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.:	27
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

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

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"). Previously, the court rejected the FDA's attempts to skirt its obligations under Federal Rule of Civil Procedure 45. Mem. Op. (Aug. 16, 2006). Since that ruling, the FDA has complied with Selden's document requests.

Now, the FDA seeks to avoid its obligations under Federal Rule of Civil Procedure 30,

which sets forth the guidelines and procedures for deposition testimony. Because the government must comply with Rule 30 requests for testimony as it must for Rule 45 requests for documents, the court denies the FDA's motion to quash and compels it to comply with Selden's properly issued subpoena request.

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 . . . about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

B. Procedural Background

In preparation of his defense, Selden, on January 29, 2007, served the FDA with a subpoena pursuant to Rule 30(b)(6) for deposition testimony. FDA's Mot. to Quash, Ex. 1. By letter dated February 6, 2007, the FDA informed Selden that it would not comply with the subpoena, asserting that Selden's subpoena failed to follow the FDA's regulations governing

[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.

requests for testimony. *Id.*, Ex. 6. The FDA also asked Selden to withdraw his subpoena on this basis. *Id.* Because Selden refused to do so, the FDA has filed a motion to quash, to which the court now turns.

III. ANALYSIS

A. Legal Standard for a Motion to Quash a Subpoena

Federal Rule of Civil Procedure 45(c)(3)(A) provides that, upon motion, the court shall quash a subpoena if the subpoena "fails to allow reasonable time for compliance," "requires the disclosure of privileged or other protected matter and no exception or waiver applies," or "subjects a person to undue burden." FED. R. CIV. P. 45(c)(3)(A).

B. The Court Denies the FDA's Motion to Quash the Subpoena

The FDA fights Selden's subpoena on two fronts. First, the FDA argues that Selden's subpoena does not constitute a valid request for documents under the FDA's regulations governing testimony by FDA employees. Mot. to Quash at 7. Second, the FDA argues that even if the request is proper, FDA regulations vest with the Commissioner of the FDA with the discretion to determine whether compliance is appropriate. *Id.* at 8. Neither of these arguments is persuasive.

Federal agency heads possess the authority "to proscribe regulations not inconsistent with law for 'the custody, use, and preservation of records, papers, and property" regarding that agency. *Touhy v. Ragen*, 340 U.S. 462, 468 (1951). In turn, subordinate federal employees have an obligation to follow these regulations. *Id.* The FDA takes the Supreme Court's *Touhy* decision to mean that its regulations govern every aspect of the subpoenas issued to the agency.

Mot. to Quash at 8. Under the FDA's regulations, a party seeking information may not submit a subpoena (as permitted under Rule 45), but instead, must "submit a request in writing to the Commissioner of Food and Drugs." *Id.* (citing 21 C.F.R. § 20.1). The FDA's argument in this regard is unfounded.

Under the Rules Enabling Act, "[t]he Supreme Court shall have the power to prescribe general rules of practice and procedure . . . for cases in the United States district courts." 28 U.S.C. § 2072(a). The Federal Rules of Civil Procedure are "as binding as any statute duly enacted by Congress." *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255 (1988); 28 U.S.C. § 2072(b).

While the FDA is correct that *Touhy* recognizes the authority of agency heads to promulgate rules for subordinate federal employees to follow in responding to document requests, *Touhy* itself recognizes that the regulations must not be "inconsistent with law." *Touhy*, 340 U.S. at 468. *Touhy* in no way stands for the proposition that agency regulations alter the procedures set forth in the Federal Rules of Civil Procedure or that agency regulations can preclude the production of documents "that are relevant to a judicial proceeding." *Touhy*, 340 U.S. at 472 (Frankfurter, J., concurring). To the contrary, "the Supreme Court in *Touhy* assumed a federal agency could be subject to a third-party subpoena . . . for otherwise the agency would not need to promulgate regulations for centralizing its response to such a subpoena." *Yousuf v. Samantar*, 451 F.3d 348, 257 (D.C. Cir. 2006).

The FDA directs the court's attention to 21 C.F.R. § 20.1, which states that "[n]o officer or employee of the [FDA] . . . shall give any testimony before any tribunal pertaining to any function of the [FDA] or with respect to any information acquired in the discharge of his official

duties." Mot. to Quash at 8-9 (quoting 21 C.F.R. § 20.1). To the FDA, this provision precludes compliance with Selden's subpoena. The government's argument boils down to the fact that the FDA's regulations conflict with Federal Rule 30; while Rule 30 opens the door to deposition testimony acquired through a subpoena of a federal agency, the FDA's *Touhy* regulations slams that door shut.

The D.C. Circuit rejected a similar argument in *Yousef*. There, the government fought compliance with a Rule 45 subpoena. Noting that the Federal Rules "were designed in 1937 to provide a 'liberal opportunity for discovery,'" the D.C. Circuit rejected the government's argument that it does not constitute a "person" under Rule 45. *Yousef*, 451 F.3d at 257. In the present controversy, there is no doubt that the FDA is subject to Rule 30. FED. R. CIV. P. 30 (stating that the subpoena notice may name the "government agency" to which the subpoena is directed). "In federal court, the federal government has waived its sovereign immunity . . . and neither the Federal Housekeeping Statute nor the *Touhy* decision authorizes a federal agency to withhold documents from a federal court." *Houston Business Journal, Inc. v. Office of Comptroller of Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) (noting that to the extent the agency's regulations conflict with the Federal Rules of Civil Procedure, those regulations "exceed[] the [agency's] authority under the Housekeeping Statute"). To the extent that the FDA's regulations prohibit that which the Federal Rules expressly permit, (*i.e.*, discovery *ad testificatum* of a government agency), those regulations fail. *Id.*; *see also Yousef*, 451 F.3d at 257 (noting that "there is probably the same right to obtain discovery against the government and its officers and agents as against private parties") (internal citations omitted).

The FDA construes the court's first Memorandum Opinion on this topic to be "clear

instruction from the court that Selden must comply with the FDA's *Touhy* regulations." Mot. to Quash at 11. The FDA further states that "Selden insists on wasting FDA's limited resources by forcing it to respond to the present subpoena." *Id.* The court's ruling, however, is clear that Selden may issue subpoenas under Federal Rule 45 and that the FDA owns the obligation to process those subpoenas, albeit through its regulatory processes. Mem. Op. a 6 (stating that the FDA must "treat the subpoenas . . . as requests for documents under its *Touhy* regulations [and] "must respond to Selden's subpoenas" pursuant to those regulations).

Regarding compliance with the subpoena, the FDA asserts that Selden's requests "may only be granted if the Commissioner or an employee designated by him" determines that "the requested testimony 'will be in the public interest' and 'will promote the objectives of the Federal Food Drug and Cosmetic Act and the agency.'" *Id.* (quoting 21 C.F.R. § 20.1(c)). In essence, the FDA argues that its regulations negate the requirements placed upon it by the Federal Rules of Civil Procedure. To the contrary, the FDA will comply with Selden's Rule 30(b)(6) subpoena, the bounds of which are ultimately defined by the court, not the FDA, consistent with the "liberal opportunity for discovery."[2] *Yousef*, 451 F.3d at 257 (quoting *Conley*

[2] The FDA has refused to comply with Selden's subpoena request believing that Selden may not seek testimony through the traditional subpoena process. For this reason, the FDA has not yet processed Selden's subpoena request and has not yet determined whether it will grant Selden's subpoena *ad testificandum* under 21 C.F.R. § 20.1(c). Should the FDA reject Selden's subpoena after processing the subpoena under its regulations, this court or another will have occasion to review that agency action. *Truex v. Allstate Ins. Co.*, 233 F.R.D. 188 (D.D.C. Jan. 10, 2006) (indicating that "when 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 in a given case, the requesting party must then proceed under the APA, and a federal court will review the agency's decision under an 'arbitrary and capricious' standard").

v. Gibson, 355 U.S. 41, 47 (1957)); *Exxon Shipping Co. v. U.S. Dept. of Interior*, 34 F.3d 774 (9th Cir. 1994) (stating that district courts should apply the federal rules of discovery when considering discovery requests made against government agencies); *Committee for Nuclear Responsibility, Inc. v. Seaborg*, 463 F.2d 788, 793 (D.C. Cir. 1971) (noting that the federal housekeeping statute, which authorizes government agencies to issues regulations with respect to custody of its papers, "does not authorize withholding information from the public or limiting the availability of records to the public. . . the ultimate determination . . . remains with the courts"). To summarize, the FDA's *Toughy* regulations apply solely to the agency's methods for handling discovery requests. The means by which parties issue subpoenas on the government, and the applicable legal standards governing compliance, are governed by the Federal Rules of Civil Procedure.

This case does not involve a private litigant intent on burdening the federal government through his own choosing. Instead, Selden seeks information to mount a defense from a government-initiated action. In such an instance, "judicial control over the evidence . . . cannot be abdicated to the caprice of executive officers." *United States v. Reynolds*, 345 U.S. 1, 9-10 1953); *see also*, *Seaborg*, 463 F.2d 793-794.

IV. CONCLUSION

For the foregoing reasons the court, this 30th day of April, 2007, denies the FDA's motion to quash Selden's subpoena *ad testificandum*. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge