UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE COALITION FOR COMMON SENSE IN GOVERNMENT PROCUREMENT, **Plaintiff,** **v.** **UNITED STATES OF AMERICA and UNITED STATES DEPARTMENT OF DEFENSE,** **Defendant.**	**Civil Action No. 08-996 (JDB)**

MEMORANDUM OPINION

On January 28, 2008, Congress enacted the National Defense Authorization Act for Fiscal Year 2008 ("NDAA-08"). Under Section 703 of the NDAA-08, pharmaceuticals paid for by the Department of Defense ("DoD") that are provided by retail pharmacies to TRICARE beneficiaries are to be subject to the pricing standards of 38 U.S.C. § 8126, known as Federal Ceiling Prices. Section 703 also directs that the existing applicable regulations be modified to implement the new statutory requirement. On February 1, 2008, DoD issued a letter to pharmaceutical manufacturers (the "Dear Manufacturer letter") that served as "the initial implementation" of Section 703. The Dear Manufacturer letter announced DoD's decision to use its current rebate program, which is effectuated through voluntary rebate agreements with pharmaceutical manufacturers, to ensure that qualified prescriptions filled at TRICARE network retail pharmacies are subject to Federal Ceiling Prices. Meanwhile, DoD has proceeded to modify the relevant regulations through a proposed rulemaking initiated on July 25, 2008.

Plaintiff Coalition for Common Sense in Government Procurement ("Coalition") brings

this action against DoD alleging that the rebate program implemented by the Dear Manufacturer letter and associated materials constitutes a substantive rule issued in excess of DoD's statutory authority under Section 703 of the NDAA-08 and in violation of the notice and comment rulemaking procedures of the Administrative Procedures Act ("APA"). Currently before the Court is the Coalition's motion for a preliminary injunction seeking to prohibit DoD from implementing and enforcing the rebate program pending a final determination of its validity on the merits. In response, DoD has filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6), arguing that the Coalition lacks standing and that it has failed to state a claim upon which relief can be granted. Upon careful consideration of the motions, the parties' several memoranda, the arguments advanced at the motions hearing held on September 10, 2008, the applicable law, and the entire record, the Court will deny the Coalition's motion for a preliminary injunction and will deny DoD's motion to dismiss.

BACKGROUND

I. Statutory and Regulatory Background

TRICARE is the health care program of the Department of Defense, and includes a Pharmacy Benefits Program. TRICARE was established for current and former members of the uniformed services and their families under the authority of 10 U.S.C. Chapter 55, principally Section 1097. See 10 U.S.C. § 1072(7). Section 701 of the National Defense Authorization Act for Fiscal Year 2000, see Pub. L. No. 106-65, § 701, 113 Stat. 512 (1999), enacted 10 U.S.C. § 1074g, which directed the Secretary of Defense to "prescribe regulations" that "establish an effective, efficient, integrated pharmacy benefits program." 10 U.S.C. § 1074g(h), (a)(1). DoD promulgated implementing regulations for the TRICARE Pharmacy Benefits Program in 2004.

See 67 Fed. Reg. 17,948 (Apr. 12, 2002) (notice of proposed rulemaking); 69 Fed. Reg. 17,035 (Apr. 1, 2004) (final rule), codified at 32 C.F.R. § 199.21.

Section 199.21 established rules and procedures to govern the selection of pharmaceuticals by the Department of Defense Pharmacy and Therapeutics Committee ("P&T Committee") that will be available to TRICARE beneficiaries. Established by 10 U.S.C. § 1074g, the P&T Committee is authorized to evaluate pharmaceutical agents in each therapeutic class for inclusion on the TRICARE uniform formulary on the basis of their relative clinical effectiveness and cost effectiveness. See 32 C.F.R. § 199.21(e)-(f). The uniform formulary is a list of pharmaceuticals that are available to TRICARE beneficiaries as "basic program benefits." Id. § 199.21(a)(3)(i). The uniform formulary is designed to control costs by limiting the number of drugs covered by TRICARE, and by giving beneficiaries a financial incentive to choose prescription drugs that are on the formulary because TRICARE will cover the cost of the prescription, minus a modest co-payment in some circumstances. See id. § 199.21(i) (detailing cost-sharing requirements under the pharmacy benefits program). Pharmaceutical agents included on the uniform formulary are available to eligible covered TRICARE beneficiaries at three different points of service: Military Treatment Facilities ("MTF"); the TRICARE Mail Order Pharmacy; and network and non-network retail pharmacies, which are non-MTF pharmacies. See 10 U.S.C. § 1074g(a)(2)(E); 32 C.F.R. § 199.21(h)(1)(i)-(iv).

For every prescription filled by an eligible covered TRICARE beneficiary, the ultimate cost incurred by DoD is contingent upon the point of service where the pharmaceutical agent was obtained. Under the Veterans Health Care Act of 1992, codified at 38 U.S.C. § 8126, there is a price limitation placed on drugs "procured by" certain federal agencies, including DoD.

Because drugs dispensed at Military Treatment Facilities and through the TRICARE Mail Order Pharmacy are "procured by" DoD through direct service agreements with pharmaceutical manufacturers, DoD gets the benefit of Section 8126's limitation on prices. Section 8126 provides that each manufacturer of a covered drug shall enter into a master agreement "under which the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price . . . ." 38 U.S.C. § 8126(a)(2). The discounted prices established by Section 8126(a)(2) are known as Federal Ceiling Prices.

By contrast, Federal Ceiling Prices have not applied to prescription drugs obtained by TRICARE beneficiaries at retail pharmacies because DoD plays no role in the procurement process. Consequently, DoD pays the full commercial price for drugs obtained by beneficiaries at TRICARE network retail pharmacies. On October 14, 2004, the Department of Veterans Affairs ("VA") sought to change that by issuing a Dear Manufacturer letter that required pharmaceutical manufacturers to refund DoD the difference between the wholesale commercial price and the Federal Ceiling Price for covered drugs provided by TRICARE network retail pharmacies. See Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affairs, 464 F.3d 1306, 1312 (Fed. Cir. 2006). The Coalition challenged the rebate requirement imposed by the Dear Manufacturer letter on the ground[1] that it was a "substantive rule" within the meaning of the APA that was issued "without observance of procedure required by law." Id. at

[1] The Coalition also argued, in the alternative, that the Dear Manufacturer letter was unlawful under 5 U.S.C. § 706 because it was "arbitrary, capricious, an abuse of discretion, or otherwise contrary to law." Because the Federal Circuit found the Dear Manufacturer letter deficient on procedural grounds, it did not reach this argument. See id. at 1319 n.6.

1317-18. In invalidating the Dear Manufacturer letter, the Federal Circuit held that the letter was a substantive rule that was enacted without compliance with the notice and comment rulemaking procedures required by the APA. Id. at 1319.

In May 2006, several months before the VA's mandatory rebate requirement was invalidated, DoD adopted a voluntary rebate program. DoD's rebate program was implemented through use of the Uniform Formulary Voluntary Agreement for TRICARE Retail Rebates ("UF-VARR" or "rebate agreement"). See Def.'s Mot. Dismiss, Ex. 1 at 1. According to DoD, the UF-VARR has provided a means for pharmaceutical manufacturers to offer incentive price agreements, voluntarily, in order to enhance the prospects that a particular drug will be placed on the uniform formulary based on its clinical and cost-effectiveness. See Def.'s Mot. Dismiss, Stmt. of Mat. Facts at 4, ¶ 8. In the three versions of the UF-VARR that have been used by DoD since 2006, none specified a required minimum rebate or indicated that the rebate should be tied to Federal Ceiling Prices. See Def.'s Mot. Dismiss, Exs. 1, 2; Pl.'s Ex. I to Allen Decl.

On January 28, 2008, Congress enacted the National Defense Authorization Act for Fiscal Year 2008. Section 703 addresses the application of Federal Ceiling Prices to drugs obtained through the TRICARE retail pharmacy network. It provides in a new 10 U.S.C. § 1074g(f) that

> . . . the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of procurement of drugs by Federal agencies under section 8126 of title 38 to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126

and that DoD, after consultation with other administering agencies, shall

> modify the regulations under [10 U.S.C. § 1074g(h)] to implement the

> requirements of [the new 10 U.S.C. § 1074g(f)]. The Secretary shall so modify such regulations not later than December 31, 2007.

Pub. L. 110-181, 122 Stat. 188 (2008).

On February 1, 2008, in response to the enactment of Section 703 of the NDAA-08, and the amendment of 10 U.S.C. § 1074g, DoD issued a Dear Manufacturer letter to serve as DoD's "initial implementation of the new statutory affirmation that qualified prescriptions filled through the TRICARE Retail Pharmacy Program are subject to Federal ceiling prices." Pl.'s Ex. D to Allen Decl. The Dear Manufacturer letter went on to state that "[i]nitial implementation of TRICARE Retail Network Refunds will be through the existing VARR processes." Id. Finally, the letter stated that "beginning with the spring meeting of the DoD Pharmacy and Therapeutics Committee, the pricing standard affirmed by the new law will be included in the evaluation of cost-effectiveness of drugs under review." Id. at 2.

Subsequent to the Dear Manufacturer letter, DoD specified additional details of the rebate program by posting information on the TRICARE website and holding a meeting with pharmaceutical manufacturers on May 1, 2008. See Allen Decl. ¶¶ 10-12 & Exs. F-K. These details include terms of an agreement for manufacturers to pay rebates at Federal Ceiling Prices, an effective date when execution of a rebate agreement would become a condition for uniform formulary review, and a statement of DoD's policy that it will not execute any rebate agreement that is not based on Federal Ceiling Prices. See id.

On July 25, 2008, DoD published formal notice of a proposed rule to implement Section 703 of NDAA-08. See generally 73 Fed. Reg. 43,394 (July 25, 2008). DoD acknowledged that "[t]he statute requires implementing regulations." Id. The notice indicated that written comments received by September 23, 2008 will be considered by the agency and addressed in

the final rule. Id. at 43,395. The proposed rule would add a new paragraph (q) to 32 C.F.R. § 199.21, the existing implementing regulations of the TRICARE Pharmacy Benefits Program. Paragraph (q)(1) repeats the new statutory requirement of 10 U.S.C. § 1074g(f). Paragraph (q)(2) provides that an agreement by a manufacturer to honor the Federal Ceiling Prices with regard to drugs purchased through the TRICARE retail pharmacy network "is a condition of inclusion of a drug on the uniform formulary." Id. Paragraph (q)(3) establishes refund procedures to ensure that pharmaceuticals obtained by TRICARE beneficiaries at retail pharmacies, and paid for by DoD, are "subject to" Federal Ceiling Prices, as required by the statute. Id.

II. Factual and Procedural Background

Plaintiff Coalition for Common Sense in Government Procurement is a multi-industry association that represents companies, including pharmaceutical companies, that provide products and services that are procured by the federal government. See Compl. ¶ 3. The Coalition's members include pharmaceutical companies that participate in the TRICARE Pharmacy Benefits Program. See id.

In the wake of the Dear Manufacturer letter, and before DoD issued formal notice of its proposed rule on July 25, 2008, the Coalition, along with other industry groups, sent letters to DoD objecting to implementation of the new statutory mandate of 10 U.S.C. § 1074g(f) without notice and comment rulemaking. The Coalition urged DoD to stop the rebate program and modify 32 C.F.R. § 199.21, the existing implementing regulations of the TRICARE Pharmacy Benefits Program, through notice and comment rulemaking. See Pl.'s Ex. M to Allen Decl. DoD did not respond to the Coalition's letters. See Allen Decl. ¶ 17. On June 10, 2008, the

Coalition filed the complaint in this action, and a motion for a preliminary injunction followed on June 23, 2008.

In its motion, the Coalition cited the significance of upcoming P&T Committee meetings, scheduled for June and August of 2008, because manufacturers would need to comply with the terms of the new rebate program or risk exclusion from the uniform formulary. See Pl.'s Mot. Prelim. Inj. at 17; Allen Decl. ¶ 15. The P&T Committee has since held its June and August meetings. See generally Def.'s Mot. Dismiss, Exs. 3-5. The Coalition asserts that at the June 2008 P&T Committee meeting six of the drugs under review for inclusion on the uniform formulary were manufactured by Coalition members. See Pl.'s Reply Prelim. Inj. at 22; Pl.'s Ex. A. The Coalition also asserts that in each instance, as per the Dear Manufacturer letter and associated materials, its members submitted a rebate agreement at or below the Federal Ceiling Price. See id. Two Coalition members that had drugs under consideration at the June 2008 P&T Committee meeting are GlaxoSmithKline, manufacturer of Imitrex, a drug used to treat migraine headaches, and Sanofi-Aventis, manufacturer of Actonel, a drug used to treat osteoporosis. Both drugs were recommended for inclusion on the uniform formulary. See Pl.'s Reply Prelim. Inj. at 23. The Coalition seeks a preliminary injunction to prohibit DoD from executing the UF-VARRs that would entitle DoD to the rebates, or otherwise implementing, relying upon, enforcing or effectuating the rebate program pending a final determination of its validity on the merits. Compl. at 11.

STANDARD OF REVIEW

Earlier this year, the United States Supreme Court gave a firm reminder that "[a] preliminary injunction is an 'extraordinary and drastic remedy,'; it is never awarded as of right."

Munaf v. Geren, 128 S.Ct. 2207, 2219 (2008) (citations omitted). Thus, a preliminary injunction should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion. See Mazurek v. Armstrong, 520 U.S. 968, 972 (1997).

With that context in mind, the standard for a preliminary injunction is well-established. To prevail, the moving party must demonstrate (1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable harm without injunctive relief, (3) that an injunction would not substantially harm other interested parties, and (4) that issuance of the injunction is in the public interest. Cobell v. Norton, 391 F.3d 251, 258 (D.C. Cir. 2004); Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998); CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995). The four factors "are not considered in isolation from one another, and no one factor is necessarily dispositive as to whether preliminary injunctive relief is warranted. Rather, the factors 'interrelate on a sliding scale and must be balanced against each other.'" Morgan Stanley DW Inc. v. Rothe, 150 F. Supp. 2d 67, 72 (D.D.C. 2001) (citations omitted). "If the plaintiff makes a particularly weak showing on one factor, however, the other factors may not be enough to 'compensate.'" Id; see also Hunter v. FERC, 527 F. Supp. 2d 9, 14 (D.D.C. 2007); Dodd v. Fleming, 223 F. Supp. 2d 15, 20 (D.D.C. 2002).

DISCUSSION

Because the Coalition's showing of irreparable harm is particularly weak, the other factors, which weigh slightly in the Coalition's favor, are not enough to compensate and tip the balance to justify the "extraordinary and drastic remedy" sought. Hence, the Court will begin its discussion with the decisive factor here -- irreparable harm.

A. Irreparable Harm

The irreparable injury requirement erects a very high bar for a movant. See Varicon Int'l v. OPM, 934 F. Supp. 440, 447 (D.D.C. 1996). A plaintiff must show that it will suffer harm that is "more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." Gulf Oil Corp. v. Dept. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). To warrant emergency injunctive relief the alleged injury must be certain, great, actual, and imminent. See Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); see also Am. Ass'n for Homecare v. Leavitt, 2008 WL 2580217, at *4 (D.D.C. 2008). In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard. See Wisconsin Gas, 758 F.2d at 674; Boivin v. US Airways, Inc., 297 F. Supp. 2d 110, 118 (D.D.C. 2003); Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.D.C. 2000). To successfully shoehorn potential economic loss into a showing of irreparable harm, a plaintiff must establish that the economic harm is so severe as to "cause extreme hardship to the business" or threaten its very existence. Gulf Oil, 514 F. Supp. at 1025; see also Wisconsin Gas, 758 F.2d at 674; Experience Works, Inc. v. Chao, 267 F. Supp. 2d 93, 96 (D.D.C. 2003); Sociedad Anonima Vina Santa Rita v. Dep't of Treasury, 193 F. Supp. 2d 6, 14 (D.D.C. 2001).

There is no dispute that the harm claimed by the Coalition here is "merely economic." In the Coalition's own words, "it is the payment of the rebates that is the focus of irreparable harm in this case." Pl.'s Reply Prelim. Inj. at 22. Constrained by its "merely economic" injury, the Coalition must compensate by demonstrating the severity of its alleged economic harm. The Coalition has not made such a showing.

Although the Coalition has attempted to quantify the harm that will be suffered by its

members, the degree of harm asserted by the Coalition does not approach the level required in this case (i.e., so severe as to cause extreme hardship to the business or threaten the very existence of Coalition members). The Coalition's alleged harm focuses on two of its members that underwent uniform formulary review at the June 2008 P&T Committee meeting: GlaxoSmithKline, manufacturer of Imitrex, and Sanofi-Aventis, manufacturer of Actonel. Pl.'s Reply Prelim. Inj. at 22-23. The Coalition claims that these companies, as well as other Coalition members, will be harmed in the form of "lost profits" attributable to the payment of rebates.[2] Based on the terms of the rebate agreements, the available usage data, see Def.'s Mot. Dismiss, Exs. 3, 4; Pl.'s Exs. E, J to Allen Decl., and other publicly available information, the Coalition estimates that "the approximate rebates would be $446,400 to $480,000 per month (or $5,356,800 to $5,760,000 per year) for Imitrex and $16,128 to $243,200 per month (or $193,536 to $2,918,400 per year) for Actonel." Pl.'s Reply Prelim. Inj. at 22-23, n.12.

Even assuming arguendo that the Coalition estimates are accurate, the degree of harm to GlaxoSmithKline and Sanofi-Aventis cannot be considered irreparable under even the most charitable of standards.[3] GlaxoSmithKline and Sanofi-Aventis are two of the largest

---

[2] The Coalition also argues that harm will result, in the form of lost profits, if Coalition members choose not to pay rebates because their drugs will be excluded from the uniform formulary and hence effectively excluded from the TRICARE market. See Pl.'s Mot. Prelim. Inj. at 35-36; Pl.'s Reply Prelim. Inj. at 21. Because the Coalition concedes that "the injury from paying the rebates is the more probable one," Pl.'s Reply Prelim. Inj. at 22, and there is nothing in the record to establish that a Coalition member (or its drug) has been excluded from the TRICARE market after a refusal to pay rebates, the Court will focus on the alleged harm from the payment of rebates.

[3] The Coalition argues that its members will suffer irreparable harm because lost profits are not likely to be recovered later in this litigation in the form of damages due to the protections of sovereign immunity. See Pl.'s Prelim. Inj. at 36-37. The Coalition asserts that unrecoverable financial losses, in the form of sales and market share, constitute irreparable injury. While it

pharmaceutical companies in the world. In 2007, both companies had revenues of nearly $40 billion (in U.S. dollars).[4] Taking the high-end of the Coalition's rebate estimates, $5,760,000 per year for Imitrex and $2,918,400 per year for Actonel, the lost profits that would result would be approximately 1/100 of 1 percent of GlaxoSmithKline's annual revenues and less than 1/100 of 1 percent of Sanofi-Aventis' annual revenues.[5] In the past, this Court has found that "merely economic" injuries, surpassing those alleged by the Coalition here, have not been sufficiently grave to constitute irreparable harm. See, e.g., Apotex, Inc. v. FDA, 2006 WL 1030151, at *16-17 (D.D.C. 2006) (loss in market sales of $9.9 million in one year out of total annual revenues of $700 million does not constitute irreparable harm); Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (loss in market sales of less than 1 percent of total sales does not constitute irreparable harm); Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 220-21 (D.D.C. 1996) (loss of .7 percent of total sales does not constitute irreparable injury).

---

may be true that an unrecoverable financial loss can constitute irreparable injury under some circumstances, it does not here. The cases cited by the Coalition are clearly distinguishable from the case at bar on the facts. See Hoffman-Laroche v. Califano, 453 F. Supp. 900, 901 (D.D.C. 1978) (challenged ceiling price would affect product that accounted for 99 percent of all sales of the class of drug); Serono Labs., Inc. v. Shalala, 974 F. Supp. 29, 35 (D.D.C. 1997) (alleged harm would result in loss that would amount to one quarter of the company's revenues); Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 28-29 (D.D.C. 1997) (alleged harm would result in "significant and irreparable" injury because plaintiffs were small companies).

[4] As reported in its 2007 Annual Report, GlaxoSmithKline's 2007 revenues were £22.716 billion, or approximately $39.762 billion in U.S. dollars. See GlaxoSmithKline Annual Report 2007, available at http://www.gsk.com/investors/reps07/annual-report-2007.pdf. Likewise, according to Sanofi-Aventis' 2007 Annual Review, its 2007 revenues were 28 billion €, or approximately $39 billion in U.S. dollars. See Sanofi-Aventis Annual Review 2007, available at http://en.sanofi-aventis.com/binaries/AR_2007_EN_tcm28-13665.pdf.

[5] The economic harm alleged by the Coalition flows from the interim rebate program. Such harm for these two drugs is actually likely to be even less, since DoD represented at the motions hearing that a final rule would be in place in January 2009.

Morever, the Coalition's estimates of harm are speculative. The speculative nature of the alleged harm is due, in part, to a lack of information regarding pricing and usage. See Pl.'s Repy Prelim. Inj. at 22 ("[T]he Coalition has no access to its members' confidential pricing information."). Thus, the Coalition has relied upon the material usage data provided by DoD, see Def.'s Mot. Dismiss, Exs. 3-4, and other publicly available information. Although the Court acknowledges the Coalition's difficulties, a lack of access to information about its own members does not lessen the Coalition's burden to demonstrate that its alleged harm is certain, great, actual, and imminent. See Wisconsin Gas, 758 F.2d at 674. Here, that burden is too great for the Coalition to overcome. Ultimately, the failure to satisfy its burden, and the Coalition's failure to demonstrate anything more than de minimis economic harm, is fatal to the Coalition's motion for the extraordinary relief of a preliminary injunction.

B. Likelihood of Success on the Merits

Given the Court's conclusion with respect to irreparable harm, it is not necessary to engage in a lengthy discussion of the remaining factors, but the Court will address them briefly. That discussion must begin with an assessment of the Coalition's likelihood of success on the merits.

The Court is persuaded that the Coalition has demonstrated some likelihood of success on the merits regarding its claim for a declaratory judgment that the Dear Manufacturer letter is invalid. See Compl. at 11. To begin with, the text of Section 703(b) of NDAA-08 is clear in requiring, through the use of the command "shall," the Secretary of Defense to "modify the regulations under [10 U.S.C. § 1074g(h)] to implement the requirements of [the new 10 § 1074g(f)]." Pub. L. 110-181, 122 Stat. 188 (2008). Although DoD has acknowledged that "[t]he

statute requires implementing regulations," 73 Fed. Reg. 43,394 (July 25, 2008), it nonetheless published formal notice of a proposed rule that was nearly identical in substance to the Dear Manufacturer letter and related materials. In the Court's view, DoD's statements and actions support the Coalition's position that the Dear Manufacturer letter was issued "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right within the meaning of 5 U.S.C. § 706(2)(C)." Compl. ¶ 27.

Moreover, the Dear Manufacturer letter appears to be a substantive rule within the meaning of the APA that should have been adopted through notice and comment rulemaking. Without addressing all of the parties' arguments on the topic, the Court is generally persuaded by the argument advanced by the Coalition that if the rebate program implemented by the Dear Manufacturer letter and related materials constitutes a statutorily authorized modification to the TRICARE Pharmacy Benefits Program regulations, set forth at 32 C.F.R. § 199.21, then it would necessarily have to issue through notice and comment rulemaking procedures. This conclusion stems from the proposition that "an amendment to a legislative rule must itself be legislative" and therefore subject to notice and comment requirements. See Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan, 979 F.2d 227, 235 (D.C. Cir. 1992); Am. Mining Congress v. Mine & Safety Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993) (a rule is legislative if it "effectively amends a prior legislative rule"); see also Sprint Corp. v. FCC, 315 F.3d 369, 374 (D.C. Cir. 2003) ("new rules that work substantive changes in prior regulations are subject to the APA's procedures").[6] The Court is not persuaded by DoD's contention that it must

[6] Moreover, in a slightly different context, the Federal Circuit held that a similar TRICARE rebate program established through a "Dear Manufacturer" letter was a substantive rule requiring notice and comment rulemaking. See Coal. for Common Sense, 464 F.3d at 1319.

implement the interim rebate program to comply with the mandate in Section 703 that TRICARE retail pharmacy prescriptions are subject to Federal Ceiling Prices, given that most drugs have not yet undergone a formulary review and therefore most TRICARE pharmacy prescriptions are still not subject to Federal Ceiling Prices. Thus, the Court finds that there is a likelihood that the Dear Manufacturer letter was issued "in violation of the notice and comment requirements of 5 U.S.C. § 553" and "without observance of procedure required by law within in the meaning of 5 U.S.C. § 706(2)(D)." Compl. ¶ 31.[7]

C. Balance of Harms and the Public Interest

Although the Coalition was not able to demonstrate any irreparable, or even significant, harm that would come about absent a preliminary injunction, DoD likewise cannot muster much of a showing of harm if the requested relief were to be granted. Chiefly, DoD asserts that it would be harmed from a preliminary injunction because "it would interfere with the government's ability to reduce its costs." Def.'s Mot. Dismiss at 40-41. This assertion is belied by the limited number of pharmaceutical manufacturers that have signed UF-VARRs, subject to Federal Ceiling Prices, relative to the total number of manufacturers that sell drugs on the uniform formulary at TRICARE network retail pharmacies. Indeed, at the motions hearing, DoD's counsel admitted that the number of rebate agreements awaiting execution by DoD that would be affected by a potential preliminary injunction was very small. Thus, even if a

[7] DoD moved to dismiss under Fed. R. Civ. P. 12 on two grounds: (1) that the complaint failed to state a claim upon which relief can be granted; and (2) that the Coalition lacks standing to bring this suit. On the first ground, the Court is not persuaded for the reasons stated in the discussion of the Coalition's likelihood of success on the merits. On the second ground, the Court is not persuaded on the present record that the Coalition lacks standing. The issue of standing may again be addressed on summary judgment based on a more complete record if DoD wishes to pursue it.

preliminary injunction were to issue, it would have almost no bearing on DoD's "ability to reduce its costs" because the agency would still be paying full commercial prices for drugs obtained through retail pharmacies that have yet to undergo formulary review in the wake of the Dear Manufacturer letter.

Likewise, the public interest does not tip the balance of interests in this case. DoD argues that a preliminary injunction would harm the public interest because taxpayer "dollars would be spent paying for drugs priced at above [Federal Ceiling Price] levels." Def.'s Mot. Dismiss at 41. Again, due to the limited number of pharmaceuticals actually impacted to date by the new rebate program, the extent of the harm to the taxpayers would be slight here, particularly in light of DoD's representation that final implementing regulations will be in place shortly. By contrast, the Coalition argues that a preliminary injunction would further the public interest by forcing DoD to comply with its statutory mandate. See Pl.'s Prelim. Inj. at 39-40. The Court is satisfied that it has considered the Coalition's public interest argument adequately as part of its analysis of the Coalition's likelihood of success on the merits.

CONCLUSION

For the foregoing reasons, the Court will deny the Coalition's motion for a preliminary injunction and will deny DoD's motion to dismiss. A separate order accompanies this memorandum opinion.

/s/
JOHN D. BATES
United States District Judge

Dated: September 19, 2008