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"). Section 703 of NDAA-08 requires that pharmaceuticals paid for by the Department of Defense ("Department" or "DoD") and provided through the TRICARE retail pharmacy program be subject to pricing standards known as Federal Ceiling Prices. The Department promulgated a final rule implementing section 703 on March 17, 2009. Under this rule, pharmaceutical manufacturers cannot receive more than the Federal Ceiling Prices for pharmaceuticals purchased by DoD for the retail pharmacy program, and must refund amounts in excess of the Federal Ceiling Prices for prescriptions filled on or after January 28, 2008. Plaintiff Coalition for Common Sense in Government Procurement ("Coalition") challenges the Department's rule, contending that it should be set aside under the Administrative Procedure Act because, inter alia, the Department erroneously interpreted NDAA-08 to require refunds by manufacturers to DoD and to require the statute's obligations to apply beginning on January 28,

2008. Before the Court are the parties cross-motions for summary judgment.[1]

I.

The Court, and the parties, have been here before. See Coal. for Common Sense in Gov't Procurement v. United States, 576 F. Supp. 2d 162 (D.D.C. 2008); see also Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affairs, 464 F.3d 1306 (Fed. Cir. 2006). A detailed retelling of the statutory and regulatory background animating this case is therefore unnecessary. Instead, it is appropriate now to focus on the Department's promulgation of the challenged rule.

Section 703 of NDAA-08 requires pharmaceuticals obtained through the TRICARE retail pharmacy program be subject to Federal Ceiling Prices. It provides in a new 10 U.S.C. § 1074g(f) that

> [w]ith respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the 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 it requires DoD, after consultation with other administering agencies, to "modify the regulations under [10 U.S.C. § 1074g(h)] to implement the requirements of [the new 10 U.S.C. § 1074g(f)]." National Defense Authorization Act for Fiscal Year 2008, Pub. L. 110-181, 122 Stat. 3, 188 (2008). In other words, section 703 requires that for any prescription filled on or after

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[1] Although the Coalition originally filed this suit to challenge an earlier DoD attempt at implementing 10 U.S.C. § 1074g(f), it amended its complaint to challenge the final rule. See Am. Compl. [Docket Entry 32].

January 28, 2008, the TRICARE retail pharmacy program is to be treated as an element of DoD for purposes of drug procurement to the extent necessary to ensure that drugs paid for by DoD are subject to Federal Ceiling Prices.

The Defense Department published a notice of proposed formal rulemaking to implement section 703 in July 2008. See 73 Fed. Reg. 43,394 (July 25, 2008). After receiving comments on the proposed rule, the Department published its final rule on March 17, 2009, to be effective May 26, 2009. See 74 Fed. Reg. 11,279 (March 17, 2009). The rule requires pharmaceutical manufacturers to honor section 703's obligation that "TRICARE retail pharmacy network prescriptions are subject to Federal Ceiling Prices." 32 C.F.R. § 199.21(q)(1)(ii).[2] The rule does so by prohibiting manufacturers from receiving amounts above the Federal Ceiling Prices for pharmaceuticals provided to the retail pharmacy program. See id.

Three provisions accomplish this outcome. First, the Defense Department and pharmaceutical manufacturers may enter into voluntary written agreements in which manufacturers agree "to honor the pricing standards required by 10 U.S.C. § 1074g(f)." Id. § 199.21(q)(2)(i). In these agreements, manufacturers "acknowledge the existence of the [Federal Ceiling Price] obligation and promise to meet it." 74 Fed. Reg. at 11,286. By recognizing the Federal Ceiling Price obligation, manufacturers also agree to refund payments in excess of this price for retail pharmacy program transactions occurring on or after the enactment of NDAA-08. See 32 C.F.R. § 199.21(q)(3)(i). If a manufacturer enters into a voluntary agreement, it receives

[2] The rule does not affect the rights or liabilities of any of the other parties that participate in the retail pharmacy program: wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries. See Pl.'s Mem. in Supp. of Pl.'s Mot. for Partial Summ. J. ("Pl.'s Mem.") [Docket Entry 44], at 4 (chart detailing the parties involved in a retail pharmacy program transaction).

market advantages: its pharmaceuticals may be considered for uniform formulary status, and may be available "through retail network pharmacies without preauthorization." Id. § 199.21(q)(2)(i).

Second, if a manufacturer does not agree to meet the Federal Ceiling Prices through such an agreement, but nevertheless provides pharmaceuticals through the retail pharmacy program, DoD may obtain refunds on transactions in excess of the Federal Ceiling Prices through a debt collection action. See id. § 199.21(q)(3)(i) ("Refund procedures . . . . may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to § 199.11."); see also id. § 199.11 (authority for debt collection under TRICARE). The Department may also obtain refunds from retail pharmacy program sales occurring on or after January 28, 2008, that were in excess of the Federal Ceiling Prices under the same authority. See id. § 199.21(q)(3)(iii); see also 74 Fed. Reg. at 11,286 ("[I]f a manufacturer was paid more than the [Federal Ceiling Price] . . . the transaction resulted in an overpayment . . . . To resolve the overpayment, the manufacturer must pay DoD a refund of the amount above the [Federal Ceiling Price]."). The Department, however, may waive or compromise the refund amount. See 32 C.F.R. § 199.21(q)(3)(iii)(A).

Finally, the manufacturer may escape the Federal Ceiling Prices altogether by voluntarily removing the drug "from coverage in the TRICARE Pharmacy Benefit Program." Id. § 199.21(q)(3)(iii)(C). In effect, the pharmaceutical manufacturer would not participate in the TRICARE program.

II.

Under Fed. R. Civ. P. 56(c), summary judgment is appropriate when the pleadings and the evidence demonstrate that "there is no genuine issue as to any material fact and that the

moving party is entitled to judgment as a matter of law." In a case involving review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 706, however, the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. See Prof'l Drivers Council v. Bureau of Motor Carrier Safety, 706 F.2d 1216, 1229 (D.C. Cir. 1983); Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89-90 (D.D.C. 2006). Under the APA, the agency resolves factual issues to arrive at a decision that is supported by the administrative record. Summary judgment is the mechanism for deciding whether as a matter of law the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971); Sw. Merchandising Corp. v. NLRB, 53 F.3d 1334, 1341 (D.C. Cir. 1995); Richard v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

A court must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), in excess of statutory authority, id. § 706(2)(C), or "without observance of procedures required by law," id. § 706(2)(D). The scope of review, however, is narrow. See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). It presumes the agency's action is valid. See Volpe, 401 U.S. at 415. And the "court is not to substitute its judgment for that of the agency." State Farm, 463 U.S. at 43. But the court must be satisfied that the agency has "'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" Alpharma, Inc. v. Leavitt, 460 F.3d 1, 6 (D.C. Cir. 2006) (quoting State Farm, 463 U.S. at 43).

III.

This Court reviews an agency's regulations according to the familiar two-step framework articulated in Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837 (1984). The first step determines "whether Congress has spoken directly to the precise question at issue," for if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id.; see also New Jersey v. EPA, 517 F.3d 574, 581 (D.C. Cir. 2008). If, however, the statute is silent or ambiguous on the specific issue, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron, 467 U.S. at 843.

When an agency's construction of a statute is challenged, its "interpretation need not be the best or most natural one by grammatical or other standards . . . . Rather [it] need be only reasonable to warrant deference." Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 702 (1991) (citations omitted). But deference "'is only appropriate when the agency has exercised its own judgment.'" Arizona v. Thompson, 281 F.3d 248, 251 (D.C. Cir. 2002) (quoting Phillips Petroluem Co. v. Fed. Energy Regulatory Comm'n, 792 F.2d 1165, 1169 (D.C. Cir. 1986)); see also Transitional Hosps. Corp. v. Shalala, 222 F.3d 1019, 1029 (D.C. Cir. 2000). "When . . . the agency's decision is based on an erroneous view of the law, its decision cannot stand." Transitional Hosps., 222 F.3d at 1029; see also SEC v. Chenery Corp., 318 U.S. 80, 94 (1943) (agency "order may not stand if the agency has misconceived the law").

Here, the parties raise two separate interpretive issues regarding 10 U.S.C. § 1074g(f). First, how may the Defense Department implement the statute's requirement that the Department not pay in excess of the Federal Ceiling Prices for pharmaceuticals sold through the TRICARE

retail pharmacy program? See, e.g., Pl.'s Mem. at 1; Def.'s Mem. in Supp. of Partial Summ. J. and Opp'n ("Def.'s Mem.") [Docket Entry 46], at 1. Second, may the Department obtain refunds from manufacturers on transactions in excess of the Federal Ceiling Prices occurring on or after January 28, 2008, but before the effective date of the final rule? See, e.g., Pl.'s Mem. at 1; Def.'s Mem. at 2. The Court takes each issue in turn.

A.

1.

The Court begins with Chevron step one, and the question whether 10 U.S.C. § 1074g(f) mandates that DoD must adopt a particular regulatory scheme. The Coalition contends that it does not. See, e.g., Pl.'s Mem. at 19 (NDAA-08 provides "no mechanism for applying Federal Ceiling Prices to retail pharmacy sales until DoD made policy choices in a final rule"); id. ("The NDAA could not be implemented until DoD chose who should bear the burden of the Federal Ceiling Price standards (and how)."); Summ. J. Hr'g Tr. 4:5-9, October 16, 2009 ("All of the defects in the final rule ultimately tie back to a fundamental error by the DoD, which is the legal conclusion that the NDAA, by operation of law, imposes an automatic legal requirement as of the date of enactment for manufacturers to pay rebates [to] DoD.").

The Department's interpretation of the statute is less clear. In its litigation papers and at the motion hearing, the Department suggests that the provisions of the final rule resulted from the exercise of its discretion. See, e.g., Def.'s Mem. at 14 ("DoD relied upon its expertise in crafting the provisions of the Final Rule."); id. at 15 (the regulation "is analyzed under step two of the Chevron framework because Congress has not spoken directly to the precise question at issue"); Def.'s Reply in Supp. of Def.'s Mot. for Summ. J. ("Def.'s Reply") [Docket Entry 52], at 5 ("The

actual text of the Final Rule and its Preamble are more than sufficient to prove that DoD exercised its discretion and that the Final Rule is a product of DoD's bringing its experience and expertise to bear in light of competing interests at stake." (quotation omitted)); Summ. J. Hr'g Tr. at 33:18-23 ("The Court: Do you agree with me that a manufacturer refund is not required under the statute? [DoD counsel]: I guess I do agree with that . . . ."); id. at 33:1-2 ("The agency exercised its discretion here . . . .").

But the Department suggested quite the opposite in the rule's preamble:

> DoD interprets the statute as establishing the fact of an overpayment and the need for a refund. These things are not dependent on the agreement to exist; they exist by operation of law under the statute.

74 Fed. Reg. at 11,286 (emphasis added). That view of the law is repeated at several points in the preamble. See, e.g., id. at 11,284 ("Therefore, with respect to prescriptions on or after January 28, 2008, drug companies had a right to payment at the Federal Ceiling Price and no more."); id. ("[I]f a manufacturer received more than the Federal Ceiling Price, the transaction produced an overpayment and an overpayment requires a refund."); id. ("Honoring the statute includes refunding overpayments that accrued on or after January 28."); id. at 11,286 ("To resolve the overpayment, the manufacturer must pay DoD a refund of the amount above the FCP."). The thrust of the preamble to the rule, then, is that DoD viewed NDAA-08 as mandating manufacturer refunds. See Summ. J. Hr'g Tr. at 32:13-14 (nothing in the preamble is inconsistent with this conclusion that refunds "exist by operation of law under the statute").

The plain language of 10 U.S.C. § 1074g(f) confirms the Coalition's interpretation -- and the Department's more recent position offered in its briefs and at the motion hearing. The inquiry begins with the statutory language. See Carcieri v. Salazar, 129 S. Ct. 1058, 1063-64 (2009);

United States v. Gonzales, 520 U.S. 1, 4 (1997). The statute requires only that "the TRICARE retail pharmacy program . . . be treated as an element of the Department of Defense for purposes of procurement . . . to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense . . . are subject to the [Federal Ceiling Prices]." 10 U.S.C. 1074g(f). DoD is instructed to modify its regulations to implement this statutory requirement. See National Defense Authorization Act for Fiscal Year 2008, Pub. L. 110-181, 122 Stat. 3, 188 (2008). By its plain terms, then, the statute does not establish a particular regulatory scheme. Congress has not dictated that manufacturers must pay the costs associated with the Federal Ceiling Prices, or that they must refund proceeds in excess of this price on retail pharmacy program transactions. Nor has Congress even indicated which of the five parties that participate in the retail pharmacy program -- manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries -- must bear any costs associated with imposing the Federal Ceiling Prices. Rather, Congress commanded DoD to promulgate regulations to achieve the statute's goals. In doing so, Congress provided "an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." Chevron, 467 U.S. at 843-44. Hence, the plain language and structure of 10 U.S.C. § 1074g(h) indicate that Congress did not speak to the "precise question" of how the Department should implement the statute's requirements.

Indeed, the Court can imagine several other regulatory schemes consistent with 10 U.S.C. § 1074g(f) that the Department could have chosen. For example, instead of requiring pharmaceutical manufacturers to pay DoD the amounts in excess of the Federal Ceiling Prices, a rule could require manufacturers to reduce the price on retail pharmacy program pharmaceuticals prospectively until the excess proceeds were reimbursed. Or DoD arguably could have adjusted

the retail pharmacy mark-ups or dispensing fees to ensure that the Department did not pay more than the Federal Ceiling Prices. The Coalition suggests two additional possibilities: "DoD could have contracted with pharmacies to purchase TRICARE beneficiaries' drugs . . . at the Federal Ceiling Price," or "DoD could have procured drugs directly from manufacturers at the Federal Ceiling Price and then distributed the drugs to pharmacies." Pl.'s Mem. at 19-20. Although these methods may not be the best approach -- or even practical -- the statute certainly does not preclude them. The Department implicitly concedes as much. See Def.'s Reply at 7.

2.

Having concluded that the statutory language does not speak to precisely how the Department should implement the statute, the Court ordinarily would move to Chevron step two, and ask whether the agency's interpretation of the statute is reasonable. See Chevron, 467 U.S. 843; Transitional Hosps., 222 F.3d at 1028. The Coalition contends, however, that the Court cannot do so here because the rule's preamble reveals that the agency mistakenly believed that Congress mandated the requirement of a manufacturer refund. See Pl.'s Mem. at 16 ("DoD announced its view that the NDAA requires manufacturers to pay rebates by operation of law . . . ." (citing 74 Fed. Reg. at 11,286)).

The discretion accorded to agencies under Chevron in interpreting a statute "must be exercised through the eyes of one who realizes he possesses it." Transitional Hosps., 222 F.3d at 1029. Therefore, an agency regulation is invalid "if it 'was not based on the agency's own judgment but rather on the unjustified assumption that it was Congress' judgment that such a regulation is desirable'" or mandated. Prill v. Nat'l Labor Relations Bd., 755 F.2d 941, 948 (D.C. Cir. 1985) (quoting FCC v. RCA Commc'ns, 346 U.S. 86, 96 (1953)); see also Peter Pan Bus

Lines, Inc. v. Fed. Motor Carrier Safety Admin., 471 F.3d 1350, 1354 (D.C. Cir. 2006); Thompson, 281 F.3d at 259; Transitional Hosps., 222 F.3d at 1029. This is so "even though the agency might be able to adopt the regulation in the exercise of its discretion." Prill, 755 F.2d at 948; see also Thompson, 281 F.3d at 259.

Here, the Department has offered two opposing interpretations of 10 U.S.C. § 1074g(f). Whereas the rule's preamble indicates quite plainly that the Department interpreted 10 U.S.C. § 1074g(f) to mandate the manufacturer refund provisions adopted at 32 C.F.R. § 199.21(q), the Department's briefing and arguments at the motions hearing suggest that it adopted the rule's provisions through an exercise of its discretion.[3] The Court, however, cannot credit the explanations the Department offers in its briefing and at the motions hearing -- "those [arguments] cannot save the rule." Public Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209, 1218 (D.C. Cir. 2004). "The expertise of the agency, not its lawyers, must be brought to bear on this issue in the first instance." Id. And "'[t]he courts may not accept . . . counsel's post hoc rationalizations for agency [regulations].'" Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 212 (1988) (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); see also Chenery Corp., 318 U.S. at 87-88 (courts must confine "review to a judgment upon the validity of the grounds upon which the [agency] itself based its action").

[3] At the motions hearing, the Department attempted to reconcile these disparate explanations, offering that in the preamble the Department simply was "interpreting the statute." Summ. J. Hr'g Tr. at 32:6-7. The Court is not convinced. The mere fact that the agency "interpreted" the statute is of no moment. An agency must always "interpret" a statute, both where the statute commands a particular result and where the agency implements the statute through the exercise of its discretion. The point here is how the agency interpreted section 1074g(f) when it promulgated the implementing rule.

Hence, the Department's only relevant interpretation of 10 U.S.C. § 1074g(f) is the one advanced in the rule's preamble -- manufacturers are subject to the refund obligations of the statute "by operation of law." 74 Fed. Reg. at 11,286. Notably, the Department admits that nothing in the preamble contradicts this position. See Summ. J. Hr'g Tr. at 32:13-14. And indeed, as reviewed above, there is much in the preamble reflecting this erroneous interpretation by DoD at the time it promulgated the rule. See, e.g., 74 Fed. Reg. at 11,284, 11,286.

Because the statutory language and structure conclusively demonstrate that DoD's interpretation as reflected in the preamble is incorrect, the agency's decision cannot stand and the Court must remand the rule to the Department. See Prill, 755 F.2d at 948; see also Thompson, 281 F.3d at 253, 259; Transitional Hosps., 222 F.3d at 1029. On remand, the Department should determine whether to adopt the current iteration of the rule (or some other approach) through the exercise of its discretion. See Transitional Hosps., 222 F.3d at 1029 (on remand "the Secretary must make a fresh determination as to whether she wishes to adopt the [same regulatory scheme]").

B.

The Court now returns to Chevron step one to examine the second issue before the Court: DoD's conclusion that 10 U.S.C. § 1074g(f) requires manufacturers to refund proceeds from retail pharmacy program sales in excess of the Federal Ceiling Prices occurring between January 28, 2008, and the rule's effective date of May 26, 2009. The relevant statutory language is quite brief: all TRICARE retail pharmacy program drug sales are subject to the Federal Ceiling Prices "[w]ith respect to any prescription filled on or after the date of the enactment of [NDAA-08]." 10 U.S.C. § 1074g(f). The Department interpreted this language to require that all retail

pharmacy program prescriptions must be subject to the Federal Ceiling Prices beginning on NDAA-08's date of enactment -- January 28, 2008. See 74 Fed. Reg. at 11,284 ("DoD interprets section 703 as precluding any start date for applying [the Federal Ceiling Prices] to covered Retail Pharmacy Network prescriptions filled other than the date of enactment, January 28, 2008." (emphasis added)); id. ("Nothing in the rule . . . will operate to change the legal landscape that was created, effective January 28, by the statute."); id. at 11,283 ("The date of enactment is clearly established as the 'implementation date' of the statutory requirement.").

Not so, according to the Coalition. Because the statute "does not mandate any rebate payments by manufacturers . . . , the statute plainly does not mandate rebate payments by manufacturers as to particular transactions." Pl.'s Mem. at 26. But this contention misapprehends the issue. The question is not whether the statute mandates manufacturer refunds beginning on January 28, 2008. Rather, the precise question is whether the statute's requirement that TRICARE drug prescriptions are subject to the Federal Ceiling Prices -- however implemented by the agency -- is active on January 28, 2008, or only once DoD promulgates a rule to implement the statute.

On this latter question, the statutory language is clear: "With respect to any prescription filled on or after the date of the enactment of [NDAA-08]," pharmaceuticals purchased through the retail pharmacy program are subject to the Federal Ceiling Prices. 10 U.S.C. § 1074g(f) (emphases added). "The word 'any' is usually understood to be all inclusive." Fin. Planning Ass'n v. SEC, 482 F.3d 481, 488 (D.C. Cir. 2007); see also New York v. EPA, 443 F.3d 880, 885 (D.C. Cir. 2006) (same). Therefore, the most natural reading of the statute is that all prescriptions "filled on or after" January 28, 2008, are subject to the statutory language applying

the Federal Ceiling Prices to retail pharmacy program transactions. In other words, the "on or after" clause modifies the rest of the statute -- the grammatical structure mandates that Federal Ceiling Prices apply beginning on January 28, 2008. See United States v. Ron Pair Enters., Inc., 489 U.S. 235, 241 (1989).

The Coalition, however, suggests that the "on or after" language refers only to "the point at which the TRICARE retail pharmacy program . . . must be treated . . . as an element of DoD that does procure drugs." Pl.'s Mem. at 37. Under its reading, "[o]nce the TRICARE retail pharmacy program is treated as a procurement program, there are actions . . . that are necessary to implement the Federal Ceiling Price standards with respect to specific prescription transactions." Id. DoD must create "the particular mechanism through which it will apply the standard" and enter "contractual agreements pursuant to the regulation." Id.

But the Coalition's suggested interpretation contravenes the plain structure of the statute, which expressly makes all prescriptions filled after the date of enactment of NDAA-08 subject to the Federal Ceiling Prices. The Coalition ignores the fact that the phrase "the TRICARE retail pharmacy program . . . be treated as an element of the Department of Defense for purposes of procurement" is not an independent clause. Instead, it is a part of a longer clause defining how DoD may apply the Federal Ceiling Prices to the retail pharmacy program. And the Coalition's interpretation ignores the fact that the retail pharmacy program's treatment as an element of the Defense Department is not a free-standing statutory component. Rather, it is a mechanism to ensure that the retail pharmacy program pharmaceutical sales are subject to the Federal Ceiling

Prices.[4] See 10 U.S.C. § 1074g(f) (TRICARE retail pharmacy is treated as an element of DoD only "to ensure that pharmaceuticals paid for by the Department of Defense . . . are subject to" the Federal Ceiling Prices).

Nor is the Coalition's interpretation saved by reference to the Medicaid rebate statute. See 42 U.S.C. § 1396r-8. The Coalition contends that the Medicaid statute also has an "on or after" provision, but that provision "does not establish the date that a manufacturer's rebate liability attaches." Pl.'s Mem. at 38; see 42 U.S.C. § 1396r-8(a)(2) ("Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991."). But the Medicaid rebate statute creates a detailed scheme tying rebate liability to the date on which a state and a pharmaceutical manufacturer enter into a rebate agreement. See 42 U.S.C. § 1396r-8(a)(1). Although the first date on which rebate liability can attach is January 1, 1991, the statute explicitly details situations in which rebate liability may attach at a later date. See id. (for rebate agreements entered into after March 1, 1991, rebates begin on date agreement was entered into; for rebate agreements entered into between January 1 and March 1, 1991, rebates begin on January 1, 1991). Section 1074g(f) creates no such scheme, and therefore the Medicaid rebate statute is inapposite to interpreting the statute here.

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[4] The Coalition ties its alternative interpretation to the contention that the statute requires "DoD to enter into contractual agreements pursuant to the regulation, the terms of which would govern future prescription transactions. It is this agreement with DoD . . . that triggers application of the Federal Ceiling Price standards under [NDAA-08]." Pl.'s Mem. at 37-38. But this conclusion ignores the statutory language -- nowhere does the statute require a contractual agreement between DoD and a pharmaceutical manufacturer to implement the Federal Ceiling Prices. Indeed, such a requirement is belied by the conclusion that 10 U.S.C. § 1074g(f) does not mandate a particular regulatory scheme, as the Court has now found.

DoD is correct, then, that section 1074g(f) requires that Federal Ceiling Prices apply to all retail pharmacy program prescriptions filled on or after January 28, 2008.[5] But, the Coalition contends, this creates a second problem -- to the extent that 10 U.S.C. § 1074g(f)'s requirements apply beginning on January 28, 2008, any party subject to the Federal Ceiling Prices would not be on notice of this obligation until after DoD promulgates a final rule.[6] See Pl.'s Mem. at 34-35. Accordingly, the Coalition asserts, requiring any party to pay refunds for transactions occurring before the rule's effective date is impermissibly retroactive because "it affects past conduct or transactions." Id. at 34 (citing Nat'l Mining Ass'n v. Dep't of Interior, 177 F.3d 1, 8 (D.C. Cir. 1999)).

The Coalition is not persuasive on this point. "Retroactive rules 'alter the past legal consequences of past actions.'" Mobile Relay Assocs. v. FCC, 457 F.3d 1, 11 (D.C. Cir. 2006) (quoting Bowen, 488 U.S. at 219 (Scalia, J. concurring)). But where an agency rule "alters the future effect, not the past legal consequences of an action," id. (quotation omitted), or only "upsets expectations based on prior law," DIRECTV, Inc. v. FCC, 110 F.3d 816, 826 (D.C. Cir. 1997) (quotation omitted), then the rule is not retroactive. Here, all parties related to the retail pharmacy program -- manufacturers, wholesalers, network pharmacies, private pharmacy benefit

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[5] Congress therefore does not have to expressly grant the Department the authority to promulgate a retroactive rule. See Pl.'s Mem. at 40-41. The statute itself made the Federal Ceiling Prices applicable to retail pharmacy transactions beginning on January 28, 2008. The Department's rule simply reflects Congress's express command.

[6] The Coalition asserts this argument in the context of challenging the rule's requirement of manufacturer refunds. This specific challenge is mooted by the Court's conclusion that DoD erroneously interpreted 10 U.S.C. § 1074g(f) to require these refunds. But the general argument remains. Because the Court concludes that Congress intended the statute to be effective on January 28, 2008, as the statute plainly states, it is appropriate to address this argument now.

managers, and beneficiaries -- were aware on January 28, 2008, that 10 U.S.C. § 1074g(f) applied the Federal Ceiling Prices to retail pharmacy program transactions as of that date. The statute plainly says so. Thus, all parties participated in the retail pharmacy program thereafter with the knowledge that their transactions would be statutorily subject to Federal Ceiling Prices and could be governed by a future rule implementing 10 U.S.C. § 1074g(f). It is the statute, not the rule, which made transactions on or after January 28, 2008, subject to Federal Ceiling Prices -- the rule only identifies how that statutory requirement is implemented. Hence, no retroactivity problem is presented.

Even if any single party involved in the retail pharmacy program did not expect to face refund liability under a final rule, "a new rule is not retroactive 'merely because it . . . upsets expectations based on prior law.'" DIRECTV, 110 F.3d at 826 (quoting Landgraf v. USI Film Prods., 511 U.S. 244, 269 (1994)); see also Landgraf, 511 U.S. at 269 n.24 ("Even uncontroversially prospective statutes may unsettle expectations and impose burdens on past conduct . . . ."). Indeed, "[i]t is often the case that a business will undertake a certain course of conduct based on the current law, and will then find its expectations frustrated when the law changes." Chem. Waste Mgmt. v. EPA, 869 F.2d 1526, 1536 (D.C. Cir. 1989). But "[s]uch expectations, however legitimate, cannot furnish a sufficient basis for identifying impermissibly retroactive rules." Nat'l Cable & Telecomm. Assoc. v. FCC, 567 F.3d 659, 670 (D.C. Cir. 2009).[7] Hence, any rule that DoD might promulgate apportioning the burden of the Federal

[7] Nor can the Coalition assert that the rule is retroactive merely because it "changes the legal landscape." Nat'l Mining Ass'n v. Dep't of Labor, 292 F.3d 849, 859 (D.C. Cir. 2002). "[I]f that were all it took to render a rule impermissible under the APA, it would spell the end of informal rulemaking." Nat'l Cable & Telecomm. Ass'n, 567 F.3d at 670.

Ceiling Prices for transactions occurring on or after January 28, 2008, but before a final rule, merely "impair[s] the future value of past bargains but has not rendered past actions otherwise sanctionable." Id. Therefore, the rule implementing 10 U.S.C. § 1074g(f) is not impermissibly retroactive on this basis either.

IV.

Because DoD improperly interpreted 10 U.S.C. § 1074g(f) to require manufacturer refunds, the Court must remand for the agency to reassess the implementing regulations based on a proper understanding of the law. There remains the question, however, whether remand should be with or without vacatur. The Coalition contends that the Court should vacate the final rule and set aside all the actions taken under it. See Pl.'s Opp'n to Def.'s Mot. for Partial Summ. J. and Reply [Docket Entry 49], at 32, 34. Vacatur, however, is not always necessary. See Louisiana Fed. Land Bank Ass'n. v. Farm Credit Admin., 336 F.3d 1075, 1085 (D.C. Cir. 2003). "The decision whether to vacate depends on [1] 'the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and [2] the disruptive consequences of an interim change that may itself be changed.'" Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n, 988 F.2d 146, 150-51 (D.C. Cir. 1993) (quoting Int'l Union, United Mine Workers v. Fed. Mine Safety and Health Admin., 920 F.2d 960, 967 (D.C. Cir. 1985)). Here, that assesment counsels against vacatur of the rule.

The agency's erroneous interpretation of 10 U.S.C. § 1074g(f) is unquestionably a material deficiency in the regulation. But the interpretation was erroneous only because the agency concluded that Congress mandated a particular regulatory approach that the agency might nevertheless be able to adopt in the exercise of its discretion. See Prill, 755 F.2d at 948 (remand

automatic in cases even where the agency might ultimately readopt the rule). Therefore, there remains a "serious possibility" that the Secretary on remand could justify the rule challenged here "in a manner that is consistent with the statute" -- "a factor that favors remanding rather than vacating." Milk Train, Inc. v. Veneman, 310 F.3d 747, 756 (D.C. Cir. 2002); see also Fox Television Stations, Inc. v. FCC, 280 F.3d 1027, 1049 (D.C. Cir. 2002) (vacatur inappropriate where not "unlikely" agency "will be able to justify a future decision to retain the rule"), reh'g granted on other issue, 293 F.3d 537 (D.C. Cir. 2002); Louisiana Fed. Land Bank, 336 F.3d at 1085 (same); WorldCom, Inc. v. FCC, 288 F.3d 429, 434 (D.C. Cir. 2002) (remand without vacatur where "non-trivial likelihood" that agency would be able to justify rule on remand). Here, DoD may conclude on remand that the statute permitted it to adopt the rule -- a plausible result given DoD's prior interpretation that the statute required the rule and more recent position that the refund approach set out in the rule was promulgated in the Department's discretion. See Heartland Reg'l Med. Ctr., 566 F.3d at 198 ("When an agency may be able readily to cure a defect in its explanation of a decision, the first factor in Allied-Signal counsels remand without vacatur.").

The second Allied-Signal factor -- the disruptive effect of vacatur -- also weighs in favor of remand without vacatur. Vacating the rule would require the Department to reimburse the refunds pharmaceutical companies have now paid to the Department under various agreements. And if the rule is repromulgated in its current form, the Department would once again have to collect refunds pursuant to 10 U.S.C. § 1074g(f) for all prescriptions filled on or after January 28, 2008. Such potential disruptions strongly counsel remand without vacatur. See Allied-Signal, 988 F.2d at 151 (vacatur disruptive where agency would have to refund fees already collected).

Indeed, to do otherwise could seriously, and adversely, affect continuing operation of the TRICARE retail pharmacy program. Moreover, vacatur would potentially render unenforceable the voluntary agreements that the Department and pharmaceutical manufacturers have entered into following promulgation of the rule. These agreements cover almost all of the pharmaceuticals currently dispensed through the TRICARE retail pharmacy program. See Def.'s Reply at 14 n.9 (99% of pharmaceuticals covered by voluntary agreements); Summ. J. Hr'g Tr. at 3:16-17 (Coalition has no "reason to disagree with those figures"). The Court need not wipe out this comprehensive voluntary scheme and set off the substantial disarray that would inevitably follow. See Louisiana Fed. Land Bank, 336 F.3d at 1085 ("[V]acatur is sure to be 'disruptive' because it would preclude a set of voluntary transactions [that the parties] find advantageous.").[8] In light of the Allied-Signal factors, then, the Court concludes that the better remedy is to remand to the agency without vacating the rule and any actions taken pursuant to it.

V.

The Court concludes that DoD erroneously interpreted 10 U.S.C. § 1074g(f) to mandate manufacturer refunds as provided in the agency's final rule. Because of this erroneous view of

[8] To be sure, the D.C. Circuit has suggested that remand without vacatur might be inappropriate where the court does not reach "the bulk" of a party's "potentially meritorious challenges." Cement Kiln Recycling v. EPA, 255 F.3d 855, 872 (D.C. Cir. 2001); see also Natural Resources Def. Council v. EPA, 489 F.3d 1250, 1262 (D.C. Cir. 2007). But this concern is present only where Allied-Signal does not counsel remand without vacatur. See, e.g., Natural Resources Def. Council, 489 F.3d at 1261 (remand-only disposition improper because unlikely that EPA can justify rule on remand); Cement Kiln, 255 F.3d at 866, 872 (remand-only disposition inappropriate because EPA must create new regulatory scheme). Here, the Allied-Signal factors strongly favor remand without vacatur. Moreover, the Court has reached the Coalition's primary challenges, and at least some of the Coalition's remaining challenges may be mooted by the Court's order here. See, e.g., Pl.'s Mem. at 41-44 (rule violates notice and comment procedures).

the law, under controlling D.C. Circuit precedent this Court must remand for the agency to consider whether it wishes to implement the regulatory scheme as an exercise of its discretion or instead to promulgate a different rule. Under governing D.C. Circuit authority, vacatur of the rule along with remand is not warranted. DoD, however, correctly interpreted the statute to require Federal Ceiling Prices to apply to retail pharmacy program transactions occurring on or after January 28, 2008. A separate order has been issued on this date.

/s/ John D. Bates
JOHN D. BATES
United States District Judge

Date: November 30, 2009