

**Department of
Veterans Affairs***W. J. Sullivan*
Memorandum

Date: JUL 15 1993

From: General Counsel (025)

Subj: Delegation of Hearing Responsibility, Title VI, P.L. 102-585, Drug Pricing Agreements

To: Secretary (00)

1. As Secretary you have several duties and responsibilities under the subject Law. The Law requires manufacturers of covered drugs to enter into Master Agreements and Pharmaceutical Pricing Agreements with VA under which a Federal ceiling price (FCP) will be set according to calculations described in 38 U.S.C. 8126(a)(2), (c) and (d). Subsection (a)(2), after setting forth the formula for ceiling price calculations, states the following narrow exception:

"...except that such price may nominally exceed such amount if found by the Secretary to be in the best interest of the Department or such Federal agencies;"

2. The procedures for determining whether a manufacturer may be granted an FCP nominally in excess of the calculated figure are not described either in the Law or the Master Agreement which was developed by VA to implement the Statute. The Master Agreement does contain dispute resolution clauses, one of which refers to the Contract Disputes Act and the Board of Contract Appeals, but these clauses do not discuss applications to the Secretary for exercise of his discretion to allow an FCP greater than the figure required by the Statute.

3. In a decision paper approved on or about December 23, 1992, Acting Secretary Principi, along with Deputy Undersecretary Hawkins and Deputy General Counsel Coy, approved adoption of certain general screening standards to be used in processing manufacturers' requests for nominal increases in their FCPs. The Law itself sets forth the first criterion, i.e., that the increase be found "...to be in the best interest of the Department or such Federal agencies;..."

4. Several companies have complained of 1993 FCP's which are below their claimed production costs. Two companies have submitted formal requests for a nominal increase. In order to process these requests and others in a fair and orderly fashion without consuming vast amounts of time and attention by the Secretary, authority to rule on requests for nominal FCP increases should be delegated to deliberative bodies with expertise in the subject area.

5. It is recommended that the authority to exercise the Secretary's discretion and grant or deny requests for nominal increases in FCPs be delegated to two separate bodies.

a) An ad hoc VA FCP Nominal Increase Board should be established consisting of three members: an attorney from the Office of General Counsel, Chief, Drug & Pharmaceutical

2.

Secretary (00)

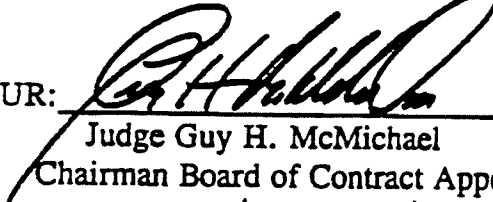
Product Management (119), Hines, Illinois, and an external auditor from VAOIG (53C). This board would have liaisons from the National Acquisition Center Pharmaceutical Division (904E), PHS and the DoD. Its function would be to receive and review nominal FCP increase applications for completeness and to determine if they meet the threshold criterion of demonstrating that an increase would be in the Government's interest. Oral presentations by applicants would be allowed if requested by them, where the Government's interest was not made evident on the face of the application.

If a request for FCP increase were found by the Board to meet the threshold issue of being in the VA's best interest, the Board would then determine the appropriate increase amount. As the decision paper above specifies, the increase in most instances could not exceed 10% of the most recently reported non-FAMP figure. The exact increase would be determined after considering the applicant's financial submissions and VA's comments and/or audit information.

b) If the manufacturer decides to appeal the decision by the FCP Increase Board, the appeal would be to the VA Board of Contract Appeals. The decision of the VABCA would be final.

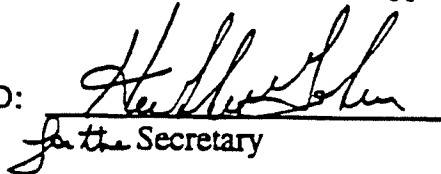
Authority for receiving and ruling on discretionary FCP increase applications (within the Secretary's guidelines) is hereby delegated to an FCP Nominal Increase Board consisting of an OGC attorney, Chief, Drugs & Pharmaceutical Products Management (119), and a VAOIG auditor (chosen by Director Contract Audits (53C). Authority to hear and determine any appeal from an adverse decision by the FCP Nominal Increase Board is hereby delegated to the VA Board of Contract Appeals, whose decision shall be final.

CONCUR:


Judge Guy H. McMichael
Chairman Board of Contract Appeals

July 16, 1993
Date

APPROVED:


for the Secretary

7-29-93
Date