MEETING WITH OIRA REGARDING DOD REGULATIONS REQUIRED TO IMPLEMENT SECTION 703 OF THE NATIONAL DEFENSE AUTHORIZATION ACT OF 2008
APRIL 23, 2008

The Anticipated Regulatory Action:

In 2007, Congress decided that contract ceiling prices applicable to DoD procurements of covered drugs should apply to prescriptions purchased by DoD beneficiaries from retail pharmacies. Section 703 of the National Defense Authorization Act for FY 2008 requires the Tricare Retail Pharmacy benefit program be treated as an "element" of DoD for purposes of procuring drugs from manufacturers under sec. 8126 of title 38, but did not specify a mechanism for obtaining prices from manufacturers on purchases from third parties. Instead, Congress directed DoD to promulgate a regulation by December 31, 2007, with respect to prescriptions dispensed on or after the date of enactment (January 28, 2008). DoD has yet to propose a regulation and has taken the position that the statute is effective without a regulation or agreement.

Background:

Sec. 8126 requires that manufacturers of covered drugs enter into a "Master Agreement" with the VA in exchange for Medicaid coverage, and specifies the Agreement terms. The Agreement promises to cap prices manufacturers charge for drugs they sell the Government under the Federal Supply Schedule or through a "depot contracting system." As consideration for entering into the Agreement, and to ensure program stability and a long term source of supply, sec. 8126(g) provides that manufacturers will be deemed compliant with the Master Agreement requirements regardless of subsequent amendments to the statutory requirements.

At DoD's request, the VA tried to interpret the statutory terms as including an obligation to rebate to DoD a portion of the prescription price it paid retail pharmacies; however, the Court of Appeals for the Federal Circuit held that such an obligation could not be read into the existing law and it invalidated the VA's action as defective rulemaking.

The Regulatory Problems:

1) **DoD's Intended Regulation Improperly Shifts the Cost of a Public Program from DoD to the VA's Contractors.** DoD intends to promulgate a regulation that would compel payment of manufacturer rebates on purchases from retail pharmacies to reduce the cost of that program. Because sec. 8126 is implemented through contractual promises, and no "element" of DoD is entitled to refunds on prescriptions under the Master Agreements, it must be assumed Congress expected DoD to devise a regulation that would use market clout and competition to obtain voluntary participation in a rebate program, not to alter the terms of executed agreements and take profits on commercial sales through compulsory rebates in order to finance its benefit program.

DoD asserts that Congress altered the terms of executed Master Agreements and gave DoD a contractual means to impose its regulatory requirements; however, that position would necessarily breach the existing Agreements. The Supreme Court has made it clear that the Government cannot by decree shift the cost burden of providing a benefit program onto its contractors without incurring liability. Accordingly, should DoD establish a mandatory rebate program by regulation, it is doubtful that participation could be enforced. Moreover, mandating large discounts in the absence of competition has a long term adverse impact on the cost and availability of innovator drugs in the commercial marketplace.

2) **An Interim Final Rule Would Be Costly and Inefficient**. DoD's regulation will raise many serious legal issues that must be addressed through notice and comment rulemaking before the final rule becomes effective. Rebate programs are complex, and manufacturer compliance requires massive investments of time and resources. It makes no economic sense to allow DoD to follow procedures for promulgating an interim rule with comment and force manufacturers to incur an enormous expense and time commitment when the rule could be changed.

3) **Retroactive Application of DoD's Intended Regulation Will Cause Economic Harm**. Even if DoD could amend contract terms by regulation, it has not established a regulatory obligation to pay rebates. Manufacturers are being told by DoD that when a rule is finally promulgated, it will require payment of rebates on prescription transactions that occurred prior to creation of the payment obligation, back to the date of enactment. Because of this potential indeterminate liability, manufacturers do not know how it will impact revenue received from prior commercial sales - whether they should accrue, how much to accrue or for how long. If DoD takes a year or more to finalize a regulation, and manufacturers must carry tens of millions of dollars in reserves, it will severely impact their financial reporting. Companies need certainty in their business dealings. It is contrary to fundamental regulatory principles to reach back and affect rights and obligations with respect to prior transactions.

Congress intended that DoD have a rule in place by December 31, 2007, and that it should apply only to transactions after the date of enactment. As there is no indication that Congress intended for DoD to apply a delayed regulation retroactively to transactions occurring more than a quarter prior to promulgation of the rule, such a rule is vulnerable to challenge.

The Solution:

DoD has placed the VA and manufacturers in an untenable situation. DoD should not be permitted to promulgate a regulation that would alter the bargain the VA struck with manufacturers and compel them to pay DoD proceeds from commercial sales for the purpose of reducing the cost of a DoD program. DoD should only be permitted to induce participation in a rebate program through leveraging its Tricare purchasing power and competition for DoD business. Such a result would obviate the need for compulsory regulatory obligations and the attendant costly legal challenges associated with such action.

Additionally, DoD should not be permitted to promulgate a regulation that covers transactions occurring more than one quarter before the effective date of the final rule.