UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id*.

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.