OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Carl Levin
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable James H. Webb
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Ike Skelton
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Howard P. "Buck" McKeon
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

This letter is in response to Senate Appropriations Committee Report 111-74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Joe Wilson
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Daniel K. Inouye
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Daniel K. Inouye
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable Jerry Lewis
Ranking Member

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

APR - 1 2010

HEALTH AFFAIRS

The Honorable Norm Dicks
Chairman, Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter is in response to Senate Appropriations Committee Report 111–74 on H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year (FY) 2010, which requests a report to the congressional defense committees within 90 days after enactment on the status of implementation of Section 703 of the National Defense Authorization Act for FY 2008, including an assessment of whether additional legislation is needed to effectuate the purpose of Section 703.

The enclosed report provides the status of implementation of the retail pharmacy Federal Ceiling Price legislation, an analysis of whether additional legislation is required, and the status of refunds.

Thank you for your continued support of the Military Health System.

Sincerely,

Charles L. Rice, M.D.
President, Uniformed Services University of the Health Sciences
Performing the Duties of the Assistant Secretary of Defense (Health Affairs)

Enclosure:
As stated

cc:
The Honorable C. W. Bill Young
Ranking Member

REPORT ON STATUS OF IMPLEMENTATION OF FEDERAL CEILING PRICE LEGISLATION

MARCH 2010

This report to the Congressional Defense Committees is in response to the request contained in Senate Report 111-74, Report of the Senate Committee on Appropriations to accompany H.R. 3326, the Department of Defense Appropriations Bill for Fiscal Year (FY) 2010.

Executive Summary.

The Committee wants to determine whether the $761 million Defense Health Program savings for TRICARE retail pharmacy Federal Ceiling Price implementation will be realized or whether current circumstances suggest a shortfall. Although the pharmaceutical industry seeks to nullify the TRICARE Retail Federal Ceiling Price statute through litigation, DoD has obtained pricing agreements covering almost all retail prescriptions and is collecting refunds under those agreements. However, early collection amounts are lower than the initial projections. Finally, in response to the Committee's request, DoD does not believe any further legislation is needed to effectuate the purposes of the TRICARE Retail Federal Ceiling Price statute. This view may change, depending on the outcome of the continuing litigation.

Background.

Senate Report 111-74, page 224, included the following:

> *Federal Procurement of Pharmaceuticals.*-- The Committee notes that the fiscal years 2008 and 2009 budgetary savings programmed by the Department of Defense and the Office of Management and Budget for manufacturer refunds for TRICARE retail pharmacy prescriptions under Section 703 of the National Defense Authorization Act for Fiscal Year 2008 have not been realized. However, the Department of Defense and the Office of Management and Budget have assumed over $760,000,000 in savings for fiscal year 2010. The Committee is deeply concerned that they too will not be realized. Coupled with a private sector care shortfall, potential prospective payment shortfall, and medical information technology unfunded requirements, this will create extreme stress on an account that directly affects service members and their families. Therefore, the Committee directs the Secretary of Defense to report to the congressional defense committees within 90 days after the enactment of this act on the status of implementation of section 703, including an assessment of whether any additional legislation is needed to effectuate the purposes of Section 703.

Statutory and Regulatory Authority.

Section 703 of the National Defense Authorization Act for Fiscal Year 2008 enacted 10 U.S.C 1074g(f), which provides:

> (f) Procurement of pharmaceuticals by TRICARE retail pharmacy program. With respect to any prescription filled on or after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2008 [January 28, 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.

The effect of this law is that for all prescriptions filled on or after January 28, 2008, all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices (FCPs). After a period for public comments under the rule making process of the Administrative Procedure Act, DoD implemented this law through the promulgation of a Final Rule (32 C.F.R. § 199.21(q), 74 Federal Register 11,279), published March 17, 2009, and effective May 26, 2009. The two primary provisions of the Final Rule are:

- Pharmaceutical manufacturers are required to sign a written agreement to honor FCPs as a condition of eligibility for preferred Tier 2 status on the Uniform Formulary (UF) and unrestricted access through retail network pharmacies. Consistent with standard commercial practice in the retail pharmacy sector and the established TRICARE program of voluntary retail refunds, FCPs are implemented through refunds of the amount above FCPs the manufacturer was paid when the drugs entered the commercial stream, typically through a sale to a distributor.

- For prescriptions not covered by a UF pricing agreement, FCPs still apply under the statute, but collection of the refund is subject to waiver or compromise, including a potential waiver of all collections if the manufacturer withdraws its drug from the TRICARE pharmacy benefits program. Waiver and compromise requests are considered based on the established TRICARE procedures under the Federal Debt Collection Act (32 C.F.R. § 199.11), which generally include Justice Department approval to waive or compromise a significant amount.

Status of Implementation of Statute and Final Rule.

Since the effective date of the Final Rule, the status of implementation on these two primary provisions is as follows.

- Agreements with manufacturers have now been signed prospectively covering the overwhelming majority of the prescriptions for covered drugs subject to FCPs. The effective dates of these prospective agreements are generally dates in June or July 2009.

- For prescriptions not covered by these agreements, particularly prescriptions filled between January 28, 2008, and the effective dates of the agreements, pharmaceutical manufacturers have requested waiver of any refunds. No company has requested removal of any of its drugs from TRICARE Pharmacy Benefits Program coverage. The waiver requests that have been submitted are pending review.

Litigation Pending.

While DoD took these steps to implement the statute, there was at the same time a litigation challenge to the validity of the Final Rule in a case called *Coalition for Common Sense in Government Procurement v. U.S.*, U.S. District Court for the District of Columbia, Civ. No. 08-996 (JDB), 2009 U.S. Dist. LEXIS 110746. The Court issued a decision November 30, 2009. This decision had four major points:

- Although 10 U.S.C. § 1074g(f) requires that FCPs shall apply, the statute does not specify how they will apply. DoD incorrectly interpreted the statute as requiring manufacturer refunds, to the exclusion of other possible approaches. DoD must reconsider the implementation of the statute as a function of its discretionary judgment, rather than only as a legal interpretation. For example, DoD should exercise its discretion to consider "which of the five parties that participate in the retail pharmacy program – manufacturers, wholesalers, network pharmacies, private pharmacy benefit managers, and TRICARE beneficiaries – must bear any costs associated with imposing the Federal Ceiling Prices."

- While DoD considers whether to readopt the Final Rule as it currently stands or to change it, the Final Rule will remain in effect, as will the manufacturer agreements that cover the overwhelming majority of TRICARE retail prescriptions for covered drugs. (This is the effect of the Court's Order that the Final Rule is "remanded without vacatur.")

- DoD correctly interpreted the statute as applying Federal Ceiling Prices to all prescriptions filled on or after January 28, 2008.

- The Court ordered that DoD file a status report with the Court by not later than March 1, 2010, "documenting its consideration on remand." DoD filed the requested report with the Court on 17 February 2010.

Following the Court order, the Plaintiff, representing the pharmaceutical companies, filed a notice of appeal to the United States Court of Appeals for the District of Columbia Circuit. DoD initiated action to comply with the Court order through a notice in the Federal Register February 9, 2010, inviting additional public comments on the matters addressed by the Court. DoD intends to consider public comments received and to reissue a Final Rule in 2010, consistent with the views expressed by the Court. The 2009 Final Rule remains in effect in the meantime. Following the issuance of the 2010 Final Rule, DoD anticipates that litigation will continue.

Status of Refunds

Through February 28, 2010, the Defense Health Program has received $168 million in refunds. The amount of FCP refunds received is lower than the original projected savings. As the amounts received represents only a small sample of the fiscal year, extrapolating this data to reflect the full year of refunds would be premature. DoD will continue to closely monitor the FCP refunds and provide an updated estimate after the mid-year review.