

12046 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

STATE OF CALIFORNIA



HEALTH AND WELFARE AGENCY

OFFICE OF THE SECRETARY

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March 10, 1975

Mark Novitch, M.D.
Deputy Associate Commissioner
for Medical Affairs
U. S. Food and Drug Administration
Rockville, MD 20852

Dear Doctor Novitch:

Thank you for your letter of February 26, 1975, regarding comments submitted by Earl W. Brian, M.D., former Secretary of the California Health and Welfare Agency, on the proposed Maximum Allowable Cost (MAC) regulations. I appreciate the opportunity to comment on Dr. Brian's letter and his cost study.

It would serve little purpose to critique Dr. Brian's study line by line. We believe it is important to recognize that the study presents only the personal conclusions of Dr. Brian. Our own assessments of California's Reimbursable Cost List Price (RCLP) program, and its successor, the current Maximum Allowable Ingredient Cost (MAIC) program, are diametrically opposed to those of Dr. Brian and, thus, Dr. Brian's position in no way reflects that of this Agency.

Staff of the California Department of Health, under my direction, have performed a thorough review and analysis of Dr. Brian's study and offer the following comments for your consideration:

1. There are numerous data and technical errors, perhaps because of the researcher's lack of access to accurate and complete data, and of specific program knowledge. Specifically, the applicable pharmacy fees for prescription dispensing and their effective dates are misquoted (page 4). The term "generic drug" is used when he should have used "RCLP" (paragraph 3, page 4). Reference is made to voluntarily submitted proposals (paragraph 2, page 5) when in actuality, at that time, the Department was actively soliciting such proposals. These are mere examples of types of inaccuracies which appear countless times throughout the study.

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