BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

April 10, 2008

Major General Elder Granger
Deputy Director, TMA
Skyline Five, Suite 810
5111 Leesburg Pike
Falls Church, VA 22041-3206

Re: Dear Manufacturer Letter Dated February 1, 2008

Dear General Granger:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the recent steps that Tricare Management Activity (TMA) has taken to implement a new rebate regime (hereinafter the Section 703 Program) for prescriptions filled through the Tricare Retail Pharmacy Network under Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA).

BIO is the largest trade organization to represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. BIO's members are stakeholders in the Tricare health care system and desire a fair and transparent framework that clearly establishes the expectations and responsibilities of interested parties. These comments are intended to assist TMA in the development of a program that is beneficial for the Department of Defense (DoD), manufacturers, and, most importantly, Tricare beneficiaries. Going forward, BIO hopes to work closely with TMA to accomplish that goal.

BIO and its members anticipate the opportunity to attend and participate in the industry forum referenced in the February 1, 2008 Dear Manufacturer Letter to industry (hereinafter the Letter). Opportunities that provide for an open exchange of ideas between the interested parties will serve to increase the success of the Section 703 Program. BIO also would request an in-person meeting to discuss these issues. In light of the significant impact that the Section 703 Program will have on manufacturers, we request that this meeting occur prior to publication of a regulation and well before implementation of the Program.

A. Background

Some background regarding the predecessor Tricare program is useful in helping to clarify the issues discussed in this letter surrounding implementation of the current Section 703 Program. In 2004, the Department of Veterans Affairs (VA), on behalf of DoD, issued a Dear

Manufacturer letter stating that DoD's Tricare Retail Pharmacy Program (TRRx) was a "virtual depot" subject to the price caps (known as the Federal Ceiling Price or FCP) set forth in Section 603 of the Veterans Health Care Act (VHCA), 38 U.S.C. § 8126. Based on this conclusion — and without any statutory, regulatory, or contractual basis for this extension of the VHCA pricing program — VA concluded that manufacturers would be required to provide quarterly rebates on Tricare retail utilization provided by DoD. In March 2005, an industry group filed a petition for review in the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) seeking to invalidate the VA's letter implementing the TRRx rebate program. In its decision, the Federal Circuit set aside the VA's letter, holding that the VA did not follow proper procedural notice and comment rulemaking requirements when implementing the program. *Coalition for Common Sense in Government Procurement v. Sec'y of Veterans Affairs*, 464 F.3d 1306 (Fed. Cir. 2006).

Despite the fate of its TRRx program, DoD has achieved some savings in the retail sector and across-the-board on its drug purchases by holding therapeutic class competitions in which it has sought voluntary agreements for retail rebates (UF-VARRs) or reduced Federal Supply Schedule (FSS) contract pricing through UF-blanket purchase agreements in return for positioning on DoD's Uniform Formulary. In 2007, however, DoD attempted to reinstate the authority it claimed under the TRRx program through Section 703 of the NDAA (hereinafter Section 703). Section 703 provides, in pertinent part, that the following language be added to 10 U.S.C. § 1074g:

> With respect to any prescription filled on or after the date of 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.

Additionally, Section 703 mandates that DoD implement the new legislation through an amendment to its Uniform Formulary regulations:

> The Secretary of Defense shall . . . modify the regulations under subsection (h) of section 1074g of title 10, United States Code . . . to implement the requirements [set forth above]. The Secretary shall so modify such regulations not later than December 31, 2007.

TMA issued the Letter on February 1, 2008 in an effort to implement the Section 703 Program. The Letter asserts that DoD is entitled to FCP-based "refunds"[1] on retail utilization based on the new statute. TMA acknowledged that Section 703 requires DoD to promulgate regulations to implement the Section 703 Program, but also stated that until such regulations are

[1] Refunds (or rebates) for each NDC-11 would be calculated as the difference between the annual Non-Federal Average Manufacturer Price and the Federal Ceiling Price multiplied by utilization for the time period.

in place, manufacturers should remit rebates using the structure of existing voluntary agreements for retail rebates (VARRs). The Letter further proclaims that "Section 703 affirms the Government's interpretation of section 8126 of title 38," *i.e.*, that the Tricare Retail Pharmacy Network is a "virtual depot" and therefore falls within the scope of the Master Agreements. Moreover, in recent updates to its website, TMA has informed manufacturers that the rebates for utilization from January 28 through March 31 are due by June 26.

B. DoD Must Issue Regulations to Implement the Section 703 Program.

BIO has serious concerns regarding the path that DoD has chosen to implement the Section 703 Program. Chief among these is DoD's failure to promulgate regulations as required by Section 703. Despite its acknowledgement that it must establish regulations, under its current Letter, TMA is demanding rebate payments without doing so. In the absence of regulations, issued only after providing an opportunity for notice and comment, TMA lacks a legal basis to demand rebates from manufacturers for retail sector utilization.

In its decision relating to the implementation of the predecessor TRRx Program, the Federal Circuit held that a letter to industry, such as the one issued by TMA on February 1, 2008, does not provide a valid legal basis for asserting a right to obtain rebates from manufacturers under the existing VHCA pricing program. As discussed above, the Federal Circuit invalidated the VA's 2004 Dear Manufacturer letter as procedurally defective because the agency attempted to create a substantive rule (*i.e.*, a retail pharmacy refund program — where no obligation to pay rebates had previously existed) without complying with the notice and comment rulemaking provisions of the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.* *Coalition*, 464 F.3d at 1317-19. Consistent with the Federal Circuit's decision, Section 703 specifically mandates that DoD amend its regulations to implement the new law. As is evident, under both the Federal Circuit decision and the explicit text of Section 703, TMA's Letter does not provide DoD with authority to demand rebates — even on a temporary basis.

Notwithstanding the legal deficiencies of TMA's Letter, DoD's persistence in attempting to implement the Section 703 Program outside of the regulatory process has resulted in significant confusion within industry. The piecemeal manner in which TMA is attempting to implement this new requirement exemplifies why notice and comment rulemaking exists: to create a coherent regulatory structure that allows those whose conduct it governs to both understand and help shape its requirements. Industry's ability to comment on the rules by which it ultimately must abide provides the agency a clearinghouse for ideas and suggestions to help it avoid the potential pitfalls a rule might present. DoD's choice to bypass rulemaking has led to the very confusion and uncertainty regarding the Section 703 Program that notice and comments serve to avoid. BIO urges DoD to follow the appropriate regulatory path by providing industry with the ability to comment on a proposed rule before demanding that manufacturers pay rebates. DoD should bring the stakeholders to the table and benefit from their input prior to rolling out the new Section 703 Program.

C. Implementation Through the VHCA Master Agreements Would Be Improper.

Section 703 provides that Tricare retail utilization shall be subject to the price ceiling provided for in Section 603 of the VHCA; however, the price ceiling set forth in the VHCA is not self-executing. Rather, it is implemented through Master Agreements entered into between the VA and pharmaceutical manufacturers. Based on the Letter, it appears that DoD intends to implement its Section 703 Program under the existing Master Agreements, as was attempted under the predecessor TRRx program.[2] While it is clear that the Section 703 Program must be implemented through a contract with manufacturers, the existing Master Agreements between the VA and manufacturers are not the appropriate contract vehicle for implementation of the new program.

1. The Section 703 Program is outside the scope of the Master Agreements.

a. The Tricare Retail Pharmacy Network is not a "depot."

Under the Master Agreements, as a condition of receiving Federal reimbursement under Medicaid and Medicare Part B, participating manufacturers have agreed to: (1) make their "covered drugs" available for procurement on a Federal Supply Schedule (FSS) contract and (2) charge no more than FCP (as defined in the VHCA) to the VA, DoD, Public Health Service (PHS), and Coast Guard (collectively the Big 4) when those agencies procure product from the FSS contract or under a depot contracting system. It is undisputed that pharmaceuticals dispensed at retail pharmacies under DoD's Tricare retail pharmacy program are not purchased by DoD off of an FSS contract. Accordingly, the new Section 703 Program falls within the scope of the Master Agreements only if it qualifies as a DoD "depot contracting system." For the reasons discussed below, it does not.

To come within the VHCA definition of "depot," covered drugs must be "***procured by*** a [Big 4] agency of the Federal Government." *See* 38 U.S.C. § 8126(h)(3)(ii) (emphasis added). "Procurement" is defined under the Federal Acquisition Regulation (FAR) as "the acquiring by contract with appropriated funds of supplies . . . by and for the use of the Federal Government." 48 C.F.R. § 2.101. Taking into consideration the FAR definition of the term "procurement," the Big 4 depot contracts contemplated by the VHCA involve contracts under which Federal agencies, or their contracted "prime vendors," purchase product and warehouse that product for distribution to health care facilities within that agency's health system. S. Rep. No. 102-401, at 62 (1992); H.R. Rep. No. 102-384 (I), at 4 (1991); *see supra* section II.A.1.

In contrast, with respect to pharmaceuticals dispensed at retail pharmacies, DoD is not procuring product; rather, it is acting as a third-party payor when its beneficiaries fill prescriptions at retail pharmacies. DoD's role as an insurer vis-à-vis retail pharmacies is vastly different than its role as a purchaser of product for its military treatment facilities and its mail

[2] Because the Master Agreements are executed, administered, and enforced by the VA, it is clear that DoD will need to obtain VA approval and concurrence to proceed under the Master Agreements.

order pharmacy. Additionally, the text of Section 703, which provides that retail pharmacy utilization "***shall be treated as*** an element of the Department of Defense for purposes of the procurement of drugs," is a tacit admission by Congress that such utilization is not, in fact, a DoD "procurement." (emphasis added).

b. The Federal Circuit declared TRRx to be a "new refund system."

The Federal Circuit's 2006 decision in the *Coalition* case further supports the conclusion that the proposed Section 703 Program falls outside the scope of the existing Master Agreements because it is not a depot contracting system as the term is used in those agreements. 464 F.3d 1306, 1317 (Fed. Cir. 2006). As part of its determination that the VA's 2004 Dear Manufacturer letter was a substantive rule, the Court held that the VA's letter "changes existing law and affects individual obligations because it creates a ***new*** refund system." *Id.* (emphasis added). If, as suggested by the Government, a retail pharmacy rebate program were already encompassed by the Master Agreements, VA's 2004 letter would not have represented a change in existing law.

2. The Government lacks authority to unilaterally amend the Master Agreements.

Section 703 cannot be understood to revise the terms of existing Master Agreements. Because FCP-based refunds for retail pharmacy utilization are not within the scope of the Master Agreements, DoD cannot use the Agreements as a vehicle for implementing its new Section 703 Program. The Master Agreements are contracts to which the VA (on behalf of the Big 4) is a party. As a contracting party, the Government is subject to the normal rules governing contractual relationships. *See, e.g.*, *United States v. Winstar Corp.*, 518 U.S. 839, 886 (1996) (applying standard contract principles to government contracting). Thus, like any other contracting party, the Government is bound by the terms to which it agreed. When manufacturers entered into their Master Agreements, they promised to provide discounted prices for DoD purchases off of the FSS or under a depot contract. The Master Agreements did not provide for a rebate system based on retail pharmacy utilization, and the Government cannot amend the contracts by fiat. Additionally, unlike the Medicaid agreements entered into with the Centers for Medicare and Medicaid Services, the Master Agreements do not require manufacturers to comply with subsequent changes to the law. *See* Medicaid Drug Rebate Agreement, Section II.c. As the Master Agreements provide, except for changes in address, "this Agreement will not be altered except by an amendment in writing signed by both parties." MA, Section VII.E.

Moreover, the VHCA explicitly states that the manufacturers' obligations under the Master Agreements will remain fixed over time:

> A manufacturer is deemed to meet the requirements of subsection (a) [entering into a Master Agreement] if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after the enactment of this section) and would have entered into an agreement under this section (as such

> section was in effect at such time), but for a legislative change in this section after November 4, 1992.

38 U.S.C. § 8126(g)(2). Section 8126(g)(2) constitutes an unmistakable promise by the Government that subsequent legislation would not affect manufacturers' rights under the VHCA and Master Agreements. *See generally Winstar*, 518 U.S. at 877 (plurality opinion) (discussing the "unmistakability doctrine"). The fact that manufacturers' obligations under the Master Agreements would remain static was a valuable part of the consideration used to induce manufacturers to participate in the VHCA pricing program. Section 703 does not alter the significant and unmistakable promise made in 8126(g)(2). Accordingly, under the terms of the VHCA, the Government cannot unilaterally impose the Section 703 Program under the existing Master Agreements.

3. Any attempt by the Government to unilaterally modify the Master Agreements will result in a breach of contract.

Even if the Government had the authority to unilaterally alter the terms of the existing Master Agreements — which it clearly does not — such action would result in a breach of contract under the *Winstar case* and its progeny. In *Winstar*, the U.S. Supreme Court held that when the Government passes legislation aimed at altering the rights of parties under specific contracts with the Government, the Government is liable for damages resulting from its breach of those agreements. *Winstar*, 518 U.S. at 881 (citing *Sun Oil v. United States*, 572 F.2d 786, 817 (Ct. Cl. 1978) (rejecting the sovereign acts defense where the Government's actions were "directed principally and primarily at plaintiffs' contractual rights")); *see also, Mobil Oil Exploration and Producing Southeast, Inc. v. United States*, 530 U.S. 604, 607, 624 (2000); *Alaska Pulp Corp. v. United States*, 48 Fed. Cl. 655 (2001).

Section 703 clearly was directed "principally and primarily" at manufacturers' obligations under the Master Agreements. The sole purpose of the legislation was to secure for DoD greater access to FCPs than is currently afforded under those Agreements. However, as explained in *Winstar*, it is well-settled that "the Constitution bar[s] the Government from forcing some people alone to bear public burdens which . . . should be borne by the public as a whole" and the Government may not "simply shift costs of legislation onto its contractual partners who are adversely affected by the change in the law, when the Government has assumed the risk of such change." *Id.* at 883 (internal quotations omitted). Therefore, to the extent that the Government relies on Section 703 as a basis to unilaterally alter the Master Agreements, the Government will be liable for breach of contract damages. *See Winstar*, 518 U.S. at 881.

Moreover, alteration of manufacturers' rights under their existing Master Agreements to require FCP-based rebates could well have an impact on Uniform Formulary Voluntary FSS blanket purchase agreements and retail rebate agreements that already have been awarded contingent on Uniform Formulary positioning. BIO hopes and expects that DoD will consider its therapeutic class competitions and any resulting agreements when moving forward with implementation of its Section 703 Program.

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BIO greatly appreciates the opportunity to comment on the important issues raised by TMA's Letter. Given the concerns surrounding implementation of the Section 703 Program under current Master Agreements, we at BIO are committed to working with DoD to identify alternative approaches to a Tricare retail pharmacy program under Section 703 and otherwise to help DoD achieve the retail savings it seeks. BIO looks forward to working with DoD and TMA to ensure that Section 703 is implemented effectively, efficiently, and in accordance with the law. We sincerely hope that you will give thoughtful consideration to our comments. Please feel free to contact Sandra Dennis at 202-962-6673 or John Siracusa at 202-312-9281 if you have any questions regarding this response.

Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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/s/

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