IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-02017 (RCL)
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

MEMORANDUM AND ORDER

Before the Court is defendants' Motion [75] to Amend/Correct the Order [36] on Motion for Preliminary Injunction. Upon consideration of the motion, the opposition, the reply thereto, and the record herein, the Court will grant defendants' motion to amend the preliminary injunction to allow defendants to provide AMP data to the Government Accountability Office.

I. BACKGROUND

Plaintiffs, the National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Association ("NCPA"), have challenged the United States Department of Health and Human Services' calculation of federal upper payment limits for Medicaid-covered generic drugs. Plaintiffs argue that, under regulations promulgated by the Department of Health and Human Services ("HHS"), pharmacies will not receive adequate compensation for the generic drugs they dispense to Medicaid patients.

In the Deficit Reduction Act of 2005 ("DRA"), Congress amended the Medicaid Act to substantially change the manner in which pharmacies would be compensated for Medicaid-covered generic drugs. Pub. L. No. 109-171, § 6001, 120 Stat. 4, 53 (2006). Effective January 1, 2007, the DRA set the federal upper payment limit ("FUL") for Medicaid-covered generic drugs at 250 percent of the average manufacturer price ("AMP") for the least costly equivalent formulation of the drug, plus a reasonable dispensing fee. *Id.* § 6001(a)(2), *codified at* 42 U.S.C. § 1396r-8(e)(5). Congress instructed the Centers for Medicare & Medicaid Services ("CMS") to promulgate a rule clarifying the term "average manufacturer price." *Id.* § 6001(c)(3)(B). CMS issued a final rule setting forth a definition of that term on July 17, 2007. 72 Fed. Reg. 39,142 (July 17, 2007). That rule became effective on October 1, 2007. *Id.* at 39,142. Since that time, prescription drug manufacturers have calculated AMPs for each of their drugs pursuant to CMS's new AMP definition and have been submitting those AMP data to CMS on a monthly basis. CMS had intended to begin setting AMP-based FULs in early 2008. Pursuant to the new public disclosure requirement of the DRA, § 6001(b)(2)(C)(v), *codified at* 42 U.S.C. § 1396r-8(b)(3)(D)(v), CMS had intended to begin publishing AMP data on its website in December 2007.

On December 14, 2007, this Court ruled that plaintiffs were likely to succeed on the merits of their claim that one or more components of CMS's AMP definition were inconsistent with the Medicaid Act. (Hr'g Tr. 54 (Dec. 14, 2007).) The Court ultimately entered an injunction that prohibited CMS from setting FULS for Medicaid-covered generic drugs based on AMP, as the DRA would have required, and from disclosing AMP data except within HHS or to DOJ. (Order [36] , Dec. 19, 2007, 2 ¶ b.) CMS therefore continues to apply its pre-DRA methodology for calculating FULs, but relies on the AMP data calculated by the challenged

definition for any purpose that does not affect pharmacy payment rates for Medicaid-covered drugs. (Defs.' Mot. to Am. 4.)

On July 15, 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"). Pub. L. No. 110-275, 122 Stat. 2494 (2008). In MIPPA, Congress imposed a statutory moratorium until October 1, 2009 on CMS's use of AMPs to set FULs so that Congress would have sufficient time to determine whether to amend the statutory definition of AMP or take some other legislative action in light of the agency's AMP definition. *Id.* § 203(a); 154 Cong. Rec. H5914 (2008) (statement of Rep. Etheridge). CMS is thus currently prohibited by both the MIPPA and by this Court's preliminary injunction from setting FULs based on AMPs, as the DRA would have required. (Defs.' Mot. to Am. at 5.)

In order to evaluate CMS's AMP definition, the ranking member of the Senate Committee on Finance, Senator Charles E. Grassley, has asked Congress's investigative arm, the Government Accountability Office ("GAO"), for a report comparing retail pharmacy acquisition costs to the FULS that would apply in an AMP-based FUL system under the challenged HHS regulation. (Defs.' Mot. to Am. at 5.) This would update the report that GAO prepared in December 2006, shortly after the DRA was enacted, on the same topic. (*See* Defs.' Mot. to Am., Ex. A & B.) While the December 2006 report used AMPs calculated under the agency's pre-DRA AMP calculation procedures, CMS understands that the update would utilize AMPs calculated pursuant to the requirements of the DRA, the AMP definition CMS promulgated pursuant to the DRA, and the "outlier" provision adopted in the AMP regulation. (*See* Defs.' Mot. to Am., Ex. C.)

To prepare the requested report, GAO requires access to AMP data held by HHS. The preliminary injunction [36] entered by this Court on December 19, 2007, however, prohibits the

agency from disclosing AMP data except within HHS or to the Department of Justice ("DOJ"). (Order [36], Dec. 19, 2007, at 2 ¶ b.) This non-disclosure provision addresses plaintiffs' concern that public release of AMP data could cause third party payers to lower their prescription drug payment rates. An unforeseen consequence of the preliminary injunction's non-disclosure provision, however, is that it now precludes HHS from providing GAO with the data GAO requires to fulfill its congressional request, thereby bringing this legislative oversight process to a halt. Defendants assert that plaintiffs will not be harmed by the disclosure of AMP data to GAO, and moreover, that the public interest will be furthered by allowing GAO to prepare this report pursuant to its authority so that Congress may consider amendments to the AMP-based FUL system. Defendants thus seek a limited modification of the injunction to provide GAO access to AMP data, subject to GAO's statutorily-imposed duty of confidentiality, so that GAO may update its 2006 report and enable Congress to perform its legislative and oversight responsibilities. (Defs.' Mot. to Am. at 6.)

Plaintiffs oppose the disclosure of AMP data to GAO for purposes of preparing the congressional report, claiming that the AMP data are flawed because they will not produce adequate payments to pharmacies for Medicaid-covered generic drugs and therefore should not be used even for the limited purpose of preparing a report evaluating the adequacy of the data. Plaintiffs also claim that the GAO, Comptroller General, and Senator Grassley do not have the authority to obtain the enjoined AMP data.

II. ANALYSIS

A. Plaintiffs Will Not Be Harmed by the Requested Modification

Disclosure of AMP data to GAO will not result in any of the harms plaintiffs have claimed in this lawsuit with respect to the agency's definition of AMP. Plaintiffs' claimed harm relates to public disclosure, which still would not occur if the AMP data were disclosed to GAO.

"Injunctive relief granted to a party in a lawsuit must be framed to remedy the harm claimed by the party." *Aviation Consumer Action Project v. Washburn*, 535 F.2d 101, 108 (D.C. Cir. 1976). "An injunction must be narrowly tailored to remedy the specific harm shown." *Id.*; *see also State of Neb. Dep't of Health & Human Servs. v. Dep't of Health & Human Servs.*, 435 F.3d 326, 330 (D.C. Cir. 2006) ("We have long held that an injunction must be narrowly tailored to remedy the specific harm shown.") (quotations omitted). An injunction should be "no broader than necessary to achieve its desired goals." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). "Injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Id.* (citing *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)) (quotations omitted).

Plaintiffs asserted that if CMS sets FULs at 250 percent of the AMPs calculated pursuant to CMS's definition, pharmacies will not receive adequate payment for the generic drugs they dispense to Medicaid beneficiaries. (Pls.' PI Memo. 39.) Consistent with this claimed harm, the preliminary injunction prohibits CMS from setting FULs based on AMPs. (Order, Dec. 19, 2007, at 2 ¶ a.) However, providing AMP data to GAO would not change the manner in which CMS sets FULs, as CMS would continue to set FULs based on published prices and not on AMPs. Pharmacy payment rates therefore will not be affected by disclosing AMP data to GAO so that GAO may prepare the requested report.

Plaintiffs also complained that if CMS were to publicly disclose the allegedly flawed AMP data on a website, third party payers could use the data to set their own pharmacy payment rates. (*See* Pls.' PI Memo. at 39; Pls.' PI Memo., Ex. B, ¶¶ 206-10.) In order to prevent this claimed harm from occurring, the preliminary injunction prohibits CMS from disclosing AMP data except within HHS or to DOJ. (Order, Dec. 19, 2007, at 2 ¶ b.) However, this non-disclosure provision is overly broad to address plaintiffs' claimed harm, thereby unnecessarily prohibiting non-public disclosures such as the requested disclosure to GAO. If GAO is given access to the AMP data, GAO will maintain the data in accordance with statutorily-imposed confidentiality restrictions in order to prevent public disclosure of the data. (*See* Defs.' Mot. to Am., Ex. C., GAO Letter, at 2-3 & n. 7.) The requested congressional report will disclose no specific AMP values but, like the December 2006 report GAO prepared for Congress, will compare AMP-based FULs to retail pharmacy acquisition costs only in summary format. (*Id.* at 3 & n. 8.) As GAO assures that it will maintain the AMP data confidentially, disclosure of AMP data to GAO would not provide third party payers with AMP data upon which they could base pharmacy payment rates.

Plaintiffs further argue that AMP cannot be disclosed to GAO and cannot possibly satisfy Senator Grassley's request because the rule pursuant to which those data were calculated does not comport with the Medicaid Act. (*See* Resp. to Defs.' Mot. to Am. [76] at 2-4.) However, for purposes of the report, it is irrelevant whether the AMP-based FULs are consistent with the Medicaid Act. Senator Grassley asked GAO to update a December 2006 GAO report that compared AMP-based FULs to pharmacy acquisition costs. (Defs.' Mot. to Am., Ex. A.) He did so in the context of a congressional moratorium partially enjoining implementation of the AMP rule pending congressional evaluation of that rule, and he requested the GAO report prior to the

expiration of that moratorium. (*Id.*) As his letter of request makes clear, Senator Grassley wishes to evaluate the effect that the current AMP rule would have on retail pharmacies if and when the partial moratorium on the AMP rule is lifted. (*Id.*) Senator Grassely plainly requested a report utilizing updated AMPs, calculated pursuant to the current AMP rule, because the December 2006 report had necessarily utilized AMP values calculated prior to the implementation of the AMP rule in 2007. (Defs.' Reply [78] 3.) As the purpose of the requested GAO report is to evaluate the effect of the current rule, inclusion of the challenged data in the report is necessary to allow Congress to deliberate on the AMP-based FUL system's adequacy.

Since plaintiffs have not shown that the disclosure of AMP data to GAO for the purposes of updating its 2006 congressional report would cause the harms of which plaintiffs complain, the preliminary injunction is more burdensome than necessary to provide complete relief to plaintiffs.

B. The Requested Modification Will Serve the Public Interest, as the Comptroller General and the General Accountability Office Have Authority to Obtain the Enjoined Data

Modification of the preliminary injunction to allow the release of AMP data to GAO would serve the public interest by allowing GAO to develop the information that will inform congressional deliberations on the adequacy of the AMP-based FUL system.

GAO, "an instrumentality of the United States Government independent of the executive departments," 31 U.S.C. § 702(a), is Congress's investigative arm. Congress created the office of the Comptroller General, the head of the GAO, to be responsible to Congress alone "to check upon the application of public funds in accordance with appropriations." *See Bowsher v. Synar*, 478 U.S. 714, 730 (1986) (quotations omitted). The Comptroller General is granted broad authority to carry out investigations and evaluations regarding public expenditures:

> The Comptroller General shall –
>
> (1) investigate all matters related to the receipt, disbursement, and use of public money;
>
> (2) estimate the cost to the United States Government of complying with each restriction on expenditures of a specific appropriation in a general appropriation law and report each estimate to Congress with recommendations the Comptroller General considers desirable;
>
> (3) analyze expenditures of each executive agency the Comptroller General believes will help Congress decide whether public money has been used and expended economically and efficiently;
>
> (4) make an investigation and report ordered by either House of Congress or a committee of Congress having jurisdiction over revenue, appropriations, or expenditures; and
>
> (5) give a committee of Congress having jurisdiction over revenue, appropriations, or expenditures the help and information the committee requests.

31 U.S.C. § 712 (1982). The Comptroller General also "shall evaluate the results of a program or activity the Government carries out under existing law (1) on the initiative of the Comptroller General; (2) when either House of Congress orders an evaluation; or (3) when a committee of Congress with jurisdiction over the program or activity requests the evaluation." *Id.* § 717(b). To allow GAO to perform its statutory duties, "[e]ach agency shall give the Comptroller General information the Comptroller General requires about the duties, powers, activities, organization, and financial transactions of the agency." *Id.* § 716(a).

The Supreme Court has recognized the "public interest served by full GAO investigations." *Bowsher v. Merck & Co.*, 460 U.S. 824, 835 (1983). *Cf. Fed. Trade Comm'n v. Owens-Corning Fiberglass Corp.*, 626 F.2d 966, 970 (D.C. Cir. 1980) ("[T]he judiciary must refrain from slowing or otherwise interfering with the legitimate investigatory functions of Congress."); *Fed. Trade Comm'n v. Anderson*, 631 F.2d 741, 747 (D.C. Cir. 1979) (noting "the necessity for courts to refrain from interfering with or delaying the investigatory functions of Congress") (quotations omitted); *see also Eastland v. United States Servicemen's Fund*, 421 U.S.

491 (1975); *Exxon Corp. v. Fed. Trade Comm'n*, 589 F.2d 582, 594 (D.C. Cir 1978) (noting "the clear public interest in maximizing the effectiveness of the investigatory powers of Congress"). The Supreme Court has also held that if GAO has the independent authority to conduct an evaluation, it is irrelevant that GAO initiated that evaluation at the request of an individual member of Congress. *Bowsher v. Merck,* 460 U.S. at 843-44. The Court emphasized that "the fact that the Comptroller General's request had its origin in the requests of congressmen or that the GAO reported the data to Congress does not vitiate its authority." *Id.* at 844.

Plaintiffs incorrectly argue that the Comptroller General lacks the authority to conduct this evaluation, disregarding both the relevant statute and case law that clearly grant the Comptroller General this authority. (*See* Resp. to Defs.' Mot. to Am. at 4-6.) Here, GAO plainly has the authority to conduct the contemplated evaluation under 31 U.S.C. § 717(b)(1). (*See* Defs.' Reply, Ex. D [78-2].) Pursuant to this provision, the Comptroller General may evaluate the results of the AMP rule on his own initiative, even though no committee has requested that evaluation. *See* 31 U.S.C. § 717(b)(1). Under *Bowsher v. Merck,* it is irrelevant that GAO exercises that authority through an individual member of Congress such as Senator Grassley. As the Supreme Court articulated, the "public interest" is served by allowing GAO to conduct such an evaluation. *See Bowsher v. Merck,* 460 U.S. at 835.

Plaintiffs' additional argument that Senator Grassley lacks the authority to request the AMP data is without merit. Plaintiffs assert that in requesting the information for the updated report, the Senator has not complied with his committee's subpoena procedures. (*See* Resp. to Defs.' Mot. to Am. at 5.) Senator Grassley has not purported to subpoena HHS for AMP data, nor has HHS argued that the Senator could do so on his own initiative. Committee rules regarding the issuance of subpoenas are therefore inapposite. Moreover, nothing in the

committee rules prevents a senator from simply asking the Comptroller General, the investigative arm for all of Congress, to conduct an evaluation. Senator Grassley is not attempting to access the AMP data as an individual member of Congress, but rather merely requesting the completed report on the AMP data from GAO. The Senator will not receive the AMP data directly from HHS, but instead will view the AMP data in summary form in the updated report. The present case can be distinguished from *Walker v. Cheney*, cited by plaintiffs, which addressed only GAO's legal standing to invoke the authority of the judicial branch to force the executive branch to release information to the legislature. 230 F. Supp. 2d 51, 75 (D.D.C. 2002). In the present case, HHS has agreed to provide the requested data to GAO, so the separation of powers concern that drove the outcome in *Walker* is not implicated. As such, plaintiffs' arguments regarding the Senator's request are irrelevant and unpersuasive.

As the Comptroller General and GAO have the lawful authority to conduct an investigation with regards to the AMP data, preventing the GAO from accessing the enjoined AMP data would frustrate Congress's performance of its legislative and oversight functions which are carried out in the public interest.

III. CONCLUSION & ORDER

For the foregoing reasons, it is hereby

ORDERED that the motion [75] is GRANTED; and it is further

ORDERED that Paragraph b of the preliminary injunction entered by this Court on December 19, 2007 is amended to read as follows:

b. Posting any AMP data on a public website or otherwise disclosing any AMP data to any individuals or entities, including but not limited to States and their representatives

or agencies, except that defendants may disclose AMP data within the U.S. Department of Health and Human Services or to the U.S. Department of Justice for their internal use or enforcement activities only, or to the U.S. Government Accountability Office for its audit and investigation activities.

SO ORDERED.

Signed by Royce C. Lamberth, United States District Judge, June 23, 2009.