BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

March 11, 2010

Federal Docket Management System Office
1160 Defense Pentagon
Washington, D.C. 20301-1160

Re: Department of Defense Office of the Secretary, CHAMPUS/TRICARE, Reconsideration of Final Rule and Request for Comments, Docket No. DoD-2008-HA-0029; 0720-AB22 (75 Fed. Reg. 6335-6, February 9, 2010)

Dear Rear Admiral McGinnis:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to comment on the Department of Defense's ("DoD") Final Rule to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008 ("NDAA"[1], entitled CHAMPUS/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals, issued on March 17, 2009 ("Final Rule").[2] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

We understand that, based on the DoD notice dated February 9, 2010, DoD is in the process of considering whether to readopt the Final Rule as it currently stands.[3] Given that BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them, we closely monitor changes that impact the availability of pharmaceutical and biological products through the TRICARE Pharmacy Benefits Program, and have taken steps to work with DoD to find mutually beneficial solutions. In September 2008, BIO submitted comments to the TRICARE Management Activity ("TMA") in support of the July 25, 2008 Proposed Rule. BIO's comments supported the voluntary prospective framework set forth in the Proposed Rule. We understand that DoD at this juncture is considering whether to readopt the Final Rule as it currently stands, based on a directive from the District Court for the District of Columbia in *Coalition for Common Sense in Government Procurement v. U.S* ("Coalition for Common Sense").[4] The court has made clear that DoD must utilize its discretion to determine whether to

[1] Pub. L. No. 110-181, § 703.
[2] 74 Fed. Reg. 11,279 (Mar. 17, 2009).
[3] 75 Fed. Reg. 6335 (Feb. 9, 2010).
[4] 2009 WL 4250077 (D.D.C. 2009).

adopt the current iteration of the rule (or some other approach)".[5] Accordingly, not only is implementation of a voluntary and prospective program within the agency's discretion, BIO strongly believes this is the proper approach.

I. Voluntary and Prospective Agreements Have Been Successful And Are the Appropriate Vehicle to Implement Pricing Programs

BIO urges DoD to implement Section 703 through voluntary, prospective agreements with manufacturers. DoD already has achieved considerable success in leveraging its market power to secure rebates from manufacturers on a prospective basis. As DoD plainly recognized in its February 9, 2010 notice to industry, manufacturer agreements already cover "approximately 99 percent of TRICARE retail prescriptions."[6] These agreements were implemented prospectively and are considered by the terms of the TRICARE Final Rule to be voluntary.[7] Given their success, there certainly is no need to go beyond this framework to obtain manufacturer participation.

Under a voluntary prospective agreement, if a company elects to participate, it obtains the benefits – the opportunity to compete for Tier 2 positioning on the Uniform Formulary and the availability of its products within the TRICARE retail pharmacy network ("TRRX"). To gain those benefits, it also pays the price by way of Federal Ceiling Price ("FCP")-based rebates on all TRRx utilization dispensed from the effective date of the agreement forward. Conversely, in a truly voluntary program, a company that chooses not to participate would not be required to pay rebates; however, that company would suffer the penalty of having its products downgraded to Tier 3 on DoD's Uniform Formulary and being subject to preauthorization. This, as a practical matter, means that the product is blocked from TRRx. This method, which uses marketplace incentives to maximize cost savings, is standard commercial practice and is the most efficient and effective way to achieve the participation and savings that DoD seeks in its TRRx program.

Apart from its consistency with commercial practice, this approach also is entirely consistent with the pricing statute that underlies the NDAA – the Veterans Health Care Act of 1992 (VHCA[8]). The VHCA, which established the Federal Ceiling Price requirement, was implemented through a series of prospective agreements: the Master Agreement, the Pharmaceutical Pricing Agreement, and the Federal Supply Schedule (FSS) contract. Per the text of the VHCA, companies were to be given the ability to decide whether to enjoy the benefits of participation and pay the "price of admission" or to decline participation and be shut out of Medicaid, Medicare Part B, and purchases by 340B covered entities, the Department of Veterans Affairs ("VA"), DoD, the Public Health Service ("PHS"), and the Coast Guard. Given that the VHCA contemplates a program under which manufacturers can opt in by signing on to the FSS and various pricing agreements, the NDAA, which is keyed off that statute, should be implemented using that same approach.

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[5] Id.

[6] 75 Fed. Reg. at 6336 (Feb. 9, 2010).

[7] 74 Fed. Reg. at 11.282.

[8] 38 U.S.C. 8126

II. The Opt Out Provision of the Final Rule Is Inadequate to Avoid Mandatory Imposition of Rebates for the Period Prior to the Final Rule

For the reasons set forth above, BIO strongly recommends that DoD's reissued Final Rule provide for a voluntary and prospective program. To the extent, however, that DoD is considering exercising its discretion to reissue its Final Rule with a program that is substantively identical to that in the March 17, 2009 Final Rule, in that it requires payment of rebates from the date of enactment of the NDAA (with the only change being text evidencing an agency exercise of discretion to apply the program announced in the original Final Rule), BIO asks DoD to consider the issues set forth below.

A. Manufacturers Did Not Have Notice that Rebate Payments Would Be Required by DoD from the Date of Enactment of the NDAA and Must Be Given a Meaningful Opportunity to Avoid Such Liability

Though DoD has asserted in its Final Rule and in the context of Coalition *for Common Sense*, that manufacturers can avoid rebate liability by opting out of the program, and that this opt-out provision results in the Final Rule being a "voluntary program," that simply is not the case. As currently written, the Final Rule clearly cannot be considered voluntary given the nature of its opt-out provision. The Final Rule provides as follows:

> Thus if there were ever a case in which a manufacturer was really involuntarily involved with DoD in relation to drugs sold into the normal commercial market, the manufacturer could request voluntary exclusion of a drug from coverage in the TRICARE Pharmacy Benefits Program and waiver of the refund obligation.[9].

The Final Rule makes reference to exclusion from the TRICARE Pharmacy Benefits Program in total – including not only retail, but Military Treatment Facilities ("MTFs") and the TRICARE mail order pharmacy ("TMOP"), as well. However, a full opt-out from the TRICARE Pharmacy Benefits Program under the Final Rule has not been possible given the manufacturers' obligations under their VHCA Master Agreements, which require the offering of their products on Federal Supply Schedule ("FSS") contracts for availability to all Big 4 agencies – including DoD. Put another way, under the VHCA, manufacturers *must* make their products available on the FSS, from which DoD is free to purchase for its TFs and TMOP. Under the Final Rule, a manufacturer could not be "out" of the TRICARE benefit program without also removing it from the FSS or somehow shielding it from DoD purchases under its FSS contract. This clash between DoD's statements surrounding its opt-out provision and the VHCA Master Agreement obligations is clear and renders the opt-out provision meaningless. Unless DoD itself were willing and able[10] to "opt out" from purchasing off of the FSS contract of a company that has chosen the opt-out route, there is no basis to label the program announced under the Final Rule as "voluntary." DoD said in the litigation that companies can avoid rebate liability by

[9] 74 Fed. Reg. at 11,286.

[10] As a practical matter, given the DoD purchases from prime vendors, a DoD opt out from the FSS contract would be difficult to apply.

removing their products from all tiers of the TRICARE formulary. That does not mean manufacturers must remove their products from the FSS contract to avoid rebate liability. DoD's rule should be clearer on what is required to opt out of the program. If DoD wants to buy a non-formulary drug under the FSS after the contractor has notified DoD that it has opted out of the Tricare program pursuant to the Rule, the manufacturer cannot be liable for rebates on retail prescriptions.

B. It Is Inappropriate for DoD to Require the Payment of Rebates for the Period Prior to the Effective Date of the Final Rule

Given that the Final Rule did create a mandatory program, despite its "opt-out" language), if DoD simply reissues the Final Rule including a pre-Final Rule rebate payment requirement, it would be applying a mandatory scheme to manufacturers prior to their notice of that requirement – an approach that is patently unfair. "Principles of fundamental fairness...require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of [an agency's final] rul[e]." *Omnipoint Corp. v. FCC*[11] (addressing the purpose of the APA's thirty-day waiting period between publication of a final rule and its effective date); *see also Pressley Ridge Schools, Inc. v. Stottlemyer*, [12] (holding that the agency violated health care provider's due process rights by retroactively applying new Medicaid standards and imposing restrictive standards on provider without meeting publication and notice requirements).[13]

Specifically, under the Final Rule, DoD for the first time required that rebates be paid by manufacturers regardless of whether they opted to execute voluntary agreements, and the rule made clear that the rebate requirement would attach back through the date of enactment of the NDAA, January 28, 2008. However, prior to its issuance of that rule, DoD issued its Proposed Rule, which contemplated a program scheme that would be implemented only through voluntary and prospective means. Even if manufacturers could opt out of the program to avoid mandatory rebates, since DoD did not provide adequate notice of a final rule that imposed liability by law, any discretionary imposition of such liability must allow manufacturers an opportunity to opt out at the point it creates such a legal obligation**.**

Based on that scheme outlined in the Proposed Rule, on March 17, 2009, the date the Final Rule was issued, manufacturers understood that DoD had been focusing on implementation of Section 703 through a rebate program, but they had no knowledge of any requirement that rebates be applied retrospectively back through January 2008. To the contrary, the Proposed Rule, issued on July 25, 2008, had announced to industry a voluntary and prospective program that would have required rebate payments only from manufacturers that elected to sign a voluntary agreement. Further, rebate liability would attach only when such a voluntary agreement became effective. In short, the Proposed Rule provided for an opt-*in* program, with no rebate liability for those companies that chose not to opt-in.

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[11] 78 F. 3d 620, 630-31 (D.C. Cir. 1996) (quotations omitted)

[12] 947 F.Supp. 929, 938-41 (S.D. W.Va. 1996)

[13] Applying a voluntary and prospective framework has permitted similar Federal pricing programs (e.g., VHCA, Medicaid, 340B) to steer clear of the concerns associated with imposing a pricing requirement for earlier periods.

Moreover, it is also clear that Section 703 did not put manufacturers on notice of such a requirement. As the District Court recognized:

> 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 FCPs, or that they must refund proceeds in excess of this price on retail pharmacy program transactions.[14]

Accordingly, neither the underlying statute (the NDAA) nor the proposed rule in place in March 2009 provided any notice to a manufacturer that a retrospective rebate requirement would be applied to manufacturers back through the date of enactment of the statute.

In sum, applying a rebate requirement from January 28, 2008 through the effective date of the Final Rule – which is what is contemplated in the Final Rule – would, in essence, bind manufacturers to a payment for a past period. Given that the statute did not mandate rebates and manufacturers did not know there would be a mandatory rebate requirement imposed by DoD during that period, they had no reason to take steps toward opting out of the program at that time. The only possible way "out" was to ask for a waiver, and obtaining a waiver is by no means guaranteed. As discussed below, if DoD does reissue the Final Rule with its original mandatory rebate requirement intact, fundamental fairness dictates that manufacturers be afforded a true ability to opt out for the quarters prior to the effective date of the Final Rule or the execution of a TRICARE voluntary agreement.

III. The Final Rule Must Include a Clear and Meaningful Opt-Out Provision

In both the Final Rule and its briefs in *the Coalition case*, TMA takes the position that compliance with the rebate program by manufacturers is voluntary because "the manufacturer could request voluntary exclusion of a drug from coverage in the TRICARE Pharmacy Benefits Program."[15] However, as discussed above, as currently written the Final Rule clearly cannot be considered voluntary given that its opt-out provision is not meaningful or effective.

BIO supports an opt-out provision, as long as it clearly provides that DoD will continue to ensure that all necessary drugs and biologics care available to Tricare beneficiaries regardless of manufacturer opt-out decisions. However, it is BIO's position that the language of the Final Rule must be clarified to narrowly tailor the opt-out provision such that it applies only to the TRRx program. The opt out provision must permit manufacturers to withdraw their products from coverage at TRRx network pharmacies while still maintaining availability of those same

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[14] Memorandum Opinion, Slip Op. at 9. In addition to recognizing that Section 703 could be implemented through various methods (with a rebate program being only one possible approach), the court also concluded that DoD would be entitled to access FCPs from the date of enactment of Section 703; we understand that the Coalition has appealed the district court's decision. Plaintiff's Notice of Appeal, Coalition for Common Sense in Government Procurement v. United States, No. 08 Civ. 996 (D.D.C. Jan. 28, 2010). Given that there were a number of approaches DoD could have taken to access FCP-based pricing starting on the enactment date of Section 703 (January 28, 2008), manufacturers did not have notice that a rebate program would have applied to them immediately starting on that date.

[15] 74 Fed. Reg. at 11,286.

drugs on the Uniform Formulary at MTFs and through TMOP. As discussed below, that approach will provide manufacturers with the option to decide whether to participate in the program.

As noted above, under the terms of the VHCA and the Master Agreement entered into between manufacturers and the VA to implement that statute, manufacturers must make their covered drugs available for procurement on a FSS contract by DoD (and the other "Big 4" agencies) at FCPs, and are contractually committed to fill DoD orders placed under their FSS contracts. Under the current opt-out provision, a manufacturer would be withdrawing its products from the TRICARE pharmacy benefit program entirely, including drugs dispensed to beneficiaries at MTFs and through its mail order pharmacy. Simply put, there is no way for a manufacturer to block DoD from purchasing its products off of its FSS contract without running afoul of that obligation. Removing a product from the formulary must be sufficient to avoid rebate liability under the program even if DoD decides to buy non-formulary products.

A more limited retail-only opt-out is in the interest of TMA, its TRICARE beneficiaries, and also manufacturers. Allowing companies to opt-out of the TRRX program serves DoD's budgetary considerations for that program – i.e. DoD will not be "paying" more than FCP for TRRx prescriptions because DoD would not reimburse for an opted-out drug at retail pharmacies. Additionally, a more limited opt-out provision is favorable for beneficiaries because it would still allow the drugs to be available at MTFs and through TMOP. And, from the manufacturer's perspective, a retail only opt-out approach allows the Master Agreement and FSS requirements to be fulfilled without any concern. It is also logistically feasible because DoD has a method to "block" products that are not subject to an agreement by coding them as non-reimbursable by TMA.

In addition to revising its scope, BIO requests that the revised Final Rule provide companies with a reasonable period of time to determine whether to opt out prospectively as well as for the period from enactment of the NDAA through the present. The opt-out should be retroactive and no rebate obligation should attach to the opt out period. Moreover, the retail-only opt-out option program back through January 28, 2008 should be made available to all companies – regardless of whether they have entered into a voluntary agreement. This approach is necessary given that companies that did not seek to opt out under the Final Rule might have done so if the opt-out provision had been appropriately tailored to impact TRRx only such that it would have provided a meaningful option for companies.

IV. DoD Has Correctly Provided for Implementation on a Drug-by-Drug Basis

BIO reiterates its support for allowing the manufacturers to decide whether to participate on a drug-by-drug basis. First, an all-or-nothing approach would be inappropriate given that the Pharmacy & Therapeutics Committee must make determinations on a drug-by-drug basis. There is no basis for excluding one drug of a manufacturer based on the cost effectiveness of the manufacturer's other drugs. Second, a drug-by-drug approach makes sense for manufacturers because it simply may not be cost effective to participate for certain products. Finally, this approach is beneficial to DoD because it ensures that its beneficiaries have access to as many products as possible by not forcing a company to opt not to participate for all of its drugs because

a few products create a disincentive to participate.

V. Classification of Rebate Amounts as "Overpayments" By DoD is Inappropriate

The Final Rule classifies DoD reimbursements in excess of FCP as overpayments to manufacturers: "a refund due under this paragraph (q) is subject to section 199.11 of this part and will be treated as an erroneous payment under that section."[16] A review of 199.11 makes clear, however, that section 199.11 is an inappropriate regulatory scheme for the collection of TRRx rebates from manufacturers. That section defines the requirements and procedures for the assertion, collection or compromise of claims for erroneous payments against, among others, a supplier of products or services under TRICARE.[17]

DoD has incorrectly applied this regulation to manufacturers. Manufacturers of covered drugs are not "debtors" under the regulation. The term "debtor" is defined as "a sponsor, beneficiary, provider, physician, other supplier of services or supplies, or any other person who for any reason ***has been erroneously paid under TRICARE***."[18] Even assuming DoD's view that, in reimbursing at a price higher than FCP, it has made an erroneous payment for products under TRICARE, such payment was not made to the manufacturer. As all of the parties involved in this program know well, the TRRx Pharmacy program does not involve DoD payment to manufacturers for the purchase of covered drugs. Rather, manufacturers sell the drugs to pharmacies in the ordinary course of their commercial business. The pharmacies then dispense the drugs to patients. When the patient that received the covered drug is a TRICARE beneficiary, DoD pays the pharmacy at the agreed-upon reimbursement rate. The DoD reimbursement is not passed on to the manufacturer by the pharmacy. Therefore, to the extent that DoD asserts that it has made an erroneous payment by reimbursing at a rate higher than FCP, such erroneous payment was made to the pharmacy, not to the manufacturer. Accordingly BIO seeks that DoD make clear in its Final rule that this regulation does not apply to manufacturers because, in fact, DoD simply does not make payments to manufacturers in connection with its TRRx prescriptions benefit..

VI. The Final Rule Must Reference the Appropriate Federal Ceiling Price

The Final Rule provides that the TRRx rebate calculation is based either on the direct pharmacy contract price or "the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP."[19] However, throughout the Final Rule (and in the template pricing agreement), DoD does not specifically define the terms "FCP" or "Federal Ceiling Price." Notably, Section 703 does not use the term "Federal Ceiling Price." Instead, the statute states that the TRICARE Retail Pharmacy program shall be "subject to the pricing standards in [38 U.S.C.] section 8126". BIO respectfully asks that DoD provide text in a final rule clarifying that the FCP from which the TRICARE rebates are calculated be the "FCP Calculated Ceiling", which is established from the

[16] 74 Fed. Reg. at 11,292.
[17] 32 CFR 199.11 (f)(2)(i).
[18] *Id.* at (f)(2)(ii)(emphasis added).
[19] 74 Fed. Reg. at 11,292; 32 CFR § 199.21(q)(3)(ii).

computations contemplated under 38 U.S.C. 8126(a)(2) and (c), and is the ceiling that would apply if DoD were procuring covered drugs through a DoD depot contracting system.

This clarification is necessary because Section 8126 establishes two distinct price points, which are set out in 8126(a)(2) and (c) and 8126(d)(1) that may be factored into the FCP calculation depending on which agency is contracting to acquire covered drugs, the type of contract under which the FCP is being offered, and the contract year at issue. Section 8126(a)(2) and (c) form the basis of what is commonly referred to as the FCP Calculated Ceiling: (Annual non-FAMP x 0.76) – additional discount). 8126(d)(1) provides that when a covered drug is subject to "***a multiyear contract*** with the Secretary [of the VA]," the "***contract price charged***" during the second and subsequent years of the contract "may not exceed the ***contract price charged***" during the prior year, increased by the CPI-U. This (d)(1) price cap is referred to as the "FSS Max Cap." For purposes of the FSS contract, in the second and subsequent years of the FSS contract, the price charged is the lower of the FCP Calculated Ceiling ((a)(2) and (c)) and the FSS Max Cap ((d)(1)).

Importantly, the "FSS Max Cap" does not set a universal FCP that is applicable in all situations; rather, it simply dictates the contract price of the FSS contract, which is a multiyear contract with the VA. This is made clear in the plain language of Section 8126(d)(1) as well as in the Master Agreement and the Pharmaceutical Pricing Agreement executed between the VA and manufacturers. The Master Agreement provides in relevant part:

> In the second and subsequent years of ***a multiyear Government contract*** for a covered drug, if the Manufacturer wishes to raise the ***contract price***, the annual Federal price ceiling will be calculated by two methods. First, Section 8126(d)(1) calls for the actual FSS ***contract price*** charged during the preceding one-year period to be increased by the annual percentage increase in the CPI-U, and, second, Section 8126(d)(2) calls for the reported annual non-FAMP for the preceding year to be multiplied by .76 minus any additional discount. The method of calculating that yields the lowest price ceiling will determine the Federal ceiling price ceiling for the second or a subsequent year of ***such a contract***.

Master Agreement, § II.3 (emphasis added). Similarly, the Pharmaceutical Pricing Agreement, which was executed at the same time as the Master Agreement, states the following:

> The above described prices charged for covered drugs which are the subject of ***multiyear Government contracts***, in the second or subsequent years ***of such contracts***, will also not exceed the ***actual contract prices charged*** during the preceding year increased by the annual increase in the CPI-U, as set forth in 8126(d)(1).

Pharmaceutical Pricing Agreement, § VIII.B (emphasis added).

Because the TRRx program does not involve a multiyear contract with the VA, the (d)(1) price cap is inapplicable. Thus, the "pricing standard" to which DoD is entitled is the FCP

Calculated Ceiling, which is calculated pursuant to 38 U.S.C. § 8126(a)(2) and (c). "Multiyear contract" is a term of art that is defined in the Federal Acquisition Regulation in pertinent part, as "a contract for the purchase of supplies or services for more than 1, but not more than 5, program years"[20]. The TRRx program is implemented through "Section 703 Pricing Agreements" with DoD. These are not procurement contracts, and they are for a one (1) year term that is renewable for subsequent one (1) year terms. Additionally, the Section 703 Pricing Agreements do not provide for the purchase of supplies by DoD from the manufacturer; they require the manufacturer to remit payment to DoD. For these reasons, it is clear that the Section 703 Pricing Agreements simply do not qualify as "multiyear contracts" with the Secretary, and therefore, the "FSS Max Cap" set forth in (d)(1) cannot properly be factored into the calculation of the FCP that is utilized to compute the TRRx rebates. In sum, the pricing standards applicable to the Tricare retail pharmacy program are the standards that would be applicable to DoD procurements under 8126(a)(2) and (c).

VII. CONCLUSION

BIO greatly appreciates the opportunity to comment on the important issues raised by the Final Rule, and we look forward to working with DoD to ensure that TRICARE beneficiaries continue to have access to critical drug and biological therapies. As discussed above, however, there are significant issues and potential complications that must be resolved in order to ensure an equitable and functional rebate program. Please feel free to contact Sandra Dennis or Lauren Neff at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

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[20] 48 CFR § 17.103