdensome in that they requested documents that were already in Biopure’s possession; (7) were unduly burdensome in that they requested “completed response letters” sent to entities other than Biopure, . . . ; and (8) did not give the FDA a reasonable time to respond.

See November 15, 2005 Letter attached as Motion to Compel Exhibit E. FDA’s counsel

_____ such documents without specifically addressing the SEC’s standing to object.

²Biopure indicates that trial in that matter is set to commence on May 8, 2006. Motion to Compel at 3.

indicated that Plaintiff Securities and Exchange Commission (“SEC”) had requested permission to release to Biopure documents that were obtained from the FDA by the SEC. The SEC has now confirmed that “transcripts of [deposition] testimony [by FDA witnesses] and copies of all documents released to the SEC by FDA have already been provided by the SEC to Biopure and the other defendants.” Response at 1-2.

On December 9, 2005, Biopure filed the instant Motion to Compel. On December 23, 2005, the SEC filed its response and non-party FDA responded by filing a consolidated opposition and motion to quash (together referred to as the “Motion to Quash”). The Motion to Compel and Motion to Quash have now been fully briefed and are ripe for determination by this Court.³

II. The FDA Challenges the Subpoenas

A. Applicability of Fed. R. Civ. P. 45

Respondent FDA’s foremost challenge to enforcement of the subpoenas is based on its argument that Fed. R. Civ. P. 45 does not authorize subpoenas, or subpoena enforcement proceedings, against non-party federal agencies or employees because under Rule 45, a subpoena may only be directed to a “person” and that term does not include federal agencies or its employees.⁴ See *Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 64 (1989) (“[T]he term ‘person’ does not include the sovereign, [and] statutes employing the [word] are ordinarily

³Biopure requested an expedited oral hearing on the Motion to Compel but the Court determined that a hearing is unnecessary.

⁴Rule 45 provides, in relevant part, that: “Every subpoena shall . . . command each person to whom it is directed to attend and give testimony or produce and permit inspection and copying of designated books, documents or tangible things in the possession, custody or control of that person,” Fed. R. Civ. P. 45(a)(1)(C).

construed to exclude [the government].”) (internal quotations omitted). *See also Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 780 (2000) (“[W]e must apply . . . our longstanding interpretive presumption that ‘person’ does not include the sovereign.”)

Defendant Biopure challenges the FDA’s assertion that Rule 45 does not authorize subpoenas against federal agencies, relying heavily on *Houston Bus. Journal, Inc. v. Office of the Comptroller, Dep’t of Treasury*, 86 F.3d 1208, 1212 (D.C. Cir. 1996), wherein the Court of Appeals for the D.C. Circuit stated that: “A federal-court litigant . . . can seek to obtain the production of documents from a federal agency by means of a federal subpoena.” The Court of Appeals further noted that to the extent that a federal agency’s regulation “may be to the contrary, it conflicts with Federal Rule of Civil Procedure 45 and exceeds the [agency’s] authority under the Housekeeping Statute [also referred to as *Touhy* regulations].”⁵ *Id.*

In *Houston Bus. Journal*, a private company sought to compel the Office of the Comptroller to comply with subpoenas issued in connection with a state court libel action in which the company was a defendant. The Comptroller refused to comply with the subpoenas, citing its regulations governing the testimony of agency employees enacted under “*Touhy* regulations,” codified at 5 U.S.C. §301. The D.C. Circuit affirmed the District Court’s denial of the motion to compel, holding that because the underlying litigation was in state court, the district court did not have jurisdiction to issue the subpoena. It is that context in which the Court of Appeals engaged in its discourse on the [differences between procedures available to

⁵*See Touhy v. Ragen*, 340 U.S. 462, 467 (1951) (holding that federal agencies, in the interest of internal administration, may promulgate regulations governing an agency’s procedures for producing documents and testimony under certain circumstances.)

state court and] federal court litigants seeking documents from a non-party government agency.

The FDA notes that the *Houston Business Journal* case did “not involve the questions of whether Rule 45's reference to ‘person’ included the government, so the Court’s statement about that issue was dicta.” Reply at 8. Respondent further alleges that the dicta from *Houston Bus. Journal* cited by Biopure is superceded by the holdings in *Vermont Agency of Natural Resources, supra.* at 781 (courts should presume that “person” excludes the government absent an “affirmative showing of statutory intent to the contrary”) and *Al Fayed v. CIA*, 229 F.3d 272, 312-13 (D.C. Cir. 2000) (where the D.C. Circuit affirmed the district court’s order quashing a subpoena issued under a statute similar in effect to Rule 45 because there was no “affirmative evidence to disturb the presumption that ‘person’ excludes the sovereign.”)

See also *Linder v. Calero-Portocarrero*, 251 F.3d 178, 181 (D.C. Cir. 2001) (“Although our past decisions have assumed that ‘person’ in Rule 45 included the federal government, we have never expressly so held and our assumption may need to be reexamined in light of *Al Fayed*) and *AlohaCare, Inc. v. Haw. Dep’t of Human Servs. (In re: Subpoena Duces Tecum to Tommy G. Thompson)*, Misc. No. 04-498 (D.D.C. June 28, 2005) (an unreported case in which the Honorable Colleen Kollar-Kotelly noted that, in *Linder, id.* at 180, the D.C. Circuit “dropped significant hints that the federal government [is] outside the purview of Rule 45[.]” and she thus concluded [Memorandum Opinion at 9] that the term “person” in Rule 45 does not include the federal government.) Biopure’s reliance on dicta from *Houston Business Journal* is not persuasive in light of the D.C. Circuit’s language in *Al Fayed* and *Linder*, and the *AlohaCare* case.

Biopure also cites Fed. R. Civ. P. 30(b)(6) in support of its contention that a

governmental agency is subject to a subpoena. That contention was discussed and dismissed in

AlohaCare, id., where that Court held that [t]here is a clear distinction between Rule 30 and Rule 45 that Aloha Care has ignored; Rule 30 and Rule 45, drafted over three decades apart, serve vastly different purposes. Rule 45 deals with subpoenas exclusively, while Rule 30 deals with subpoenas in the limited context of their application to oral depositions. * * * Rule 30(b)(6) simply establishes a discrete procedure for a narrow circumstance in which a party seeks testimony from an organizational entity, and obliges that party to identify the natural person who will testify. The Rule applies to both a party (“notice”) and to non-party (“subpoena”) depositions. . . . If the Government is a party, Rule 30(b)(6) certainly applies to it; however, when it is not a party, the availability of a subpoena is governed by Rule 45. If Rule 45 was intended to extend to the federal government, the Judicial Conference and Congress had ample opportunity to amend the Rule in conformity with the language of Rule 30. Given both the lack of clear expression of such an intent and the governing rules of statutory construction, the Court rejects AlohaCare’s request for it to judicially amend the Federal Rules of Civil Procedure and instead emphasizes the clear distinction between the scope of the twin Rules.

In addition to United States District Court Judge Kollar-Kotelly’s decision in *AlohaCare*, several other judges from this Court have recently addressed whether, as a matter of interpretation, the word “person” in Fed. R. Civ. P. 45 includes the federal government, and all have concluded that it does not. *See Yousuf v. Samantar*, Misc. No. 05-110, 2005 U.S. Dist. LEXIS 8488, at *14 (D.D.C. May 3, 2005) (where the Honorable Reggie Walton found that “a federal government agency is not a ‘person’ within the meaning of Rule 45 and thus [a court] cannot enforce a Rule 45 subpoena served on such an agency.”)⁶ *See also United States ex rel. Taylor v. Gabelli*, Misc. No. 04-534, 2005 U.S. Dist. LEXIS 8489, at *7 (D.D.C. May 2, 2005) (wherein the Honorable Richard Leon held that “the term ‘person’ in Rule 45, in the absence of a satisfactory basis to override this interpretive presumption [that ‘person’ excludes the sovereign], does not include the federal government”); *Lerner v. District of Columbia*, Civil

⁶This decision has been appealed. *See* 2005 U.S. App. LEXIS 21043 (D.C. Cir. Sept. 26, 2005).

Action No. 00-1590, 2005 U.S. Dist. LEXIS 10154, at *17 (D.D.C. Jan. 7, 2005) (where the Honorable Gladys Kessler found that the Court lacked jurisdiction to subpoena two federal agencies because “the ‘requisite affirmative indications’ that the term ‘person’ in Rule 45 includes the federal government [we]re absent”); and *Truex v. Allstate Ins. Co.*, Misc. No. 05-439, 2006 U.S. Dist. LEXIS 424, at *11 (D.D.C. Jan. 1, 2006) (“In response to *Al Fayed* and *Linder*, the District Court has re-examined the assumption that Rule 45 applies to the federal government and held that ‘person’ as used in Rule 45 does not include the federal agencies.”) *See generally* *Chen v. Ho*, 368 F. Supp.2d 97,98 (D.D.C. 2005) (“[W]hen a federal agency, pursuant to so-called *Touhy* regulations, prohibits its employees from responding to a *subpoena ad testificandum* without agency approval and declines to grant that approval . . . , the requesting party must then proceed under the APA, and a federal court will review the agency’s decision”) (citation omitted).

In footnote 5 of its Opposition, Biopure cites two cases from this District Court, which allegedly counter the impact of the aforementioned recent decisions. *See Providian Financial Corp. Securities Litigation*, 222 F.R.D. 22 (D.D.C. 2004), and *Ho v. United States*, 374 F. Supp.2d 82 (D.D.C. 2005). It does not appear however that the governmental parties in these two cases raised the argument that they were not persons within the meaning of Rule 45. *See Providian, supra.*(summarizing relevancy and privilege based objections made by the Comptroller of the Currency) and *Ho v. United States*, 374 F. Supp.2d 82, (D.D.C. 2005) (accepting the Department of Homeland Security’s argument that it could not be compelled to respond to the plaintiff’s Rule 45 subpoena because the agency had enacted valid *Touhy* regulations).

Biopure attempts to distinguish the recent decisions from this Court, cited by FDA, by noting that “in contrast to the litigation here, in none of these cases was the federal government the plaintiff.” Motion to Compel at 6. Biopure does not cite any cases to support this proposition; instead, it asserts that the FDA has provided “active assistance” to the SEC, and accordingly, “under the particular circumstances of this case, any claim that the FDA should not be required to comply with a federal subpoena, issued out of court whose jurisdiction was invoked by the federal government with the cooperation of the FDA, is frivolous and should be rejected.” Motion to Compel at 9. The FDA argues that Biopure’s suggestion that, in cases brought by one federal agency, the entire federal government and all of its agencies are to be treated as parties to the litigation for purposes of discovery, is unsupported by any authority.⁷

Following the Court of Appeals’ reasoning in *Al Fayed, supra*. and the recent cases from this Court determining that the Government is not a party subject to the subpoena power of Rule 45, and finding no support for Biopure’s proposition that because the SEC [Government] is a party, then other branches of the Government such as the FDA should also be treated as a party, the Court finds that the word “person” in Rule 45 does not apply to the FDA, and accordingly Biopure’s subpoenas are not enforceable against the FDA.

⁷The FDA proffers that it has located one case from this district holding that different agencies should be subject to discovery in a case brought by a single agency. *See United States v. AT&T*, 461 F. Supp. 1314 (D.D.C. 1978). FDA explains that the *AT&T* case is inapposite because it involved “unique” circumstances and “peculiar facts, which involve[d] massive and wide-ranging allegations, and . . . many departments and their evidence,” such that the government could not “claim to be merely the Department of Justice.” *Id.* at 1334. The court in *AT&T* cautioned that its holding should be limited to that particular case because if not so confined, it “might encourage other litigants in other cases to rummage through the files of the entire government, and so paralyze both the work of numerous agencies and that of the court.” *Id.* The FDA contends that because this case deals with issues within the purview of the SEC, an independent agency, it should not be subjected to discovery which would paralyze the FDA and keep it from performing its functions.

B. Touhy Regulations

Even assuming *arguendo* that the FDA is treated as a “person” under Rule 45, Biopure has not complied with the FDA’s *Touhy* regulations in crafting its subpoena requests. The FDA asserts that “[c]ounsel for Biopure was informed that Biopure’s third-party subpoenas did not constitute a proper request for testimony pursuant to the FDA’s Touhy’s regulations.” Motion to Quash at 6; *see* 21 C.F.R. §20.1. “In order to obtain the testimony of the FDA records custodians, Biopure must submit a written request to the Commissioner of Food and Drugs.”

Id. There is no evidence in the record before this Court that Biopure has complied with the FDA’s *Touhy* regulations in its efforts to obtain the testimony of FDA employees. The FDA further asserts that “[e]ven if Biopure’s subpoenas could be construed as a valid request for FDA documents, . . . , it will be approximately three years before FDA will be able to begin its search for responsive documents” Motion to Quash at 7; *see* Declaration of Joanne Binkley, ¶35, attached as Exhibit 1. The FDA has suggested that Biopure “convert its subpoenas into a request for documents pursuant to FOIA,” with the understanding that a narrowing of the request will “expedite production of the documents.” Motion to Quash at 6-7; Binkley Decl. at ¶36.⁸ Biopure alleges that the FDA’s refusal to provide testimony is particularly unfair in light of the FDA’s providing documents and testimony to the SEC pursuant to a “blanket authorization” enabling FDA employees to share information with the SEC. Reply at 18. The

⁸Biopure states that “[p]ursuant to FDA regulations, service of the subpoenas automatically triggers the FOIA process.” Opposition at 5 n.8, citing 21 C.F.R. §20.2(a). The FDA suggests that as an alternative to granting the Motion to Quash, the Court should enter an order directing the parties to confer for the purpose of narrowing the scope of Biopure’s request and allowing the FDA a reasonable amount of time to respond, and requiring Biopure to pay the costs associated with document production. FDA Reply at 21.

FDA contradicts this allegation, noting that it provided documents to the SEC through its “regulations permitting the inter-agency disclosure of documents, 21 C.F.R. §20.85” and furthermore, “unlike Biopure, the SEC complied with FDA’s Touhy regulations in order to obtain testimony from FDA employees.” Motion to Quash at 16. Moreover, the documents that were given to the SEC by the FDA have also been provided to Biopure. There is no indication that Biopure has complied with the FDA’s *Touhy* regulations in an effort to obtain discovery and accordingly, Biopure’s Motion to Compel should also be denied on those grounds and the FDA’s Motion to Quash should be granted.

DATED: January 20, 2006

ALAN KAY
UNITED STATES MAGISTRATE JUDGE