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,

Defendants.

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 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 were required to refund amounts received in excess of the Federal Ceiling Prices for pharmaceuticals paid for by DoD in the retail pharmacy program or after January 28, 2008. This Court previously concluded that, in promulgating this rule, DoD erroneously interpreted the statute to mandate manufacturer refunds. The Court remanded for DoD to consider whether it wished to implement manufacturer refunds as an exercise of its discretion or instead promulgate a different rule. On remand, the Department considered a variety of alternatives before

eventually issuing a rule on October 7, 2010 that was, for the most part, identical to the prior rule. Plaintiff Coalition for Common Sense in Government Procurement again challenges the rule on the grounds that DoD lacks authority under NDAA-08 to require refunds from manufacturers that have not voluntarily agreed to them.[1] The Coalition also argues that the Department does not have authority to require refunds on transactions occurring before the promulgation of the rule. Now before the Court are the parties' cross-motions for summary judgment. For the reasons set out below, the Court will grant summary judgment in favor of the Department.

I. Introduction

The Court and the parties have been here several times before. See Coal. for Common Sense in Gov't Procurement v. United States, 671 F. Supp. 2d 48 (D.D.C. 2009); 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). The Court will therefore not retell the history of this case at length, but instead will proceed directly to the background relevant to the Coalition's latest challenge to the rule.

DoD provides pharmaceuticals to beneficiaries through the TRICARE Pharmacy Benefits Program. Beneficiaries receive drugs through four "points of service": Military Treatment Facilities, the TRICARE Mail Order Pharmacy, private retail network pharmacies (the "TRICARE Retail Pharmacy Network"), and private retail non-network pharmacies. See 74 Fed. Reg. 11,279, 11,279 (March 17, 2009); Pl.'s Mot. for Summ. J. ("Pl.'s SJ Mot.") [Docket Entry

[1] The Coalition originally filed this suit to challenge the earlier DoD action implementing NDAA-08, but has amended its complaint to challenge the most recent rule. See Second Am. Compl. [Docket Entry 71].

72] at 1-2. Drugs provided to beneficiaries by Military Treatment Facilities and the TRICARE Mail Order Pharmacy are procured by DoD directly from manufacturers or distribution agents. See Pl.'s SJ Mot. at 2. By contrast, drugs provided to beneficiaries by pharmacies are sold through commercial supply chains from manufacturers to the pharmacies; DoD pays its share of the cost to pharmacies, by way of a pharmacy benefits manager, rather than directly to manufacturers or distribution agents. See 75 Fed. Reg. 63,383, 63,385 (Oct. 15, 2010). This case concerns pharmaceuticals provided to beneficiaries by network pharmacies.

Section 703 of NDAA-08 required that pharmaceuticals obtained through the TRICARE retail pharmacy program be subject to Federal Ceiling Prices. It provided 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 the statute 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).[2]

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[2] 10 U.S.C. § 1074g(f) has since been amended to replace the words "on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008" with the words "after January 28, 2008," which was the date of enactment of NDAA-08. National

The Department published the original regulation ("2009 rule") implementing NDAA-08 on March 17, 2009. 74 Fed. Reg. at 11,279. In response to the Court's remand of that rule, the Department published a notice soliciting comment on both the 2009 rule and other approaches to the regulation. See 75 Fed. Reg. 6,335 (Feb. 9, 2010). After considering these comments and several alternatives, the Department decided to reissue the regulation ("2010 rule") with only minor changes to the 2009 rule. See 75 Fed. Reg. at 63,383.

The 2010 rule, like its predecessor, 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). 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. By contrast, the rule does not affect the rights or liabilities of other parties to the program (wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries). See 75 Fed. Reg. at 63,388-91. Three provisions – again, virtually identical in both iterations of the rule – accomplish this outcome.

First, the 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

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Defense Authorization Act for Fiscal Year 2010, Pub. L. No. 111-84, 123 Stat. 2190, 2473 (2009). The parties do not contend that this revision affects the outcome of this case.

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 advantageous treatment in the program.[3]

Second, if a manufacturer does not agree to meet the Federal Ceiling Prices through such an agreement, but nevertheless provides pharmaceuticals to beneficiaries through network pharmacies, DoD may obtain refunds from manufacturers for transactions in which the manufacturer has received prices in excess of the Federal Ceiling Prices. These refunds are obtained either through a separate agreement with the manufacturer or through a debt collection agency. 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 obtain refunds from retail pharmacy program sales occurring on or after January 28, 2008 (the date of NDAA-08's enactment) that were in excess of the Federal Ceiling Prices. 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 Federal Ceiling Prices altogether by voluntarily removing the drug "from coverage in the TRICARE Pharmacy Benefit Program." Id. § 199.21(q)(3)(iii)(C). Under this provision, a manufacturer may remove one or some of its drugs

[3] The pharmaceuticals that are the subject of the agreement may be considered for uniform formulary status and may be available "through retail network pharmacies without preauthorization." Id. § 199.21(q)(2)(i).

from TRICARE without removing all of its pharmaceuticals. See 75 Fed. Reg. at 63,395 ("The opt-out provision continues to be on a drug-by-drug basis.").

The 2010 rule left these provisions of the 2009 rule intact. The 2010 rule also made some relatively minor adjustments to the rule that do not affect the outcome of this case.[4]

II. Summary Judgment Standard

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

[4] The substantive change between the rules regards the treatment of manufacturers that either provide pharmaceuticals through the retail pharmacy program without a voluntary written agreement or that request waiver or compromise of a refund amount. Under the 2009 rule, manufacturers that provided pharmaceuticals without a written agreement with the Department were subject to the same remedy as manufacturers who made such an agreement but failed to honor it: the Director of TRICARE is authorized to "take any other action authorized by law" against such manufacturers. 32 C.F.R. § 199.21(q)(4); see 75 Fed. Reg. at 63,395. In response to comments from the pharmaceutical industry that choosing not to make an agreement is not the same as making and then failing to honor an agreement, the 2010 rule no longer subjects manufacturers that do not make voluntary agreements to this remedy. See 75 Fed. Reg. at 63,395-96. Furthermore, under the 2010 rule, when a manufacturer requests waiver or compromise of a refund amount, that manufacturer is not, while the request is pending, considered to be in noncompliance with its obligations regarding the request's subject matter. 32 C.F.R. § 199.21(q)(3)(B); see 75 Fed. Reg. at 63,396.

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. Merch. 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). The agency's action is presumed 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. Analysis

This Court reviews an agency's regulations according to the familiar two-step framework articulated in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). Step one 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). Especially relevant here, "[i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." Chevron, 467 U.S. at 842-43.

At step two of the Chevron dance, "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. See also, e.g., Nat'l R.R. Passenger Corp. v. Bos. & Me. Corp., 503 U.S. 407, 417-418 (1992). In determining whether the agency's construction of the statute is reasonable, a court looks to its consistency with the statute's language and purpose. "The 'reasonableness' of an agency's construction depends on the construction's 'fit' with the statutory language as well as its conformity to statutory purposes." Abbott Labs. v. Young, 920 F.2d 984, 988 (D.C. Cir. 1990).

At this stage of the litigation, the Coalition presents two objections to the Department's regulations under 10 U.S.C. § 1074g(f). First, the Coalition argues that "DoD lacks statutory authority under the NDAA-08 to require price rebates from manufacturers without their express voluntary agreement to pay." Pl.'s SJ Mot. at 13. Second, the Coalition argues in the alternative that even if the manufacturer refund requirement is lawful, "DoD exceeded its statutory authority by imposing rebate liability for prescription transactions prior to the effective date of the 2010 rule." Id. at 39.

A. The Rule

1. Chevron Step One Argument

The Court begins with whether the Department has the authority to require refunds from manufacturers without their explicit agreement. The Coalition has primarily focused its attention on Chevron step one, contending that the statute requires an "express voluntary agreement"

between a manufacturer and the Department before a rebate may be imposed. The Coalition presents four arguments in support of this assertion. The first two rely on the statute's text and the last two regard Congressional intent.

First, the Coalition notes that NDAA-08 references Federal Ceiling Prices by means of a cross-reference to the Veterans Health Care Act (38 U.S.C. § 8126). NDAA-08 states that "pharmaceuticals paid for by the Department of Defense" are "subject to the pricing standards in such section 8126." The Veterans Health Care Act limits to Federal Ceiling Prices the amount that DoD may pay manufacturers for drugs it procures directly (for provision to beneficiaries at Military Treatment Facilities and the TRICARE Mail Order Pharmacy).[5] 38 U.S.C. § 8126(a)(2). Significantly, the Coalition argues, section 8126 provides not only that prices shall be limited to Federal Ceiling Prices, but also that the actual prices shall be set by means of a "master agreement" between manufacturers and the government. Id. § 8126(a). Therefore, the Coalition argues, "[a]n inherent feature of the section 8126 pricing standards is that they are only binding and enforceable on manufacturers if they voluntarily enter into a series of express bilateral agreements." Pl.'s SJ Mot. at 15.

Second, the Coalition notes that NDAA-08 refers in three instances to the retail pharmacy program as "procurement" of pharmaceuticals. The beginning of the operative sentence of NDAA-08 states that "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." Furthermore, two statutory headings in NDAA-08 refer to the "procurement" of pharmaceuticals

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[5] This limit also applies to the Department of Veterans Affairs, the Public Health Service, and the Coast Guard. 38 U.S.C. § 8126(b).

by the TRICARE retail pharmacy program. When DoD engages in "procurement," the Coalition contends, the Department "necessarily establishes a price through the seller's submission of a bid price or a negotiated price agreement." Pl.'s SJ Mot. at 17. The Coalition argues that the Department has turned the beginning of the sentence into surplusage by failing to give effect to this language of "procurement" and the reference to "section 8126."

Third, regarding Congressional intent, the Coalition argues that Congress intended the TRICARE Retail Pharmacy to incorporate "best business practices." Although the phrase is not mentioned in NDAA-08 or its legislative history, the current structure of TRICARE originated from a Congressional redesign of the program in the late 1990s intended to incorporate "best business practices." See Pl.'s SJ Mot. at 4, 22. According to the Coalition, "[m]andatory prescription rebates are unknown in the private health care sector and therefore are not a business practice at all, much less a best business practice." Id. at 23.

Finally, the Coalition points out that other statutes providing for the reduction of expenditures on pharmaceuticals operate through express voluntary agreement with manufacturers. "It defies common sense to conclude that Congress would have authorized such an extreme deviation from other parallel drug discount programs that have exactly the same purpose of reducing government expenditures for pharmaceuticals." Id. at 24.

If the Coalition's reading of the statute were correct, only two arrangements would be possible for drugs provided to beneficiaries in the retail pharmacy program without an agreement to pay refunds. The manufacturer could receive more than the FCP for some transactions, and the Department could be reimbursed for the amount in excess of the FCP by some other party in the system (or perhaps by the manufacturer through some mechanism other than refunds).

Alternatively, the Department could, at the end of the day, simply end up paying more than the FCP for some drugs. In other words, if the manufacturer receives more than the FCP, the money has to come from somewhere. Of course, an altogether different option would be that these drugs would simply not be provided to beneficiaries in the TRICARE Retail Pharmacy Program.

The Department reviewed each of these options in its rulemaking on remand. It considered "[w]ho bears the burden of applying FCPs" (the manufacturer or another party), "[h]ow will FCPs be applied" (by refund or some other mechanism), and "[t]o what do FCPs apply" (to all drugs or only to some drugs).[6] 75 Fed. Reg. at 63,386. The Department considered each from the perspective of "(1) [h]armony with the statute and legislative history; (2) consistency with best business practice; and (3) practicability of administration." Id. at 63,384.

In comments submitted for the rulemaking, the Coalition appears to have sought that the Department not apply FCPs to some drugs. The Coalition did not suggest that some other party should reimburse the Department for the amount paid over FCP or that the manufacturer should remunerate by some mechanism other than refunds. See Letter from Larry Allen, President, Coalition for Common Sense in Government Procurement, to Admiral Thomas McGinnis, TRICARE (March 11, 2010) ("Coalition Comment Letter"), Administrative Record at 460-66. The Coalition instead suggested that the Department should sometimes pay more than FCP. See, e.g., id. at 464 ("As manufacturers of generic drugs are not statutorily required to pay refunds, DoD may and should, as a discretionary matter, exclude from the Final Rule all prescriptions

[6] The Department also considered "[w]hen do FCPs apply," which the Court addresses below.

filled with 'A' rated generic drugs . . . ."). The Department certainly read the Coalition's comments to suggest this reading of the statute. See 75 Fed. Reg. at 63,391 ("The industry recommendation is that DoD not apply FCPs to *all* covered prescriptions filled through the TRICARE Retail Pharmacy Program and paid for by DoD, but only those prescriptions covered by prospective procurement contracts between DoD and the manufacturer or comparable agreements having certain attributes they associate with procurement contracts."). DoD considered and rejected these arguments, concluding that the manufacturer is the most appropriate party to bear the burden of applying FCPs, that refunds are the most appropriate mechanism to do so, and that FCPs apply to all prescriptions filled through the TRICARE Retail Pharmacy program. Id. at 63,388, 63,391, 63,393.

2. Analysis of Chevron Step One

Neither the statute's text nor its legislative history support the Coalition's argument that Congress spoke directly to whether DoD may require refunds from manufacturers without their explicit agreement. The Court's inquiry begins with the statutory text. See Carcieri v. Salazar, 129 S. Ct. 1058, 1063-64 (2009); United States v. Gonzales, 520 U.S. 1, 4 (1997).

In enacting NDAA-08, Congress gave DoD express authority to promulgate regulations carrying out the statute's goals. When Congress explicitly provides that an agency shall make regulations to carry out a statutory provision, it expressly delegates interpretive authority to the agency. Heckler v. Campbell, 461 U.S. 458, 466 (1983). Therefore, that Congress called for the Department to issue implementing regulations itself signals that Congress delegated to DoD the authority to determine the mechanism by which prescriptions provided in the TRICARE retail pharmacy program would become subject to Federal Ceiling Prices. As this Court noted

previously, "the statute does not establish a particular regulatory scheme. . . . Rather, Congress commanded DoD to promulgate regulations to achieve the statute's goals." Coal. for Common Sense, 671 F. Supp. 2d at 54.

Moreover, the text of the provision itself indicates that Congress delegated to the Department the decision on how to subject pharmaceuticals to FCPs. The Coalition correctly notes that the statutory text specifies both "the *end* of paying lower drug prices" and "the *means* Congress specified to achieve that end." Pl.'s SJ Mot. at 20. That is, NDAA-08 requires that the Department "ensure that pharmaceuticals paid for by the Department . . . are subject to the pricing standards in such section 8126" by means of treating the TRICARE pharmacy program "as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under Section 8126 of title 38." 10 U.S.C. § 1074g(f). However, rather than imposing the means in a specific or restrictive manner, Congress instructed DoD to implement the means only "to the extent necessary": "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 . . . are subject to the pricing standards in such section 8126." Id. (emphasis added). The words "to the extent necessary" indicate that Congress was letting the Department decide how much of section 8126 to incorporate into the TRICARE pharmacy program. If Congress had intended to import all of section 8126's features or any specific feature, it would have used more restrictive language. Cf. Morgan Stanley Capital Group Inc. v. Pub. Util. Dist. No. 1, 554 U.S. 527, 557 (2008) ("If Congress had intended to

impose such detailed constraints on the Commission's authority . . ., it would have done so itself . . . .").

Similarly, there is little indication that, by referring to the inclusion of the TRICARE retail pharmacy program in "procurement," Congress intended to require the Department to operate by express voluntary agreement. Again, the reference to procurement in the body of the statutory text is within the phrase that is modified by "to the extent necessary," which belies the notion that Congress used the word to restrict the Department's choice in how to subject pharmaceuticals to FCPs.

Contrary to the Coalition's assertion that the Department is turning the part of NDAA-08 that references "procurement" and "section 8126" into surplusage, the Department has, in fact, given effect to the entirety of this provision. If the first part of the sentence were truly being treated as surplusage, it would be doing no work under the Department's reading of the statute; the second part of the sentence could stand alone, and the Department's interpretation would still make sense. But, as the Department accurately points out, the second half of the sentence refers only to "the program" and "such section 8126." Def.'s Mot. for Summ. J. ("Def.'s SJ Mot.") [Docket Entry 75] at 16. These phrases would not make sense if the second part of the sentence stood alone, because the reader would not know which program or which section 8126. Under the Department's reading, then, the first part of the sentence provides the antecedents for the phrases used in the second half of the sentence. This is hardly an untenable reading of a statute that would justify overruling an agency at Chevron step one.

Furthermore, to the extent that the statute refers to "procurement," including in section headings, there is no reason to believe that Congress intended the word to have the meaning that

the Coalition assigns. "Procurement" is both an ordinary legal word and a technical term. In its ordinary legal sense, procurement is the "act of getting or obtaining something or of bringing something about." Black's Law Dictionary 1327 (9th ed. 2009). The ordinary sense of the word presents no problem for the Department; the rule governs how the TRICARE retail pharmacy program obtains pharmaceuticals. And there is no indication in the statute that Congress meant "procurement" in anything other than the ordinary legal sense.

Procurement also technically describes the formal process by which the government purchases things. When the Department typically "procures" drugs (for example, for use in Military Treatment Facilities), it goes through the procurement process – that is, it buys drugs directly from manufacturers (or distribution agents) with an explicit agreement. With respect to the pharmacy program, the Department considered buying drugs directly from manufacturers but concluded it was impractical, given that the program supplies drugs to beneficiaries in thousands of pharmacies throughout the United States. See 75 Fed. Reg. at 63,389-90. The Coalition did not suggest then – and does not suggest now – that the Department really should run the pharmacy program by purchasing drugs directly from manufacturers, even though that is what procurement would, in the technical sense, mean. See id. at 63,390 ("No commenter recommended this system."). Instead, under the Coalition's view, "procurement" may or may not entail the direct purchase of items by the government, but must include express agreements on prices. There is no reason to believe that Congress intended to give "procurement" this specific, yet somewhat idiosyncratic, meaning.

At Chevron step one, the Department need only show that Congress has not spoken directly to the question at issue, not that its reading of the statute is superior to others. Indeed, at

neither stage of the Chevron analysis need an agency show that its choice was comparatively better than other choices. See Dep't of Treasury, IRS v. FLRA, 494 U.S. 922, 928 (1990) ("We must accept that construction if it is a reasonable one, even though it is not the one we ourselves would arrive at.") Nonetheless, it is significant here that the interpretation that the Coalition prefers might actually be barred by the statute at Chevron step one.

When the Court remanded the rule to the agency in late 2009, it listed some possible alternatives to the rule the Department eventually readopted. These alternatives were all other mechanisms by which DoD could be made whole for payments in excess of the FCP, either by manufacturers or by another party in the system. See Coal. for Common Sense, 671 F. Supp. 2d at 54-55. In the rulemaking process, the Department considered and rejected these sorts of alternatives, which the Coalition also did not support. See 75 Fed. Reg. at 63,386-91. The Court did not suggest, however, the possibility that DoD might apply Federal Ceiling Prices to a subset of pharmaceuticals in the program – that is, that DoD might, at the end of the day, simply pay more than the FCP for some drugs. Although the Department did not need to choose from among the alternatives identified by the Court, it would need to choose an option consistent with the statute. And as the Department noted on remand, the statute flatly applies to "any prescription filled" after January 28, 2008, not "some prescriptions filled." 75 Fed Reg at 63,392. "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). Furthermore, the statute, by its own terms, directs that the Department "shall" – not may – "ensure that pharmaceuticals" – not just some pharmaceuticals – "paid for by the Department. . . are subject to the pricing standards." It cannot be the case that the Department is legally bound

to deviate from this language in favor of a voluntariness requirement never explicitly referenced in the statute. Cf. Am. Hosp. Ass'n v. NLRB, 499 U.S. 606, 614 (1991) (upholding agency when statute's text was "contrary to the meaning advanced by petitioner").

The legislative history likewise confirms that Congress was focused on applying FCPs to all pharmaceuticals in the TRICARE retail pharmacy program and hence does not support the Coalition's reading of the statute. The conference report states that NDAA-08 "would require that any prescription filled . . . through the TRICARE retail pharmacy network will be covered by the Federal pricing limits applicable to covered drugs under section 8126 of title 38, United States Code." H.R. Rep. No. 110-407, at 938 (2007) (Conf. Rep.). In addition to repeating the statutory requirement that the measure apply to "any prescription," this language makes especially clear that the portion of section 8126 that Congress sought to import was the "Federal pricing limits." It does not reference any other specific provisions of section 8126 nor the procurement process in any way.

As for the Coalition's arguments about Congressional intent, they boil down to the same idea: the policy being adopted by the Department is so unusual that Congress could not have intended it. Thus, the Coalition argues that the rule is inconsistent with "best business practices" and also with other similar statutes.

Neither of these arguments, however, finds support in NDAA-08. Neither NDAA-08 nor its legislative history mentions "best business practices." The only mention of "best business practices" offered by the Coalition is from the National Defense Authorization Act for 1999. Not only was this nearly ten years prior to the enactment of NDAA-08, but it (at most) referred to the requirement, instituted by statute the following year and having nothing to do with Federal

Ceiling Prices, that DoD put pharmaceuticals on a tiered formulary. See Pl.'s SJ Mot. at 22. The Coalition's claim that Congress "never altered the original congressional intent," id., is thus extremely weak evidence of NDAA-08's requirements. Furthermore, the Court has already rejected the argument that because Congress constructed a policy regime in other statutes, it must necessarily have adopted that same scheme in NDAA-08. See Coal. for Common Sense, 671 F. Supp. 2d at 57-58 (concluding that "the Medicaid rebate statute is inapposite to interpreting the statute here"). The name of plaintiff's organization notwithstanding, appealing to common sense cannot add a requirement to NDAA-08 merely because it is present in other statutes.

In any case, the Coalition overstates how unusual the policy at issue here is. The Coalition argues that "[i]t is well established that when the government acts in its commercial capacity, it cannot exercise its 'sovereign' authority to impose terms unilaterally on a private party." Pl.'s SJ Mot. at 18. The modern cases the Coalition cites, however, all concern instances in which the government was alleged to have breached a pre-existing contract. See Mobil Oil Exploration & Producing Se., Inc. v. United States, 530 U.S. 604 (2000); United States v. Winstar Corp., 518 U.S. 839 (1996); Yankee Atomic Elec. Co. v. United States, 112 F.3d 1569 (Fed. Cir. 1997). Those cases do not stand for the proposition that the government cannot change the terms on which it participates in ongoing commercial transactions. Moreover, the government is here hardly imposing terms on pharmaceutical manufacturers. If the manufacturers do not like the prices being offered for their products, they can always walk away

from TRICARE. See 75 Fed. Reg. at 63,393 ("Manufacturers make a voluntary choice to do business with DoD under the applicable terms.").[7]

3. Chevron Step Two Argument

The Coalition also argues that DoD's interpretation of the statute is unreasonable and therefore fails at Chevron step two for two reasons. First, the Coalition argues that DoD misrepresents the facts of the commercial marketplace. DoD maintains that pharmaceutical manufacturers "do business" with DoD, 75 Fed. Reg. at 63,393, when, the Coalition points out, manufacturers and the Department actually have no direct business relationship in the TRICARE pharmacy program. Thus, "in real life the manufacturer transacts no business with DoD and instead sells products to the commercial marketplace, where TRICARE beneficiaries purchase them at DoD's expense." Pl.'s SJ Mot. at 35.

Second, the Coalition argues that DoD's effort to justify the rule by its consistency with best business practices is unreasonable. Singing a familiar refrain, the Coalition asserts that "[b]ecause DoD has used a regulatory mandate instead of an express voluntary agreement to establish entitlement to rebates, DoD cannot reasonably claim to have based the 2010 rule on best business practice." Id. at 37. Since DoD chose best business practices as a criterion and applied that criterion unreasonably, the Coalition maintains, DoD's action was arbitrary and capricious.

4. Analysis of Chevron Step Two

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[7] As of the promulgation of the 2010 rule, no manufacturer had chosen to opt out of TRICARE. 75 Fed. Reg. at 63,395.

Neither of the Coalition's Chevron step two arguments is persuasive. First, it is hardly unreasonable for the Department to say that pharmaceutical manufacturers and the Department "do business." The Department does not buy manufacturers' drugs directly, but it pays for them. The difference is semantic; the distinction is immaterial. That DoD functions as a third-party payer for the drugs rather than buying them directly does not make it unreasonable to say that DoD and manufacturers have a business relationship or "do business." The Department has articulated a satisfactory explanation for its action with a rational connection between the facts and the choice. Alpharma, 460 F.3d at 6.

Semantics aside, the Department's policy choice is also quite reasonable. Again, it is useful to compare the policy promulgated by the Department with the policy suggested by the Coalition, in light of the requirements of NDAA-08. Cf. PDK Labs., Inc. v. DEA, 438 F.3d 1184, 1190 (D.C. Cir. 2006) ("Even at Chevron's second step, we begin with the statute's language."). NDAA-08 does not contain a requirement that the cost of the policy be imposed on a party with which the Department "does business." But the statute does require that FCPs be applied to "any prescription." It therefore better fits the statute to require manufacturers to reimburse the Department than it would for DoD to pay more than the FCP for these pharmaceuticals. Cf. Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (upholding agency construction that "is at least as plausible as competing ones" and "so closely fits the design of the statute as a whole and its object and policy"); Reed v. R.R. Ret. Bd., 145 F.3d 373, 376 (D.C. Cir. 1998).

Second, although the Department's practice under the rule is different than that of an ordinary business, this distinction does not mean that the Department is behaving inconsistently

with best business practices. Congress has ordered the Department to ensure that pharmaceuticals provided in the TRICARE retail pharmacy program are subject to Federal Ceiling Prices. As the Department now notes, consistency with best business practices does not necessarily require operating identically to a business. Def.'s SJ Mot. at 28-29. The Department observed on remand that "prevailing business practice for a plan sponsor is to get the best value that is feasible at each step of the commercial chain." 75 Fed. Reg. at 63,387. The Department considered limiting payments to other parties in the commercial chain and concluded that doing so would not be feasible under TRICARE's "business model." See 75 Fed. Reg. at 63,387. It was not unreasonable for the Department to conclude that manufacturers could reimburse DoD without disruption of TRICARE. And it was certainly not such a "clear error of judgment" as to be arbitrary and capricious. See Volpe, 401 U.S. at 416.

B. Timing of Rule's Applicability

The Court next considers whether the Department had the authority to require refunds on transactions occurring before the promulgation of the 2010 rule. The Court previously rejected the Coalition's argument that the 2009 rule exceeded DoD's statutory authority by imposing rebate requirements on transactions prior to the promulgation of that rule. See Coal. for Common Sense, 671 F. Supp. 2d at 56-59. The Coalition had argued that, because the statute did not mandate that the Department impose manufacturer refunds, it also did not mandate that this requirement begin on January 28, 2008. Id. at 56. Furthermore, the Coalition argued that requiring rebates on transactions occurring before the promulgation of the rule was impermissibly "retroactive." Id. at 58. The Court concluded, however, that NDAA-08 expressly required that TRICARE prescriptions filled on or after January 28, 2008 would be subject to

FCP, regardless of the mechanism the Department chose to implement that requirement, and that the parties were on notice of such a requirement when NDAA-08 was enacted. Id. at 57-58.

The Coalition's argument against the timing applied by the 2010 rule is, for the most part, a rewarming of its rejected argument against the timing of the 2009 rule's applicability. The Coalition argues now, as before, that the Department cannot impose rebates on transactions before the successful promulgation of a rule. See Pl.'s SJ Mot. at 39-42. The Coalition thus notes correctly that, until the promulgation of the 2010 rule, the Department had not sufficiently exercised its discretion in choosing an appropriate rule. See id. at 41. But the same was true when the Court considered the 2009 rule. Simply put, it was the passing of the statute, not the promulgation of a regulation, that determined when prescriptions became subject to FCPs. On January 28, 2008, all parties – manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and beneficiaries – were on notice that TRICARE prescriptions would be subject to Federal Ceiling Prices. That it took the Department more than two years to successfully promulgate regulations implementing that requirement is irrelevant.

The Coalition also now adds a twist to its previous argument, asserting that the timing of the rebate requirement is invalid because, prior to the promulgation of a final rule, manufacturers had no regulatory option to opt out of the TRICARE program. That is, the final rule provides both a mechanism by which manufacturers can ask DoD to waive the refund owed for a particular drug, see 32 C.F.R. § 199.21(q)(3)(iii)(A), and a mechanism to remove the drug from the TRICARE program completely, see 32 C.F.R. § 199.21(q)(3)(iii)(C). Before the 2010 rule implemented these measures, however, manufacturers selling drugs in the commercial marketplace might be (depending on what rule the Department ultimately adopted) subject to

rebate liability if their drugs were sold, downstream, by pharmacies to beneficiaries; their only way to be sure to avoid liability was to remove the drug from the commercial marketplace. Of course, as the Coalition somewhat candidly notes, this was equally true when the Coalition challenged the 2009 rule (with respect to transactions occurring before the promulgation of that rule) as it is now with respect to transactions occurring before the promulgation of the 2010 rule. See Pl.'s SJ Mot. at 43. ("[T]he 2009 rule included both procedures . . . ."). In any case, the Coalition argues that rebates during these periods were not "voluntary" because the ability to waive or remove did not exist prior to the promulgation of the rule. See id. at 42-44.

The problem with the Coalition's argument here, as before, is that it has little foundation in the statute. The fact that DoD now allows manufacturers to seek waiver or removal does not turn those options into requirements of a statute that nowhere mentions a "voluntariness" requirement. NDAA-08, at its enactment, imposed a cold reality: DoD would no longer be paying more than FCPs for drugs, and manufacturers or some other party in the system would be out the difference. If manufacturers or other parties to TRICARE wished to avoid that reality, their only choice over the limited period of time before the rule's enactment was to stop participating in the sale of pharmaceuticals in the commercial marketplace. (That no manufacturers have taken advantage of the removal provision suggests that this reality was not quite as cold as the Coalition might suggest.) In any case, that was the choice Congress made in mandating a January 28, 2008 effective date in NDAA-08.

IV. Conclusion

The Court concludes that DoD had statutory authority under NDAA-08 to require manufacturers to refund amounts received in excess of the Federal Ceiling Price for

pharmaceuticals paid for by DoD in the TRICARE pharmacy program, including on transactions occurring before the promulgation of the 2010 rule. A separate order has been issued on this date.

/s/

JOHN D. BATES

United States District Judge

Dated: October 25, 2011