United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 07-2299

Fresenius Medical Care,	*	
	*	
Appellant,	*	
	*	Appeal from the United States
v.	*	District Court for the Eastern
	*	District of Missouri.
United States of America,	*	
	*	
Appellee.	*	

Submitted: February 15, 2008
Filed: May 16, 2008

Before BYE, RILEY, and BENTON, Circuit Judges.

BENTON, Circuit Judge.

The United States Attorney for the Eastern District of Missouri issued two subpoenas to Fresenius Medical Care, seeking, as relevant here, information related to the administration of Epogen, a drug given to dialysis patients. Fresenius sought to quash or modify the subpoenas. The district court[1] denied the motion. Fresenius appeals. Having jurisdiction under 28 U.S.C. § 1291, this court affirms.

[1] The Honorable Rodney W. Sippel, United States District Judge for the Eastern District of Missouri.

I.

Fresenius Medical Care (FMC), a hemodialysis provider, operates more than 1,500 outpatient dialysis facilities in the United States. FMC's patients require dialysis because they have End Stage Renal Disease (ESRD). Medicare has a special program for ESRD patients, who are entitled to coverage for medical expenses. The vast majority of FMC's patients receive the drug Epogen, which reduces or eliminates anemia in dialysis patients. Providers, like FMC, are reimbursed a fixed amount per volume unit of Epogen prescribed and administered. The cost of Epogen is significant. Physicians commonly prescribe it using algorithms, which lower or raise the amount prescribed in response to changes in the patient's blood. For example, a physician may direct that, if a patient's hemoglobin is greater than 12, the Epogen dosage should be reduced a certain percentage.

In October 1995, the United States Attorney for the District of Massachusetts began investigating National Medical Care, Inc., which FMC acquired shortly thereafter. The investigation resulted in the production of more than six million pages of documents. FMC's use and billing of Epogen were among the subjects of the investigation. In January 2000, FMC entered into a series of guilty pleas and civil settlement agreements. FMC agreed to pay the United States approximately $253 million, and in exchange, received releases and dismissals with prejudice from some claims. The United States Attorney refused, however, to release FMC from any subject dealing with Epogen until it investigated other complaints.

The Office of the Inspector General also investigated FMC's Epogen practices, and in December 2001, published a report titled "Review of Epogen Internal Control Procedures at FMC Massachusetts Providers for Calendar Year 1999." The report reviewed about 4,600 Epogen claims, and found that FMC "generally established adequate internal controls and procedures to ensure that claims submitted for [Epogen] are supported and billed in accordance with Medicare rules and regulations." It also

identified 14 claims, out of a random sample of 200, where more Epogen was administered than prescribed by the physician.

As a result of further investigation, the United States Attorney for the District of Massachusetts asserted that FMC improperly billed Medicare for Epogen administered to patients as part of a clinical trial. FMC entered a civil settlement on this issue in May 2002, paying the government approximately $1.6 million, and obtaining a release. Along with the settlement, the United States Attorney issued a "cold comfort letter" to FMC. The letter stated:

> [N]either the United States Department of Justice nor the Office of Inspector General for the Department of Health and Human Services has any open or pending civil or criminal investigations or cases against the Companies except [for the two Epogen cases being settled in association with the letter.] In addition . . . neither the Department of Justice nor the Inspector General has any present intention, based on the facts now known to them, to initiate any investigation and/or to file or pursue litigation against the Companies. . . . The representations made in this letter are made as of April 19, 2002, and are based on surveys we conducted or caused to be conducted of the office of Inspector General of the Department of Health and Human services, the United States Attorneys for all districts, and of certain organizational parts of the Department of Justice which the Companies and my Office agreed to be relevant.

On April 25, 2002, six days after the representation date in the cold comfort letter, a False Claims Act complaint was filed by a qui tam relator in the United States District Court for the Eastern District of Texas. The complaint accused Amgen, the maker of Epogen, of (among other things) improperly creating physician protocols that overused Epogen, causing excess payments by Medicare. The complaint stated

the FMC did *not* employ such protocols. The complaint acknowledged that the relator made a witness statement to the United States before the complaint was filed.

For several years before 2005, the United States Attorney for the Eastern District of Missouri investigated Gambro Healthcare, Inc., a dialysis provider and competitor of FMC. As part of the Gambro investigation, the United States Attorney received an allegation that FMC had submitted Medicare claims for Epogen that was not medically necessary. On April 1, 2005, the United States Attorney issued an administrative subpoena to FMC, seeking, in part, information regarding FMC's Epogen policies and practices, from December 1, 1996, through April 30, 2005. After the subpoena issued, the United States Attorney conducted a review of FMC's Medicare claims for Epogen, using information directly from Medicare. The review showed that FMC submitted a significant number of claims for patients whose hematocrit levels exceeded 37.5% on a rolling average basis.[2] The United States Attorney found this suspicious, and issued another subpoena to FMC on February 14, 2006. The second subpoena sought more specific information about FMC's Epogen policies, including patient records and audits regarding the medical necessity of Epogen. The second subpoena covered January 1, 1996, through March 10, 2006.

FMC moved to quash or modify the subpoenas, arguing that the previous settlements and cold comfort letter precluded the government from investigating FMC's Epogen policies and practices before April 19, 2002. The district court denied

---

[2] Hematocrit level is the volume of red blood cells in a given volume of blood. *See* **Robert K. Ausman, MD & Dean E. Snyder, JD, Medical Library: Lawyers Edition 6- 13:1 (1990)**. The suggested target hematocrit range for patients prescribed Epogen is 30 to 36 percent. *See* **Thompson, Physicians' Desk Reference 565 (Kathleen Engel ed., 62nd ed. 2008)**. The Department of Health and Human Services suggests that providers like FMC "use a threshold hematocrit value of 37.5 percent in targeting aberrant cases." **Department of Health and Human Services, Health Care Financing Administration, Program Memorandum Intermediaries/Carriers, HCFE-Pub. 60AB (July 1998).**

FMC's motion, finding the subpoenas a valid exercise of the investigatory power of the United States Attorney under 18 U.S.C. § 3486. The court also found that the subpoenas "are not overly burdensome," and "the information the subpoenas seek is not precluded by the previous settlements and cold comfort letters."

II.

A district court's decision to enforce an administrative subpoena is reviewed for an abuse of discretion. ***EEOC v. Technocrest Sys., Inc.***, 448 F.3d 1035, 1038 (8th Cir. 2006).

A subpoena is properly enforced if (1) issued pursuant to lawful authority, (2) for a lawful purpose, (3) requesting information relevant to the lawful purpose, and (4) the information sought is not unreasonable. ***United States v. McDonnell Douglas Corp.***, 751 F.2d 220, 226 (8th Cir. 1984), *citing* ***Oklahoma Press Publ'g. Co. v. Walling***, 327 U.S. 186, 208-09 (1946).

The two subpoenas here meet the first three requirements. The subpoenas were issued pursuant to 18 U.S.C. § 3486, authorizing the Attorney General to issue administrative subpoenas in "any investigation relating" to a federal health care offense. **18 U.S.C. § 3486(a)**. *See* ***United States v. Bailey (In re Subpoena Duces Tecum)***, 228 F.3d 341, 350 (4th Cir. 2000) ("[T]he § 3486 subpoena power [for health care offenses] falls within the legitimate governmental power of inquisition on a matter in which the government has a legitimate interest. . . ."). The lawful purpose of the subpoenas was to investigate FMC's Epogen practices, due to allegations of wrongdoing. *See* **18 U.S.C. § 286** (crime of conspiracy to defraud the United States with respect to claims); **18 U.S.C. § 1035** (crime of knowingly making false statements involving a health care benefit program); **31 U.S.C. § 3729** (False Claims Act); **42 U.S.C. § 1320c-5(a)** (health care providers must ensure that services paid for by the government are medically necessary and supported by evidence of medical

necessity). Finally, the documents sought, mostly relating to FMC's policies and use of Epogen, and its relationship with Amgen, are "reasonably relevant to an authorized investigation." *See* ***Technocrest***, 448 F.3d at 1040 (ordering production of documents reasonably relevant to the investigation), *citing* ***United States v. Morton Salt Co.***, 338 U.S. 632, 652 (1950); ***Doe v. United States***, 253 F.3d 256, 267 (6th Cir. 2001) ("[T]he DOJ's subpoena power in investigating federal health care offenses is meant to be broad.").

FMC asks this court to quash or modify the subpoenas to "preclude the production of documents related to FMC's use and administration of Epogen prior to April 19, 2002, and FMC's use or implementation after that date of policies and procedures that were adopted prior to that date." FMC asserts that the required production of these documents is unreasonable, because it is entitled to rely on the government's assertion in the cold comfort letter that it did not intend to "initiate any investigation and/or to file or pursue litigation against" FMC "based on the facts now known."

At issue is whether the cold comfort letter immunizes FMC from further investigation relating to Epogen. The letter states, "neither the Department of Justice nor the Inspector General has any present intention, based on the facts now known to them, to initiate any investigation and/or to file or pursue litigation against [FMC]." This is simply an assurance from the government that, based on the facts it *then* knew, it was not *then* planning any further investigation. The letter does not preclude the United States from investigating FMC based on new facts. In fact, allowing the preclusive effect FMC seeks would hinder the United States Attorney in carrying out lawful duties. *See* ***Oklahoma Press***, 327 U.S. at 213 (allowing district courts to decide statutory coverage at the subpoena stage would substantially affect the Department of Labor's ability to carry out its investigative duty); ***Doe***, 253 F.3d at 267 (one main legislative purpose of HIPPA, containing § 3486, is to combat health care fraud and abuse). Since the government received allegations against FMC during the

Gambro investigation, the cold comfort letter does not have any preclusive effect on the two subpoenas.[3]

FMC contends that in order for it (and the courts) to fully understand the scope of the comfort letter, the government should disclose the Texas relator's pre-filing witness statement, and its theories for the current Epogen investigation. Since this court has determined that the comfort letter does not preclude investigation, there is no need for these disclosures.

FMC also argues that the subpoenas are unreasonable because they request documents given the government in previous investigations. It is generally unreasonable for the government to subpoena documents already in its possession. *See* ***Doe***, 253 F.3d at 265 (for a subpoena to be properly enforceable the information cannot already be in the DOJ's possession); ***In re Special April 1977 Grand Jury***, 581 F.2d 589, 594 (7th Cir. 1978) ("As [Judge Weinfeld's rule in *Iozia* regarding subpoenas under Fed. R. Crim. P. 17(c)] has been applied, it is used to avoid allowing a party who may have the needed document in its own possession, or could easily obtain it from another source, to force the subpoenaed party to bear the costs of searching for the document."). *See also* ***United States v. Powell***, 379 U.S. 48, 56 (1964) (IRS Commissioner must show that "that the information sought is not already

[3] Since the government has not asserted any particular claims against FMC, it is premature to address the full preclusive effect, if any, of the cold comfort letter. *See* ***Endicott Johnson Corp. v. Perkins***, 317 U.S. 501, 509 (1943) (subpoenas were enforceable even though company claimed it was not covered by the statute because "if there were no [violations] found, the issue of coverage would be academic"); ***Texas v. United States***, 523 U.S. 296, 301 (1998) ("Determination of the scope . . . of legislation in advance of its immediate adverse effect in the context of a concrete case involves too remote and abstract an inquiry for the proper exercise of the judicial function."), *quoting* ***Int'l Longshoremen's and Warehousemen's Union, Local 37 v. Boyd***, 347 U.S. 222, 224 (1954).

within the Commissioner's possession" before a subpoena issued under IRC § 7602 will be enforced).

Here, however, FMC does not identify which subpoenaed documents are already in the government's possession. Some of the documents the OIG obtained for its investigation may be covered by the current subpoenas. However, the OIG's investigation covered only Massachusetts providers in the year 1999, while the subpoenas cover all providers from 1996 through 2006. The January 2000 settlement agreement covered allegations through 1999, but was entirely related to Intradialytic Parenteral Nutrition (IDPN), a topic not covered by these subpoenas. The May 2002 settlement agreement relates to Epogen, but covers only conduct through June 1996. From the record here, it is not possible to determine which subpoenaed documents are already in the government's possession. Given FMC's failure to identify the documents already in the government's possession, it was not an abuse of discretion for the district court to refuse to modify the subpoena.[4] *See* ***Doe***, 253 F.3d at 268-69 (enforcing administrative subpoena where individual made only "general and conclusory statements" as to why the subpoena was an undue burden, and individual "made no attempt to reach a reasonable accommodation with the government"), *citing* ***Morton Salt***, 338 U.S. at 653.

III.

The judgment of the district court is affirmed.

---

[4] On remand, the district court has discretion to modify the subpoenas upon an identification of specific documents already in the government's possession, or an agreement between FMC and the government about documents already in the government's possession.