d. Provide the following transportation data for FY 1971:

	Receipts		Shipments	
	No.	Short tons or pounds (Indicate)	No.	Short tons or pounds (Indicate)
Carload				
LCL				
Truckload				
LTL				
Railway Express				
Air				
Parcel Post				
Other				
Total				

e. Supply support of depot items to other Federal agencies:

	No. of Destinations	Dollar Value
Drugs		
Other medical material		
Nonperishable subsistence		
Other		
Total		

F. Workload

a. Indicate for material in stock as of June 30, 1971.

	No. of Items	Dollar Value	Short Tons
1. Drugs			
2. Other medical material			
3. Nonperishable subsistence			
4. Other			
5. Total			

b. Provide the following receipt and issue data for FY 1971.

	Receipts			Issues		
	No. of Line Items	Dollar Value	Short Tons	No. of Line Items	Dollar Value	Short Tons
1. Drugs						
2. Other medical material						
3. Nonperishable subsistence						
4. Other						
5. Total						

c. Do you issue any drugs, other medical material, or nonperishable subsistence with any authority other than a shipping order from the inventory control point? If so, what documents do you honor and from what sources do these documents originate? Do not include those instances in which a requisition will be submitted to the ICP to formalize the action.

Data Processing Equipment Application

	Total	Medical Material	Nonperishable Subsistence	Other
ADPE (Identify mainframe(s))				
Functional Application				
_____				
_____				
_____				
EAM (Other than peripheral equipment for above)				
Type_____				
_____				
_____				

D. Other characteristics

1. What are you facilities and capacity for receipt and shipping material?

2. What is the value of your materials handling equipment? List permanently installed equipment separately.

E. Data Processing Equipment

	Date Installed	Monthly Rental Cost	Govt.-owned Monthly Maintenance Cost
ADPE (List each mainframe and major component such as tape unit)			
_____			
_____			
_____			
EAM (List each machine)			
_____			
_____			
_____			

	Total	Medical	Drugs	Nonperishable Subsistence
(g) Real property rental costs				
(h) Materials handling equipment maintenance				
(i) Other operating costs (Specify)				
(j) Total costs				

(3) What portion of the total personnel and other operating costs is financed from stock or supply funds; from appropriated funds?

C. Space

	Total	Medical Material	(Drugs)	Nonperishable Subsistence
1. Gross sq. ft. of storage space				
2. Net usable				
(a) Open				
(b) Shed space				
(c) Closed warehouse space				
3. Net occupied				
(a) Open				
(b) Shed space				
(c) Closed warehouse space				
(1) Bulk				
(2) Bin				
(3) Security Storage				
(4) Refrigerated storage				
(5) Inflammable storage				
4. Administrative space (ADP)	( )	( )	( )	( )

B. Operating Costs.

(1) Provide the following personnel strength and cost data: If military and civilian, indicate each.

	Total Personnel	Total Salary Costs	Medical Pers.	Medical Salary Costs	Drugs Pers.	Drugs Salary Costs	Nonperishable Subsistence Pers.	Nonperishable Subsistence Salary Costs
(a) Management								
(b) Other Administra.								
(c) Receipt, storage & Issue								
(d) ADP operations								
(e) Traffic Mgt.								
(f) Stock Control								
(g) Financial Operations								
) Facility Support (Maintenance & Security)								
(i) All other, Identify								

(2) Provide other operating cost data:

	Total	Medical	Drugs	Nonperishable Subsistence
(a) Utilities				
(b) Travel				
(c) Transportation				
(d) Operating supplies & equipment				
(e) Real property maintenance				
ADP				
(1) rental				
(2) procurement				

A. Organization and Management

1. What is your assigned mission? Are you limited to geographical locations for activities you support? If so, what are the geographical boundaries of your area of responsibility?

2. Provide a copy of your current organizational charts and functional statements.

3. What support, e.g., administrative, is received from or provided to other activities by your organization? Indicate each other activity, specific support received or provided, and whether reimbursable. If reimbursed, indicate amount for each for FY 1971.

Organization name and location: _____

_____

_____

Name of person to contact for further info: _____

_____

_____

Telephone: Area Code_____ Telephone No._____

APPENDIX C

(3) What portion of the operating and personnel costs indicated in the previous charts is financed from stock or supply funds; from appropriated funds?

CHART #2

OPERATING COSTS CY 1971
(Dollars in Thousands)

*If not separable from medical material so indicate.

	Medical Material*				Drugs (FSC 6505)*				Nonperishable Subsistence				All Other Commodities				Total			
	End Str.	Man Yrs.	Salary Costs	Other Costs	End Str.	Man Yrs.	Salary Costs	Other Costs	End Str.	Man Yrs.	Salary Costs	Other Costs	End Str.	Man Yrs.	Salary Costs	Other Costs	End Str.	Man Yrs.	Salary Costs	Other Costs
Total Personnel (Mil & Civilian)																				
(a) Item Management																				
Military																				
Civilian																				
(b) Stock Control																				
Military																				
Civilian																				
(c) Cataloging																				
Military																				
Civilian																				
(d) Standardization																				
Military																				
Civilian																				
(e) Purchas. & Contr.																				
Military																				
Civilian																				
(f) Contract Admin.																				
(1) Other than Inspec.																				
Military																				
Civilian																				
(2) Inspection																				
Military																				
Civilian																				
(g) Management																				
Military																				
Civilian																				
(h) ADP operations																				
Military																				
Civilian																				
(i) Other Adm. Support																				
Military																				
Civilian																				
(j) Facility Support																				
Military																				
Civilian																				

F. Operating Costs.

(1) Provide personnel costs as indicated in the attached chart 2:

(2) Provide other operating costs for CY 1971 as indicated in the following chart:

	Total Costs	% Medical Items	% Nonperishable Subsistence
Utilities			
Travel			
Transportation			
Administrative supplies and equipment			
Real property maintenance			
Administrative space			
Owned (Sq. Ft._____)			
Rented (Sq. Ft._____)			
ADP applicable to supply operations			
Rental			
Purchase			
Maintenance			

E. Data Processing Equipment and Application

	Total	Medical Material	Nonperishable Subsistence	Date Installed
ADPE (List each mainframe and major component, such as tape unit and functional application)				
_____	____	_____	_____	_____
_____	____	_____	_____	_____
_____	____	_____	_____	_____
_____	____	_____	_____	_____
EAM (List each machine, other than peripheral equipment for above)				
_____	____	_____	_____	_____
_____	____	_____	_____	_____
_____	____	_____	_____	_____
_____	____	_____	_____	_____

(c) How many shipments did you order to be made from a commercial source to a using point during CY 1971? Provide the point of origin of each shipment and the destination of each shipment. Provide total tonnage and transportation costs involved. Provide the dollar value of (a) drugs, (b) other medical items, and (c) nonperishable subsistence of these shipments.

(b) For each storage point in the wholesale distribution system, provide the following:

(1) The number of shipping orders issued by you during CY 1971.

(2) The destination point (installation name) of the shipments and total tonnage shipped to each point in (a) drugs, (b) other medical items, and (c) nonperishable subsistence. For foreign shipments provide the CONUS city or port of exit and tonnage, for each.

(3) The dollar value in (a) drugs, (b) other medical items, and (c) nonperishable subsistence shipped to each point.

(4) What was the total transportation costs for these shipments?

(n) Do your responsibilities include the assembling, manufacturing, or repairing of any medical item, the compounding or repackaging of drugs, or the direction of such activities? If so, specify the items and present arrangements for such actions.

(o) Describe briefly your system for inventory accounting.

5. Distribution System

(a) For your distribution system, provide the following:

(1) In which depots by location are these commodities stored?

(2) Specific storage, distribution, and maintenance mission of each. Identify key missions.

(3) If distribution mission is wholly or partly geographical, indicate area for each depot and primary users in each area.

(4) What is the rationale for the particular distribution system (pattern) used?

(5) Are additional storage facilities identified and available for temporary storage needs or for permanent positioning of stock for shifting distribution patterns? If so, where are they located and what is the gross storage space available in each?

(6) Do you manage or rotate any stock owned by another activity, e.g., civil defense stockpile, prepositioned war reserves, etc.? If so, identify the location of storage and amount of stock in short tons, dollar value, and line items for each commodity.

(k) Explain the methods used to compute each level of supply, e.g., types and period of issue data used, smoothing techniques, factors, etc.

(l) What types of stocks require specific rotation plans and what methods are employed to accomplish? Indicate any stocks which require rotation that are not under your "ownership."

(m) Provide the dollar value of stocks destroyed during CY 1971 because deterioration had occurred or shelf life had expired.

Data as of December 31, 1971 (Dollars in Thousands) Chart #1

Level of Supply *	MEDICAL MATERIAL								Nonperishable Subsistence			
	Drugs (FSC 6505)				Other Medical Material							
	No. of days auth. **	$ Value of auth. level	$ Value on hand	$ Value due in								
Safety Level												
_____												
_____												
_____												
_____												
Specify Other Levels												
_____												
_____												
_____												
Excess Stocks												

* Title of each level in this column. Attach exact definition of each level of supply.

** Provide as applicable. Explain where not applicable or when more than a single number is authorized for a given level.

(i) What criteria is employed for return of material to the wholesale system and how is credit for these commodities determined?

(j) What levels of supply are authorized and maintained and what are the inventory assets against each? Provide this data on the attached Chart 1:

(f) What surcharges to you impose on acquisition cost? What are the elements of each surcharge, how are they determined, and what percentage of item cost does each constitute? What was the dollar value of each element recovered during CY 1971? If these surcharges are not identical for all customers, identify each and the customers affected. What percentage of operating costs did these surcharges recover?

(g) Excluding surcharges, what is your criteria for basic item pricing?

(h) What criteria is employed for reducing item prices below cost in order to create activity or to move excess stocks?

(d) Provide the volume of requisitions and supply effectiveness for CY 1971. Include the following:

	Medical Material	Drugs	Nonperishable Subsistence
(1) Number of requisition line items			
(2) Percent supply availability (on hand when requisition is processed for filling)			
(3) Percent supply effectiveness (delivered within prescribed time limits)			
(4) Number of back orders on hand Dec. 31, 1971			

(e) Describe briefly how decisions are made for filling a given requisition. Include:

(1) ADP and manual data used to determine whether to fill from on hand stock, direct delivery from contractor, etc.

(2) Criteria used for selection of depot from which to issue from on hand stock.

(3) Criteria used to direct shipment from any other storage location when shipment cannot be made from the storage point originally selected. Provide the quantity and percentage of referrals made during CY 1971.

(4) Proportion of requisitions processed manually and criteria for manual versus ADP.

4. Inventory Management

(a) What is the item scope of supply management mission for (a) drugs, (b) other medical material, and (c) nonperishable subsistence?

(b) Provide quantitative data as required by D1(b), page 5, for these items.

(c) Provide a brief description of the system and procedures used for requisitioning on and supplying from the central supply system. If different systems and procedures exist for drugs, other medical items, and nonperishable subsistence, describe each. Include the following:

(1) Method and channels of requisition submission.

(2) Prescribed frequencies or cycles for requisitioning an item or group of items.

(3) Central editing.

(4) Priority system and methods used to effect delivery of material when required.

(5) Methods used to direct issues from depots.

2. Inspection and Quality Control

(a) Is inspection and/or testing accomplished for (a) drugs, (b) other medical items, and (c) nonperishable subsistence? If this is accomplished by another Federal or commercial activity, specify the activity and indicate the type of items tested and inspected.

(b) How much do you rely on Food and Drug Administration for drug and other medical items inspection? How much do you rely on the Department of Agriculture for nonperishable subsistence inspection?

3. Item Identification and Standardization

(a) What are your responsibilities in regard to obtaining Federal Stock Numbers for items you purchase and supply? Are all items repetitively procured assigned FSN's? At what point is the life of an item is a FSN assigned?

(b) What are your responsibilities in regard to developing or participating in the development of specifications? Did you develop and publish any specifications during the period subsequent to Jan. 1, 1971? If so, what was the title of each for (a) drugs, (b) other medical items, and (c) nonperishable subsistence? What background data was used in the development, i.e. manufacturers specifications, test results, etc.?

(f) Of those schedules indicated in D1(b)(4), what procedures exist and what kinds of information are prescribed to obtain volume of purchases and dollar values for each? What was the number of line items purchased and dollar value for each schedule for (a) drugs, (b) other medical items, and (c) nonperishable subsistence for CY 1971? If possible, provide these figures by using agency or department.

(g) Who performs preaward plant inspection on each type of contract?

(h) Are you responsible for administering each type of contract after award? If not, what activity assumes this responsibility for each type of contract?

(i) What are your responsibilities in regard to assuring industrial mobilization production capacity for these commodities?

	Purchase Actions	Number of Line Items	Dollar Value
(2) Purchases of items without assigned Fed. Stock Numbers			
Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____

(d) What is the average procurement lead time (from initiation of a purchase request to receipt of material) Provide as follows:

	Procurement Lead Time (Days)		
	Administrative Lead Time	Production Lead Time	Total
Medical Material:			
Specify subcategories			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Nonperishable Subsistence			
Specify subcategories:			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

(e) What are your responsibilities for purchasing those items indicated in (c)(2) above? What is your system for determining if an item has been previously purchased? At what point is an item which has had multiple purchases reviewed for central management and for assignment of a FSN?

	Purchase Actions	Number of Line Items	Dollar Value
(2) Purchases for Direct Delivery			
Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____
(3) Awards of Centralized contracts for direct ordering by users			
Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____
(4) Awards of Federal Supply Schedules			
Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____

(c) Of the awards indicated in (a) above, provide the following:

	Purchase Actions	Number of Line Items	Dollar Value
(1) Purchases for other agencies-Specify and provide for each agency:			
Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____

6. How many new items in (a) drugs, (b) other medical items, and (c) nonperishable subsistence entered the system in CY 1971? How many items in (a), (b), and (c) were removed from the system in CY 1971?

7. Provide, as of June 30, 1971, and December 31, 1971, the number of items in (a) drugs, (b) other medical items, and (c) nonperishable subsistence designated for each method of supply, e.g., stock, Federal Supply Schedules, other centrally managed schedules, local purchase, etc. Define each indicated method of supply.

). Operational Management

1. Purchasing and contracting

(a) For CY 1971, provide the following data:

Total Procurement Awards made for	Number of Line Items	Dollar Value
Medical Material	_____	_____
Drugs, FSC 6505	_____	_____
Nonperishable Subsistence	_____	_____

(b) Of the awards indicated in (a) above, provide the following procurement workload data:

	Purchase Actions	Number of Line Items	Dollar Value
(1) Purchases of Stock Medical Material	_____	_____	_____
Drugs, FSC 6505	_____	_____	_____
Nonperishable Subsistence	_____	_____	_____

2. By what method is a new item determined to be authorized for use? Specify the criteria used to determine if the method of supply for those items should be from stock, Federal Supply Schedules, local purchase, or other method.

3. How and by whom is the determination made that an item should no longer be authorized for use?

4. What kind of inactive item review program do you employ to determine when an item should be removed from the system?

5. What is the present status of the inactive item review program for these commodities?

6. What other support (e.g. administrative) is received from or provided to other activities by your organization? Indicate each other activity, specific support received or provided, and whether reimbursable. If reimbursable, indicate amount for each for CY 1971.

B. Installation Data

1. What is the gross square footage of administrative space of each type used for each commodity? Provide as follows:

	Total sq. ft.	Medical material	Nonperishable subsistence
General	_____	_____	_____
ADP	_____	_____	_____
Total	_____	_____	_____

2. What is the present market value of your real property?

3. How is this value derived?

C. Commodity Management

1. How are you informed of local purchases made in these commodities, the type of items being purchased, or other information from the user level to determine the volume of items being obtained by a method other than through your distribution system or through centralized contracts and schedules? How do you monitor volume of purchases of those items you have declared to be local purchase? If different methods exist for individual Federal Supply Classes or commotities, please specify each.

A. Organization and Management

1. What is your assigned mission in medical material on nonperishable subsistence? What is the legal or delegated authority for your mission including these commodities?

2. Provide current organizational charts, with number of personnel indicated for each unit, and functional statements for your entire organization with all activities involved with drugs, other medical material, and nonperishable subsistence identified.

3. Provide copies of any interagency support agreements that you use to either receive or supply items in these commodity groups.

4. What controls and procedures are employed to police activity within the scope of these agreements?

5. What has been the activity in line items and dollars in each agreement for CY 1971? Provide the amount of reimbursement for each agreement for FY 1971.

Specific Federal Supply Classes involved are as follows:

1. Group 65 - Medical, Dental and Veterinary Equipment and Supplies

   6505 - Drugs, Biologicals and Official Reagents
   6508 - Medicated Cosmetics and Toiletries
   6510 - Surgical Dressing Materials
   6515 - Medical and Surgical Instruments, Equipment and Supplies
   6520 - Dental Instruments Equipment and Supplies
   6525 - X-Ray Equipment and Supplies, Medical, Dental, Veterinary
   6530 - Hospital Furniture, Equipment, Utensils, and Supplies
   6532 - Hospital and Surgical Clothing and Textile Special Purpose Items
   6540 - Opticians Instruments, Equipment and Supplies
   6545 - Medical Sets, Kits and Outfits

2. Group 68 - Chemicals and Chemical Products

   6810 - Chemicals

3. Group 89 - Subsistence

   8905 - Meat, Poultry and Fish
   8910 - Dairy Foods and Eggs
   8915 - Fruits and Vegetables
   8930 - Bakery and Cereal Products
   8925 - Sugar Confectionery and Nuts
   8930 - Jams, Jellies and Preserves
   8935 - Soups and Bouillons
   8940 - Special Dietary Foods and Food Specialty Preparations
   8945 - Food Oils and Fats
   8950 - Condiments and Related Products
   8955 - Coffee, Tea and Cocoa
   8960 - Beverages, Non-Alcoholic
   8965 - Beverages, Alcoholic
   8970 - Composite Food Packages
   8975 - Tobacco Products

To further clarify any questions in the attached, the following definitions apply:

Other Medical Material - includes all Federal Supply Classes 6508 through 6545 and 6810 used for medical purposes. Do not include any prosthetic item in the above FSC's which is procured for a specific individual or any item in FSC's other than those above.

Drugs - All items classified in FSC 6505.

Nonperishable subsistence (food products only) - all FSG 89 except perishable items, i.e., not requiring refrigeration. These shall include nonperishable subsistence for use and resale by military commissary and nonappropriated fund activities.

Organization name and location:_____

_____

_____

Name of person to contact for further info:_____

_____

_____

Telephone: Area Code _____ Telephone No._____

APPENDIX B

14. A six-week period immediately following the last field visit will be devoted to analysis of reports, ADP output review, and preparation of preliminary report for presentation to the steering group.

15. Submission of the study final report and disbandment of the steering and study groups is tentatively scheduled for 45 days after steering group review of the preliminary report indicated in the foregoing paragraph.

7. The study group will complete study methodology and the development of ADP requirements the week of May 15, 1972, in order that this activity can commence with the receipt of completed questionnaires which will be scheduled for not later than June 30, 1972.

8. The last trip of fiscal year 1972 will be to the Atlanta, Georgia, area the week of May 22, 1972. Activities to be visited will be Army General Depot, May 22, 1972; Federal Prison Farm, May 23, 1972; VA Hospital, May 24, 1972; and Fort Benning, May 25, 1972.

9. Because of budget apportionment activities required during June 1972, no study activity will take place during the period May 30, 1972, through July 4, 1972. Study group members will be at their agency positions during this period.

10. The study group will reconvene July 5, 1972, to review the completed questionnaires and to process for key-punching the data and preparing for machine processing.

11. A joint meeting of the steering group and study group will take place July 20, 1972, to provide progress reporting and to present final methodology for steering group review and approval. The study group will present any recommendations for redirection of the study effort and identify any additional data it feels is required for study completion. Steering group decisions for any redirection of study effort will be made at this time. If further visits are necessary, firm dates will be developed for those visits tentatively identified in the following paragraphs.

12. The first field visit of fiscal year 1973 is tentatively scheduled for the Denver, Colorado-Albuquerque, New Mexico areas. Activities to be visited will be GSA Depot, Denver; VA Hospital, Denver, and BIA Depot, Gallup, New Mexico, and Indian Health Regional Office, BIA Regional Office, and GSA Subdepot, Albuquerque, New Mexico.

13. The final field visit of the study, scheduled for Northern and Southern California, will be for a two-week period. Activities to be visited in the San Francisco area will be Defense Depot, Tracy, California; Travis AFB, Fairfield, California; Letterman Army Hospital, VA Hospital, PHS Hospital and Kaiser Foundation, San Francisco, California; and Naval Supply Center, Oakland, California. Visits in the Los Angeles area will be to VA and Naval Hospitals, Naval Supply Center and Long Beach Memorial Hospital, Long Beach; VA Subdepot, Bell; and March AFB and BIA school, Riverside.

General Services Administration
Defense Supply Agency
Department of State and Agency for International Development
Defense Medical Materiel Board
Veterans Administration
Bureau of Prisons
Health Services and Mental Health Administration
Surgeon General, Department of the Army
Bureau of Indian Affairs

4. Study group work on data processing requirements and methodology for ADP output products will begin the week of April 24, 1971. Arrangements for keypunching and ADP facilities will also be made during that period. The study group will develop this methodology to assure that ADP products will provide data on transportation costs from origin to ultimate using installation, manpower, and other costs at ICP, depot, and sampled user installations. Products will indicate commonality of items at the ICP level and also commonality of items purchased locally at the user level. Commonality at the user level will involve items assigned FSN's and also those not assigned FSN's. A full listing of ADP products to be developed and final methodology for completion of the study will be provided to each member of the steering group not later than July 10, 1972, for an additional meeting of the steering group scheduled for July 20, 1972. The purpose of this meeting is provided in paragraph 11 of this section.

5. The first field trip of the study group will be made on April 28, 1972, to Public Health Service Depot at Perry Point, Maryland. Additional visits will be made to the Defense Personnel Support Center, Philadelphia on May 1 and 2, 1972. Visits to the VA and Naval hospitals on May 3, 1972. The Army and Air Force Liaison Offices in Phoenixville, Pennsylvania will be visited on May 4, 1972, in order to develop the relationship of those activities to their parent services and the DPSC. Information to be gathered at DPSC will include workload and cost data, inventory management information, procurement, receipt, and issue data, and depot storage data.

6. The second field visit will be to the Chicago, Illinois, area the week of May 8, 1972. Activities to be visited will be VA Marketing Center and Depot, Hines, Illinois, May 8 and 9, 1972; Great Lakes Naval Training Center, May 10, 1972, and VA Hospital, Downey, Illinois, May 11, 1972.

C. Study Schedule.

1. The first meeting of the study group will be held on February 8, 1972. Thereafter, the study group will meet for four days each week to develop questionnaires and itinerary for field visits necessary to complete the study. These will be presented to the steering group for approval and further recommendations on March 24, 1972. Any changes to the questionnaires suggested by the steering group will be accomplished during the week beginning March 27, 1972, with actual testing of the "user" questionnaire to be accomplished at meetings at Fort Belvoir on April 4, 1972, with Mr. C. Dobbs, the Base Commissary Officer and Major Garvin, the Medical Supply Officer for the DeWitt Army Hospital. Further questionnaire testing will be conducted April 5, 1972, with Mr. Samick, the Assistant Supply Officer for the VA Hospital in Washington, D. C. and Lt. Commander Lawson, the Supply Officer for the National Naval Medical Center in Bethesda, Maryland. Questionnaire modifications required as a result of these meetings will be accomplished on April 6, 1972, with further progress reporting and presentation of this Study Plan to the steering group to be accomplished April 13, 1972. At this meeting, the steering group representatives will also present information on that data requested in the inventory control point and depot questionnaires that are available from a headquarters location and therefore not required from the subordinate activities.

2. Printing of approved questionnaires in sufficient quantities for all recipients will commence April 17, 1972, with actual mailing to be accomplished not later than April 24, 1972, to the activities constituting the twenty percent sample and these activities scheduled for personal visits after July 1, 1972. Copies to be supplied to those activities scheduled for personal visits prior to June 30, 1972, will be Xeroxed and mailed April 14, 1972. Schedules for the personal visits appear below.

3. Meetings and briefings will be arranged with headquarters organizations in the Washington, D. C. area for the week beginning April 17, 1972. These meetings will be to provide the headquarters activities the purpose and plans for the study and to enable the study group to be acquainted with the missions of their activities involved in the study commodities, the headquarters relationship to those activities, and any workload and cost figures available. Arrangements will be made for meetings of approximately three hours duration to each of the following:

CHARTER PROVISIONS

FOR INTERAGENCY STUDY

OF OPTIMUM MILITARY AND CIVIL SUPPORT

OF NONPERISHABLE SUBSISTENCE AND MEDICAL MATERIAL

A. Purpose:

Pursuant to the Federal Property and Administrative Services Act of 1949, as amended, initiate an interagency study which will provide an economic analysis and appropriate recommendations for achieving effective and economical Government-wide support of medical and nonperishable subsistence supplies.

B. Organization and Administration:

1. The Steering Group shall be formed of representatives of the DOD, GSA, HEW, VA and OMB under the chairmanship of OMB.

2. The Study Group shall be comprised of representatives of DOD, GSA, HEW, VA and OMB under the chairmanship of OMB.

3. Administrative support for the Study Group, including secretarial assistance, work space, and data processing will be provided by GSA.

4. Pay and travel expenses for each Study Group member will be provided by his employing agency.

5. Functions of the Steering Group:

a. Provides their agencies' official position on study recommendations.

b. Provides final approval of all elements of the study schedule.

ATTACHMENT 3

STUDY PLAN

A. Study Authority. This study is being conducted in accordance with the provisons of the Study Charter. (See this report, Attachment 3)

B. General.

1. The study will be conducted under the guidance and direction of a Steering Group composed of Mr. James D. Currie, OMB Chairman, and Mr. Harry S. Spaulding, Defense; Mr. John M. Donovan, HEW, Mr. Louis Sorett, GSA; and Mr. Clyde Cook, VA as members. The Study Group will be composed of Mr. Richard Adams, OMB Chairman; and Mr. John Gee, Defense; Mr. Arnold Weiss, HEW, Mr. I. P. Ginsburg, GSA; and Messrs. William Jones and John Shea, VA, as members.

2. The study will be directed toward a review and analysis of the present central supply systems for drugs, and other medical material, and/or nonperishable subsistence of the Departments of Defense, HEW, and Interior, and the GSA and VA, with additional data to be collected at each agency's retail level. Data will also be obtained from all other Federal agencies having requirements for these materials such as the Departments of Justice, State, and Transportation, and the Agency for International Development. Questionnaires will be developed to obtain inventory, procurement, workload, issue, transportation, and other cost data for inventory control points and the depot activities toring and shipping these commodities. Personal visits will also be made to each inventory control point, three VA depots, three Defense depots, and one PHS depot.

3. A questionnaire will also be developed and directed to the hospitals, schools, and military post, camp, and station activities which receive support from the central systems. Those questionnaires will be submitted to twenty percent of Public Health Service, Veterans Administration and Department of Defense hospitals, and a selection of military camps, posts, and stations with little or no hospital activity. These questionnaires will be utilized to obtain data on those items being purchased locally outside the central systems, the procurement and personnel costs involved in subsistence items necessary for their operation and their comments on and recommendations to improve the central system. An additional personal visit will be made to the maximum number of twenty-three user activities in Philadelphia, Chicago, Denver-Albuquerque, Northern-Southern California, and Atlanta. These visits will be to obtain expanded answers to the questions contained in the questionnaire, to get a first-hand look at their operations, to personally speak to such individuals as the dieticians, pharmacists, and supply and procurement personnel.

4. The data base for all information to be obtained shall be for the period of calendar year 1971.

USER ACTIVITIES SAMPLED

Veterans Administration

Activity	Hospital Bed Size	Activity	Hospital Bed Size
Phoenix, Ariz.	207	Northport, Long Island	1,200
Fresno, Calif.	275	Salisbury, N. C.	904
Martinez, Calif.	492	Cleveland (Breckville)	949
Ft. Lyons, Colo.	600	Roseburg, Ore.	436
Gainsville, Fla.	450	Lebonon, Pa.	1,000
Dublin, Ga.	461	Providence, R. I.	364
Danville, Ill.	1,494	Sioux Falls, S. D.	325
Indianapolis, Ind.	717	Amarillo, Tex.	130
Ft. Howard, Md.	307	Kerrville, Tex.	346
Brockton, Mass.	1,039	White River Function, Vt.	200
Iron Mt., Mich.	233	Seattle, Wash.	317
Jackson, Miss.	498	Clarksburg, W.Va.	200
Ft. Harrison, Mont.	160	Wood, Wisc.	958
Reno. Nev.	224	Alexandria, La.	387
Castle Point, N. Y.	258		

Public Health Service

4 Regular Hospitals

New Orleans	403	Boston	190
Baltimore	237	Staten Island	636

PHS Regional Offices for Indian and Native Hospitals

Army (CONUS)

Ft. Huachuca, Ariz.	110	Ft. Polk, La.	386
Ft. Gordon, Ga.	1,200	Ft. Dix, N.J.	910
Ft. Benjamin Harrison, Ind.	85		

Navy (CONUS)

Twenty-Nine Palms, Calif.	38	Chelsea, Mass.	45
Pensacola, Fla.	250		

Air Force (CONUS)

Mathes AFB, Calif.	100	Wright-Patterson AFB, Ohio	44
USAF Academy, Colo.	135	Lackland AFB, Tex.	1,000
Patrick AFB, Fla.	45	Francis F. Warren AFB, Ohio	30
K. I. Sawyer AFB, Mich.	35	Travis AFB, Calif.	385
Plattsburg AFB, N. Y.	50		

ATTACHMENT 2

STORES DISTRIBUTION - INVENTORY CONTROL POINTS - USING HOSPITALS

STORES DISTRIBUTION SYSTEMS

3 GSA DEPOTS	3 VA DEPOTS
4 DSA DEPOTS	3 DOD DEPOTS
1 BIA DEPOT	1 PHS DEPOT

INVENTORY CONTROL POINTS

VETERANS ADMINISTRATION - HINES, ILLINOIS

BUREAU OF INDIAN AFFAIRS - GALLUP, NEW MEXICO

DEFENSE PERSONNEL SUPPORT CENTER - PHILADELPHIA, PA

U. S. PUBLIC HEALTH SERVICE - PERRY POINT, MARYLAND

FEDERAL SUPPLY SERVICE - WASHINGTON, D. C. (R-3, CO)

FEDERAL SUPPLY SERVICE - KANSAS CITY, MO (R-6)

FEDERAL SUPPLY SERVICE - DENVER, COLORADO (R-8)

*FIELD OPERATIONS - CONUS

169 VETERANS HOSPITALS

10 PUBLIC HEALTH SERVICE HOSPITALS

51 INDIAN HEALTH SERVICE HOSPITALS

49 U. S. ARMY HOSPITALS

85 U. S. AIR FORCE HOSPITALS

38 U. S. NAVAL HOSPITALS

17 FEDERAL PRISONS HOSPITALS

419 TOTAL

TOTAL HOSPITAL BEDS - 141,603 *CY 71

ATTACHMENT 1

4. A government-wide quality assurance program for drugs and medical items should be developed.

Because the Food and Drug Administration by law has a national responsibility in these procurement areas, it is recommended that the Director of OMB request the Secretary of HEW to arrange for FDA to assume responsibility for the quality assurance program for all Federal agency procurements; stores and nonstores programs.

In the meantime, the interagency committee should take steps to see that the specific requirements for such a program are developed.

The using activities, however, should continue to requisition in accordance with current prescribed procedures but they should be provided access to all pertinent civil and military agency stores catalogs.

b. Essential usage data should be collected on items obtained from other than central depot distribution systems in order to improve the procurement from other than stores depots.

The Federal Cataloging Program should be the basis for this system of reporting. There should be instituted a continuous market research program designed to cause the overall system to be responsive to the needs of the end users.

c. Make and implement plans for further coordination of efforts for improvement in procurement and supply management including the consolidation of warehouse facilities.

These plans should be made in a continuous effort to cause the system and subsystems to be not only economical but fully responsive to using agency needs, including mobilization planning and military necessity.

V. Recommendations

1. There should be established a single system for government-wide management of drugs, medical items and non-perishable subsistence for the Federal Government.

2. The system should utilize the operational competence and capability for purchasing drugs, medical items and non-perishable subsistence now existing in the Department of Defense and the Veterans Administration. The corresponding purchasing responsibilities currently being carried out in the General Services Administration and the Department of Health, Education and Welfare should be transferred to DOD and VA.

3. The Administrator of General Services should assume lead responsibility for developing the system through an interagency committee, chaired by GSA, with a membership comprised of representatives of DOD, VA and DHEW, with other affected agencies participating when appropriate. The following actions should be first orders of priority:

a. Duplication and overlapping of purchasing effort should be eliminated by fixing in a single purchasing office all purchasing responsibility for a single family of items.

b. Analysis of purchase documents received from the 55 activities sampled indicate that the largest dollar volume of sales against Federal Supply Schedules is to military activities. An in-depth Government-wide analysis of drug and medical item purchases, on an item by item basis, has never before been undertaken because the large number of items on Federal Supply Schedules was considered unmanageable. Based on purchase data submitted by 22 of the 55 hospitals, the number of items being repetitively purchased is much lower (approximately 5,000 items) than the total number of items available on Federal Supply Schedules. Consequently, the number of items actually used can indeed be managed.

c. Action should be taken to negotiate prices on individual items of high annual demand in lieu of negotiating an "across-the-board" discount for all items in a manufacturers' or distributors' lines of products.

local vendors, the ADP program previously described herein was applied to process order documents of an eleven station configuration identified below by location and total bed capacity.

Name of Facility	No. of Beds
VA Hospital, Cleveland, Ohio	1,729
Naval Hospital, Long Beach, Calif.	350
PHS Hospital, Staten Island, N. Y.	636
VA Hospital, Martinez, Calif.	498
PHS Hospital, Oklahoma City, Oklahoma	260
March Air Force Base, Calif.	175
Naval Hospital, Chelsea, Mass.	600
Ft. Benning, Ga.	650
Patrick Air Force Base, Ga.	45
PHS Hospital, Gallup, N. M.	200
Army Hospital, Letterman, San Francisco, Calif.	900
Total	6,043

4. Feasibility Of Improving Multiple Award Federal Supply Schedules

a. The current Federal Supply Schedules for drugs and pharmaceutical products and X-Ray film contain approximately 75,000 line items with contractor reported annual sales of approximately $75.0 million. Federal Supply Schedules for other medical equipment contain approximately 58,000 line items with contractor reported annual sales of approximately $19.4 million. While the schedules for drugs and pharmaceuticals are mandatory for use by civil agencies, their use is optional to military medical activities. The Federal Supply Schedules for other medical equipment are mandatory for all civil agencies except VA and Postal Service. Their use is optional to the VA, Postal Service and military activities.

access to all central supply systems.

3. Computer Analysis Of Field Installations Indicate Unreliability Of Agency Reports On Procurement Actions

a. On November 15, 1972, GSA assumed the responsibility of processing for computer application the purchase data for 11 of the 55 selected medical facilities covering drugs and other medical items.

Based on the ADP machine runs for 11 field installations, total local purchases amounted to $3,491,879 which includes orders placed against Federal Supply Schedule Contractors and local vendors. If this figure ($3,491,879) were projected to the 55 activities who responded to questionnaires, the total amount expended would amount to $17.5 million annually. This figure ($17.5 million) is in conflict with the $12.2 million reported by the 55 field installations in their questionnaires. The $5.3 million dollar difference for these 55 activities, when extended to the total 419 medical activities in CONUS ($5.3 million x 7.6), indicates possible unreported procurements of $40.2 million in the drug commodity area. According to the computer runs, approximately 64 percent of actual purchase orders were made against Federal Supply Schedule contractors. Based on this percentage (64%), the total local purchases extended to the unreported figure of $40.2 million indicates that more than $20.0 million of sales against Federal Supply Schedules is not being reported by Federal Supply Schedule Contractors.

In the area of local purchase actions which covers orders placed with Federal Supply Schedule Contractors and open market order placed with

2. Field Installations Are Making Local Purchases Of Items That Are Available From A Government Depot And Are Paying Substantially Higher Prices

a. Discussions with personnel at field stations indicated that each system develops orders of priority for obtaining needed items. Within the DOD the directed first order of priority is to DPSC for items available from stock or which have been determined to require procurement at the central level. All other items are authorized for local purchase. Although the use of Federal Supply Schedules by military activities is not mandatory, a review of purchase documents indicates they are extensive users of such contracts.

b. The VA order of priority is: first, VA central supply; second, decentralized contracts; third, Federal Supply Schedules; fourth, local purchase. The Public Health Service order of priority is: first, PHS central supply; second, VA Central supply; third, Federal Supply Schedules; fourth, local purchase. Because of each agency's established systems of priority, a medical activity resorts to Federal Supply Schedules or local purchase for items available in another agency's supply system.

c. Inasmuch as supply catalogs are tailored to and distribution is made only in a particular agency, there is no data available at the local level which would indicate those items that are available in each supply system. Also, in most cases, there is no requirement or mechanism for the use of another agency's supply system in lieu of local purchasing or use of Federal Supply Schedules. Many routine and emergency purchases from commercial sources at much higher prices could be precluded if activities had knowledge of and

directed solely to those items which are being purchased for depot storage and distribution and disregards the very large amount of material purchased by field installations from Federal Supply Schedules or other local sources.

C. Field Installations

1. Wholesale Systems (Depots) Are Not The Prime Source of Supply For Field Installations, In Many Cases

An analysis of data submitted by the 55 field installations indicated total drug and pharmaceutical procurements of $25,778,000. Of this total, 53 percent, or $13,585,100, were supplied from a government depot system. Local purchases, which include Federal Supply Schedules, accounted for $12,192,900, or 47 percent of the total dollar volume. These reported statistics clearly indicate that the military and civil agency stores distribution systems do not supply the bulk of the field medical activities' requirements.

Statistics on page 5 indicate, by dollar volume, how field installation requirements are met through government depot sources, Federal Supply Schedules, and local purchases.

Field Installations Are Purchasing A Considerable Volume Of Items Locally That Should Be Centrally Managed

a. Following a review of statistical data submitted by the 55 field installations and after analyzing the computer runs of their purchase documents, it was determined that field installations are purchasing items locally that should be supplied from an established source of supply. Also, that field installations are purchasing identical items on the open market at a wide range of prices.

6. Agencies Are Not Sufficiently Participating In The Federal Cataloging Program

a. The Study Group in its review of the field installations' purchase documents, noticed that very few civil and military agencies were complying adequately with the Federal Cataloging Program. Agency purchase documents did not indicate the appropriate FSN although their local storeroom catalogs and stores issue listings had an assigned Federal Stock Number for the items being ordered.

b. Military activities' purchase documents, likewise, did not indicate the appropriate FSN on the ordering document. In many instances they did indicate an 11 digit number with the first four numbers containing the appropriate FS Class; however, the remaining 7 numerics were locally assigned with insertions of alphas. These items were for issue from local field installation storeroom distribution systems indicating that these items were repetitively used. There is no need to go into the reasons or citing the economic benefits as to why an activity should apply through their agency's channels for the assignment of a Federal Stock Number. The benefits from the use of such a system have been well publicized. The Cataloging program operated by the Defense Logistics Services Center, Battle Creek, Michigan, is geared to support all Federal agencies in this endeavor.

7. Each Agency Operates Its Own Quality Assurance Program

a. Each of the four agencies presently purchasing medical material for depot storage and distribution conduct, to some degree, independently operated quality control programs. Each agency's quality control office has its own system for inspection and testing of the items they contract for. This effort, however, is

5. There Is No Unified Government Reporting System or Centralized Market Research Effort to Determine Agency Requirements or New Market Trends

a. In order for the Study Group to determine the scope of central management and the extent to which user requirements are presently satisfied outside the central systems, the Study Group gathered approximately 125,000 purchase documents from 55 field stations for computer analysis. See attachment 2 for listing of agencies who submitted data.

b. None of the major agencies concerned with the management of these commodities could furnish the Study Group with the required detailed procurement information as to what was being purchased locally on an item by item basis. Although various reports are prepared by FS Schedule contractors and field installations, the reports spoke only in terms of total dollar volume of sales.

c. A review of field installations ordering documents indicate that there are many items being repetitively purchased, in considerable quantities that are not available from any government wholesale system. Based on statistics submitted by field installations, the civil and military agencies wholesale systems are not their primary source of supply support.

3. Duplicative Efforts

At both the central and field levels the Study disclosed that there was little evidence of the existence of a government-wide procurement and supply system which could provide for the avoidance of duplicative efforts.

Because each affected agency has a great degree of expertise and commodity orientation, these resources should be utilized cooperatively in the logistic and technical areas.

This is not now being done.

4. There Is Little Formal Exchange of Product Information Between Civil and Military Agencies in the Drug, Medical and Nonperishable Subsistence Commodity Groups

a. Evaluation of drugs and medical items are now being performed by two professional groups. These groups are identified as the Defense Medical Material Board (DMMB) and the civilian agencies' Inter-Governmental Professional Advisory Council on Drugs and Devices (IPADD). The DMMB has the management responsibility for determining what kind of items should be cataloged for entry into DOD's supply system. While the IPADD group exchanges information related to the medical field, there is no evidence to indicate that within the past two years a joint exchange of information on a coordinated military or civil agency basis was being accomplished adequately.

b. With four major agencies operating supply programs autonomously and independently, (in these commodity areas), it is impossible to avoid a duplication of effort and overlap of functions. This has resulted in a fragmented supply system with civil and military agencies competing with one another in the market place.

On the civil agency side, the Veterans Administration was assigned the responsibility of issuing the Federal Supply Schedule for Drugs and X-Ray Film for use of all civil agencies on a mandatory basis, and on an optional use basis for the military services. The VA also issues its own decentralized contracts for other medical items which are used extensively by its own activities. However, some of the military and civil agency users have availed themselves of these contracts on an optional use basis. In addition to the VA contracts, the GSA issues a Federal Supply Schedule for additional medical items. All of the items in the above contracts are classified in FSC Group 65.

Nonperishable subsistence items are similarly distributed with split responsibilities for procurement and distribution assumed by several civil and military agencies.

own system with laudable effectiveness but with little evidence of coordinating with other agencies.

This lack of government-wide management by one agency, endowed with proper legal authority, has led to a situation which is replete with unnecessary costs to the government.

At present, each agency which operates a system is at the same time its manager. This has caused a parochialism which has resulted in the needs of the government on an overall basis to be obscured.

This can be seen readily at the central management level merely by examining the contents of applicable supply catalogs which disclose duplication of items.

At the field level, an analysis of procurement and supply management by the Study Team displayed the fact that field activities' management needs were not being met by central management.

a. There are four major agencies currently involved in the management and operation of supply systems in the medical and nonperishable subsistence commodity groups. Each agency is operating primarily with one objective in mind, and that it is to satisfy the needs of its own constituent users. While there are many supply support cross-servicing agreements in effect, their use is not mandatory. The Study Group found that within the VA and DoD stores distribution systems, over 90 percent of the items were issued to their own customers. Other agencies' requirements were satisfied outside the wholesale systems.

The efforts by these agencies were performed in CY 71 by 2,600 personnel with annual salaries of $29 million and other operating costs of $4.6 million.

An analysis of the study sample of the 55 activities (attachment 2) indicated that approximately 37% of the agencies' requirements were supplied through depot systems; 26% by use of Federal Supply Schedules or other decentralized contracts negotiated by the agencies' central inventory control points and the balance of approximately 37% by local purchasing efforts.

b. NPS Commodity Group

A similar situation exists in the NPS area with additional efforts being made by the Bureau of Indian Affairs Regional Office in Gallup, New Mexico.

Operating statistics for central management in CY 71 were 1,333 personnel with annual salaries of $15.7 million and $2.3 million other operating costs.

2. There is No Single Agency providing government-wide leadership in the Management of Existing Supply Systems.

The entire effort of the Study Team revealed the fact that there exists currently a vacuum of overall government leadership in the procurement and supply management areas which pertain to drugs, medical items and non-perishable subsistence. The study has disclosed that each agency operates its

It should be noted that the local purchase figures for all 419 activities is not known. Only those for the 55 study sample activities were recorded. Problems of management were defined sufficiently from the study sample.

Also the contractor reported sales from Federal Supply Schedules are suspect because many contractors do not or cannot report all of their sales to government.

Therefore, the grand total is probably closer to $1,600,000,000 for medical and nonperishable subsistence items than is the figure of $1,179,547,753.

B. Central Management - Significant Findings

1. There is considerable overlap and duplication of item management in the medical and NPS commodity areas. DoD, VA, GSA and DHEW systems operate virtually separate systems despite the considerable degree of commonality of the items.

a. The Medical Commodities

DoD, DHEW, VA and GSA each maintains central systems for central procurement, storage and distribution. In the drug and medical supply area there is overwhelming evidence that many of the items managed by these agencies are identical.

SUMMARY OF VOLUMES FOR CY 1971 BY AGENCY

	Medical	NPS	Totals
Department of Defense			
Depot Sales (Include direct delivery from contractors)	$201,181,700	$301,520,000	$ 502,701,700
1/ Local Purchases	4,997,100	9,216,800	14,213,900
Supply Contract Bulletins	0	3/ 500,000,000	500,000,000
	$206,178,800	$810,736,800	$1,016,915,600
Veterans Administration			
Depot Sales	42,643,900	9,065,900	51,709,800
2/ Federal Supply Schedules	75,000,000	168,100	75,168,100
1/ Local Purchases	6,745,100	360,300	7,105,400
	$124,379,000	$ 9,594,300	$ 133,983,300
General Services Administration			
Depot Sales	2,045,455	3,308,100	5,353,555
2 /Federal Supply Schedules	19,400,000	0	19,400,000
	$ 21,445,455	$ 3,308,100	$ 24,753,555
Department of Health, Education and Welfare			
Depot Sales	2,000,000	0	2,000,000
1/ Local Purchases	1,676,300	219,000	1,895,300
	$ 3,676,300	$ 219,000	$ 3,895,300
Grand Totals	$355,679,555	$823,858,200	$1,179,547,753

1/ All figures for local purchases apply only to the 55 field activities studied. These are listed on attachment 2. Detailed figures for the balance of the 419 activities for local purchases were not obtained.

2/ Contractor reported sales for all government agencies.

3/ DPSC states this is a rough estimate. An effort is underway to obtain more accurate data which DPSC states may cause the true figure to be between 700,000,000 and 1 billion annual sales.

7. What items, on a line item basis, are being purchased by field activities from other than a central system; in other words, locally?

8. What is the extent of interagency support?

9. How much does it cost to operate the various central and field systems?

10. Is it feasible to develop an optimum system or systems which would be truly cost-effective for the government and at the same time be responsive to the needs of the end user?

Attachment 1 is a presentation of the specific agency stores distribution systems, their central inventory control points, and the field activities which are supplied with medical and NPS items.

Attachment 2 discloses the specific field activities which were the subjects of intensive study in order to ascertain on a total and detailed basis the medical and NPS items purchased from every source during Calendar Year 1971 by these activities. Copies of each purchase document were to be obtained, studied and processed. The data to be derived from this effort was to be used to determine in part the effectiveness of each central system to the needs of these 55 users.

IV. Findings

A. In order to assess the separate systems which purchase medical and NPS items and to understand the magnitude of these systems, the following chart is presented:

2. Study Plan

The study plan is included as appendices to Attachment 3 of this report.

The major objectives, findings and recommendations which will be stated below are based on the execution of the study plan, the reading of which will disclose the methodology employed by the study group.

III. Major Objectives

A reading of the Study Plan will disclose the specific kinds of information that had to be gathered, collected and systematically displayed in order to be able to make appropriate decisions for management.

In general, this information can be expressed best in the following series of questions:

1. What items specifically are being purchased?

2. How are items being purchased?

3. Who is purchasing the items?

4. Is there duplication of purchasing?

5. Is there duplication in the stocking of items in central depots?

6. How responsive are the separate agency central systems to the needs of their field activity users?

These resulted in the making of specific agency assignments for the management of these commodity groups. These assignments were made either by delegation by the Administrator of General Services under the authority of Section 205(e)(3) of the Federal Property and Administrative Services Act of 1949, as amended, or by various formal and informal inter-agency cross-servicing agreements.

Despite these efforts to effect a government-wide system for these commodity areas, it became increasingly apparent that each agency had developed its own basic system. While there have been continual efforts to achieve cross-servicing, these have not been able to prevent overlapping and duplication of procurement and supply efforts.

Therefore, OMB made the decision to lead a study which would lead to recommendations for sound government-wide management of drugs, medical items and NPS items.

II. Legal Authority and Study Plan

1. Legal Authority

The study was conducted under the legal authority contained in section 201(a)(1) of the Federal Property and Administrative Services Act of 1949, as amended.

I. Background

1. On June 14, 1971, the Office of Management and Budget requested that all agencies involved in procuring, supplying and using drugs, medical items, and nonperishable subsistence (NPS) items participate under OMB's leadership in an interagency study.

The purpose of the study was to provide an economic analysis of the management of these items and on the basis of this analysis to make appropriate recommendations for achieving effective and economical Government-wide support for drugs, medical items and NPS items.

The first meeting was attended by OMB, DoD, DHEW, DOT (Coast Guard), Interior (Bureau of Indian Affairs), Justice (Bureau of Prisons), Veterans Administration and Agency for International Development.

Agreement was reached that an interagency study should be conducted to determine the optimum system, or systems, for providing medical and NPS support to all Federal activities. It was also agreed that OMB would chair the study with participation by DoD, VA, DHEW and GSA.

A study charter (Attachment 3) was developed. This received final acceptance on December 27, 1971.

2. Over the past years, there have been a number of studies by interagency groups and by commercial research firms with the same objective in mind.

ATTACHMENT A

STUDY OF

AN OPTIMUM PROCUREMENT AND DISTRIBUTION

SYSTEM(S) FOR MEDICAL AND NONPERISHABLE SUBSISTENCE ITEMS

PARTICIPATING AGENCIES

OFFICE OF MANAGEMENT AND BUDGET
DEPARTMENT OF DEFENSE
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
VETERANS ADMINISTRATION
GENERAL SERVICES ADMINISTRATION

Finally, the supply system should be more responsive to the needs of the users when the effort is supported by the yet-to-be developed Government-wide quality assurance system.

This completes our written testimony Mr. Chairman. We would be glad to address ourselves to any questions you might have.

5. A method of collecting and maintaining continuous usage data on items in the system that will be managed on a non-stock basis.

6. The development of a Federal Supply Catalog which will contain all the items being managed intensively, whether they be stocked or not.

7. Finally, an examination of the impact of the implementation of the task group's recommendation on the Federal establishment.

The Committee on February 20, 1975, directed the task group to amplify its concept. We anticipate receiving their recommendations within 30 to 60 days. If adopted, the recommendations will then be the basis for the actual establishment of the single management system.

The details, including specific purchasing assignments, will then become definite. The concept will become the plan. When complete, this system should lead to significant economies not only in drug procurement but also for medical devices and nonperishable food. Since the total dollar volume of all those items was $1.5 billion in FY 1972, the savings should be significant.

screened and recommended for item entry, and those items that met predetermined criteria would be assigned a national stock number, and the decision rendered whether the item would be centrally stocked or managed on a non-stock basis. The implementation of this concept would then provide for the management of not only depot stocked items but of the larve volume of now locally purchased items which meet predetermined criteria.

However, please note that the following procedures for Government-wide management have to be developed for the first time in order to manage all the items purchased repetitively and in high volume whether they be stock items or non-stock items:

1. A method of collecting data on non-cataloged locally purchased items which would be candidates for item entry and control.

2. A Government item entry and review procedure.

3. A Government procedure to determine the best method of supply.

4. A Government procedure to determine the best method of procurement and the appropriate agency to procure the item.

for effective procurement. Therefore, a new system has to be devised to manage not only stock items but high demand items that may not need to be stocked because they may be supplied by means of commercial distribution.

As you can see, we are attempting a fundamental improvement in procurement and supply management which we consider to be responsive not only to OMB's June 4, 1974, memorandum but to the criticisms of GAO in its 1973 Report on Drug Procurement. Development of the single system will be difficult, but each agency is working together diligently toward this end.

As to the current status of the Committee's effort, the first and immediate effort will be to eliminate duplication in central procurement and to effect the necessary purchasing assignments without duplication to DOD and to VA. The next step is to bring under control the items which meet predetermined criteria for central procurement which are now being procured locally. The task group submitted a preliminary report dated January 14, 1975, which described as a concept a management system in which non-cataloged locally purchased items would be reported through a data collection system,

Service, General Services Administration; and National Institutes of Health, Department of Health, Education and Welfare was formed in order to categorize items into "families of items." This was necessary in order to make purchasing assignments to DOD and VA nonduplicative.

In order to describe a major problem confronting the Medical/NPS Committee and the Task Group, I should like to quote from the OMB Study Report which states that "Wholesale systems (depots) are not the prime source of supply for field installations in many cases. Further, the GAO stated in its report of December 6, 1973 that local purchases - or purchases from other than depots - comprise such a large dollar percentage of drug procurement that a method of managing the high volume items now being purchased locally has to be developed. The Committee is now addressing itself to the problem of bringing these items under management control.

As of now, each agency confines its intensive management to stock items. The methods of procurement used by individual medical activities to purchase locally are primarily Federal Supply Schedule Contracts and open market purchasing. Neither method provides for accumulating demand data on a line item basis which is a precondition

a. Eliminate duplication in purchasing by assigning all purchasing responsibility for a single family of items in a single purchasing office. The using activities should continue to requisition in accordance with current prescribed procedures.

b. Collect essential usage data on items obtained repetitively and in high volume from other than central depots in order to enter these items into the supply system.

c. Plan for further coordination to improve procurement and supply management including consolidation of warehouse facilities.

d. Cause the system to be not only economical but responsive to agency needs, including mobilization planning and military necessity.

The fourth recommendation deals with Government-wide quality assurance. A plan for this is now being developed under the leadership of the Secretary of Health, Education and Welfare.

To continue, a task group consisting of members from the Defense Personnel Support Center, Department of Defense; the Veterans Administration Marketing Center; Federal Supply

Shortly after the establishment of this Committee in July 1974, the Committee drafted a charter which was signed by all of the participating agencies in September 1974. It then set in motion the process of implementing the first three recommendations of the Study. Prior consideration was given to eliminating duplication of purchasing effort by fixing in a single purchasing office all purchasing responsibilities for a single family of items.

I shall now summarize the first three recommendations:

1. Establish a single system for Government-wide management of drugs, medical items and nonperishable subsistence for the Federal Government.

2. Utilize the competence and capability which now exist in DOD and VA to purchase these items, and transfer the corresponding purchasing responsibilities that GSA and DHEW now have to DOD and VA.

3. The Administrator of General Services should assume lead responsibility for developing the system through an interagency committee with membership comprised of DHEW, DOD and VA to be chaired by GSA by taking these steps:

supply business. Mr. Sorett is with me today and is also available to answer questions and to provide any additional information you may require.

The DOD member of the Committee is the Staff Director, Supply Management Policy Directorate, Office of the Assistant Secretary of Defense (Installations and Logistics); the DHEW member is the Director, Materiel Policy Regulations Development; the VA member is the Director, Supply Service of the Department of Medicine and Surgery; the FDA liaison member is the Director of the Compliance Coordination and Policy Staff, and the GSA member is the Assistant Commissioner for Interagency Support, Federal Supply Service, the appropriate operational entity of GSA.

Copies of a complete documentary history of the Committee have been furnished to you and the members of your staff in order that you may be able to perceive the progress made. The documents trace this progress from the inception of the OMB Interagency Study in 1971 to the minutes of the last meeting of the Medical/NPS Committee held on March 18, 1975. All of the documents to which I shall refer are contained in this history.

UNITED STATES OF AMERICA
GENERAL SERVICES ADMINISTRATION
Office of Federal Management Policy
Washington, DC 20405

April 24, 1975

STATEMENT OF RONALD E. ZECHMAN
ASSOCIATE ADMINISTRATOR
OFFICE OF FEDERAL MANAGEMENT POLICY
BEFORE THE SUBCOMMITTEE ON MONOPOLY
OF THE SENATE SMALL BUSINESS COMMITTEE

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to appear before you today and describe the organization and operation of the Interagency Medical Nonperishable Subsistence Supply Management Committee. This Committee is in the process of implementing the procurement and supply aspects of the issues stated by Mr. Witt.

As Mr. Witt stated, the Committee was established in response to a request by the Director of OMB to the Administrator of General Services. The responsibility to form the Committee was then delegated by the Administrator of General Services to me. Great care was taken to staff the Committee with experienced personnel whose level was high enough to have easy access to decision makers in their agencies, but at the same time close enough to agency operations to know their practical problems.

To chair the Medical/NPS Committee, I selected a management analyst from my office, Mr. Louis Sorett, with broad experience in the commercial hospital and laboratory

Responsibility for developing an implementation plan for the fourth recommendation, to consolidate under the Food and Drug Administration a quality assurance program for all Federal procurement of drugs and medical items, was assigned to the Secretary of Health, Education and Welfare. Substantial progress has been made toward achieving the objectives of that recommendation, Mr. Chairman, and a full report will be given the subcommittee by the Food and Drug Administration's Commissioner Schmidt.

At this time, Mr. Chairman, I would like to ask that Mr. Zechman be permitted to describe for the subcommittee the progress being made in the executive branch to carry out the first three recommendations of the Office of Management and Budget study. At the conclusion of Mr. Zechman's statement we will be happy to respond to any questions that members of the subcommittee may have.

4. That the Food and Drug Administration in the Department of Health, Education and Welfare should assume responsibility for the quality assurance for all agency procurement of drugs and medical devices.

The full recommendations can be found on pages 18, 19 and 20 of the Office of Management and Budget Study.

The report and recommendations were endorsed by the agencies and approved by the Director of the Office of Management and Budget by letter of June 4, 1974, to the heads of the four agencies concerned. In that letter, which also assigned implementing responsibilities, the Director emphasized that effective implementation of the single system recommendation should ultimately assure timely deliveries of required supplies by methods which result in the least total cost to the Federal Government.

Responsibility for implementing the first three recommendations was assigned to an interagency committee comprised of representatives of the Department of Defense, the Department of Health, Education and Welfare, the Veterans Administration and the General Services Administration with lead responsibility to be carried forward by the General Services Administration's Office of Federal Management Policy. Under the leadership of GSA Associate Administrator Ronald Zechman, an Interagency Medical/Nonperishable Subsistence Supply Management Committee was established to implement the study recommendations.

the optimum system or systems for their effective and economical Government-wide support.

The interagency effort was concluded early in 1974. I understand, Mr. Chairman, that copies of the study group report entitled "Study of an Optimum Procurement and Distribution System(s) for Medical and Nonperishable Subsistence Items" have been provided for the information of the subcommittee. The report made four basic recommendations which I shall summarize as follows:

1. That a single system should be established for Government-wide management of drugs, medical devices and nonperishable subsistence.

2. That the Department of Defense and the Veterans Administration should be assigned, on a non-duplicative basis, purchasing responsibility for these items and that related purchasing functions performed in the General Services Administration and the Department of Health, Education and Welfare should be transferred to the Department of Defense and the Veterans Administration.

3. That the General Services Administration should assume lead responsibility for developing the system through an interagency implementing committee chaired by the General Services Administration with membership from the Department of Health, Education and Welfare, the Department of Defense and the Veterans Administration.

EXHIBITS PROVIDED BY OMB AND GSA

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FOR RELEASE ON DELIVERY
Expected at 10:00 a.m.
Thursday, April 24, 1975

STATEMENT OF HUGH E. WITT
ADMINISTRATOR FOR FEDERAL PROCUREMENT POLICY
OFFICE OF MANAGEMENT AND BUDGET
BEFORE THE SUBCOMMITTEE ON MONOPOLY
OF THE SENATE SMALL BUSINESS COMMITTEE

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to appear before you today to discuss the steps we are taking to improve the procurement and management of drugs and medical items which are required to support the needs of the Federal Government. Within the Office of Management and Budget these problem areas are among my responsibilities as Administrator for Federal Procurement Policy. My Office was established in OMB by the Office of Federal Procurement Policy Act, Public Law 93-400, enacted on August 30, 1974.

Over the years there has been a growing awareness of the need for greater coordination, economy and efficiency in the procedures, processes and systems employed by the various agencies in the executive branch whose responsibilities include the acquisition and supply of drugs and medical items. In 1971 the Office of Management and Budget established an interagency group to study military and civil agency procurement and distribution of these commodities and to recommend

ADDENDUM I

MEDICAL ADVISORY COUNCIL

I. Composition of Council - Dictated by Statute

2 M.D.'s

1 Doctor of Osteopathy

1 Owner of Licensed Nursing Home

1 Administrator of Licensed Hospital

1 Licensed Registered Nurse

1 Licensed Registered Pharmacist

1 Podiatrist

1 Dentist

1 Optometrist

1 Director of Department of Social Services
Ex Officio

1 Director Department of Health
Ex Officio

3 Members not associated with Medical Services
(1) Union Representative
(2) Public at Large

Careful studies should be conducted on any third-party program which has presently an Acquisition Cost, and a comparison of the savings versus the RED BOOK or Average Wholesale Price should be conducted--taking into account such variables as the Professional Fee, the number of prescriptions each recipient receives, the average prescription price, overall total drug costs, and administrative costs.

Finally, if such a proposal is adopted in the State of Colorado, the state would expect support from the Regional H.E.W. Office in such a capacity that the complexity and problems resulting from adopting such a policy would be specifically detailed to accomplish a change-over, since our present staff and budget limitations will not allow the Department to convert to the new program without resultant major problems.

The Department does commend the U. S. Department of Health, Education, and Welfare for your efforts in attempting to resolve a problem area, and we would offer our services and assistance, if such are needed, in any further evaluation or explanatory information.

The Department would encourage that from a Federal level, drug pricing information comparisons be made available to physicians, so that the physician is able to compare drug prices in considering which is the drug of choice. A list of drugs subject to the Maximum Allowable Cost Reimbursement Policy could be issued by the U. S. Department of Health, Education, and Welfare, to state agencies administering Drug Programs which could be used by the state for consideration, but in no way be mandatory.

It is further suggested that the acquisition cost proposal be optional and not mandatory. Those states presently utilizing acquisition cost should be carefully evaluated as to whether they are actually cutting costs in the Drug Program with a resultant saving. When acquisition cost is utilized as the base drug cost in some third-party drug programs, and the acquisition cost policy is not properly enforced, its feasibility is questioned.

IN SUMMARY, the Department welcomes the proposal for adoption of a Maximum Allowable Cost (MAC), but would recommend that states be allowed to adopt their own Maximum Allowable Costs through their own Pharmaceutical Reimbursement Boards, similar to that presently in existence in the State of Colorado. Adoption of Acquisition Cost, as outlined in the Proposal, should be discouraged, as it is our feeling that any savings resulting from adoption of the Acquisition Cost would be lost from the additional administrative costs required, as well as a resultant increase in the Dispensing Fee. Participation by the Community Pharmacist is encouraged, and in some areas is difficult to obtain. Therefore, adoption of rules and regulations which would hinder Community Pharmacies from participating in the Medicaid Drug Program should be discouraged.

The Department takes issue with the requirement that cost of drugs should be acquisition cost or actual cost paid for the drug. Such a policy is not practical, and would be extremely difficult to monitor. Information received from those third-party drug programs which utilize acquisition cost is that the administrative expense of having field auditors monitor the acquisition cost of each pharmacy is quite significant. A few years ago, a professor from the University of Colorado School of Pharmacy, who conducted a study to determine what professional fee should be allowed for the community pharmacist, recommended that the Department not adopt acquisition cost, and that Average Wholesale Price be adopted. The pharmacist should be allowed the advantage of volume purchasing, discounts, et cetera, and that this was a good purchasing practice and an incentive which should not be taken away.

It was stated that the pharmacist would be penalized for running a good business, if acquisition cost were adopted. In theory, "Twenty-five percent of the amount of the cost of the drug plus the acquisition cost" refund to the pharmacist sounds like a good policy--but, in all practicality, our Department staff say that it would be most difficult to administer and monitor. The administrative costs and problems would be overwhelming. Before such a policy is imposed, I would ask how the Federal government proposes that states comply with such a policy?

This reduction in drug costs could not be entirely allocated to the Maximum Allowable Cost Colorado policy. Factors that should be considered were not identifiable in dollar amounts, i.e., what effect did the M.A.C. policy have on other drugs being prescribed, were in fact lesser expensive generic drugs being prescribed, were there other policies such as "Drug Utilization Review" lowering drug costs?

In summary, it was quite appropriate to assume the bulk of the drugs' cost reduction was due to adoption of the Colorado Maximum Allowable Cost policy.

HEW-SRS PROPOSED REIMBURSEMENT OF DRUG COST:

Recent proposals to adopt the Maximum Allowable Cost on a national basis for the Title XIX Medical Program solicited a response from our Department, which I wish to share with this Committee.

The Department does not take exception to adoption of a Maximum Allowable Cost for certain specific generic drugs, but feels that at this point in time, it would be more acceptable if the Federal government would recommend to each individual state establishment of its own Pharmaceutical Reimbursement Boards, and its own Maximum Allowable Costs, rather than to have the Federal government from a national standpoint dictate to states what the upper limits of the Maximum Allowable Cost should be. Drug manufacturing, marketing, and distribution policies vary from one area of the United States to another, and therefore the Maximum Allowable Cost established for one state many times may be impractical in another state.

Patient and physician acceptance of the generic drug were key factors considered in establishing the Maximum Allowable Cost. It was recommended that each generic drug have its own drug number. This would prevent the pharmacist from dispensing a lesser-priced generic drug and billing the Department for the Maximum Allowable Cost selected. It would also give the Department realistic statistics regarding what was happening for each generic product identified with the manufacturer. Establishment of the Maximum Allowable Cost has met with good acceptance by medical and pharmaceutical professional personnel.

It is the Department's feeling that establishing the Maximum Allowable Generic Cost to be that price which is the lowest generic price available would not be acceptable.

The present Drug Program establishes a Maximum Allowable Cost for 36 categories of drugs available generically.

A Study was conducted to determine what effect establishment of a "Maximum Allowable Cost" regarding generic drugs in the area of "cost effectiveness" resulted. Statistics reflected a reduction in expenditures for the expensive generic drugs of some $461,900 based on statistics for the period of January 1, 1972, through June 30, 1972, compared with the period July 1, 1972, through December 31, 1972.

Further, a reduction in the amount reimbursed per recipient demonstrated a decrease from $53.72 to $46.44 per recipient annually. Roughly, this amounted to a savings of approximately $1,092,000, based on an average recipient population of 150,000 recipients.

recommendations of the ColoR_x Drug Formulary Committee, an Advisory Committee composed of professional appointed by the Colorado Pharmacal Association and the Colorado Medical Society. This Committee took into consideration a number of standards in selecting the Maximum Allowable Cost. The Committee was presented with a list of the generic drugs, ranking the drug from the least expensive to the most expensive available product. The generic drugs listed in this printout reflected only those drugs which were on demand or utilized within the Colorado area, or for which the Department had received a request to add such a generic drug as a benefit.

A number of factors were considered in establishing and recommending the Maximum Allowable Cost. For example, was the drug manufacturer an established and reputable drug manufacturer? Was the drug available from more than one wholesaler in the State of Colorado? The Committee took into consideration bioavailability information, dissolution rates, drug recalls, physician acceptance, and--above all--their own personal experience with the drug. For example, during the ColoR_x Drug Formulary Committee meetings in which the Maximum Allowable Cost was discussed, members would point out they had received a number of complaints regarding certain generic drugs manufactured by a specific drug manufacturer. In this case, this drug manufacturer's price was not considered in determining the Maximum Allowable Cost.

addresses itself to five percent of recipient abuse and penalizes the 95 percent of recipients who are in direct need of a drug benefit.

GENERIC DRUGS:

In july of 1972, the Colorado Medicaid Drug Program adopted a new policy concerning reimbursement whenever a drug was available generically. Prior to July 1, 1972, the State of Colorado was reimbursing participating pharmacy vendors based on Average Wholesale Cost of the drug, plus a professional fee of $1.85 or usual general price, whichever was lower. In the case of generics, the profit realized by pharmacists was exorbitant in some specific instances. For example, one drug manufacturer at that date listed the Average Wholesale Cost of Ampicillin 250 MG Capsules at $22.34 per hundred capsules. Actually, the pharmacist was paying $9.60 per one hundred capsules in the majority of the time by buying direct from the manufacturer. Pharmacists were realizing a profit of $12.74, in addition to the $1.85 professional fee. The same principle could be applied to a number of drugs which were generically available. This policy encouraged pharmacists to dispense the more expensive generic drug in order to realize a greater mark-up, and thus a larger profit.

The policy implemented on July 1, 1972, established a Maximum Allowable Cost whenever the drug was available generically. This Maximum Allowable Cost was based upon the professional

This policy is disliked by physicians as well as pharmacists, primarily because of the paper work involved in requesting special approval. The Department feels this policy is a necessary control, and again, until peer review of drugs is established, the policy is an effective control measure.

CO-PAYMENT:

There is no co-payment policy in the State of Colorado. Co-payment has been considered, and at one time the Pharmacy Advisory Committee strongly urged the adoption of co-payment. There are pros and cons for co-payment. We feel to administratively monitor the co-payment would be a nightmare of bookwork. We feel that some pharmacies would not collect the co-payment, and use this as a means of advertising to attract the recipient to his pharmacy. The pharmacist could collect the co-payment portion of the prescription and still bill the Department for the full amount of the prescription, and it would be extremely difficult for us to monitor such a policy. We feel co-payment would encourage overutilization, and some recipients would demand the physician to prescribe larger quantities in order that the co-payment would be paid only once.

Arguments in favor of co-payment are that the prescription volume would be tremendously reduced. This is quite possible, but we feel our overall objective is to provide quality medical care to the recipient, and not introduce a control which

presently adopted and utilized in our Program, and has met with great success; based upon input from DRUG TOPICS periodical, prices are updated on the drug pricing file to maintain current prices.

OVER-THE-COUNTER DRUGS:

The Department does not include over-the-counter drugs as a benefit, with few exceptions. Recently the Colorado Medical Society recommended to the Department that the Drug Program be changed to allow the Physicians to prescribe any drug as an allowable benefit in the Drug Program, whether prescription legend or over-the-counter. It is extremely difficult to monitor and control over-the-counter drugs, especially for nursing home recipients. Every nursing home recipient is desirous of taking a laxative, an antacid, vitamins, et cetera. Until proper peer review and drug utilization review can be accomplished, over-the-counter drugs will continue to present problems.

There are over-the-counter drug exceptions, such as iron for anemic children, Tedral for the asthmatic child, which the Department is considering for adoption as a benefit.

RESTRICTED DRUGS:

There are certain categories of drugs which present inherent problems, namely: amphetamines and vitamins. The Department has adopted the policy that amphetamines, vitamins, and any drugs not listed in the Drug Formulary should not automatically be allowed as a benefit without prior approval.

"POSSIBLY EFFECTIVE" OR "INEFFECTIVE" DRUGS:

For a number of months, the State of Colorado has enforced a policy whereby the Department would not include as a benefit drugs classified by the Food and Drug Administration to be "medically ineffective" or drugs discontinued by the Food and Drug Administration for other reasons; drugs found by the Food and Drug Administration to be "possibly effective," unless included in the "ColoR_x Drug Formulary." Removal of this group of drugs from our drug formulary caused more complaints than any single policy yet implemented, but the policy accomplished two things:

1. It focused attention to the Drug Program, and motivated the Colorado Medical Society to appoint two Physicians to serve on the ColoR_x Drug Formulary Committee.
2. A new policy was developed whereby those drugs approved by the Drug Formulary Committee which were "possibly effective" could be allowed as a benefit.

PRICING--RED BOOK vs. ACQUISITION COST:

The Colorado Medicaid Drug Program for some time reimbursed Pharmacists based on Average Wholesale Price. This pricing information was obtained from Colorado drug wholesalers. Several months ago it became apparent because of discrepancies among the drug wholesalers regarding the drug prices, that our allowable cost for the drugs should be revised. The Average Wholesale Price as published in the RED BOOK is

Profile," a "Social Summary" from the county, a "Patient Detail Profile" showing physicians and hospital activity regarding the recipient, as well as other pertinent information.

The Committee evaluates and recommends corrective action. Based upon a number of parameters, for example, recipients who visit more than one physician and/or one pharmacy and receive the same drug, recipients who receive prescriptions costing more than $25 per prescription, recipients who receive more than five prescriptions per month, et cetera, in "drug utilization review" cases are developed. Literally hundreds of letters are mailed to Pharmacists, Physicians, and County personnel.

We consider the activities of these three drug committees are essential contributions to the success of the Colorado Medicaid Drug Program.

A brief resume is in order of the overview for the procedures governing the Program in the State of Colorado.

BILLING FORM AND PLASTIC IDENTIFICATION CARD:

The Drug Program in the State of Colorado utilizes a three-part individual prescription billing form in conjunction with a plastic I.D. card, which is used with a data recorder. There have been, and still exist, problems concerning the use of a plastic I.D. card, a Medicaid Authorization Card, and the data recorder. It is my personal feeling that the plastic I.D. card has been beneficial in recording the State I.D. Number on the billing forms.

The "Colo$^{R}_{x}$ Drug Formulary Committee" was established. This committee's function and responsibilities were to develop the drug formulary. It meets monthly to deliberate on what drugs shall be included in the drug formulary, which drugs should be restricted, what pricing information is recommended, and what maximum allowable price should be reimbursed whenever the drug is available generically.

The other committee is the "Drug Utilization Review Advisory Committee." This committee meets monthly, and reviews individual cases developed by the Pharmacy Section, and recommends to the Department corrective action concerning Drug Utilization Review. This committee reviews those cases of overutilization, corresponds with Physicians, Pharmacists, and County Caseworkers, in an attempt to curtail drug over-utilization and abuse.

Colorado has had a Drug Utilization Review Committee composed of one Physician and several Pharmacists for some four and a half years. Several months ago, a second Physician and additional Pharmacists were added to this committee because of the increase in work load. This committee travels from different parts of Colorado at no reimbursement, and spends one-half day monthly with Pharmacy Section personnel reviewing those cases of drug abuse and overutilization which have been developed based on certain parameters: a "patient

Like most states, Colorado enacted enabling legislation to implement the Title XIX Program. The enabling statute created a 15-person Medical Advisory Council, to be appointed by the Governor. The membership of this Council specified by law provided representation on the Council from the following organizations.* As the name implies, the Council's function was to advise the Department on issues and problems which occurred in administering the Medicaid Program. The same enabling legislation mandated that "as to drugs for which payment is made, rules and regulations for payment thereof shall include but need not be limited to the use of generic names on commonly used drugs."

PHARMACY COMMITTEES

Early in 1969 the Medical Advisory Council created, by appointment, special committees composed of Pharmacists and Physicians to deal with matters relating to the administration and management of the Medicaid Drug Program. Perhaps the most singular important function of these committees was the establishment of a communication link between the Department of Social Services - Medical Division, and the Physicians and Pharmacists of our state.

The main subcommittee to the Medical Advisory Council is the "Pharmacy Advisory Committee." Generally stated, this committee deals with specific policy questions or specific problems relating to the Drug Program.

Two working committees, both very important, were established to deal with specific areas in the administration of our Drug Program.

* Medical Advisory Council - Addendum I

EXHIBITS PROVIDED BY THE COLORADO DEPARTMENT OF SOCIAL SERVICES

STATEMENT

by

MR. PETER SAMAC, DEPUTY DIRECTOR

COLORADO DEPARTMENT OF SOCIAL SERVICES

before

THE SUBCOMMITTEE ON MONOPOLY -

SENATE SMALL BUSINESS COMMITTEE

MARCH 21, 1975

* * *

Mr. Chairman, Members of the Committee:

I am pleased to be here today, and to have the opportunity to share with the Committee the experiences we in the State of Colorado have had in administering the state's Title XIX Medicaid Drug Program.

Before proceeding with this statement, I feel it is necessary to acknowledge the efforts of Mr. Douglas T. Margreiter, R.Ph., M.P.H., our Chief of the Pharmacy Section, in working with the many loyal and dedicated pharmacists and physicians in our state to develop our Medicaid Drug Program.

Briefly, my presentation will highlight the processes used to develop the program, and the policies that evolved as a result of the process.

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE
(Pursuant to Government Code Section 11380.1)

The State Department of Health has determined that pursuant to Section 2231 of the Revenue and Taxation Code, no increased costs or new costs to local governments will result from the regulation change proposed in this order.

The Director of Health finds that the foregoing regulation, which amends Maximum Allowable Ingredient Costs, assures that eligible persons will receive prescription drug services representative of the prescription drug services or medical supply products which are available to the public generally without discrimination or segregation based purely on their economic disability.

for David A. Winton
William Mayer, M.D.
Director of Health

Dated: 12/31/74

DO NOT WRITE IN THIS SPACE

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE

(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

FINDING OF EMERGENCY

The State Department of Health finds that an emergency exists and that the foregoing regulation is necessary for the immediate preservation of the public peace, health and safety or general welfare. A statement of the facts constituting such emergency is:

STATEMENT OF FACTS

These amendments are necessary to update the maximum allowable ingredient cost (MAIC) list to reflect price changes in certain of the products listed. Failure to implement these amendments immediately will adversely affect drug product availability under the Medi-Cal program.

Immediate adoption of these regulation amendments is necessary in order to avoid a reduction in the availability of drug products under the Medi-Cal program.

The said regulation is therefore adopted as an emergency regulation to take effect upon January 1, 1975 as provided in Section 11422 (c) of the Government Code.

STATE DEPARTMENT OF HEALTH

David A. Winston

for William Mayer, M.D.
Director of Health

Dated: 12/31/74

67042-78* 8-72 15M OSP

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE

(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Theophylline, Ephedrine and Phenobarbital			
Tablets		$.90/100	2953A ea.
Thermometer		$.84/ea.	9831A ea.
Thyroid			
Tablets (plain)	15mgm	$.50/100	6700A ea.
	30mgm	$.59/100	6700B ea.
	65mgm	$.70/100	6700C ea.
	120mgm	$1.31/100	6700D ea.
	200mgm	$2.12/100	6700E ea.
	250mgm	$2.42/100	6700F ea.
	325mgm	$2.59/100	6700H ea.
Trichlormethiazide			
Tablets	2mgm	$2.82/100	3507A ea.
	4mgm	$4.44/100	3507B ea.
Trisulfapyrimidines			
Tablets	0.5 Gm.	$2.84/100	0106A ea.
Liquid		$4.94/480cc	0106B cc.
Vaporizer		$5.30/ea.	9843A ea.
Vitamins A, D, and C			
Chewable Tablets	100s	$2.40/100	7150H ea.
Vitamins A, D, and C with Sodium Fluoride			
Tablets	100s	$2.64/100	7152A ea.
Vitamins A, D, C, and B6 with Sodium Fluoride			
Chewable Tablets	100s	$2.27/100	7153B ea.

FORM 400A

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Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Promethazine Expectorant with Phenylephrine			
Liquid		$2.25/480cc	2513A cc.
Quinine			
Tablets or Capsules	200mgm	$5.91/100	0555R ea.
	325mgm	$8.53/100	0555C ea.
Reserpine			
Tablets	0.1mgm	$.40/100	2644D ea.
	0.25mgm	$.45/100	2644E ea.
Secobarbital			
Capsules	100mgm	$1.56/100	2157F ea.
Sodium Fluoride			
Tablets	2.2mgm	$.75/100	8901A ea.
Sulfacetamide Sodium			
Ophthalmic Ointment	10%	$0.66/4 Gm.	9400A Gm.
Ophthalmic Solution	10%-15cc	$1.55/15cc	9400D cc.
Sulfisoxazole			
Tablets	0.5 Gm.	$2.20/100	0163C ea.
Terpin Hydrate and Codeine			
Liquid		$2.54/480cc	2502A cc.
Tetracycline			
Tablets or Capsules	100mgm	$3.63/100	0244E ea.
	125mgm	$2.15/100	0244F ea.
	250mgm	$2.85/100	0244H ea.
	500mgm	$6.50/100	0244J ea.
Liquid	125mg/5cc	$3.60/480cc	0244K cc.
Drops	100mg/cc	$.75/10cc	0244M cc.

FORM 400A

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FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE

(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Pentobarbital			
Tablets or Capsules	100mgm	$1.61/100	2155H ea.
Phenobarbital			
Tablets or Capsules	15mgm	$.42/100	2156J ea.
	30mgm	$.45/100	2156K ea.
	65mgm	$.50/100	2156M ea.
	100mgm	$.55/100	2156N ea.
Potassium Chloride			
Liquid	10%	$1.50/480cc	3950K cc.
	20%	$1.70/480cc	3950N cc.
Prednisolone			
Tablets	5mgm	$3.89/100	8940J ea.
Prednisone			
Tablets	5mgm	$1.69/100	8945C ea.
Promethazine Expectorant with Codeine			
Liquid		$2.60/480cc	2507A cc.
Promethazine Expectorant Pediatric			
Liquid		$2.85/480cc	2508A cc.
Promethazine Expectorant Plain			
Liquid		$2.00/480cc	2506A cc.
Promethazine Expectorant with Phenylephrine and Codeine			
Liquid		$3.00/480cc	2514A cc.

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE

(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Nicotinic Acid			
Tablets	50mgm	$.61/100	7070B ea.
	100mgm	$.76/100	7070C ea.
Nitrofurantoin			
Tablets and Capsules	50mgm	$4.00/100	0080B ea.
	100mgm	$7.90/100	0080C ea.
Papaverine			
Long-acting Capsules	150mgm	$4.95/100	3327D ea.
Paregoric and Protective			
Liquid		$2.22/480cc	4800C cc.
Penicillin G			
Tablets	200,000u	$1.45/100	0204B ea.
	250,000u	$1.80/100	0204C ea.
	400,000u	$2.30/100	0204D ea.
Liquid	400,000u/5cc-80cc or 100cc	$1.70/100cc	0204P cc.
	400,000u/5cc-150cc or 200cc	$2.86/200cc	0204R cc.
Penicillin V (K) (Solution, Suspension, Syrup only)			
Liquid	125mg/5cc-40cc	$.84/40cc	0209A cc.
	125mg/5cc-100cc	$1.00/100cc	0209S cc.
	125mg/5cc-200cc	$1.70/200cc	0209T cc.
	250mg/5cc-100cc	$1.50/100cc	0209L cc.
	250mg/5cc-200cc	$2.60/200cc	0209W cc.
Pentaerythritol Tetranitrate			
Tablets	10mgm	$1.90/100	3309A ea.
	20mgm	$2.80/100	3309B ea.

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE

(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Diphenhydramine Expectorant			
Liquid		$1.95/480cc	2505A cc.
Diphenhydramine Hydrochloride			
Tablets or Capsules	25mgm	$1.14/100	8008D ea.
	50mgm	$.95/100	8008E ea.
Liquid	10mgm/4cc	$1.05/480cc	8008F cc.
Erythromycin			
Tablets or Capsules	250mgm	$10.15/100	0265K ea.
Ferrous Gluconate			
Tablets or Capsules	325mgm	$1.07/100	5261A ea.
Ferrous Sulfate			
Tablets	325mgm	$.94/100	5262B ea.
Fountain Syringe			
Limit One		$1.78/ea.	9819A ea.
Hot Water Bottle			
Limit One		$1.69/ea.	9821A ea.
Hydrochlorothiazide			
Tablets	25mgm	$3.69/100	3504A ea.
	50mgm	$5.82/100	3504B ea.
Hydrocortisone Topical			
Cream or ointment	½%	$5.00/454Gm.	9101A Gm.
	½%	$7.80/454Gm.	9101B Gm.
	1%	$12.00/454Gm.	9101C Gm.
Isoniazid			
Tablets	100mgm	$1.05/100	0020C ea.

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FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE
(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Calcium Lactate			
Tablets	325mgm	$0.79/100	7801A ea.
	650mgm	$1.17/100	7801B ea.
Catheters	5cc	$3.10/ea.	9811A ea.
	30cc	$3.45/ea.	9811C ea.
Chloral Hydrate			
Capsules	250mgm	$1.85/100	2250A ea.
	500mgm	$1.98/100	2250B ea.
Chlorpheniramine Maleate			
Tablets	4mgm	$.45/100	8005C ea.
Liquid		$2.80/480cc	8005D cc.
Chlorpheniramine Maleate with Phenylephrine			
Liquid		$3.22/480cc	2503A cc.
Codeine, Aspirin, Phenacetin and Caffeine			
Tablets or Capsules	15mgm	$2.90/100	2302B ea.
	30mgm	$3.85/100	2302C ea.
	65mgm	$7.60/100	2302D ea.
Colchicine			
Tablets	0.6mgm	$1.86/100	8900C ea.
Condoms		$1.00/12	9890A ea.
Dichlorphenamide			
Tablets	50mgm	$7.76/100	3502A ea.
Digitoxin			
Tablets	0.1mgm	$1.15/100	3001F ea.
	0.2mgm	$1.69/100	3001H ea.
Digoxin			
Tablets	0.25mgm	$1.03/100	3007B ea.

FORM 400A

CONTINUATION SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE
(Pursuant to Government Code Section 11380.1)

DO NOT WRITE IN THIS SPACE

(1) Amends Section 51513.3 (b) to read:

(b) Maximum Allowable Ingredient Cost List.

Generic Drug Type/ Medical Supply Type	Strength and/or Size	Maximum Allowable Ingredient Cost	Generic Drug Type Code/Medical Supply Type Code Number
Aluminum Hydroxide and Magnesium Trisilicate Gel			
Tablets or Capsules		$1.36/100	4304A ea.
Liquid		$1.26/355cc	4304B cc.
Aluminum and Magnesium Hydroxide Gel			
Tablets		$1.35/100	4302A ea.
Liquid		$1.35/355cc	4302C ea.
Ampicillin			
Injection	250mgm	$1.08/ea.	0221B ea.
	500mgm	$1.42/ea.	0221C ea.
Tablets or Capsules	250mgm	$12.50/100	0221E ea.
	500mgm	$22.16/100	0221F ea.
Liquid	125mgm/5cc-80cc	$1.47/80cc	0221J cc.
	125mgm/5cc-150cc	$2.43/150cc	0221K cc.
	250mgm/5cc-80cc	$2.27/80cc	0221N cc.
	250mgm/5cc-100cc	$2.64/100cc	0221P cc.
	250mgm/5cc-150cc	$3.78/150cc	0221R cc.
Drops	100mgm/cc-20cc	$1.15/20cc	0221T cc.
Belladonna Alkaloids with Barbiturate(s)			
Tablets or Capsules		$.67/100	1800A ea.
Liquid		$2.75/480cc	1800B cc.
Butabarbital			
Tablets	15mgm	$.65/100	2153B ea.
	30mgm	$.99/100	2153C ea.

Form 400 (REV. 9-64)

FACE SHEET
FOR FILING ADMINISTRATIVE REGULATIONS
WITH THE SECRETARY OF STATE
(Pursuant to Government Code Section 11380.1)

JAN 3 1975

RECEIVED FOR FILING
DEC 31 1974
Office of Administrative Hearings

ENDORSED
APPROVED FOR FILING
(Gov. Code 11380.2)
DEC 31 1974
Office of Administrative Hearings

DO NOT WRITE IN THIS SPACE

Copy below is hereby certified to be a true and correct copy of regulations adopted, or amended, or an order of repeal by:

Department of Health
(Agency)

Date of adoption, amendment, or repeal:

12/31/74

By: David A. Smith for William Mayer, M.D.
Director of Health

James E. Jenkins
Secretary, Health and Welfare Agency

ENDORSED
FILED
in the office of the Secretary of State
of the State of California
DEC 31 1974
At 5:30 o'clock P M
EDMUND G. BROWN Jr., Secretary of State

DO NOT WRITE IN THIS SPACE

DO NOT WRITE IN THIS SPACE

ORDER ADOPTING, AMENDING, OR REPEALING REGULATIONS OF THE STATE DEPARTMENT OF HEALTH

Pursuant to the authority vested by Sections 14105 and 14124.5 of the Welfare and Institutions Code, and to implement, interpret, or make specific Sections 14053 and 14105 of the Welfare and Institutions Code, the State Department of Health repeals, amends and adopts regulations in Title 22, Division 3, California Administrative Code, as follows:

(Register 75, No. 1—1-4-75)

Generic Drug Type/ Medical Supply Type	*Strength and/or Size*	*Maximum Allowable Ingredient Cost*	*Generic Drug Type Code/Medical Supply Type Code Number*
Promethazine Expectorant with Phenylephrine and Codeine			
Liquid		$3.00/480cc	2514A cc.
Promethazine Expectorant with Phenylephrine			
Liquid		$2.25/480cc	2513A cc.
Quinine			
Tablets or Capsules	200mgm	$5.91/100	0555B ea.
	325mgm	$8.53/100	0555C ea.
Reserpine			
Tablets	0.1mgm	$.40/100	2644D ea.
	0.25mgm	$.45/100	2644E ea.
Secobarbital			
Capsules	100mgm	$1.56/100	2157F ea.
Sodium Fluoride			
Tablets	2.2mgm	$.75/100	8901A ea.
Sulfacetamide Sodium			
Ophthalmic Ointment	10%	$.66/4 Gm.	9400A Gm.
Ophthalmic Solution	10%—15cc	$1.55/15cc	9400D cc.
Sulfisoxazole			
Tablets	0.5 Gm.	$2.20/100	0163C ea.
Terpin Hydrate and Codeine			
Liquid		$2.54/480cc	2502A cc.
Tetracycline			
Tablets or Capsules	100mgm	$3.63/100	0244E ea.
	125mgm	$2.15/100	0244F ea.
	250mgm	$2.85/100	0244H ea.
	500mgm	$6.50/100	0244J ea.
Liquid	125mg/5cc	$3.60/480cc	0244K cc.
Drops	100mg/cc	$.75/10cc	0244M cc.
Theophylline, Ephedrine and Phenobarbital			
Tablets		$.90/100	2953A ea.
Thermometer		$.84/ea.	9831A ea.
Thyroid			
Tablets (plain)	15mgm	$.50/100	6700A ea.
	30mgm	$.59/100	6700B ea.
	65mgm	$.70/100	6700C ea.
	120mgm	$1.31/100	6700D ea.
	200mgm	$2.12/100	6700E ea.
	250mgm	$2.42/100	6700F ea.
	325mgm	$2.59/100	6700H ea.
Trichlormethiazide			
Tablets	2mgm	$2.62/100	3507A ea.
	4mgm	$4.44/100	3507B ea.
Trisulfapyrimidines			
Tablets	0.5 Gm.	$2.84/100	0106A ea.
Liquid		$4.94/480cc	0106B cc.
Vaporizer		$5.30/ea.	9843A ea.
Vitamins A, D, and C			
Chewable Tablets	100s	$2.40/100	7150H ea.
Vitamins A, D, and C with Sodium Fluoride			
Tablets	100s	$2.64/100	7152A ea.
Vitamins A, D, C, and B_6 with Sodium Fluoride			
Chewable Tablets	100s	$2.27/100	7153B ea.

History: 1. Amendment of subsection (b) filed 8-5-74 as an emergency; effective upon filing (Register 74, No. 32). For prior history, see Register 74, No. 25.
2. Amendment of subsection (b) filed 10-1-74 as an emergency; designated effective 10-1-74 (Register 74, No. 40).
3. Certificate of Compliance filed 11-29-74 (Register 74, No. 48).
4. Amendment of subsection (b) filed 12-31-74 as an emergency; designated effective 1-1-75 (Register 75, No. 1). For prior history, see Register 74, No. 48.

Generic Drug Type/ Medical Supply Type	*Strength and/or Size*	*Maximum Allowable Ingredient Cost*	*Generic Drug Type Code/Medical Supply Type Code Number*
Ferrous Sulfate Tablets	325mgm	$.94/100	5262B ea.
Fountain Syringe Limit One		$1.78/ea.	9819A ea.
Hot Water Bottle Limit One		$1.69/ea.	9821A ea.
Hydrochlorothiazide Tablets	25mgm	$3.69/100	3504A ea.
	50mgm	$5.82/100	3504B ea.
Hydrocortisone Topical Cream or ointment	½%	$5.00/454Gm.	9101A Gm.
	½%	$7.80/454Gm.	9101B Gm.
	1%	$12.00/454Gm.	9101C Gm.
Isoniazid Tablets	100mgm	$1.05/100	0020C ea.
Nicotinic Acid Tablets	50mgm	$.61/100	7070B ea.
	100mgm	$.76/100	7070C ea.
Nitrofurantoin Tablets and Capsules	50mgm	$4.00/100	0080B ea.
	100mgm	$7.90/100	0080C ea.
Papaverine Long-acting Capsules	150mgm	$4.95/100	3327D ea.
Paregoric and Protective Liquid		$2.22/480cc	4800C cc.
Penicillin G Tablets	200,000u	$1.45/100	0204B ea.
	250,000u	$1.80/100	0204C ea.
	400,000u	$2.30/100	0204D ea.
Liquid	400,000u/5cc–80cc or 100cc	$1.70/100cc	0204P cc.
	400,000u/5cc–150cc or 200cc	$2.86/200cc	0204R cc.
Penicillin V (K) (Solution, Suspension, Syrup only) Liquid	125mg/5cc–40cc	$.84/40cc	0209A cc.
	125mg/5cc–100cc	$1.00/100cc	0209S cc.
	125mg/5cc–200cc	$1.70/200cc	0209T cc.
	250mg/5cc–100cc	$1.50/100cc	0209L cc.
	250mg/5cc–200cc	$2.60/200cc	0209W cc.
Pentaerythritol Tetranitrate Tablets	10mgm	$1.90/100	3309A ea.
	20mgm	$2.80/100	3309B ea.
Pentobarbital Tablets or Capsules	100mgm	$1.61/100	2155H ea.
Phenobarbital Tablets or Capsules	15mgm	$.42/100	2156J ea.
	30mgm	$.45/100	2156K ea.
	65mgm	$.50/100	2156M ea.
	100mgm	$.55/100	2156N ea.
Potassium Chloride Liquid	10%	$1.50/480cc	3950K cc.
	20%	$1.70/480cc	3950N cc.
Prednisolone Tablets	5mgm	$3.89/100	8940J ea.
Prednisone Tablets	5mgm	$1.69/100	8945C ea.
Promethazine Expectorant with Codeine Liquid		$2.60/480cc	2507A cc.
Promethazine Expectorant Pediatric Liquid		$2.85/480cc	2508A cc.
Promethazine Expectorant Plain Liquid		$2.00/480cc	2506A cc.

(b) Maximum Allowable Ingredient Cost List

Generic Drug Type/ Medical Supply Type	*Strength and/or Size*	*Maximum Allowable Ingredient Cost*	*Generic Drug Type Code/Medical Supply Type Code Number*
Aluminum Hydroxide and Magnesium Trisilicate Gel			
Tablets or Capsules		$1.36/100	4304A ea.
Liquid		$1.26/355cc	4304B cc.
Aluminum and Magnesium Hydroxide Gel			
Tablets		$1.35/100	4302A ea.
Liquid		$1.35/355cc	4302C ea.
Ampicillin			
Injection	250mgm	$1.08/ea.	0221B ea.
	500mgm	$1.42/ea.	0221C ea.
Tablets or Capsules	250mgm	$12.50/100	0221E ea.
	500mgm	$22.16/100	0221F ea.
Liquid	125mgm/5cc–80cc	$1.47/80cc	0221J cc.
	125mgm/5cc–150cc	$2.43/150cc	0221K cc.
	250mgm/5cc–80cc	$2.27/80cc	0221N cc.
	250mgm/5cc–100cc	$2.64/100cc	0221P cc.
	250mgm/5cc–150cc	$3.78/150cc	0221R cc.
Drops	100mgm/cc–20cc	$1.15/20cc	0221T cc.
Belladonna Alkaloids with Barbiturate(s)			
Tablets or Capsules		$.67/100	1800A ea.
Liquid		$2.75/480cc	1800B ea.
Butabarbital			
Tablets	15mgm	$.65/100	2153B ea.
	30mgm	$.99/100	2153C ea.
Calcium Lactate			
Tablets	325mgm	$.79/100	7801A ea.
	650mgm	$1.17/100	7801B ea.
Catheters	5cc	$3.10/ea.	9811A ea.
	30cc	$3.45/ea.	9811C ea.
Chloral Hydrate			
Capsules	250mgm	$1.85/100	2250A ea.
	500mgm	$1.98/100	2250B ea.
Chlorpheniramine Maleate			
Tablets	4mgm	$.45/100	8005C ea.
Liquid		$2.80/480cc	8005D cc.
Chlorpheniramine Maleate with Phenylephrine			
Liquid		$3.22/480cc	2503A cc.
Codeine, Aspirin, Phenacetin and Caffeine			
Tablets or Capsules	15mgm	$2.90/100	2302B ea.
	30mgm	$3.55/100	2302C ea.
	65mgm	$7.60/100	2302D ea.
Colchicine			
Tablets	0.6mgm	$1.86/100	8900C ea.
Condoms		$1.00/12	9890A ea.
Dichlorphenamide			
Tablets	50mgm	$7.76/100	3502A ea.
Digitoxin			
Tablets	0.1mgm	$1.15/100	3001E ea.
	0.2mgm	$1.69/100	3001H ea.
		P	
Digoxin			
Tablets	0.25mgm	$1.03/100	3007B ea.
Diphenhydramine Expectorant			
Liquid		$1.95/480cc	2505A cc.
Diphenhydramine Hydrochloride			
Tablets or Capsules	25mgm	$1.14/100	8008D ea.
	50mgm	$.95/100	8008E ea.
Liquid	10mgm/4cc	$1.05/480cc	8008F cc.
Erythromycin			
Tablets or Capsules	250mgm	$10.15/100	0265K ea.
Ferrous Gluconate			
Tablets or Capsules	325mgm	$1.07/100	5261A ea.

(9) Any interested party may in accordance with the Administrative Procedure Act petition the Department requesting the repeal of a regulation or a portion of a regulation fixing an MAIC. Such petition shall state clearly and concisely the substance or nature of the repeal requested and the reason for the request. The Department shall within thirty (30) days deny the petition in writing or schedule the matter for public hearing pursuant to the provisions of the Administrative Procedure Code.

(10) The Director may order a reconsideration of all or part of the case on his own motion. The establishment of the MAIC may be reconsidered by the Director on all the pertinent parts of the record and such additional evidence and argument as is presented.

(11) Judicial review of any finding, determination, rule, ruling or order prescribing an MAIC may be had pursuant to the provisions of Section 1094.5 of the Code of Civil Procedure or any other appropriate remedy.

In reviewing regulations prescribing MAICs, the superior court may exercise its independent judgment on the evidence considered by the Director in adopting any MAIC.

History: 1. Repealer and new section added 8-1-73 as an emergency; designated effective 8-10-73 (Register 73, No. 31). For prior history, see Register 72, No. 5.
2. Repealer and new section filed 12-6-73 as an emergency; designated effective 12-6-73 (Register 73, No. 49).
3. Certificate of Compliance filed 4-3-74 (Register 74, No. 14).
4. Amendment filed 4-30-74; effective thirtieth day thereafter (Register 74, No. 18).

51513.3. Maximum Allowable Ingredient Cost. (a) Paragraph (b) is an alphabetical list of generic drug types and medical supply type codes covered under Sections 51513, 51413, and 51320 for which payment shall be made in accordance with Sections 51513 and 51520.

(g) Substantial evidence that a drug product is "equivalent in quality" shall mean evidence consisting of adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate equivalence. Provided, however, that when the Director has made every reasonable effort to secure such investigations, but has been unable to obtain them, he may rely upon a recommendation concerning comparative therapeutic effect made by the Medical Therapeutics and Drug Advisory Committee, as provided for in Welfare and Institutions Code Section 14180 et seq., and such recommendation shall be considered to be substantial evidence.

(h) The evidence which the Director intends to rely on at the public hearing for the establishment of the MAIC shall be available to any member of the interested public for copying and inspection at reasonable times and places and the notice of the hearing shall so state and announce. The hearing officer shall grant a continuance of no more than thirty (30) days for further hearing upon request of any interested party for the purpose of rebuttal of any such evidence which was not made so available at least thirty (30) days prior to the hearing.

(i) Proceedings before the Director for the establishment of MAICs shall be undertaken at public hearing and in accordance with the following procedures and all other procedures required by law:

(1) At least thirty (30) days prior notice shall be given to all interested parties of the time and place of the public hearing. Upon request, the Department shall furnish any interested party a copy of the proposed regulation and the name or names of the manufacturers of the drug products used to establish the MAICs.

(2) Oral evidence shall be taken only on oath or affirmation administered by the Director or his duly authorized representative.

(3) The director shall consider all relevant matter presented to him before establishing the MAIC, and his decision shall be based solely on that evidence.

(4) During the course of the public hearing, any interested party shall be given an opportunity to examine any witness and to present relevant evidence.

(5) The hearing need not be conducted according to technical rules relating to evidence and witnesses.

(6) Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of such evidence over objection in civil actions. Irrelevant or unduly repetitious evidence may be excluded.

(7) If the hearing is presided over by a person other than the Director, such person shall be present during consideration of the establishment of the MAICs by the Director, and shall assist and advise the Director.

(8) Where good cause is shown the hearing officer may hold the hearing record open for a period of up to thirty (30) days in order to receive additional relevant evidence.

51513.2. Establishment of Maximum Allowable Ingredient Cost. The Maximum Allowable Ingredient Cost (MAIC) shall be established by the Director in accordance with the following:

(a) In establishing the MAIC the Director shall do so in such manner as to assure that eligible persons shall secure prescription drug services or medical supply products in the same manner employed by the public generally, and without discrimination or segregation based purely on their economic disability, and he shall make available prescription drug services at least equivalent to the level provided in 1970–71 in accordance with Section 14000 and 14000.1 of Welfare and Institutions Code.

The Director's determination shall be based upon the record of the public hearing provided herein and shall include a finding that the MAIC's adopted assure that eligible persons will receive prescription drug service representative of the prescription drug services or medical supply products which are available to the public generally without discrimination or segregation based purely on their economic disability.

(b) Generic drug type code and medical supply type code usage data for the past fiscal year shall be arrayed by dollar volume in generic drug type code numbers and medical supply type code numbers.

(c) All generic drug type codes and medical supply type codes shall be reviewed at least annually: (1) In priority of dollar volume purchased, or (2) by changes in market conditions, as identified by the Director, affecting supply and/or cost.

(d) Upon the selection of a generic drug type code or a medical supply type code for review, all related generic drug type code numbers or medical supply code numbers within that particular generic drug type or medical supply type shall be reviewed by the Director.

(e) Companies, identified on the Manufacturers Code Listing contained in Section 59999 (d), supplying the drug products or medical supply products within the reviewed generic drug types or medical supply types shall have their drug products or medical supply products arrayed by AWP in ascending order.

(f) The MAIC may only be established at the AWP of a drug product which has been demonstrated by the Director at public hearing by substantial evidence, in conformity with the provisions of subparagraph (a) of this section, to be a drug product that is generally equivalent in quality to those drug products prescribed by physicians throughout the state and available throughout the state to outpatient pharmacies through usual and customary distribution channels in sufficient quantities to meet the needs of the Medi-Cal program. "Equivalent in quality" shall mean a drug product which, when administered in like amounts, will provide essentially the same patient response as other drug products of the same generic drug type code when used for the purposes for which the drug product is generally used.

Rauwolfia Serpentina (Whole root)

50 mg. per tablet	.55/100
100 mg. per tablet	.75/100

Reserpine USP

0.1 mg. per tablet	.55/100
0.25 mg. per tablet	.80/100
1.0 mg. per tablet	1.80/100

Tetracycline USP

100 mg. per capsule or tablet	11.60/100
250 mg. per capsule or tablet	26.01/100
Syrup (125 mg. per 5 cc)	15.61/Pint

32637 12-60 70M SPO

PART IV

Drugs Restricted by Price Ceilings

Price ceilings have been established for the following drugs by the State Department of Social Welfare. Listed with the drugs in this section are specific maximum allowable wholesale costs. The pharmacist shall apply these costs or his actual cost, whichever is lower, in calculating the prescription price according to the California Public Assistance Prescription Fee Schedule. The price to the department shall never exceed the pharmacist's regular retail price.

The pharmacist shall dispense the lowest cost item he has in stock which meets the requirements of the prescriber as shown on the prescription form. This applies to all parts of the formulary.

Restricted drugs with maximum allowable wholesale costs:

Cortisone Acetate tablets USP 25 mg.	$ 8.00/100
Demethylchlortetracycline	
Capsules 150 mg.	26.01/100
Penicillin tablets, USP Buffered (Penicillin G Potassium)	
100,000 Units per tablet	1.80/100
200,000 Units per tablet	2.50/100
250,000 Units per tablet	3.00/100
400,000 Units per tablet	4.75/100
Penicillin V (Oral capsules or tablets) (Includes Penicillin V Potassium)	
125 mg. per capsule or tablet	13.02/100
250 mg. per capsule or tablet	21.66/100
Prednisolone (Oral tablets)	
1.0 mg. per tablet	1.75/100
2.5 mg. per tablet	2.80/100
5.0 mg. per tablet	4.00/100
Prednisone (Oral tablets)	
1.0 mg. per tablet	1.75/100
2.5 mg. per tablet	2.80/100
5.0 mg. per tablet	4.00/100
Quinidine Sulfate (Oral Tablets)	
0.2 Gm. per tablet	1.50/100

California Public Assistance Medical Care Program

Drug Formulary

Effective March 1, 1961 for

OLD AGE SECURITY
AID TO THE BLIND
AID TO THE DISABLED
AID TO NEEDY CHILDREN

PART I Single Drugs Unrestricted by Diagnosis

PART II Combinations of Drugs Unrestricted by Diagnosis

PART III Drugs Restricted by Specific Diagnosis

PART IV Drugs Restricted by Price Ceilings

STATE OF CALIFORNIA
DEPARTMENT OF SOCIAL WELFARE
J. M. WEDEMEYER, *Director*

If I or my agency can be of further assistance, please do not hesitate to call on us.

Sincerely,

MARIO G. OBLEDO
Secretary

cc: Mr. Casper Weinberger, Secretary
Department of Health, Education,
and Welfare
330 Independence Avenue, S.W.
Washington, DC 20201

generic drug.) Product mix changes have a particular influence on listed savings or losses. The convenience of reporting without specifically identifying each item is recognized; however, it is of great significance in this study.

7. Demonstrated savings under the RCLP program during Fiscal Year 1972-73, while less than anticipated under more favorable conditions, were nevertheless significant. These savings represented over seven percent reduction in prescription ingredient costs for the RCLP items. The savings were generated under a set of hostile circumstances which included the normal difficulties of implementing a new concept and, most notably, a legal action** taken by the Pharmaceutical Manufacturers' Association (PMA) against the State which limited the RCLP program very soon after its inception. We are convinced that the effectiveness of a program of drug price ceilings as a reasonable and practicable expenditure control has been proven in our State. We are further convinced that such a program, properly implemented, continues to make available to its beneficiaries safe and effective drugs.

8. Finally, the report distorts the short-term savings realized and the long-term savings potential of a ceiling price program by confusing the very small impact of the drug volume refund program operational during the same period of time with price ceilings. It must be restated that they were separate, distinct programs, not interdependent.

   Additionally, the comments on the 50-50 federal match reducing savings is irrelevant since the Federal Government bears 50 percent of costs as well.

Without citations or acknowledgments, the study cannot be verified, nor data validated. In short, the study is not a scientifically reproducible piece of research.

I fully agree with and endorse the above eight points made by Department of Health staff, and reiterate our support, subject to the suggested technical changes noted in the California Department of Health's comments on the proposed MAC regulations in their January 8, 1975, letter to your Hearing Clerk.

** Superior Court of the State of California in and for the County of Sacramento, Pharmaceutical Manufacturers' Association, et al vs. Brian, No. 221773.

charges. How can the study make such comparisons of unlike items? It must be recognized that drug product mix, drug needs seasonality, type of medication being compared and, most important, the direct comparison of ingredient cost with ingredient cost are all important variables which cannot be ignored.

5. We agree, there is a degree of "disaffection" with the Medi-Cal program on the part of some of the health care providers. This is always true with large government programs which must maintain fiscal integrity. The thrust of the complaints regarding Medi-Cal have been oriented toward utilization controls (i.e., prior authorization, Medi-Cal service label requirements), and limitations on ingredient cost updates (quarterly), which are other elements of Dr. Brian's Medi-Cal Reform Plan. Very little provider objection has focused upon ceiling prices for drugs; in fact, the California Pharmaceutical Association publically supports the ceiling price concept.

   When administering programs of such proportions, reasonable controls must be used in order to ensure that the objective will be attained. Be assured our MAIC program, like the proposed MAC program, will not set drug price ceilings unless safe, therapeutically effective products are available at or below the stipulated ceiling.

   The purpose of a program of price ceilings is to achieve economies in the ingredient cost component. In California, the cost of ingredients in prescriptions at the time of the study represented 55 percent of the total expenditures for drug prescriptions. It would seem correct to represent the savings as a percentage of the total ingredient cost for the test period rather than as a percentage of the total annual prescription cost as was done in Table 1 of the study. The report compares apples to oranges, and to the wrong oranges at that!

6. It is extremely important to point out that Table 2 apparently omitted Sulfonamides, Nitrofurantoin, and Antiasthmatics. These omissions, by themselves, render any conclusion arrived at through this study valueless.

   Additionally, Table 2 has utilized a theraputic class listing for demonstrating savings or losses. These classifications contain many generic drugs each. The report fails to point out which generic drugs (or which drug product within any generic drug) are represented on his table. This can have profound effects on the conclusions. We are uninformed as to any specific inclusions, omissions, or product mix changes. (Product mix is the assortment of drug products within a

2. There is considerable lack of clarity and the report tends toward an editorial rather than factual approach. See, for example, the remarks on "administrative costs" (page 5). The facts clearly support that the RCLP program generated an insignificant administrative expense. The RCLP program, with an administrative expense under $50,000, accounted for a total gross program savings of $2.1 million dollars during Fiscal Year 1972-73, a ratio of $42 saved for every $1 spent on administration. The first year of an innovative program is generally recognized as a difficult year to use for evaluation purposes. The study may have been able to verify even greater savings if cognizance were taken of the MAIC program which succeeded RCLP.

3. Under "Methodology", Brian states "November 1972 payments were chosen as the actual payments for study". The very next paragraph states that one of the reasons for selecting this time period is "the professional fee received by the pharmacists had remained constant". The fact is that the pharmacy fee went up 5 percent (from $2.30 to $2.42) effective November 1, 1972. This fact, if not taken into consideration, could result in an overstatement of the cost of ingredients component depending on calculation methodology used. Dr. Brian may have meant to say "October" 1972 payments since paragraph 1, page 7 reads: "As indicated above, calculations of pre-RCLP and post-RCLP costs were based on Medi-Cal month of payment drug paid claims files for April 1972 and October 1972." Was it October or November? The date becomes very important in determining the credibility of this document.

4. Conclusions are reached (paragraph 2, page 9) regarding the significance of a 1.2 percent reduction in number of units per prescription and how this could "represent a major portion of the 2.5 percent" reduction in total prescription cost.* In arriving at this conclusion, the author "judged" an 8.6 percent increase in the number of prescriptions filled during the test period as being insignificant. What was the basis for his judgement? Logic is offended at this point. A 1.2 percent reduction in prescription ingredient quantity is compared with a 2.5 percent reduction of total annual prescription retail

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* The 2.5 percent reduction in total prescription cost came entirely from RCLP drugs. The proper expression of the worth of RCLP would be:

$$\frac{\text{actual cost of drugs with RCLP}}{\text{potential cost of drugs in numerator above (not in entire program)}} \times 100 = \text{7.3 percent reduction in cost for items affected}$$

STATE OF CALIFORNIA

HEALTH AND WELFARE AGENCY

OFFICE OF THE SECRETARY

915 CAPITOL MALL, ROOM 200
SACRAMENTO, CALIFORNIA 95814 (916) 445-6951

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.

TABLE 2, cont.

THERAPEUTIC CLASS	AMOUNT		Difference Saving or (Loss)
	Actual	Pre-RCLP	
Hypotensive	39,458	44,612	5,154
Ophthalmic Preparations	22,249	21,594	(655)
Parathyroid	3,260	3,040	(220)
Replacement Solutions	51,208	56,545	5,337
Sedatives and Hypnotics	219,471	250,706	31,235
Spasmolytic Agents	78,060	103,717	25,657
Thyroid and Antithyroid	41,105	41,890	785
Vasodilating Agents	40,693	46,495	5,802
Vitamins	11,121	11,054	(67)
Medical Supplies	8,441	8,553	112

TABLE 2

MEDI-CAL PROGRAM

ACTUAL AMOUNT PAID OCTOBER 1972 FOR PHARMACEUTICAL PRODUCTS ON THE RCLP, COST OF SAME PRODUCTS AT PRE-RCLP PRICES AND DIFFERENCE- SAVINGS OR (LOSS) BY THERAPEUTIC CLASS EXCLUSIVE OF ADMINISTRATIVE COSTS

THERAPEUTIC CLASS	AMOUNT		Difference Savings or (Loss)
	Actual	Pre-RCLP	
TOTAL	2,150,130	2,319,382	169,252
Anti-Infectives	75,618	81,585	5,967
Anti-Inflammatory	26,428	28,426	1,998
Anti-Malarial	6,991	7,029	38
Anti-Tubercular	5,586	5,658	72
Cardiac Drugs	122,627	135,726	13,099
Dermatological Preparations	253,423	272,240	18,817
Diuretics	183,696	181,279	(2,417)
Diuretics-Carbonic	1,145	1,129	(16)
Adrenal Corticosteroids	858	785	(73)
Analgesics	338,866	355,215	16,349
Antacids and Absorbents	49,696	59,240	9,544
Antibiotic	253,729	276,123	22,394
Anticholinergic	65,073	66,823	1,750
Anti-Dental Cary	1,762	1,656	(106)
Anti-Diarrhea Agents	7,137	6,747	(390)
Antihistamine	77,107	84,953	7,846
Expectorants and Cough Preparations	122,798	125,072	2,274
Hematinics	42,524	41,490	(1,034)

TABLE 1

MEDI-CAL PROGRAM

ESTIMATED EFFECT OF THE RCLP[1/]

FOR OCTOBER 1972 MONTH OF PAYMENT

USING ONLY PHARMACEUTICALS ON RCLP

EXCLUSIVE ADMINISTRATIVE COSTS

Expected Costs Based on Pre-RCLP Rates	$2,319,382
Actual Costs	2,150,130
Difference	169,252
Percent Reduction in Total Rx Costs	2.50%
Total Annual Rx Costs	81,700,000

1/ Reimbursable Cost List Price a maximum reimbursement established for the Medi-Cal Program.

the savings described above plus the distortions that are outlined below, it appears the overall program costs significantly outweigh the benefits of direct cost controls on prescribed drugs.

Third, in California there is a growing perception that one of the real long-term effects of overt controls on any segment of health care delivery system is an increasing disaffection on the part of many of the health care providers. This is especially apparent among many physicians who have expressed concern over the fact that differences in therapeutic equivalence are not recognized by programs that limit product selection through price alone. Also physicians have expressed concern over the RCLP program in that it interferes with their decision making process and has a detrimental effect on the quality of care being provided. At a time when a major aspect of our nation's health care problem centers around the quantity and quality of health care services, direct control programs apparently are a significant disincentive to the attraction and retention of needed quality health care personnel to deliver these services.

From the experience in California it is clear that the medium and long-term costs of a direct drug price control program completely outweigh the short-term benefits of relatively minor drug procurement savings. With the possibility that a MAC program would be a precedent for pending National Health Insurance, this leaves the concern that there will be a far reaching disruption of the health care delivery system in the United States.

Discussion

California's Medicaid Reimbursable Cost List Price Program (RCLP), which placed direct price controls on the drug costs of prescriptions paid for from Medicaid funds, is very similar to the HEW's recent proposed Maximum Allowable Cost (MAC) proposal. As such the California experience serves as a means of testing the effectiveness of such programs. The dramatic size of the California program and the accumulated expertise of its administrators add validity to this test. Overall a conclusion can be drawn that, based on the California experience, a MAC-type program has not resulted in the most efficient purchase (at least cost) of pharmaceutical products under public assistance medical care programs.

Three clearly discernible characteristics of the California experience point to this conclusion. First, under RCLP there were some minor short-term savings in direct drug costs, but the anticipated "savings" were significantly (threefold) less than originally forecasted. (In addition, if one takes into account the 1.2% decline in the average prescription size that occurred between the two time periods of this study, the total gross savings on prescription drug expenditures amounts to 1.3% (or less) instead of the 2.5% shown above.)

Second, although direct measures of administrative costs are not available, there are strong indications that these costs are not insignificant. When these are coupled with the overestimate of

On the other hand, there were a number of instances where savings were negligible or increased costs occurred. The major cost increase occurred with diuretics where the actual costs were one percent higher than expected. Part of these cost increases may have bec caused by pharmacists shifting to the drug product at the price specified in the RCLP.

Another factor could have been a change in prescription size. Reducing the size of the prescription would have increased the cost of prescriptions for a given volume of products. Examination of the increases and decreases failed to uncover any consistent pattern in one way or the other. Overall, the average prescription size for all RCLP products was 93.7 items per prescription for the pre-RCLP base period and 92.6 for the test period. The pre-RCLP period utilized 587,386 prescriptions and the test period 637,830. The difference in this latter pair of numbers was not judged as being a significant factor in this study. However, the reduction in the average prescription size could be significant because it represents a 1.2% reduction in quantity which in and of itself could represent a major portion of the 2.5% savings shown.

However, it must be pointed out that in choosing two fairly divergent time periods distortions may have occurred that are not explained through prices alone. There could have been differences in the "product mix" between the two periods such that changes in the relative weights of the products were, at least in part, the cause of the savings. There is no precise way of measuring this element.

Findings

Although prior to program implementation it was estimated that $2.0 million would be saved by the volume refund portion of the program, actual savings were negligible. The absence of significant savings was due to there being fewer volume refund agreements than expected and to the high administrative costs relative to administering the program.

The results of the application of the methodology described above demonstrated RCLP savings which were significantly less than anticipated. These savings represented a maximum overall gross savings of about 2.5 percent to the Medi-Cal drug program (Table 1).

Total savings to the State of California were somewhat less than 50% of the $2.1 million gross savings for the year after subtracting administrative costs and the 50% match due to the federal government.

The gross savings by therapeutic class are shown in Table 2. It will be noted that the highest savings occurred for sedatives and hypnotics, spasmolytic agents and antibiotics. Savings for these pharmaceuticals were relatively substantial running from around 12.5% to 25% below the costs at pre-RCLP rates.

As indicated above, calculation of pre-RCLP and post-RCLP costs were based on Medi-Cal Month-of-Payment Drug Paid Claims files for April 1972 (for January-March 1972 services) and October 1972 (July-September 1972 services). Using the pre-RCLP file, all generic drug type codes which were subsequently to be covered by the RCLP were priced out at pre-RCLP Medi-Cal Program payments on the basis of dollars per 100 units. Units included capsules, cubic centimeters for fluids, grams, or unit counts for such items as hot water bottles, etc. These pre-RCLP costs for each generic drug type code were then applied to the post-RCLP, generic drug type code list. Pre-RCLP costs were multiplied by post-RCLP quantities, item by item, to measure the costs which would have been obtained at pre-RCLP prices. The sum of all such items was then compared with the actual post-RCLP costs and the difference between the two amounts represents the gross savings due to the RCLP.

The methodology would have been complicated somewhat if the Department's original intentions had been followed. The original intention was to periodically update the RCLP to reflect Red Book and Blue Book cost increases or decreases. However, legal actions taken against the Department by the Pharmaceutical Manufacturers Association (PMA) precluded the periodic review. The periodic review may not have resulted in much change in reimbursement rates because of the stability of drug costs; and during the study period there were no dramatic price changes.

Methodology

The estimate of savings under the RCLP was based on computing the "expected" costs, (those which would have occurred without the RCLP) and comparing expected costs to actual costs. November 1972 payments, which cover July-September prescriptions, were chosen as the actual payments for study. The expected costs for study were derived from claims paid in April 1972 for January-March prescriptions. There were various reasons for choosing these two time periods.

The Medi-Cal Reform program began October 1, 1971, and the disruptions caused by program changes had been ironed out by the beginning of the year; copayment for provider services and drugs had commenced January 1, 1972, and the same proportions of Medi-Cal beneficiaries had a copayment obligation in the before and after periods described above (30.1% vs. 30.6%). The professional fee received by the pharmacists between the two periods did not change nor were other program changes introduced that might confound the results. In fact, the changes in the program resulting from the introduction of the RCLP were minimal since the program had had a drug formulary since its inception in 1966 and since generic drug types had always been included in the formulary. In short, the effects measured may be attributed specifically to the introduction of the RCLP element of the program.

An alternative approach was provided through which the pharmaceutical manufacturer would rebate to the Medi-Cal program a percentage of the program's costs of all the manufacturer's drugs. These refund programs were the basis for the second phase of the drug cost reduction efforts.

The second phase consisted of reviewing any and all volume refund proposals voluntarily submitted to the State by various pharmaceutical manufacturers. Contracts were let for proposals which appeared to offer a substantial refund and program saving to the Department.

Prior to program implementation it was estimated that the combination of the RCLP and volume refund program would result in overall net drug program savings of approximately $7 million annually, $5 million from RCLP and the remainder from volume refunds.

Refunds generated by the combined program are <u>not</u> net savings to California. Title XIX of the Social Security Act federal financial participation (FFP) is provided through a 50/50 match in California. Consequently, the federal government participates with a 50 percent share of any savings realized against actual costs. Additionally, administrative costs - not available but estimated to be substantial - also consume a significant portion of the gross savings.

State pharmaceutical consultants reviewed products and selected a Blue or Red Book listed cost as the maximum the State would pay for the product. This selected cost usually tended toward the middle of the range of listed costs. If a pharmacist dispensed a more expensive product he received the RCLP fee. However, if he dispensed a less expensive product he received the listed cost of the less expensive product rather than the RCLP figure. Of course, the pharmacist also received the standard professional fee ($2.40 per prescription dispensed until January 1, 1975 - now $2.71 per prescription dispensed.) Computerized pricing made feasible such a procedure for the huge volume of Medi-Cal prescriptions. Still, some hand processing was necessary.

Since the very beginning the Medi-Cal Program has promoted generic prescribing through its formulary. Even with the formulary there has been some tendency for prescribing by manufacturer. The introduction of the RCLP emphasized generic prescribing only, allowing the pharmacist to fill the prescription with the product he had on hand. Otherwise, the pharmacist had to take a loss by filling the prescription with the brand specified or contact the physician to change the prescription.

Under related provisions of California law some pharmaceutical manufacturers offered to rebate to the State the difference in cost between their drugs and the generic drugs if their drugs were listed on the RCLP. The State would reap the savings while the market for the manufacturer's drugs would be protected.

Reimbursable Cost List Price (RCLP) for a number of generic drugs and certain other products was established. The RCLP was based on cost data published in the pharmaceutical industries' "Red Book" and "Blue Book". To be placed on the RCLP a product had to be produced by a number of manufacturers or distributors, the list price had to vary considerably, the product had to be widely used, and the product had to be generally available throuout the State.

To determine whether a drug product had been demonstrated to be safe and effective the Department relied on the Federal Food and Drug Administration, and also on the manufacturer's guarantee that his drug product met all provisions of the Federal Food, Drug and Cosmetic Act or the California Sherman Food, Drug and Cosmetic Act. Other requirements included that the drug meet the requirements of the United States Pharmacopoeia (U.S.P.) or National Formulary (N.F.), and that the drug had been reviewed by the National Academy of Science-National Research Council, if applicable.

In the establishment of RCLPs only multisource generic drug types, those drugs produced or marketed by more than one manufacturer, were considered. Of the approximate 600 drugs listed in the Medi-Cal Drug Formulary 35 percent are multisource and 65 percent are single source. RCLPs were established originally for 196 generic drug types and medical supplies (see attached list) which the Department had determined met the criteria described above. These drugs potentially represented the greatest possible dollar savings due to their high utilization and price range differentials.

dissatisfactions expressed by both pharmacists and program administrators. Government program planners have long been aware of the wide variations in wholesale drug costs for some similar products. In order to reduce inequities and problems in the Medi-Cal Program, the administration introduced the Medi-Cal Reform Plan during the 1971 legislative session.

One element in the Medi-Cal Reform Plan provided the State Department of Health with the statutory authority to purchase needed health services for eligible beneficiaries while keeping within available resources. Section 14105.3 of the California Welfare and Institutions Code gives the California State Department of Health the legal authority for developing and implementing both a therapeutically and fiscally sound drug program. The State is considered to be the purchaser of drugs prescribed under the Medi-Cal program, but not the dispenser or distributor. The purpose is to enable California to obtain the most favorable price for drugs from manufacturers taking into account the large quantities purchased by the Medi-Cal Program. The section also enables the State to seek discounts, rebates, or refunds from manufacturers based on the quantities of drugs purchased through the Medi-Cal program.

Early in 1972, California initiated a two stage plan designed to bring the private and public sectors together in order to establish a therapeutically and fiscally sound drug program. First, a

THE CALIFORNIA MAC-LIKE EXPERIENCE

by

EARL W. BRIAN, M.D.
UNIVERSITY OF SOUTHERN CALIFORNIA
CENTER FOR HEALTH SERVICES RESEARCH

For many years California has had a significant stake in the purchase of prescription medication and medical supplies for public assistance recipients and other persons financially unable to meet their health care needs. The number of services and recipients have increased to the point that such purchases have increased from $8.5 million in 1957-58, the first year of the Public Assistance Medical Care Program (PAMC), to $20.1 million in its last year (1964-65). Ten years later $90.1 million was budgeted for prescription pharmaceutical products under Medi-Cal, the successor to the PAMC Program.

These figures represent costs for products purchased by prescription for non-hospitalized patients. Under these public programs reimbursements to pharmacists have been made in several ways; but basically the programs have allowed an ingredient cost plus a standard professional fee. The ingredient cost may be (or may have been) the wholesale cost with or without a markup, or a cost based on a "standard" package, while the standard professional fee may be (or may have been) increased to allow for extemporaneously compounded prescriptions. Regardless of how these reimbursements have been determined, there always have been some

3. Overall, as long as primary responsibility for a patient's successful treatment rests with the physician, he must be free to exercise his professional skill and judgment unencumbered by unproductive and restrictive influences such as MAC.

Sincerely,

/s/

Earl W. Brian, M.D.
Director

From this experience it can only be concluded that the short-term "savings" on drug costs will be completely overwhelmed by the medium and long-term costs that such programs impose on the system.

Aside from the demonstrated absence of significant savings from a price control system, such as the California Reimbursable Cost List Price program which is very similar to the proposed MAC plan of HEW, there are other features of MAC which, while not subject to empirical measurement, I believe, as a physician, are contrary to the public interest.

1. The proposed regulations omit any requirement for demonstrated therapeutic equivalence or quality on the part of the lowest cost drugs. If a drug product does not deliver the anticipated therapeutic response, its value may not only be negated but in some cases be hazardous to the patient because its use will result in delay in employing effective therapy and thus may expose the patient to additional potential side-effects. Such a situation is counterproductive in cost-saving programs for it results not only in additional total drug usage but also in extra visits to the physician or possibly even hospitalization.

2. The regulations would subordinate the professional judgment of the physician and the pharmacist in product selection and represent unwarranted interference in patient care by a government board (Pharmaceutical Reimbursement Board). At a time when concern is mounting from virtually every quarter regarding the quality of medical care, it seems most inappropriate to further muddle the physician/pharmacist/patient professional relationship by adding an intervening government agency which is almost certainly going to decrease both the quality and the efficiency of the pharmaceutical delivery system. Although the proposed regulations offer the opportunity to "certify" the need for a particular manufacturer's product, the provisions are so vague that they fail to offset the foregoing concerns.

LOS ANGELES, CALIFORNIA 90033

February 10, 1975

Miss Jennie C. Peterson
Hearing Clerk
Food and Drug Administration (HFC-20)
Room 4-65
5600 Fishers Lane
Rockville, Maryland
20852

Dear Miss Peterson:

In response to the Department of Health, Education and Welfare's recently proposed Maximum Allowable Cost (MAC) program regulations, the following is respectfully submitted.

Through my recent personal experience as Secretary of Health and Welfare for the State of California, where for four years I exercised jurisdiction over the nation's largest state public medical care assistance program, I have developed a study that yields several conclusions related to the DHEW's proposed MAC program. This report is attached for your consideration. The basic conclusions reached by this study are as follows:

1. California experience with a program very similar to MAC shows that the gross savings from such a direct cost control program are minimal and that the potential gross savings estimated prior to program operation were exaggerated over threefold.

2. There is a tendency for the administrative costs to be underestimated and they alone may outweigh the minimal gross drug savings.

3. California's MAC-like drug cost control program may be raising the costs of other components of the health care delivery system.

4. Based on my observations, direct control programs (such as MAC) cause a significant amount of disaffection among professional health care providers. This has had a detrimental effect on the quality of health care services subsequently delivered.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

February 26, 1975

The Honorable Mario Obledo
Secretary
Health and Welfare Agency
714 P Street
Sacramento, California 95814

Dear Mr. Secretary:

On November 15, 1974, the Secretary of Health, Education and Welfare published for public comment a proposed regulation establishing upper limits of Federal cost sharing for drugs provided under Medicare, Medicaid and other HEW-funded programs. A copy of the proposal and background materials are enclosed.

An important provision of the proposed regulation would establish upper limits on multiple source drugs similar in many respects to the Maximum Allowable Ingredient Cost List established under California's Medi-Cal program. A letter in response to the proposal has been received from Dr. Earl W. Brian, former Secretary of Health and Welfare of California. Dr. Brian enclosed a document summarizing the Medi-Cal drug reimbursement program and a cost study concluding that the MAC-like program in California experienced savings three-fold less than originally forecasted.

I am enclosing a copy of Dr. Brian's letter and cost study. I would greatly appreciate your analysis of and comments on them.

With best wishes,

Sincerely,

Mark Novitch, M.D.
Deputy Associate Commissioner
for Medical Affairs

Enclosures

It is our opinion that the requirement under the conditions of participation for skilled nursing facilities effective February 19, 1974 which provides for pharmaceutical services to be under the supervision of a qualified pharmacist affords more quality of care assurance than can ever be claimed for or attributed to a drug distribution system.

We respectfully recommend that this provision be dropped from the proposed regulations and not be reconsidered until such a time when substantial detailed, and accurate information on which to base a decision is available.

Comments on (45 CFR, Part 250) Reimbursement of Drug Cost - Medical Assistance Program (Federal Register, Vol. 39, No. 230 - Wednesday, November 27, 1974)

Comments and recommendations on Maximum Allowable Cost (MAC), actual acquisition cost, and other aspects of the proposed regulations appear in Attachment 1. My comments and recommendations herein are limited to reimbursement for unit dose dispensing.

We respectfully oppose a variable dispensing fee to be paid for drugs furnished to recipients of medical assistance in long-term care facilities by pharmacies employing a unit dose system.

At this time there is not conclusive evidence in support of all the merits attributed to unit dose systems.

We have found that:

1. a more thorough analysis of unit dose systems of drug distribution is needed to substantiate the claims being attributed to such systems; and,

2. unit dose systems are mere drug distribution vehicles which, by themselves contribute very little to improved patient care.

As you know, unit does systems are being promoted to long-term care facilities on the basis of both cost savings and increased quality of care. Once the long-term care facility accepts the principle, the pharmacy servicing the facility, in many cases, is allowed to purchase the system and to implement its utilization.

It has not been proven to our satisfaction that either claim attributed to unit dose systems has been achieved in any long-term care facility.

For example: "Are the economies realized by paying only for drugs which are actually consumed significant when compared to the cost of achieving such economies?" We have not been convinced that they are.

We also find difficulties in accepting claims of "increased quality of care" resulting from fewer drug interactions in view of the "completely unreliable"* estimates of magnitude and cost of adverse drug reactions being widely circulated.

*Karch, Fred and Lasagna, Louis; Medicine in Public Interest, University of Rochester.

We would also like to respectfully request that the language under proposed 45 CFR Part 19, Section 19.3 (b) be changed to delete the words "or which will be effective for that patient". Since therapeutic equivalence of the drug would have already been established, the above statement is contradictory and inappropriate.

The publication of a monograph or list covering items 1 and 2 above would be a slight modification of the recommendations which were made by the Drug Bioequivalence Study Panel, Office of Technology Assessment, to the Congress of the United States on July 15, 1974.

Another alternative which we feel would realize savings is the establishment of the maximum allowable cost price of drug product enjoying a high volume of usage based on the most commonly purchased package size of the drug product. For example, a product commonly purchased in 1000s by the pharmacy provider and reimbursed at the 1000s base price by Medicaid programs would not only encourage providers to attain savings through volume buying but would also tend to discourage price manipulation by the manufacturer (i.e., high cost for 100s, exceptionally low cost for 1000s).

Reimbursement at 98 percent of the average wholesale price of a specific product as listed in the Drug Topics Red Book or American Druggist Blue Book is another alternative to achieving savings. This method would ensure that the 2 percent trade discount would be passed on to the government as a volume purchaser meanwhile still providing the pharmacy provider an incentive to purchase economically in larger quantities. This system would not interfere with automated claim processing, and would not require large degree of monitoring and auditing.

A combination of the preceding recommendations, we feel, would be as effective if not more effective than actual acquisition cost in achieving savings with minimal amount of manpower, controlling, and auditing. It is our opinion that actual acquisition cost could prove to be counter-productive by tending to eliminate provider incentive to purchase as economically as possible.

We also respectfully oppose the 25 percent incentive for products with an MAC as being ineffective, and requiring as much controlling and auditing as actual acquisition cost. We believe this incentive at the provider level will not prevent manufacturers from increasing their prices to make the established MAC the floor as well as the ceiling. It has been our experience here in California, that manufacturers not only make the ceiling the floor but also manipulate prices on package sizes which they then use as a sales gimmick to gain advantage on the state Medicaid program. This leads us to believe that if incentives are to work they must be made available to manufacturers as well as to providers.

Our recommendation would be to set the MAC as low as possible at a participating manufacturer's product's AWP and enter into some type of price holding agreement as a condition of participation. Also, utilize the appropriate federal agency as a source of information to advise the individual states so that they may possibly set more stringent price ceilings at the state level.

COMMENTS ON (45 CFR PART 19) MAXIMUM ALLOWABLE COSTS FOR DRUGS (FEDERAL REGISTER, VOL. 39, NO. 222 - FRIDAY, NOVEMBER 15, 1974)

The State of California agrees with and supports the establishment of federal limitations on reimbursement for drugs. We have been using a similar program of price ceilings in California's Medicaid program, in one form or another, since March 1, 1961. Our experience has shown that it is possible to accumulate savings in excess of four million dollars on purchases of drugs amounting to forty million dollars. This supports that savings of 5 to 8 percent of overall prescription drug expenditures, as stated in the Federal Register, Vol. 39, No. 222 - Friday, November 15, 1974, are realistic and attainable.

In contrast to our successful California program of price ceilings, is our ineffective attempt to reimburse drug providers at the actual acquisition cost.

Our actual acquisition cost program proved extremely difficult to control and administer. Most providers billed at the average wholesale price (AWP) as published in Drug Topics Red Book or American Druggist Blue Book. Auditing and certification of ingredient costs became a massive, cost ineffective procedure which required an excessive outlay of funds and manpower. Our actual acquisition cost program was in effect from 1960 to 1968. Our experiences proved that it was virtually impossible for a large state like California to effectively administer a program based on actual acquisition cost. Pharmacies purchase from multiple sources at different prices making it virtually impossible to determine actual acquisition cost.

There are, however, alternatives which we feel would allow the federal and state governments to achieve meaningful savings.

The establishment of maximum allowable costs (MACs) is, in our opinion, the most effective method to achieve savings. As MACs are established, we would encourage the appropriate federal agency to publish a detailed monograph covering:

1. the relative importance of bioavailability on the specific drug products; and,

2. the comparative therapeutic equivalence of all available brands of the specific generic drug.

This information could be used by the individual states in setting ceilings (lower than federal MAC in some instances) on generic drug products which are available with adequate distribution on an intrastate basis.

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH
714 P STREET
SACRAMENTO, CALIFORNIA 95814

January 8, 1975

Hearing Clerk
Food and Drug Administration, Room 4-65
Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

Dear Sir:

MAXIMUM ALLOWABLE COST FOR DRUGS (45 CFR PART 19) AND REIMBURSEMENT OF DRUG COST - MEDICAL ASSISTANCE PROGRAM (45 CFR PART 250)

This is in regard to the proposed rules on the above subjects, published in the Federal Register, Vol. 39, No. 222 - Friday, November 15, 1974; and Idem., No. 230 - Wednesday, November 27, 1974. Thank you for the opportunity to submit our comments.

The attached comments are cross referenced to the text of the proposed rules as published.

The California Department of Health agrees in principle with the proposed regulations, however, in some instances, we question the practicality and feasibility of the proposed approach.

We sincerely hope that our comments, suggestions, and objections will provide you with a deeper insight into some of our past experiences with similar approaches to program control and that in turn this may prove useful in solidly structuring the regulations which will ultimately be adopted.

Sincerely,

Original Signed by

William Mayer, M.D.
Director of Health

Attachments
cc: James S. Dwight, Jr.
Administrator, Social and Rehabilitation Service
Department or Health, Education and Welfare
P.O. Box 2382
Washington, D.C. 20013

HE CONCLUDED THAT THE CALIFORNIA RCLP AND VOLUME REFUND PROGRAMS WERE NOT COST EFFECTIVE.

AT THE REQUEST OF HEW, MR. MARIO OBLEDO, THE NEW SECRETARY OF CALIFORNIA'S HEALTH AND WELFARE AGENCY, DIRECTED THE STATE DEPARTMENT OF HEALTH STAFF TO THOROUGHLY ANALYZE THE STUDY AND DR. BRIAN'S COMMENTARY. MR. OBLEDO IN HIS RESPONSE TO HEW, WHICH IS AN ATTACHMENT TO MY STATEMENT, INCLUDED A CALIFORNIA DEPARTMENT OF HEALTH DETAILED COMMENT ON DR. BRIAN'S ALLEGATIONS AND CONCLUSIONS. THE STUDY, IN THE OPINION OF DEPARTMENT OF HEALTH STAFF, LACKED SCIENTIFIC RESEARCH METHODOLOGY. IT DOES NOT APPEAR THAT DR. BRIAN WAS FULLY AWARE OF THE REAL AND FULL VALUE OF THE PROGRAM WHICH HE, JUST A FEW YEARS EARLIER, HAD INITIATED.

IN SUMMARY, CALIFORNIA HAS HAD LONG EXPERIENCE WITH PRICE CEILINGS ON DRUGS; MEDI-CAL'S PROCEDURES FOR ESTABLISHING THE CEILINGS HAVE BEEN DEVELOPED THROUGH A LONG AND PROVEN EVOLUTIONARY PROCESS; WE HAVE WEATHERED LEGAL OPPOSITION TO THE CEILING PRICE PROGRAM; WE STRONGLY FEEL THAT CEILING PRICES ARE A VALID AND COST-EFFECTIVE CONTROL; FINALLY, WE ARE CONVINCED OUR EXPERIENCE IS MOST USEFUL TO THE FEDERAL GOVERNMENT'S PROPOSED MAC PROGRAM.

THANK YOU.

LET US BACKTRACK JUST ONE MOMENT AND RESTATE THE SAVINGS FIGURES IN THEIR PROPER PERSPECTIVE. WE HAVE SAVED MORE THAN $2,000,000 ON INGREDIENT COSTS. WHAT DOES THIS REPRESENT OF INGREDIENT COST FOR ITEMS WITH PRICE CEILINGS, NOT TOTAL PRESCRIPTION CHARGES, AT RETAIL? IT IS MORE THAN 7 PERCENT, WHICH WE IN CALIFORNIA FEEL IS REASONABLE, WHILE NOT SEVERELY CONSTRAINING THE HEALTH CARE PROVIDER FROM PROVIDING ANY PATIENT WITH ANY DRUG UNDER ANY CIRCUMSTANCE.

HOWEVER, CRITICS HAVE TAKEN THESE FACTS AND HAVE ATTEMPTED TO DISTORT THEM TO MEAN THAT THE PROGRAM DOES NOT MEET ITS PROJECTED GOAL. THE DEPARTMENT READILY ADMITS THAT, TO DATE, WE HAVE NOT HAD THE ADVANTAGE OF A FULLY IMPLEMENTED PROGRAM. WE FEEL THAT THE FEDERAL PROPOSED MAC PROGRAM SHOULD CARRY ON WHERE THE STATE OF CALIFORNIA MAIC PROGRAM PIONEERED.

THE MOST IMPORTANT CRITICISM TO DATE OF CALIFORNIA'S MAIC PROGRAM IS THAT OF EARL W. BRIAN, M.D., FORMER DIRECTOR OF THE STATE OF CALIFORNIA'S DEPARTMENT OF HEALTH CARE SERVICES, AND LATER SECRETARY OF THE STATE HEALTH AND WELFARE AGENCY, A POST ON FORMER GOVERNOR RONALD REAGAN'S CABINET. DR. BRIAN, IN A RECENT COMMENTARY TO THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (HEW), HAS USED HIS PERCEPTION OF THE CALIFORNIA PROGRAM TO QUESTION THE VALUE OF FEDERALLY PROPOSED MAC TYPE PROGRAMS. WITH THE COMMENTARY TO HEW, DR. BRIAN INCLUDED A STUDY IN WHICH

ARRAY, THEN PROCEEDED WITH ADOPTING PRICE CEILINGS ONLY ON THE HIGHEST VOLUME GENERIC DRUG TYPES AND MEDICAL SUPPLY CATEGORIES FOR WHICH AN ADEQUATE EVIDENTIARY BASE FOR THERAPEUTIC SAFETY AND STATEWIDE DISTRIBUTION WAS AVAILABLE. THAT IS TO SAY, TO SET A CEILING PRICE, SOME DRUG PRODUCT WOULD HAVE TO BE AVAILABLE AT THAT PRICE ON A STATEWIDE BASIS, DISTRIBUTED THROUGH THE USUAL AND CUSTOMARY CHANNELS, SHOWN TO HAVE PROVEN SAFETY, AND PROVEN THERAPEUTIC EFFECTIVENESS. THE DRUG PRODUCTS ARE FURTHER REQUIRED TO BE COMPARABLE TO THOSE DRUG PRODUCTS WHICH ARE GENERALLY PRESCRIBED BY A PHYSICIAN AND OTHER PRESCRIBERS THROUGHOUT THE STATE OF CALIFORNIA.

EVEN WITH THE SAFEGUARDS OF THE STANDARDS ESTABLISHED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION, AND OUR OWN STATE FOOD AND DRUG SECTION, WE HAD TO TAKE EXTRA STEPS. EVEN MEETING THESE LIMITATIONS AND EXTRA REQUIREMENTS, THE MAIC PROGRAM ACCOUNTED FOR MORE THAN $2,000,000 WORTH OF SAVINGS IN THE 1972-73 FISCAL YEAR ON TOTAL DRUG EXPENDITURES OF $81,479,170. IN A PROGRAM OF MORE THAN 2,600 DRUG ITEMS AVAILABLE, PRICE CEILINGS ON ONLY 125 HAVE ACCOUNTED FOR SAVINGS OF OVER $2,000,000 AT AN ADMINISTRATIVE COST OF SOMETHING LESS THAN $40,000 -- A 2½ PERCENT SAVINGS OVERALL.

AND COMPANY, MCKESSON LABORATORIES, AND STRONG-COBB-ARNER (NOW KNOWN AS ICN PHARMACEUTICALS) -- AND OFFERED TO PARTICIPATE IN THIS PROGRAM.

SOON AFTER THESE PROGRAMS HAD BEGUN, THE DEPARTMENT WAS SUBJECTED TO A LAWSUIT FILED BY THE PHARMACEUTICAL MANUFACTURERS' ASSOCIATION (PMA) CLAIMING THE VOLUME REFUND PROGRAM AND THE REIMBURSABLE COST LIST PRICE PROGRAM ILLEGAL ON THE GROUNDS THAT THE DEPARTMENT DID NOT FOLLOW PROPER ADMINISTRATIVE PROCEDURES IN ADOPTING THESE PROGRAMS. THIS FROZE THE TWO PROGRAMS AT THE LEVEL EXISTING IN JUNE 1972, AND NO FURTHER CHANGES WERE MADE. THEY REMAINED INTACT AND OPERATIONAL (BUT FROZEN FROM EITHER EXPANDING OR CONTRACTING) UNTIL THEY WERE FINALLY SHUTDOWN IN AUGUST 1973. EFFECTIVE IN AUGUST 1973 A NEW PROGRAM, THE CURRENT MAXIMUM ALLOWABLE INGREDIENT COST PROGRAM (MAIC), WAS ADOPTED. THIS PROGRAM SALVAGED A NUMBER OF THE ELEMENTS OF THE RCLP PROGRAM BY FOLLOWING A VERY STRICT COURT DICTATED ADMINISTRATIVE PROCEDURE THAT HAS NOW BECOME PART OF OUR DEPARTMENTAL REGULATIONS. THE PROCEDURE IS PRESENTED IN EVIDENCE AS AN ATTACHMENT TO THIS STATEMENT.

THE MAIC PROGRAM IS LIMITED IN THAT ONLY 125 GENERIC DRUG TYPES AND ONLY 5 MEDICAL SUPPLY CATEGORIES CURRENTLY ARE SUBJECTED TO PRICE CEILINGS. IN COMPLIANCE WITH THE ADMINISTRATIVE PROCEDURE, THE DEPARTMENT CHARTED DRUG UTILIZATION IN A DOLLAR VOLUME

THE FIRST LIST OF RCLP PRICES BECAME EFFECTIVE APRIL 1, 1972. THIS WAS A LISTING OF SOME 198 LINE ITEMS; THAT IS TO SAY, DRUGS AND MEDICAL SUPPLIES LISTED BY THEIR GENERIC NAMES, STRENGTHS, AND DOSAGE FORMS. WE ARE NOT TALKING ABOUT 198 DRUGS, BUT RATHER 198 SEPARATE AVAILABLE DOSAGE FORMS AND STRENGTH OF DRUGS WHICH WERE SUBJECT TO CEILING PRICES. ON THE OVERALL, WE HOPED TO SAVE FOR THE DEPARTMENT SOME $5,000,000 PER FISCAL YEAR FOR A FULLY IMPLEMENTED AND EFFECTIVELY OPERATED RCLP PROGRAM.

AT THE SAME TIME, INDEPENDENTLY, BUT WITH THE SAME GOAL IN MIND OF EFFECTING SAVINGS OR REDUCING DRUG COSTS, A PARALLEL PROGRAM WAS INTRODUCED KNOWN AS THE VOLUME REFUND PROGRAM. THIS SECOND PROGRAM WAS A REENACTMENT OF AN EARLIER SET OF CIRCUMSTANCES WHEREIN MANUFACTURERS CAME TO THE STATE AND OFFERED REBATES BASED ON THE VOLUME OF THEIR DRUG PRODUCTS DISPENSED THROUGH THE MEDI-CAL PROGRAM.

IF ALL COMPANIES WHO WERE PARTICIPATING IN THE MEDI-CAL PROGRAM WERE TO COME FORWARD AND OFFER A FAIR SHARE REBATE, THESE TWO PROGRAMS TOGETHER WERE ANTICIPATED TO SAVE THE STATE APPROXIMATELY $13,000,000 PER FISCAL YEAR. A SO-CALLED FAIR SHARE REBATE WAS CONSIDERED TO BE THE DIFFERENCE BETWEEN THE AVERAGE WHOLESALE PRICE (AWP) OF THE MANUFACTURERS' DRUG PRODUCT AND THE RCLP IN EFFECT ON THAT PARTICULAR GENERIC DRUG AT THE TIME. SOME COMPANIES CAME FORWARD IMMEDIATELY -- NOTABLY, ELI LILLY

SELLING FOR LESS THAN $1. THE RANGE OF PRICES WAS THE RATIONALE FOR ADOPTING PRICE CEILINGS.

THE MAWC CEILING PRICES WERE NOT INTENDED TO LIMIT AVAILABILITY OF GENERIC DRUGS TO THE LOWEST COST ITEM WITHIN A GENERIC TYPE. THEY WERE, HOWEVER, INTENDED TO BRING ABOUT REASONABLE CONTROLS OVER A BROAD BAND OF DRUG PRODUCT PRICES THAT WERE AS PREVALENT THEN AS THEY ARE TODAY.

THIS BRINGS US THEN TO 1966 AND THE ADVENT OF THE CURRENT MEDICAID PROGRAM PURSUANT TO PUBLIC LAW 89-97, WHEREIN A STATE COULD ASSUME CENTRALIZED CONTROL OF ADMINISTRATION OF A HEALTH PROGRAM FOR THE POOR AND NEAR POOR UNDER TITLE 19 OF THE SOCIAL SECURITY ACT. FOR THE FIRST FOUR YEARS OF CALIFORNIA'S MEDICAID PROGRAM, WHICH WE HAVE LABELED THE "MEDI-CAL PROGRAM", MAWC WERE CONTINUED JUST AS BEFORE AFFECTING A VERY LIMITED NUMBER OF DRUG PRODUCTS IN A SMALL NUMBER OF GENERIC TYPES.

IN 1971, IN AN EFFORT TO CONTAIN RUNAWAY COSTS WITHIN THE MEDI-CAL PROGRAM, THE MEDI-CAL REFORM PLAN (MRP) WAS ADOPTED BY THE STATE LEGISLATURE. MRP BROUGHT ABOUT A NEW, INTENSIFIED CEILING PRICE PROGRAM FOR THE DRUG COMPONENT OF MEDI-CAL. THIS PROGRAM BECAME KNOWN AS THE REIMBURSABLE COST LIST PRICE (RCLP) PROGRAM.

CALIFORNIA'S DRUG PROGRAM AS I HAVE KNOWN IT OVER THE LAST SEVERAL YEARS. I PLACE PARTICULAR EMPHASIS ON THE PRICE CEILINGS THAT WE MAY HAVE HAD IN EFFECT, AT ONE TIME OR ANOTHER, PARTICULARLY OUR CURRENT PROGRAM KNOWN AS THE MAXIMUM ALLOWABLE INGREDIENT COST (MAIC) PROGRAM. I FEEL MAIC IS THE INSPIRATION FOR THE FEDERAL MAXIMUM ALLOWABLE COST (MAC) PROGRAM WHICH WE ARE DISCUSSING HERE TODAY.

MORE THAN A DECADE AGO, CALIFORNIA WAS INVOLVED IN WHAT WAS KNOWN AS THE PUBLIC ASSISTANCE MEDICAL CARE (PAMC) PROGRAM. THE PAYMENT FOR SERVICES WAS ADMINISTERED BY COUNTIES HANDLING FEDERAL AND COUNTY RESOURCES AND WAS NOT A DIRECT STATE-ADMINISTERED PROGRAM AS WE KNOW IT TODAY. PAMC PROVIDED OUTPATIENT DRUGS THROUGH COMMUNITY PHARMACIES.

EVEN IN THOSE DAYS, I'M REFERRING NOW TO THE EARLY 1960'S, CALIFORNIA HAD A LIMITED NUMBER OF CEILING PRICES KNOWN AS "MAXIMUM ALLOWABLE WHOLESALE COST" (MAWC) FOR SEVERAL DRUGS WHICH WERE AVAILABLE GENERICALLY. THESE INCLUDED ITEMS SUCH AS PREDNISONE, PENICILLIN-G, THYROID, PHENOBARBITAL, AND A LIMITED NUMBER OF OTHERS. THESE CEILING PRICES WERE AN ATTEMPT TO CONTAIN VERY HIGH DRUG COSTS. ALTHOUGH THE DRUGS WERE AVAILABLE GENERICALLY, MANY PRODUCTS MAINTAINED A VERY HIGH PRICE PROFILE. FOR EXAMPLE, SCHERING CORPORATION'S METICORTEN WAS SELLING IN THE RANGE OF $17 PER 100 TABLETS FOR THE 5MG SIZE AS OPPOSED TO OTHER GENERICALLY AVAILABLE BRANDS OF THE SAME GENERIC DRUG

EXHIBITS PROVIDED BY THE CALIFORNIA DEPARTMENT OF HEALTH

(STATEMENT BY:
(CARLO P. MICHELOTTI
(ASSISTANT CHIEF
(MEDI-CAL BENEFITS SECTION
(CALIFORNIA DEPARTMENT OF HEALTH
(BEFORE SUBCOMMITTEE ON MONOPOLIES
(U.S. SENATE SMALL BUSINESS COMMITTEE
(MARCH 21, 1975

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE:

MY NAME IS CARLO MICHELOTTI. I AM THE ASSISTANT CHIEF OF THE MEDI-CAL BENEFITS SECTION, CALIFORNIA STATE DEPARTMENT OF HEALTH. MY PROFESSIONAL BACKGROUND IS AS A PHARMACIST. I WAS EDUCATED AT THE UNIVERSITY OF THE PACIFIC, SCHOOL OF PHARMACY AND HAVE POST-GRADUATE TRAINING IN MANUFACTURING PHARMACY AND IN PHARMACEUTICAL CHEMISTRY. I PRACTICED COMMUNITY PHARMACY FOR SOME 11 YEARS PRIOR TO COMING TO THE STATE DEPARTMENT OF HEALTH IN 1972. ADDITIONALLY, I AM CURRENTLY ENROLLED IN A GRADUATE PROGRAM LEADING TO THE DEGREE OF MASTER OF PUBLIC HEALTH AT THE UNIVERSITY OF CALIFORNIA, SCHOOL OF PUBLIC HEALTH.

I AM HERE TODAY TO PRESENT TO YOU A PROFILE OF THE CEILING PRICE PROGRAM FOR DRUGS AVAILABLE THROUGH THE MEDICAID PROGRAM IN CALIFORNIA. THE PURPOSE OF THIS TESTIMONY IS TO SHARE THIS EXPERIENCE AND IN DOING SO EXTEND THE SUPPORT OF THE CALIFORNIA DEPARTMENT OF HEALTH TO THE PROPOSED FEDERAL MAC PROGRAM SUBJECT TO THE SUGGESTED TECHNICAL CHANGES NOTED IN OUR LETTER OF JANUARY 8, 1975 PROVIDING COMMENTS ON THE PROPOSED REGULATIONS. A COPY OF THAT LETTER IS AN ATTACHMENT TO THIS TESTIMONY. THE BEST WAY TO PROCEED, I FEEL, IS TO PRESENT A CHRONOLOGY OF

AMERICAN MEDICAL news

MARCH 3, 1975

MD attacks arguments against MAC program

☐ This is in reply to your Feb. 3, 1975, editorial in which you criticize the implementation of the MAC (maximum allowable cost) program for the government-funded prescription drug costs.

First, why all the concern over quality of generic equivalents versus "brand-name drugs"? The only true example of an inferior generic equivalent I have heard of in the past few years is among the generic equivalents of "Lanoxin" (Burroughs-Wellcome & Co.), some of which have had lower bioavailability of digitalis. If there are other examples of truly inferior generic equivalents, I would certainly like to be informed of them.

Second, to suggest that doctors know the relative costs of the drugs they are prescribing, with the exception of a few popular drugs, is both ridiculous and naive. How can the average doctor possibly keep track of the rapidly escalating prices of a dozen different generic equivalents?

Third, to suggest that government is controlling the practice of medicine by trying to substitute the least expensive generic equivalent, and thereby trim health-care costs, is really just an excuse for making sure the physician prescribes brand-name drugs; thereby insuring high profits for the pharmaceutical manufacturers. Why in heaven's name do we need 10 different brands of tetracycline?

Last, and most important, I contend prescribing brand-name drugs actually is a waste of a physician's valuable time. For example, when a patient recently showed me an antibotic called "Panmycin" (Upjohn), which he was taking for a sore throat, I wasted approximately five minutes finding out it was just plain old tetracycline, a poor choice at best, anyhow.

Thus, I conclude there is no valid argument for being opposed to MAC or substitution laws, provided the physician retains the right to state "dispense as written" on his prescriptions, if he so chooses.

NORTON J. COOKSEY, MD
Southfield, Mich.

require that a state agency pay only the lesser of drug product cost plus professional fee or the pharmacy's actual charge for a specific prescription to the general public. This procedure requires only sample audits for effective enforcement.

The definition of "charge to the general public" should peg this figure at the lowest charge at which the prescription is generally available or available to a class of patients of significant size, for example, "senior citizens."

Finally, returning to the subject of the "actual acquisition cost" requirements of the proposed regulations, it should be clear to anyone that pharmacists who generally have been dependent upon a 15-25 percent "cushion" between actual acquisition cost and catalog drug product prices to reimburse them for the additional administrative and financing expenses involved in federally supported health care programs, cannot give up this form of reimbursement without an immediate equitable adjustment of professional fees. APhA has consistently urged that these additional administrative costs experienced by pharmacists be properly compensated as a part of the professional fee rather than as a hidden "cushion" factor in drug product cost reimbursement. The Association believes that adequate professional fees would be far preferred by pharmacists as a substitute to "fictitious" drug product cost figures.

Pharmacists feel they have been unfairly forced to play unbecoming games with drug product costs reimbursement because of inadequate professional fees. Unfortunately, the problem which pharmacists now foresee, taking into account comments regarding the proposed regulations received by the Association from its members, is that equitable adjustments of professional fees will not be made concurrently with imposition of the actual acquisition cost requirement. If such concurrent adjustments are not made by the states and federal programs, the Association has every reason to believe that for many pharmacists the choices will be (1) terminate their participation in the program, (2) fail economically, or (3) circumvent the regulation. Neither the profession, the government nor the public would benefit if any one of these possibilities becomes fact.

Reluctantly, APhA would be forced to withhold its historic support for pharmacist participation in federally supported health care programs unless the proposed regulations in final form require concurrent equitable fee adjustments, or at least retroactive equitable fee adjustments, in those states which will now move to the actual acquisition cost basis for drug product cost reimbursement and unless such adjustments are actually made. Similar adjustments clearly must also be made in those states where "actual acquisition cost" is already in effect. APhA would suggest that the regulations require a participating state to pay a professional fee to each pharmacy which reasonably relates to the fee each pharmacy respectively charges the self-paying public.

Moreover, the final regulations must provide for regularized, periodic review of professional fees and adjustments as indicated. "Indexing" professional fees may be a feasible approach.

CONCLUSION

This Association has continuously supported the participation of pharmacists in federally supported health care programs and has cooperated fully with government efforts to improve the administration of these programs, including support for the MAC policy announced in December, 1973 by Secretary Weinberger. The Association would not be entitled to the support of its members, however, were it to accept on their behalf any less than full recognition of their contribution to these programs and their entitlement to fair compensation and fair treatment in return for that participation.

The object of government policy and administration in federally supported health care programs must be to compensate prudently, but fairly and with an even hand, all who are involved in drug product manufacture and drug product distribution. The failure of the government to acknowledge and satisfy these essential philosophical and practical criteria can only result in the ultimate failure of the system and the inability of these programs to fulfill their Congressionally intended objectives.

maceutical service. Even "consumer leaders" with whom the Association has discussed the existing professional fee situation have recognized its inherent unfairness and irrationality.

If correspondence addressed to the Association is any indication, pharmacists will no longer tolerate situations in which professional fees in state Medicaid programs remain static for several years in the face of spiraling inflation. Pharmacists cannot understand why manufacturers have been permitted unlimited "pass-through" of price increases at their expense. In several states, there has been an effort to reduce fees rather than increase them in order to compensate for increased drug product costs resulting from higher manufacturer prices.

At the same time, pharmacists have been expected to continue financing these programs with their own capital because of inordinate delays in claims payment in many states—when interest rates have skyrocketed. Members are telling APhA that they can no longer tolerate or absorb such financing costs, even if they were willing to do so—which they are not.

The simple fact is that the present Medical Assistance Program regulations permit, and administration of the program has condoned, the payment of a professional fee of $1.25 in the state of Missouri and at the same time, a professional fee of $2.42 in the state of California. The close to 100 percent difference among state Medicaid professional fees is ample argument for mandatory federal regulation. In all candor, APhA is beyond the point of even trying to explain to the nation's pharmacists how the government can permit such gross disparities in the treatment of pharmacists by the states.

Present HEW regulations require the payment of a "reasonable dispensing fee" for the professional services provided by the pharmacist. If fees actually paid in 1969 were then "reasonable," the same, or only minimally increased fees are clearly unreasonable in 1975 when inflation during this period has accumulated to 34.5 percent according to the Bureau of Labor Statistics. It is clear that HEW has failed to observe and enforce its own regulations.

The following table shows the fees paid in 26 state Medicaid programs which utilized a uniform fee for pharmacist professional services during the 1969-73 period. In 1969 the average fee for these 26 states was $1.77; in 1973 the average fee was $1.87—a 5.8 percent accumulative increase in five years. In twelve states the fee was not increased one cent. Just to keep pace with the CPI measure of inflation, the average fee for the 26 states should have been increased $.61 to $2.38.

These facts taken individually and collectively reflect a gross abuse of pharmacists which APhA regards as a national disgrace.

State Medicaid Professional Fees 1969 and 1973

	1969	1973
Alabama	$1.50	$1.50
California	2.30	2.42
Colorado	1.85	1.85
Connecticut	1.75	2.00
Delaware	2.00	2.00
Dist. of C.	1.50	1.60
Georgia	1.85	1.95
Indiana	1.85	1.85
Iowa	2.00	2.00
Kentucky	1.40	1.65
Louisiana	1.80	1.80
Maine	1.75	2.00
Maryland	1.75	1.75
Massachusetts	1.80	1.85
Michigan	2.00	2.00
Mississippi	1.50	1.50
Missouri	1.10	1.25
New Hampshire	1.85	2.20
New Jersey	1.85	2.05
New Mexico	2.00	2.00
New York	1.80	1.80
North Carolina	1.75	2.00
Rhode Island	1.50	1.90
South Carolina	1.90	1.90
Tennessee	1.85	1.95
Vermont	1.75	1.85

There can be little question that if the Department can establish mandatory requirements for "state-plan" programs with regard to reimbursement for drug product cost, the Department can likewise establish a mandatory requirement that states adopt a variable fee system which reflects the differences in professional service provided by individual pharmacies and which also adequately compensates individual pharmacies for such service. Certainly, the Department can establish such requirements for its own "in-house" programs.

APhA wishes to voice its support for the "unit dose" system provisions of Section 250.30(b) (2) (i) (b) of the proposed Medical Assistance Plan regulations, but believes they should be expanded. The Association would note, however, that administration of this provision should effectively require the establishment of a unit dose *system* for dispensing and not merely the obtaining and dispensing of drug products in unit dose packaging. Unfortunately, the provisions of this subsection are inadequate in that they do not require payment for non-drug dispensing professional services provided by pharmacists in long-term care facilities, although such services are required under the Medical Assistance Program for the facility to qualify as a recipient of federal funds.

The Commissioner of the Medical Services Administration has recently stated his view, that the failure of a facility to pay for such professional services provided by a pharmacist separate and apart from payment for the dispensing of drug products, is, in effect, a "kickback" situation and a violation of federal law. While APhA might concur in this assessment, it would also have to point out that the situation is one which has been created by the fact that states do not generally reimburse long-term care facilities for such services because federal regulations and program guidelines do not require the states to pay for them. "Unit Dose" provisions should also be included in the Public Health Service regulations whether or not such systems are currently employed in those programs.

Section 250.30(b) (2) (i) (c) of the proposed Medical Assistance Program regulations setting a provider reimbursement limit is, in its present form, an open invitation to take advantage and divert federal Medical Assistance Program funds for the benefit of persons not entitled to participate in the program. This is because the regulation would continue to permit state agencies to evaluate the appropriateness of a particular pharmacy's professional fee by testing that the *average* prescription price paid the pharmacy by the state agency does not exceed the *average* prescription price paid by the general public. To enforce this requirement, a state agency would have to audit every charge for all the prescriptions dispensed by a particular pharmacy. Unless the word "average" is stricken from this provision, the government and taxpayers will continue to overpay in the fashion reported recently by the General Accounting Office in its review of the District of Columbia Medicaid program.

It can be documented virtually nationwide that some pharmacies, usually chains and so-called "discounters" have been collecting from Medicaid programs drug product cost (often on a catalog price basis) plus full professional fee for prescriptions which they are dispensing to the general public at "loss leader" prices. Not only have these pharmacies not extended to the government their usual pricing policies, but the windfalls received from federal funds reimbursed on a full cost plus fee basis have been used to subsidize "giveaway" prices to patients who do not qualify as Medicaid participants. The only way for the government to put a stop to these abusive and unlawful practices is to

and the taxpayer, but it also places the government in the position of providing operating capital which can be used to wipe out the competitive presence of lower volume independent pharmacies.

Any claim that providers should be rewarded for large volume buying practices is met by the provision of Section 19.3(b) which would award any pharmacy 25 percent of the difference between a MAC and the price at which the pharmacy is able to purchase a particular drug product. This concession should not be increased for what in practice is one class of pharmacies—large volume purchasers —by awarding additional "gravy" above actual acquisition cost.

A related matter involves the proposed reimbursement for so-called "warehousing" costs to "a provider who maintains a warehouse separate from his retail place of business." This proposed warehousing allowance is discriminatory in that it primarily benefits large volume drug chains, while failing to take into account the fact that all providers, including independent pharmacies, have costs associated with getting a drug product from their source of supply to their stock shelves. These costs are not attributable to the drug product itself, however, but represent operational costs and overhead which would properly be accounted for in the determination of all providers' professional fees. If the regulations in final form award what is really merely a special "handling" allowance only to large volume purchasers, they would be discriminatory on their face and, in the view of APhA subject to legal challenge.

All providers must be treated the same and any possible drug product handling costs should be limited to the actual costs of handling the drug products themselves (eliminating costs of handling unrelated merchandise) with an established upper cost limit.

APhA comments regarding the drug product cost component of pharmaceutical service, save one, have already been made with regard to the proposed Departmental regulations. The remaining comment is applicable to all of the proposed regulations, which would authorize the payment of actual acquisition cost for a drug product, without regard to any MAC limitation which may be established for that drug, if the prescriber has certified in writing that the specific drug product prescribed is the only one which can be tolerated or which will be effective for the patient involved.

Beyond stating that certification by the prescriber would be required in writing, the proposed regulations do not specify the precise form of certification, to whom the certification would be made, or the means by which the pharmacist would establish the fact of certification to obtain actual acquisition cost reimbursement in such situations. The lack of specificity in the proposed regulations may be aimed at permitting each program to establish its own requirements for prescriber certification. It would be far better, however, were all of the program regulations themselves to specify with regard to prescriber certification at least the following elements:

1. A form which would identify the patient and the drug product, such information to be provided in the prescriber's own handwriting and signed by him.
2. Transmittal of the certification in duplicate to the pharmacist (along with a written prescription order), one copy to be retained in the pharmacist's files and one copy to be transmitted to the state agency as support for the pharmacist's claim for reimbursement. This procedure should not be available for oral prescription orders.

The certification provisions of all of the proposed regulations are also deficient in that they fail to provide for "actual acquisition cost" reimbursement when the pharmacist, in the exercise of his professional judgment, determines that the patient requires a particular drug product. In several states, whose number will be increasing rapidly, pharmacists have the right of drug product selection even though the prescriber may have ordered a drug by a particular brand name. The pharmacist should be able to dispense a more expensive brand as a matter of professional judgment in the same manner as the physician. Since reimbursement is based on actual drug product cost there can be no claim that such pharmacist discretion will be influenced by economic incentives.

If, for example, a prescriber orders a particular drug product for a diabetic patient not realizing that sugar is included in the formulation, the pharmacist would be able to dispense the same drug in a formulation containing an artificial sweetener which could be tolerated by the patient. Such a product might fall outside the MAC limitation for the drug, and the regulations should provide for actual acquisition cost reimbursement on the basis of the pharmacist's certification rather than the physician's.

PHARMACIST PROFESSIONAL FEES

Comments which follow address themselves primarily to the Medical Assistance Program "reasonable charges" regulations in Section 250.30 and PHS regulations in Section 50.504.

The most vigorous disagreement APhA has with regard to the proposed Medicaid "reasonable charges" and Public Health Service regulations is the fact that Sections 250.30(b) (2) (i) and 50.504, respectively, do little more than repeat the language of present provider reimbursement regulations. Although officials of HEW have assured APhA that it is their intention that state Medicaid and other programs move to a professional fee structure which would terminate the present almost universal "uniform fixed fee" situation, the proposed regulations clearly do not require such action by any state or Public Health Service program. Thus, the proposed regulations are inadequate and unacceptable because they are neither adequately specific nor explicitly mandatory.

In Sections 250.30(b) (2) (i) and 50.504(a) (2), all of the specified criteria for professional fee determination could continue to be used to establish a "uniform fixed fee" on an "average" pharmacy basis. A perpetuation of this fee structure would represent an absolute breach of faith by the Department and its component agencies with the nation's pharmacists.

In the above referenced sections, the continued suggestion that states should consider the payment practices of other third party organizations is a clear signal that the present "uniform fixed fee" will continue to be tolerated since virtually all existing third party payment programs have established professional fees on this basis. APhA must again point out, as it has so many times previously, that a uniform fixed fee results in the unfair overpayment of some pharmacists and the unfair underpayment of others, while a third group is appropriately compensated on the basis of operating costs related to services provided. The final regulations must make "crystal clear" the Department's intention that this gross inequity be terminated.

The feasibility of establishing professional fees on an individual pharmacy basis is no longer in question since this approach has been demonstrated successfully in the state of Kansas since 1970, a fact which is brought to the attention of all states by the Medical Assistance Program in the Medical Assistance Program Manual (see CCH Medicare and Medicaid Guide, Vol. 2, p. 6387). Texas now utilizes a similar approach.

The time has long since passed for the Department to demonstrate its good faith and interest in equitable treatment for pharmacists by requiring a variable professional fee for phar-

sured. The proposed regulations seem to stress the Committee's advice on policy and economic considerations of placing drugs on the MAC roster, but the Committee should also be utilized to advise HEW in the area of bioequivalency and quality assurance.

In order for the Committee to fulfill the above responsibilities, the Academy recommends that composition of the Pharmaceutical Reimbursement Advisory Committee include an expert in biopharmaceutics and an expert in clinical pharmacology. The Committee's ability to analyze the adequacy of current standards, that will be depended upon to assure quality and performance of the MAC listed drugs, rests upon adding these additional experts. We urge HEW not to rely entirely upon their own FDA in matters of drug quality and bioequivalence.

With respect to the issue of drug product quality, and specifically the report of the Office of Technology Assessment referred to in the above-quoted APS comments, APhA notes, as APS points out, that the OTA panel report concludes that "current standards and regulatory practices do not assure bioequivalence for drug products." By the same token, the OTA panel also concluded that "it is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products."

Affirmatively, the OTA panel recommended that an official list of interchangeable drug products be developed as rapidly as possible and that such a list distinguish between those drugs which might present bioavailability problems and those drugs "for which evidence of bioequivalence is not considered essential."

In response to this latter recommendation, the Association, with the full cooperation and assistance of the Academy of Pharmaceutical Sciences, proffered to the Department at its request a list of drugs intended to aid in implementing the OTA panel recommendation. Thus, it appears to APhA that events which have already transpired taken in combination with the "FDA clearance" procedure will provide the necessary assurance that establishment of a MAC for a particular drug will not represent a threat to the public health.

As the Association has repeatedly stated, and as the OTA panel itself implicitly recognized, there is no way, even through the expenditure of unlimited funds, that pharmaceutical scientists, the pharmaceutical industry, or the government can assure a "zero defect" level of drug product quality. What can be provided is a vigorous assurance that drug product quality in the United States is extremely high overall and that the incidence of inadequate drug product quality is extremely low. As a means of continuing this assurance, the Association urges the FDA to consider application of dissolution requirements in its "clearance" procedure, as previously recommended by the Association, as well as any additional available laboratory tests representing current technology.

The Association supports the APS suggestion that a biopharmaceutics expert serve on the Pharmaceutical Reimbursement Advisory Committee and notes that the proposed regulations are sufficiently broad to encompass such specific expertise. The Association assumes that the Committee will advise with regard to, among other matters, the quality standards to be applied to drug products under MAC consideration.

DRUG PRODUCT COST

APhA believes that the provisions of Section 19.6, which assure not only a regular review of MAC determinations, but also the right of any individual or organization to request imposition of, adjustment of, or termination of a particular MAC at any time is both eminently fair and capable of efficient administration. The Association notes, however, that a provision which is capable of efficient administration may be worthless unless it is, in fact, efficiently administered. In the absence of prompt administrative decisions by the Department, the entire reimbursement mechanism for pharmaceutical service in federally supported health care programs is in danger of failing. The final regulations should address themselves in Section 19.6 to two specific eventualities.

First, the Board should be empowered to make MAC determinations on an emergency basis without resort to the advisory committee procedure when such action is deemed necessary by the Department. A specific situation which might require such emergency action would be in the case of sudden and unexpected drug product shortages which, among other effects, might have abnormal disruptive effect on drug product prices. Such situations have already been experienced in the cases of quinidine, heparin and injectable ampicillin. A similar situation may be anticipated in the next one or two years in light of projected shortages of codeine.

Second, the final regulations must contain in Section 19.6, or elsewhere, provision for automatic retroactivity of upward MAC adjustments, once an initial MAC has been established for a particular drug, to compensate for possible delays in the MAC determination procedure and expected computer update delays at the state level. Downward MAC adjustments can be made concurrent or prospective in application.

Probably the most controversial aspect of the proposed regulations is the imposition of an "actual acquisition cost" reimbursement basis for drug product cost in all federally supported health care programs. This requirement is presently in effect in only a few states. Despite the fact that many pharmacists may not yet fully understand the following reasons for this decision, APhA is constrained to support this requirement as reflected in Section 19.3 of the proposed Departmental regulations and also in Section 250.30(b) (2) (ii) of the proposed Medical Assistance Plan regulation, Sections 50.502 (d) and 504(b) of the proposed Public Health Service Regulations, and Section 405.333(a) of the proposed Medicare regulations.

Imposition and *enforcement* of the actual acquisition cost requirement is deemed mandatory by APhA to protect the government, taxpayers and competing pharmacists against economic windfalls which accrue to large volume purchasers of drug products when drug product cost reimbursement is based on published "list," "average wholesale prices" or other fictitious price data.

It is well known among pharmacists, third party program administrators and government officials, that drug products cost reimbursement based on catalog prices is based on fictitious price information and that actual acquisition costs by pharmacists generally range below published figures. Depending upon the purchasing power of particular pharmacies and the proclivities of drug manufacturers and their salesmen, actual acquisition costs have resulted in "significant" to "gross" overpayment for the drug product component of prescriptions paid for, at least in part, with federal funds. Large volume and other "favored" purchasers such as dispensing physicians have been the chief recipients of special economic windfalls.

When the Pharmaceutical Reimbursement Board obtains true price information from drug manufacturers, the Board will learn that price concessions have frequently been granted to such purchasers to a level of 40-50 percent and more below published catalog prices. This fact is confirmed by the earlier referred to Council on Economic Priorities study. Reimbursement to such purchasers based on catalog prices, therefore, not only constitutes a "rip off" of the government

Department on its own motion, particularly in view of the Committee's broad based representation, can only serve to facilitate communications between the Department and those interest groups most directly affected by the proposed regulations.

A major pitfall in the proposed MAC regulations is the failure to provide in Section 19.5, or elsewhere, that the Pharmaceutical Reimbursement Board may require the submission of actual drug product sales price information by drug manufacturers and wholesalers. APhA has, for years, focused attention on the utterly chaotic marketing practices of the drug industry which make it virtually impossible for pharmacists or third party program administrators to know the real cost of a drug product dispensed in a specific prescription. Unless and until true price information is required of manufacturers and wholesalers by the government, any effort to establish a MAC for any drug on the basis of "the lowest unit price at which the drug is widely and consistently available" is doomed to be an utter and complete failure.

Unless the proposed regulations are amended as APhA suggests, the Board will experience incredible frustration, which will surely come when it attempts to determine its first MAC. At that point, APhA predicts, the Board will either throw up its hands at an impossible task or will develop proposed MACs on the basis of fictitious price information, thereby perpetuating the very situation the Department is seeking to end. If this results after the months of planning and effort which purportedly have been devoted to this project, the MAC program will become a laughing stock. Certainly, the "price information" aspect of the MAC program, for which the Department has expressed great expectations is totally dependent on the obtaining of current true price information. Without it, the game goes on.

An economic study by the Council on Economic Priorities, released January 3, 1974, notes that while several drug manufacturers cooperated in providing true sales price information for that study, other manufacturers resisted disclosure of such information. In fairness to all drug manufacturers, a mandatory disclosure requirement should be included in the regulations and evenly applied.

In addition to the necessity of obtaining true price information, there should be an additional principle that a MAC should be established at the lowest price level at which a drug manufacturer sells a particular quantity of a specific drug product without regard to the nature of the purchaser. In other words, any effort by the Department to identify "the lowest unit price at which the drug is *widely and consistently available*" is also fated to be an exercise in sheer futility. By its very nature, and the nature of drug industry pricing practices, even if government sales are eliminated from consideration, the phrase "widely and consistently available" clearly requires a purely subjective interpretation by the Board. Just as clearly, however, the lowest price for a specific quantity of a drug product at which a manufacturer actually sells, is a purely objective fact readily determinable from actual sales records which a manufacturer can and should be required to provide. There simply is not apparent a more equitable way in which all sellers and purchasers of drug products can be treated by the government and no more realistic way to bring order out of present drug manufacturer pricing chaos.

The MAC program is not a situation in which the government can turn its back on private sector practices and accept whatever goes on in the marketplace as "competitive." In this situation, it is government money obtained from the taxpayers which is being spent and the taxpayers have every right to expect that the government will not only make the most prudent use of that money, but also that the government *will know* that it is making the most prudent use of that money.

APhA takes the position that application of the MAC limitation merely to multi-source drugs is inadequate, because, even for single-source drug products, selling prices by manufacturers and wholesalers vary widely and irrationally. Implicit recognition of this fact is contained in Section 405.433 (b) (2) and (3) of the proposed Medicare regulations. These provisions make "prudent and cost-conscious" buying practices the rule for Medicare and make this rule applicable even to single-source products. The other proposed regulations should be consistent and do the same.

If it wishes the continued cooperation of practicing pharmacists, who are now being asked to accept changes in the means for determining their professional fees, the government must assure pharmacists they will not be required to carry the double burden of a continued lack of fair treatment and a continuation of chaotic marketing practices in the drug industry. If this assurance is not forthcoming in the final formulation of the referenced proposed regulations, pharmacist cooperation likely will not be forthcoming and there will be little that this Association, any other pharmacy organization, or the government will be able to do. Now is the time for the Department to assure the continued goodwill of the nation's pharmacists.

DRUG PRODUCT QUALITY

As previously indicated, APhA and its members have an enduring interest not only in the economic issues raised by these proposed regulations, but also in the professional and scientific issues which have been widely discussed since Secretary Weinberger's December 19, 1973 testimony.

APhA supports the provisions of Section 19.5(b) calling for review by the Food and Drug Administration of each drug under MAC consideration and "clearance" by the FDA for any drug which would be subjected to a MAC limitation. The Academy of Pharmaceutical Sciences, a subdivision of APhA, has offered the Association a summary of its viewpoints regarding these proposed regulations, pertaining specifically to matters of drug product quality, and the composition of the Pharmaceutical Reimbursement Advisory Committee. APhA believes that these viewpoints can best be evaluated if this summary is presented *in toto:*

Drug Quality

The Academy of Pharmaceutical Sciences is concerned over the dependence placed by the HEW on the current standards, practices and regulations of the FDA and USP/NF to assure the equivalent quality and performance of drug products to be placed on the MAC list. We urge HEW to pay greater attention to the recommendations of the Office of Technology Assessment Report which clearly stated, that "Current standards and regulatory practices do not assure bioequivalence for drug products." Similarly the Academy, in its list of drugs submitted through APhA to HEW, specifically stated that before drugs are actually included on a proposed MAC list, that at least equivalent in-vitro *performance to an established prototype product be demonstrated by discriminating methodology. We urge HEW to implement these added assurances through the wording of the final regulations.*

Pharmaceutical Reimbursement Advisory Committee

The APS wishes to recommend that the responsibilities proposed for this Committee be broadened. Their responsibilities should include the ability to give advice on the adequacy of the standards, which will be applied to the drug products for the MAC list, in order that equivalent quality and performance is as-

Comments of the

AMERICAN PHARMACEUTICAL ASSOCIATION

on

PROPOSED RULEMAKINGS:

- ► Maximum Allowable Cost for Drugs (39 F.R. 40302)
- ► Reimbursement of Drug Costs—Medical Assistance Program (39 F.R. 41480)
- ► Public Health Service Health Services Delivery Programs (40 F.R. 3218)
- ► Federal Health Insurance for the Aged and Disabled (40 F.R. 3219)

February 15, 1975

Pursuant to notice of proposed rulemakings "Maximum Allowable Cost for Drugs" published on November 15, 1974 (39 F.R. 40302); "Reimbursement of Drug Costs—Medical Assistance Program" published on November 27, 1974 (39 F.R. 41480); "Public Health Service Health Services Delivery Programs" published on January 20, 1975 (40 F.R. 3218); and "Federal Health Insurance For the Aged and Disabled" published on January 20, 1975 (40 F.R. 3219); the following comments are offered by the American Pharmaceutical Association.

INTRODUCTION

The American Pharmaceutical Association is the national professional society of pharmacists. Its 52,000 members include practicing pharmacists, pharmaceutical scientists, pharmaceutical educators and pharmacy students. APhA and its membership, which represent every aspect of the pharmacy profession have a vital and continuing interest in the professional, scientific and economic issues raised in these rulemaking proceedings.

On February 1, 1974, testifying before the Health Subcommittee of the Senate Labor and Public Welfare Committee, APhA announced its support for what has become known as the "MAC" policy unveiled before that subcommittee on December 19, 1973 by Secretary Weinberger. This policy has resulted in the promulgation of the referenced proposed regulations. In stating its support for the concepts embodied in the MAC policy, however, APhA has explicitly reserved the right to criticize specific regulations which might be promulgated by HEW to implement the Secretary's announced policy.

Having now reviewed the specific regulatory proposals published, and having sought the viewpoint of its membership, state pharmaceutical associations, and other pharmacy organizations regarding these proposals, APhA is now prepared to comment on them in detail. These comments are intended to be a constructive effort to assist HEW in accomplishing the policy objectives announced in late 1973 by Secretary Weinberger. When they were first announced, APhA said these policy objectives were sound and should be implemented. APhA has not changed its views.

In the view of the Association, however, the proposed regulations as presently drafted are not adequate to assure accomplishment of HEW objectives—economies in the cost of pharmaceutical service in federally supported health care programs commensurate with continued viability of those programs through adequate availability of pharmaceutical service.

Although Secretary Weinberger originally focused on cost savings which might be achieved through more prudent purchase of and reimbursement for the drug product component of pharmaceutical service, the referenced proposed regulations address not only that factor but also the other cost component of pharmaceutical service—the pharmacist's professional fee.

As an initial comment, APhA wishes to commend the Department's recognition that pharmaceutical service includes both the providing of a drug product and the professional services of a pharmacist. It is unfortunate, while the language of two of the instant proposed regulations makes specific reference to "professional services," that other specific language (i.e. "retail place of business") fails to be consistent. It would be most helpful, in terms of the Department's self-concept of pharmaceutical service, if its regulations were couched in terms which recognize that the practice of pharmacy is a professional practice no matter in what environment that practice is conducted.

Generally, APhA is satisfied with the initial approach taken by the proposed regulations with regard to the drug product cost component. Acceptance of "actual acquisition cost" reimbursement for drug product cost, however, is dependent on the recognition by HEW that equitable adjustments in pharmacists' professional fees under federally supported health care programs are not only now called for, but are, in fact, long overdue. Thus, APhA support for the "total package" of regulations addressed in these comments can continue only if that total package in final form represents not only prudent "buying" policies on the part of the government, but also "fair treatment" of pharmacists by the government.

DRUG PRODUCT MAC PROCEDURES

Turning specifically first to the proposed Departmental regulations (39 F.R. 40302), APhA believes that the Pharmaceutical Reimbursement Board and Pharmaceutical Reimbursement Advisory Committee structures and procedures set forth in Sections 19.4 and 19.5 are generally appropriate. Under Section 19.4(b) (2), however, the Association would suggest that the Pharmaceutical Reimbursement Advisory Committee should be free to raise with the Board and the Secretary questions concerning Departmental policies and to provide advice of its own volition, rather than merely "upon request."

It would seem clear that if the Committee is competent to provide advice at the Department's request, it should not be precluded from assisting by a technical formality. Permitting the Committee to come forward to the

MR. CHAIRMAN, WE SINCERELY PLEAD THAT YOU AND YOUR CONGRESSIONAL COLLEAGUES DO EVERYTHING WITHIN YOUR POWER TO SEE THAT PAST AND PRESENT WRONGS ARE REDRESSED.

THE CRITICS OF THE MAC PROGRAM CHARGE THAT THE ESTIMATED SAVINGS ARE GROSSLY INFLATED. APHA DOES NOT KNOW HOW MUCH MONEY WILL BE SAVED TAKING INTO ACCOUNT PROSPECTIVE ADJUSTMENTS IN PROFESSIONAL SERVICE COSTS AND DRUG PRODUCT COSTS. WE DO BELIEVE THAT WORTHWHILE SAVINGS WILL BE ACHIEVED. HOWEVER, IN OUR JUDGMENT THE MAJOR COST SAVINGS POTENTIAL LIES IN REDUCING PRESENT ADMINISTRATIVE COSTS IN ALL FEDERALLY SUPPORTED HEALTH CARE PROGRAMS. WE BELIEVE THAT THE SAVINGS WHICH CAN BE EASILY ACHIEVED IF THE MAC PROGRAM STANDARDIZES AND SIMPLIFIES THE ADMINISTRATIVE PROCEDURES WILL MORE THAN COVER THE ADJUSTMENT NEEDED TO PROVIDE PHARMACISTS A FAIR FEE FOR THEIR SERVICES.

APHA CALLS FOR THE APPLICATION OF THE MOST BASIC PRINCIPLES OF FAIRNESS. OUR VIEWS WITH REGARD TO THE FUTURE OF THE MAC POLICY AND ITS IMPLEMENTATION ARE SUCCINCTLY STATED IN THE LAST PARAGRAPH OF OUR MAC REGULATION COMMENTS:

> "THE OBJECT OF GOVERNMENT POLICY AND ADMINISTRATION IN FEDERALLY SUPPORTED HEALTH CARE PROGRAMS MUST BE TO COMPENSATE PRUDENTLY, BUT FAIRLY AND WITH AN EVEN HAND, ALL WHO ARE INVOLVED IN DRUG PRODUCT MANUFACTURE AND DRUG PRODUCT DISTRIBUTION. THE FAILURE OF THE GOVERNMENT TO ACKNOWLEDGE AND SATISFY THESE ESSENTIAL PHILOSOPHICAL AND PRACTICAL CRITERIA CAN ONLY RESULT IN THE ULTIMATE FAILURE OF THE SYSTEM AND THE INABILITY OF THESE PROGRAMS TO FULFILL THEIR CONGRESSIONALLY INTENDED OBJECTIVES."

OF SUCH PROGRAMS, PHARMACISTS ARE UNILATERALLY TERMINATING THEIR PARTICIPATION BECAUSE IT HAS BECOME ECONOMICALLY IMPOSSIBLE FOR THEM TO CONTINUE IN SUCH PROGRAMS. IF EQUITABLE REVISIONS IN THE PROPOSED IMPLEMENTATION OF THE MAC POLICY ARE NOT FORTHCOMING, APHA CAN ONLY PROJECT THAT PHARMACY PARTICIPATION WILL BE FURTHER REDUCED TO A LEVEL WHICH WILL EMASCULATE THE PROGRAMS INVOLVED. SUCH A RESULT WOULD FRUSTRATE THE OBJECTIVES OF CONGRESS, THE EXECUTIVE ADMINISTRATION, THE STATES, AND CERTAINLY THOSE OF THE PROFESSION OF PHARMACY.

APHA COMMENTS FILED WITH HEW ON THE MAC REGULATION PROPOSALS (A COPY OF WHICH IS ATTACHED TO THIS STATEMENT) CONTAIN A TABLE SHOWING WHAT HAS HAPPENED--OR MORE ACCURATELY, WHAT HAS NOT HAPPENED--IN THE FACE OF SPIRALING INFLATION WITH REGARD TO PHARMACISTS' PROFESSIONAL FEES IN A NUMBER OF STATE MEDICAID PROGRAMS OVER A PERIOD OF SEVERAL YEARS. PHARMACISTS ARE DEMANDING THAT THEY NOT BE FURTHER VICTIMIZED BY GOVERNMENTAL INACTION. THE ECONOMICS OF PHARMACY PRACTICE IN RELATION TO FEDERALLY SUPPORTED HEALTH CARE PROGRAMS HAS BEEN CONTINUOUSLY OPEN TO PUBLIC SCRUTINY AND A CAREFUL LOOK WILL SHOW THAT MANY PHARMACISTS HAVE BEEN DRIVEN TO THE BRINK OF ECONOMIC CRISIS AND OTHERS HAVE FAILED. AT THE SAME TIME, BOTH FEDERAL AND STATE GOVERNMENTS HAVE BEEN PERFECTLY WILLING TO PAY DRUG MANUFACTURERS WHATEVER THEY WISH TO CHARGE FOR THEIR DRUG PRODUCTS.

AT THE SAME TIME, HEW OFFICIALS SAY THE MAC PROGRAM IS NOT INTENDED TO REDUCE THE AVAILABILITY OF PHARMACEUTICAL SERVICE TO THE PUBLIC BY CAUSING PHARMACY ECONOMIC FAILURES. THEN THEY TURN AROUND AND SAY, IN EFFECT, THAT HEW CAN DO NOTHING TO ASSURE THAT SUCH ECONOMIC FAILURES WILL NOT OCCUR IF THE "ACTUAL ACQUISITION COST" REQUIREMENT IS EFFECTUATED.

MR. CHAIRMAN, I WANT TO MAKE CLEAR TO YOU AND THIS COMMITTEE, AS WE HAVE ATTEMPTED TO MAKE CLEAR TO HEW IN OUR COMMENTS ON THE MAC PROPOSED REGULATIONS, THAT WE BELIEVE "ACTUAL ACQUISITION COST" IS THE PROPER BASIS FOR DRUG PRODUCT REIMBURSEMENT. BUT, THIS IS A VIABLE APPROACH ONLY IF FEES FOR THE PHARMACISTS' PROFESSIONAL SERVICES ARE ADEQUATELY INCREASED TO COVER INCOME WHICH PRESENTLY IS REPRESENTED BY THE DIFFERENCE BETWEEN PRESENT DRUG PRODUCT REIMBURSEMENT AMOUNTS AND "ACTUAL ACQUISITION COSTS."

SINCE ECONOMICS ARE SUBSTANTIALLY INVOLVED IN THE MAC POLICY, THOSE CONCERNED WITH THIS POLICY CAND ITS IMPLEMENTATION, INCLUDING THIS COMMITTEE, MUST RECOGNIZE SEVERAL PHARMACY-RELATED ECONOMIC FACTS OF LIFE. EVERY PHARMACY REQUIRES A CERTAIN LEVEL OF INCOME OVER EXPENSES TO REMAIN VIABLE FROM AN ECONOMIC STANDPOINT. OVER THE PAST SEVERAL YEARS, ALL AVAILABLE DATA SHOW THAT PHARMACIES NATIONWIDE HAVE BEEN TREADING ON ECONOMIC THIN ICE. FOR MANY, THE ICE IS NOW CRACKING. IF HEW AND THE STATES ARE GOING TO TAKE AWAY WITH ONE HAND, THEY WILL HAVE TO GIVE WITH THE OTHER, OR THERE SIMPLY WILL NOT BE ANY BASIS FOR FURTHER PHARMACY PARTICIPATION IN FEDERALLY SUPPORTED HEALTH CARE PROGRAMS. FOR THE FIRST TIME SINCE THE BEGINNINGS

WITH THE ASSISTANCE OF ITS ACADEMY OF PHARMACEUTICAL SCIENCES, APHA HAS SUGGESTED SPECIFIC MEANS BY WHICH HEW CAN REINFORCE SUCH ASSURANCES TO MEDICAL AND PHARMACY PRACTITIONERS AND THE PUBLIC. WHERE IT CAN PROVIDE SUCH ASSURANCE, IT WOULD BE ABSURD, IN OUR VIEW, FOR HEW NOT TO TAKE INTO ACCOUNT THE RELATIVE COSTS OF INTERCHANGEABLE DRUG PRODUCTS.

BEYOND HEW'S APPARENT RELUCTANCE TO REQUIRE FACTUAL, CURRENT OR PROSPECTIVE DRUG PRODUCT PRICE INFORMATION FROM DRUG MANUFACTURERS, APHA HAS LEVELED A MAJOR CRITICISM OF THE PROPOSED MAC REGULATIONS INSOFAR AS THEY INADEQUATELY ADDRESS THEMSELVES TO FEES FOR PHARMACISTS' PROFESSIONAL SERVICE. THERE HAS BEEN EVIDENT WITHIN HEW A DEFINITE "HANDS OFF" ATTITUDE WITH REGARD TO PHARMACISTS' PROFESSIONAL FEES. SOME HEW REPRESENTATIVES APPARENTLY HAVE BEEN TAKING THE POSITION THAT THE DEPARTMENT CAN EXERCISE AUTHORITY WITH REGARD TO AMOUNTS THAT WILL BE PAID BY STATE MEDICAID PROGRAMS FOR DRUG PRODUCT COSTS BUT THAT IT HAS NO AUTHORITY WITH REGARD TO AMOUNTS THAT WILL BE PAID BY STATE MEDICAID PROGRAMS WITH REGARD TO PROFESSIONAL FEES. SUCH A "HANDS OFF" POSITION IS PATENTLY WITHOUT MERIT SINCE THE HEW MEDICAID REGULATIONS FOR YEARS HAVE REQUIRED PAYMENT OF "A REASONABLE FEE."

EVERYONE RECOGNIZES THAT IN MANY STATES, IMPLEMENTATION OF THE "ACTUAL ACQUISITION COST" DRUG PRODUCT REIMBURSEMENT FEATURE OF THE MAC PROGRAM WOULD TIGHTEN THE ECONOMIC VISE ON PHARMACISTS TO AN EXTENT GREATER THAN EVER EXPERIENCED TO DATE.

OR AUTOMOBILES IN THIS MANNER. AND, ALTHOUGH THE PHARMACIST IS ACTING AS THE GOVERNMENT'S DE FACTO PURCHASING AGENT, HE IS DENIED INFORMATION AS TO THE BEST DRUG PRODUCT PRICES AVAILABLE. WE BELIEVE THAT WITH SUCH INFORMATION, THE MAC PROGRAM CAN ACHIEVE ITS OBJECTIVES; WITHOUT IT, THE MAC PROGRAM WILL FAIL.

WE HAVE STATED REPEATEDLY THAT WE BELIEVE PHARMACISTS ESSENTIALLY WANT TWO THINGS IN ANY THIRD-PARTY PAYMENT HEALTH CARE PROGRAM--SAFE AND EFFECTIVE DRUG PRODUCTS TO DISPENSE AND FAIR, ADEQUATE COMPENSATION FOR THEIR SERVICES.

THE BASIC HEW MAC POLICY IS BASED ON THE PREMISE THAT THERE EXIST IN THE MARKETPLACE SAFE AND EFFECTIVE DRUG PRODUCTS WHICH CAN BE INTERCHANGED WITHOUT DANGER TO THE PUBLIC HEALTH. THE CHAIRMAN OF THE EXPERT PANEL CONVENED BY THE OFFICE OF TECHNOLOGY ASSESSMENT TO ASSESS THIS ISSUE FROM A SCIENTIFIC STANDPOINT HAS STATED THAT 85 TO 90 PERCENT OF THE DRUG ENTITIES CURRENTLY MARKETED IN THE UNITED STATES PRESENT NO PROBLEM IN THIS REGARD, AND COULD IMMEDIATELY BE PLACED WITHIN A PROGRAM OF THE MAC TYPE. THAT LEAVES, BY HIS ESTIMATE, A MAXIMUM OF 10 TO 15 PERCENT OF ALL MARKETED DRUG ENTITIES WHICH MAY OR MAY NOT INVOLVE INTERCHANGE PROBLEMS. IT HAS ALWAYS BEEN APHA BELIEF THAT A MUCH SMALLER PERCENTAGE OF DRUG ENTITIES WOULD BE INCLUDED IN ANY GROUP AMONG WHICH DRUG PRODUCT INTERCHANGE SHOULD NOT TAKE PLACE. IN ANY EVENT, HOWEVER, WE ARE SATISFIED THAT THE GOVERNMENT HAS IT WITHIN ITS ABILITY TO ASSURE THAT THOSE DRUG ENTITIES AND DRUG PRODUCTS TO WHICH THE MAC POLICY WOULD APPLY WOULD INVOLVE NO PUBLIC HEALTH THREAT FROM THE STANDPOINT OF DRUG PRODUCT INTERCHANGE.

MINIMIZED. IT IS ABSOLUTELY UNCONSCIONABLE FOR ANYONE TO PERMIT VITALLY NEEDED HEALTH CARE PROGRAMS TO FLOUNDER OR FAIL BECAUSE THE COSTS OF OPERATING SUCH PROGRAMS APPROACH OR EXCEED THE VALUE OF THE DIRECT BENEFITS PROVIDED THE BENEFICIARY--PATIENTS.

IN THIS DAY AND AGE, CLAIMS PROCESSING MUST BE AUTOMATED AND THE NECESSITY FOR TIME-CONSUMING AND EXPENSIVE AUDITING PROCEDURES ELIMINATED. WITH ACCURATE DRUG PRODUCT COST DATA, CLAIM PREPARATION COULD BE REDUCED TO PATIENT IDENTIFICATION, DRUG PRODUCT IDENTIFICATION AND STATEMENT OF QUANTITY DISPENSED. A COMPUTER COULD DO EVERYTHING ELSE. THIS COULD BE DONE EASILY UNDER THE MAC PROGRAM IF HEW WILL DO ONLY ONE THING--REQUIRE DRUG MANUFACTURERS TO TELL THE GOVERNMENT THE PRICES THEY ACTUALLY CHARGE PHARMACISTS FOR THEIR DRUG PRODUCTS. WE HAVE URGED HEW TO REQUIRE SUCH INFORMATION OF ALL MANUFACTURERS AS A CONDITION OF HAVING THEIR DRUG PRODUCTS REIMBURSABLE UNDER FEDERALLY SUPPORTED HEALTH CARE PROGRAMS. IT IS DRUG MANUFACTURERS' RESISTENCE TO PROVIDING THIS INFORMATION--FOR WHICH THEY ARE THE ONLY DIRECT, IMMEDIATE, AND RELIABLE SOURCE--WHICH THREATENS THE MAC PROGRAM AND, ALONG WITH IT, THE VERY EXISTENCE OF THE MEDICAID PROGRAM, OTHER HEALTH CARE PROGRAMS, AND A PHARMACEUTICAL SERVICE BENEFIT AS A PART OF A NATIONAL HEALTH INSURANCE PROGRAM.

AT PRESENT, THE FEDERAL GOVERNMENT IS, IN EFFECT, BUYING DRUG PRODUCTS WITHOUT KNOWING IN ADVANCE WHAT IT WILL HAVE TO PAY FOR THEM. THE FEDERAL GOVERNMENT DOES NOT BUY TYPEWRITERS

I CAN SAY PERSONALLY, THAT IN MY ENTIRE PROFESSIONAL EXPERIENCE, I HAVE NEVER WITNESSED A MORE INTENSIFIED PROPAGANDA CAMPAIGN THAN THAT WHICH HAS BEEN AND IS STILL BEING CONDUCTED BY DRUG INDUSTRY OPPONENTS OF THE MAC PROGRAM.

AT APHA WE MAKE A SINCERE EFFORT TO SEPARATE FACT FROM FICTION. OUR UNDERSTANDING OF THE FACTS, HAS, AS I HAVE INDICATED, LED US TO CONCLUDE THAT THE BASIC MAC POLICY IS STILL WORTHY OF SUPPORT, WHILE THE REGULATIONS PROPOSED TO IMPLEMENT THAT POLICY ARE WORTHY OF SUBSTANTIAL CRITICISM. AND, WE HAVE NOT HESITATED TO CRITICIZE IN AN EFFORT TO HELP GET THIS PROGRAM ON THE RIGHT TRACK.

SENATOR NELSON, OUR FRUSTRATION OVER THE DELAY IN IMPLEMENTING THE MAC PROGRAM IS COMPOUNDED BY OUR SINCERE BELIEF THAT THIS PROGRAM CAN BE SIMPLY AND EFFECTIVELY IMPLEMENTED WITHOUT ECONOMIC DISASTER OR DISRUPTION OF PROFESSIONAL PRACTICE JUDGMENTS IF HEW WILL ONLY FACE UP TO A FEW BASIC PRINCIPLES. IT IS TO THESE PRINCIPLES THAT I WILL NOW ADDRESS MYSELF.

PHARMACISTS, BOTH AS HEALTH CARE PROVIDERS AND AS TAXPAYERS, WANT A PHARMACEUTICAL SERVICE BENEFIT IN FEDERALLY SUPPORTED HEALTH CARE PROGRAMS THAT WILL MAXIMIZE BENEFITS TO THE PUBLIC AND MINIMIZE PROGRAM COSTS, CONSISTENT WITH HIGH QUALITY CARE AND FAIR TREATMENT OF BOTH THE DRUG INDUSTRY AND THE PHARMACY PROFESSION. WE DO NOT WANT EITHER THE QUALITY OR QUANTITY OF MEDICAL CARE REDUCED.

IT IS CLEAR TO APHA THAT TO MINIMIZE TOTAL PROGRAM COSTS, ADMINISTRATIVE COSTS OF THE PROGRAMS THEMSELVES MUST BE

COMMENTS CLEARLY DISTINGUISH, HOWEVER, BETWEEN THE BASIC POLICY ANNOUNCED BY THE SECRETARY AND THE PROPOSED PROGRAM FOR IMPLEMENTATION OF THAT POLICY, AT LEAST IN ITS PRESENT FORM AS PUBLISHED AS A SERIES OF PROPOSED REGULATIONS IN THE FEDERAL REGISTER BEGINNING IN NOVEMBER, 1974.

WITH RESPECT TO THE PROGRAM FOR IMPLEMENTATION, WE FIND MANY FEATURES TO BE SOUND AND REASONABLE. HOWEVER, THERE ARE ALSO SEVERAL DETAILS WITH WHICH WE ARE NOT SATISFIED AND WHICH ARE CRITICAL AS TO OUR ABILITY TO SUPPORT THE RESULTANT PROGRAM.

BEFORE DISCUSSING SPECIFICS OF THE PROPOSED PROGRAM, WE FEEL COMPELLED TO MENTION THAT IT IS MOST DISTRESSING TO US THAT HEW HAS PERMITTED THE CONTROVERSY OVER THE MAC PROGRAM TO FERMENT FOR WHAT IS NOW OVER A YEAR SINCE THE POLICY WAS ANNOUNCED. THIS DELAY IN PUTTING THE POLICY INTO EFFECT HAS PERMITTED ITS OPPONENTS THE OPPORTUNITY TO DEVELOP AND CONDUCT A WELL-ORGANIZED PROPAGANDA CAMPAIGN TO BUILD OPPOSITION IN SEVERAL QUARTERS TO THE MAC PROGRAM.

APHA IS WELL AWARE FROM COMMUNICATIONS IT HAS RECEIVED FROM PHARMACISTS THROUGHOUT THE COUNTRY THAT PHYSICIANS AND PHARMACISTS HAVE BEEN SUBJECTED TO AN INTENSE PRESSURE CAMPAIGN BY CERTAIN FIRMS IN THE DRUG INDUSTRY IN AN EFFORT TO GENERATE THEIR OPPOSITION TO THE MAC PROGRAM. WE ALSO KNOW FROM PROPAGANDA MATERIALS TRANSMITTED TO APHA THAT WHAT PHARMACISTS AND PHYSICIANS HAVE BEEN AND ARE BEING TOLD ABOUT THE MAC PROGRAM AND THE FACTS OF THE MAC PROGRAM--BASED UPON OUR OWN REVIEW AND ANALYSIS OF THE MAC REGULATIONS--ARE FREQUENTLY ENTIRELY DIFFERENT THINGS.

WHATEVER PRICE THE MANUFACTURER DECIDES.

FOR EIGHT YEARS MEDICARE OUTPATIENTS HAVE BEEN DENIED COVERAGE OF ESSENTIAL PRESCRIPTION DRUGS BECAUSE OF THE CONTROVERSY OVER CONTROLLING THE PRICE TO BE PAID FOR THE DRUG PRODUCT."

THE FACT IS THAT IN THE MEDICAID PROGRAM, FOR EXAMPLE, THE PHARMACIST HAS BEEN CONTINUOUSLY SQUEEZED BETWEEN DRUG PRODUCT COST INCREASES LEVIED WITHOUT RESTRAINT BY THE MANUFACTURERS AND THE UNWILLINGNESS OF THE STATES TO PAY AN ADEQUATE FEE FOR THE PHARMACIST'S PROFESSIONAL SERVICES. APHA UNDERSTANDS AND APPRECIATES WHY A MANUFACTURER MAY HAVE TO INCREASE ITS PRICES TO PHARMACISTS BECAUSE THE COST OF RAW MATERIALS AND PRODUCTION ARE INCREASING. BUT, WHAT EVERYBODY MUST UNDERSTAND IS THAT PHARMACISTS ARE SUBJECTED TO THE SAME INFLATIONARY PRESSURES. STATE MEDICAID PROGRAMS REQUIRED TO OPERATE WITHIN FIXED APPROPRIATIONS HAVE PAID FOR DRUG PRODUCT COST INCREASES BY NOT INCREASING, AND IN SOME CASES BY REDUCING, PHARMACISTS' FEES. THE BOTTOM LINE IS THAT AFTER THE MANUFACTURER GETS PAID FOR HIS PRODUCT AND THE THIRD PARTY ADMINISTRATOR GETS PAID FOR HIS SERVICES, THE PHARMACIST GETS WHAT'S LEFT--WHICH IS ALWAYS INSUFFICIENT.

APHA HAS NOW FILED WITH HEW ITS COMMENTS ON THE SPECIFICS OF THE PROPOSED MAC REGULATIONS. THOSE COMMENTS STATE THAT APHA HAS NOT CHANGED ITS VIEWS REGARDING THE SOUNDNESS OF THE PROPOSED HEW POLICY AS SET FORTH BY SECRETARY WEINBERGER. THE

SENATOR NELSON, I KNOW THAT YOU PERSONALLY ARE WELL AWARE THAT APHA HAS STOOD VIRTUALLY ALONE IN SUPPORT OF THE "MAC" POLICY SINCE IT WAS UNVEILED BY SECRETARY WEINBERGER. YOU KNOW THAT APHA HAS PUBLICLY ENDORSED THE BASIC CONCEPT EMBODIED IN THIS POLICY AS FAIR AND MAKING GOOD SENSE.

IN TESTIMONY IN FEBRUARY OF LAST YEAR, APHA NOTED THAT--

> "WHAT THE SECRETARY HAS SAID IN ESSENCE IS THAT THE FEDERAL GOVERNMENT AND THE TAXPAYERS WHO SUPPORT IT SHOULD NOT PAY DRUG MANUFACTURERS MORE FOR DRUG PRODUCTS OF ACCEPTABLE QUALITY THAN A COMPETITIVE MARKETPLACE REQUIRES. IMPLICIT IN THE PROPOSED FEDERAL POLICY IS A RECOGNITION THAT AT PRESENT THE FEDERAL GOVERNMENT IS PAYING MORE FOR SOME DRUG PRODUCTS THAN IT SHOULD HAVE TO PAY."

WE ALSO NOTED AT THAT TIME THAT, WHILE NO CONTROLS HAD BEEN APPLIED TO DRUG PRODUCT COSTS, THE PROFESSIONAL SERVICE COMPONENT OF THE PRESCRIPTION CHARGE HAS ALWAYS BEEN TIGHTLY REGULATED UNDER FEDERALLY SUPPORTED HEALTH CARE PROGRAMS:

> ". . . WHILE DIRECT CONTROLS OVER THE FEES REIMBURSED TO PHARMACISTS HAVE BEEN EXERTED BOTH BY GOVERNMENT AND THE PRIVATE THIRD-PARTY MANAGERS, NO SIMILAR CONTROLS HAVE BEEN IMPOSED WITH REGARD TO THE DRUG PRODUCT COMPONENT OF THE PRESCRIPTION COST. DRUG PRODUCTS ARE PAID FOR ON THE BASIS OF

EXHIBITS PROVIDED BY THE AMERICAN PHARMACEUTICAL ASSOCIATION

STATEMENT
OF THE
AMERICAN PHARMACEUTICAL ASSOCIATION
TO THE
SELECT COMMITTEE
ON SMALL BUSINESS
OF THE
UNITED STATES SENATE
94TH CONGRESS, 1ST SESSION
WASHINGTON, D.C.
MARCH 20, 1975

MR. CHAIRMAN, MEMBERS OF THE SUBCOMMITTEE, I AM DR. WILLIAM S. APPLE, EXECUTIVE DIRECTOR OF THE AMERICAN PHARMACEUTICAL ASSOCIATION (APHA) WHICH, AS YOU KNOW, IS THE NATIONAL PROFESSIONAL SOCIETY OF PHARMACISTS IN THE UNITED STATES. I AM PLEASED, ONCE AGAIN, TO APPEAR BEFORE THIS DISTINGUISHED COMMITTEE WITH MY ASSOCIATES, DR. EDWARD G. FELDMANN, ASSOCIATE EXECUTIVE DIRECTOR FOR SCIENTIFIC AFFAIRS, AND MR. CARL ROBERTS, APHA ASSOCIATE GENERAL COUNSEL.

THIS IS THE THIRD OPPORTUNITY WHICH APHA HAS HAD TO EXPRESS ITS VIEWS DIRECTLY TO CONGRESS REGARDING THE MAXIMUM ALLOWABLE COST POLICY ANNOUNCED BY HEW SECRETARY WEINBERGER ON DECEMBER 19, 1973. HOWEVER, IT IS THE FIRST OPPORTUNITY WE HAVE HAD TO COMMENT ON THE PROPOSED IMPLEMENTATION OF THAT POLICY.

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-281/387-5	Intravenous Solutions, Glass Blood Containers, and Vials containing Diluents, Electroylte, Anesthetics, Muscle Relaxants and Dextrose Injections. ** All lots of all parenterals produced at the Milledgeville, Ga. plant.	**	Mfr: McGaw Labs Milledgeville, Ga. Recaller: McGaw Labs Div. America Hospital Supply Glendale, Calif.	Lack of assurance of sterility.	FDA Init.	II	Rx
D-388-5	Aminophylline Injection USP 10 cc ampuls 25 mg.	2 lots	Mfr. & Recaller: Torigian Labs Queens Village, N.Y.	The potency statement on the individual ampuls appears in two places. The first potency statement : "25 mg. per cc" is correct. The second statement "each cc contains: Aminophylline 0.25 gm" is incorrect. It should read "10cc contains Aminophylline 0.25 gm."	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-267-5	Tincture of Benzoin Compound USP	One lot	Mfr: National Pharmaceutical Mfg. Co. (aka Barre Drug Co. Inc.) Baltimore, Md. Recaller: Relabeler Consolidated Midland Corp. Brewster, N.Y.	Labeled as Tincture of Iodine USP	Vol.	II	OTC
D-272-5	Iron-Tabs (Ferrous Sulfate USP) 5 gr.	One lot	Mfr. & Recaller; Faraday Labs Inc. Hillside, N.J.	Vitamin B 12 tablets labeled as Iron Tabs	Vol.	II	OTC
D-277-5	Phlemazin Expectorant with Dextromethorphan Hydrobromide, Pediatric	One lot	Mfr. & Recaller: Progress Labs Los Angeles, Calif.	Mislabeled - a 10% solution of Potassium Chloride labeled as Phlemazin Expectorant	Vol.	II	Rx
D-280-5	Sorbo Sorbitol Solution 70% USP Pints, Gallons & Five Gallons	One lot	Recalling & Repacking firms: Amend Drug & Chemical Co. Irvington, N.J. and Ruger Chemical Co. Inc. Irvington, N.J. Mfr: ICI America Inc. Atlas Chemical Div. Wilmington, Del.	An unknown number of repacked containers of the product labeled as Sorbitol actually contain Formaldehyde.	Vol.	I	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-240-5	1.5% Glycine Solution urologic irrigating solution 2000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-241-5	0.25% Acetic Acid in irrigating container container 1000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-242-5	Saline Solution Kit one Kit Containers: 12 ea, 250 ml. units 20% Sodium Chloride Solution in irrigating Container Adapter Caps.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-243-5	Pentids 200 (Penicillin powder) for oral solution	7	E. R. Squibb & Sons Princeton, N.J.	Subpotency - lack of assurance of potency	Vol.	II	Rx
D-244-5	Pentids 400 (Penicillin powder) for oral solution	31	E. R. Squibb & Sons Princeton, N.J.	Subpotency - lack of assurance of potency	Vol.	II	Rx
D-245-5	Veetids 125 (Potassium phenoxy-methyl penicillin) Powder for oral solution	5	E. R. Squibb & Sons Princeton, N.J.	Subpotency - lack of assurance of potency	Vol.	II	Rx
D-246-5	Veetids 250 (Potassium phenoxy-methyl penicillin) Powder for oral solution	14	E. R. Squibb & Sons Princeton, N.J.	Subpotency - lack of assurance of potency	Vol.	II	Rx
D-247-5	Oxytetracycline Hydrochloride Capsules 250 mg.	1	Rondex Labs. Elizabeth, N.J.	Unsatisfactory Bioavailability	Vol.	II	Rx
D-253-5	Estrone Suspension 30 cc ml. multiple dose vials - 5 mg. per ml.	1	D-M Pharmaceutical Mfg. Co., Inc. (MFR & RECALLER) Darby Drug, Inc. New York, N.Y. (DIST.)	Mislabeling - vials of estrone suspension injection labeled as promethazine HCl Injection	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-234-5	0.225% Sodium Chloride in irrigating container - 2000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-235-5	Ringers Solution in Irrigating container all sizes	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-236-5	Lactated Ringers in irrigating container 1000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-237-5	Silver Nitrate Solution mixing Kit containing 6 ea 2000 ml. bottles distilled water in irriqating container (cat. No. R1005) & 6 ea 10 gram vials of silver Nitrate Crystals	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-238-5	33% Sorbitol Solution Urologic irrigating fluid concentrate 1000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-239-5	15% Glycine in distilled water urologic irrigating fluid concentrate 1000 ml.	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-223-5	Distilled Water 1000 ml. & 2000 ml. Irrigating solution	14	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Glendale, Ca. (RECALLER)	High potential for mold contamination and leaking containers	Vol.	II	Rx
D-224-5	3.3% Sorbitol 2000 ml. Irrigating solution	3	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Glendale, Ca. (RECLALER)	High potential for mold contamination and leaking containers	Vol.	II	Rx
D-225-5	5% Mannitol Water 2000 ml. & 500 ml. Irrigating solution	2	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Glendale, Ca. (RECALLER)	High potential for mold contamination and leaking containers	Vol.	II	Rx
D-226-5	Normal Saline 500 ml. & 1000 ml. Irrigating solution	9	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Glendale, Ga. (RECALLER)	High potential for mold contamination and leaking containers	Vol.	II	Rx
D-228-5	10 ml. Abboject Pediatric Sodium Bicarbonate Inj. USP 8.4% Meq (1 meq/ml)	1	Abbott Labs. Rocky Mt., N.C. (MFR) Abbott Labs. N. Chicago, ILL. (RECALLER)	A stray vial of epinephrine in a box of sodium bicarbonate injection	Vol.	I	Rx
D-230-5	AKineton (Biperiden HCl) tablets	1	Knoll Pharmaceutical Corp. Whippany, N.J.	Physician sample packages of a prescription drug erroneously mailed to consumers	Vol.	II	Rx
D-232-5	5% Dextrose in distilled water in irrigating containers - all sizes	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx
D-233-5	0.45% Sodium Chloride in irrigating containers - all sizes	all lots with letters "G" or "M"	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Lack of assurance of sterility and leaking containers	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-203-5	Pyelokon R (sodium Acetrizoate Sol. 20%) for Retrograde Pyelography	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile	Vol.	I	Rx
D-204-5	Cysto-Conray (meglumine iothalamate 43% (W/V) for Retrograde Cystography, Cysto-Urethrography, & Retrograde Pyelography	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile.	Vol.	I	Rx
D-209-5	Dantrium (Dantrolene Na) 25 mg. Capsules	1	Eaton Labs. Div. Norton-Norwich Products, Inc. Norwich, N.Y.	Product fails USP content uniformity requirement	Vol.	II	Rx
D-214-5	McGaws "Suby's" Solution G urinary calculi Solvent in irrigating container 1000 ml.	1	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Mold contamination	Vol.	II	Rx
D-215-5	Maalox (Magnesia and Alumina Oral Suspension) 355 ml. - 12 fl. oz.	1	Wm. H. Rorer Co. Fort Washington, Pa.	Bacterial contamination	Vol.	II	OTC
D-216-5	Dexamethasone 0.75 mg. tablets	1	Danbury Pharmacal, Inc. Danbury, Conn.	Contaminated with methyl testosterone	Vol.	II	Rx
D-217-5	McGaw 1000 ml. Normal Saline in Irrigating Container	2	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp. Glendale, Ca. (RECALLER)	Leaking containers - suspended white flocculent material	Vol.	II	Rx
D-219-5	Sodium Diphenylhydantoin 1 1/2 gr (100 mg.) Capsules - 1000's	1	Kasar Labs. Niles, Ill.	Labeling mix-up - sodium diphenylhydantoin capsules labeled as aspirin tablets.	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-190-5	Theelin Aqueous Suspension (estrone suspension) 10 ml. vial of 2 mg. (20,000 units) per ml.	all	Parke Davis and Co. Detroit, Mich.	Crystallization	Vol.	II	Rx
D-191-5	Theelin Aqueous Suspension (estrone suspension) 5 ml. vial of 5 mg. (50,000 units) per ml.	all	Parke Davis and Co. Detroit, Mich.	Crystallization	Vol.	II	Rx
D-195-5	Physiological Irrigating Solution in irrigating containers 1000 ml. Cat. No. R1300	1	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp., Glendale, Ca. (RECALLER)	Contamination with fusarium, penicillium and mucor mold	Vol.	II	Rx
D-198-5	3.3% Sorbitol Solution Urologic Irrigating Solution - Cat. No. R2015 2000 ml.	1	McGaw Labs. Milledgeville, Ga. (MFR) McGaw Labs. Div. American Hospital Supply Corp., Glendale, Ca. (RECALLER)	Nigrosporin mold found in the product and the units were found to leak from the cap.	Vol.	II	Rx
D-199-5	Conray (Meglumine iothalamate Inj. USP 60%) for intravenous Urography & Angiography 50 ml.	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile	Vol.	I	Rx
D-200-5	Conray 400 (Sodium iothalamate Inj. USP 66.8%) for intravenous Urography, intravascular Angio cardiography, & Aortography 50 ml.	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile	Vol.	I	Rx
D-201-5	Angio-Conray (Sodium iothalamate Inj. USP 80%) for intra vascular Angio Cardiography & Aortography 50 ml.	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile	Vol.	I	Rx
D-202-5	Vascoray (meglumine iothalamate 52% (W/V) and Sodium iothalamate 26% (W/V)	all	Mallinckrodt, Inc. St. Louis, Mo.	High potential for some units to be non-sterile	Vol.	I	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-174-5	Isuprel HCl Brand of isuproterenol HCl 1:200	6	Winthrop Labs. Myerstown, Pa.	label error - 12 unit shelf carton labeled 1:100 instead of 1:200 **	Vol.	II	Rx
D-176-5	Aspirin tablets 5 gr. Uncoated	6	Otis Clapp & Sons, Inc. Cambridge, Mass.	Failed USP disintegration test	Vol.	II	OTC
D-179-5	Aspirin-free Arthritis Pain formula tablets	all	Whitehall Labs. Hammonton, N.J. (MFR) Elkhart, Ind. Whitehall Labs. Div. American Home Products New York, N.Y. (RECALLER)	No approved NDA - misbranded - potential health hazard as labeled.	FDA Init.	II	OTC
D-180-5	Saloxium Analgesic/ Anti-inflammatory Tablets	all	Whitehall Labs. Hammonton, N.J. (MFR) Elkhart, Ind. Whitehall Labs. Div. American Home Products New York, N.Y. (RECALLER)	No aporoved NDA - misbranded - potential health hazard as labeled	FDA Init.	II	OTC
D-181-5	Viaflex plastic containers various large volume parenterals	all	Travenol Labs. Morton Grove, Ill.	Product removal not involved. Recall consists of issuance of Wall Chart to hospitals titled "How to Set-Up a Viaflex Plastic IV Solution Container".	Vol.	II	Rx
D-182-5	Conray Injection 50 ml. - Meglumine Iothalamate Injection USP	1	Mallinckrodt, Inc. St. Louis, Mo.	Non-sterile	Vol.	I	Rx
D-183-5	Aspirin Tablets 5 gr. Medic Brand	1	International Drugs, Inc. Smyrna, Tenn.	Cross contamination with methyl testosterone	Vol.	II	OTC
D-184-5	"Nods" Hard Gelatin Capsules Carroll Brand (Methapyrilene-scopolamine)	1	Carroll Chemical Co. Div. International Drugs, Inc. Smyrna, Tenn.	Cross contamination with methyl testosterone	Vol.	II	OTC
D-185-5	Sodium edecrin (sodium ethacrynate)	56 lots (all lots with the suffix "s")	Merck Sharp & Dohme West Point, Pa.	Subpotent	Vol.	II	Rx

** Letter was mailed to pharmacists, hospitals and wholesalers on November 8, 1974, notifying them of possible mis-labeled shelf cases and requesting that stocks be examined and any mislabeled cases destroyed. The product itself is not being recalled.

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-148-5	Kelvin Tetracine 250 mg. Capsules	1	ICN Pharmaceuticals Cincinnati, Ohio (MFR) Kessel Labs. Hialeah, Fla. (REPACKER) Kelvin Pharmaceutical, Inc. Miami, Fla. (RECALLER)	The capsules were repacked without re-certification	Vol.	II	Rx
D-150-5	Diphenhydramine HCl Capsules 25 mg. Anti-histamine	1	J. W. S. Delavau Co. Philadelphia, Pa.	Product failed USP XVIII content uniformity requirements	Vol.	II	Rx
D-151-5	Digoxin Tablets 0.25 mg.	1	Lederle Labs. Div. American Cyanamid Co. Pearl River, N.Y.	Unit dose blister pack labeled xxx Digoxin tablet 0.25 mg. xxx & Actually contain 2 tablets totaling 0.50 mg. in some units	Vol.	II	Rx
D-156-5	Phenobarbital elixir 20 mg/5 ml.	2	Abbott Labs. N. Chicago, Ill.	Over fill of unit dose containers	Vol.	II	Rx
D-157-5	Phenobarbital elixir 15 mg/3.75 ml.	1	Abbott Labs. N. Chicago, Ill.	Over fill of unit dose containers	Vol.	II	Rx
D-164-5	Progesterone in glass vials	1	Medwick Labs., Inc. Melrose Park, Ill.	Clumping of suspension	Vol.	II	Rx
D-165-5	Sodium Salicylate tablets 100's & 1000's	3	Kirkman Labs., Inc. Portland, Ore.	Product failed to meet USP disintegration requirements for enteric coated tablets	Vol.	II	OTC
D-170-5	Digitoxin "Purodigin" 0.05 mg. tablets	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-171-5	Digitoxin "Purodigin" 0.1 mg. tablets	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-172-5	Digitoxin "Purodigin" 0.15 mg.	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-173-5	Digitoxin "Purodigin" 0.2 mg.	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx

** Letters were sent to all pharmacists and wholesalers with replacement inserts on November 21, 1974. The letters called attention to the fact that the insert contained an incorrect digitalizing dose for infants. The notification was provided to all segments of the profession who would be in a position to initiate any corrective action. The product itself is not being recalled.

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-138-5	Methenamine Mandelate Tablets 0.25 gr. E.C.	1	Richlyn Labs., Inc. Philadelphia, Pa. (MFR. & RECALLER) (Dist. under Richlyn Labs. label & the following private labels: Spencer Mead Valley Stream, N.Y. Wolins Melville, N.Y. Robinson Labs. San Francisco, Ca.)	Product failed USP disintegration tests conducted by the manufacturer.	Vol.	II	Rx
D-139-5	Septi-Phene Presurgical Soap USP liquid concentrate 2%	5	Pan Western Trading Corp. Inglewood, Ca. (RECALLER)	Labels of the product declare HCP, but the product does not contain HCP	Vol.	II	Rx
D-140-5	Bio-Sol	5	Pan Western Trading Corp. Inglewood, Ca. (RECALLER)	Labels of the product declare HCP, but the product does not contain HCP.	Vol.	II	Rx
D-143-5	Digitoxin 0.1 mg. 100, 500, 1000, & 5000's tablet bottles	1	Westerfield Labs., Inc. Cincinnati, Ohio	Product failed content uniformity requirements	Vol.	II	Rx
D-145-5	Liquid Lytren Oral Electrolyle Solution for Oral Use Only (Ready-to-use solution with Beniflex disposable Nurser 32 fl. oz.)	SAD-17 followed by the letters A-M representing 13 retort loads	Mead Johnson Labs. (MFR) Bellville, Ontario, Canada Mead Johnson & Co. Evansville, Ind. (RECALLER)	Bacteriological contamination	Vol.	I	OTC Hospital use only - not for retail outlets.
D-146-5	QID Pen V-K (Potassium phenoxymethyl penicillin USP) 250 mg. (400,000 units) per 5 ml. in 100 ml. bottles	1	Mylan Pharmaceutical Inc. Morgantown, W. Va.	Mislabeled - label declares 250 mg./5 ml. - bottles contain 125 mg./5 ml.	Vol.	II	Rx
D-147-5	Digoxin Tablets 0.25 mg.	1	American Pharmaceutical Co. Bronx, N.Y. (MFR) Daylin Medical Inc. Los Angeles, Ca. (RECALLER)	Product failed USP dissolution test and requirements set forth in the FR 1/22/74	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-107-5	Methenamine Mandelate USP 0.25 gm. Tablets	4	Richlyn Labs. Philadelphia, Pa. (MFR) Robinson Laboratory, Inc. San Francisco, Ca. (RECALLER)	Questionable disintegration	Vol.	II	Rx
D-110-5	Allopurinol 100 mg. Zyloprim Brand Tablets	all	Burroughs Wellcome Co. Greenville, N.C. (MFR.) Research Triangle Park, N.C. (RECALLER)	Properly labeled zyloprim bottles were found packed in 12 bottle Imuran Carriers. **	Vol.	II	Rx
D-124-5	Prefrin-Z Ophthalmic Solution 1/2 oz.	7	Allergan Pharmaceutical Irvine, Ca.	A number of Ophthetic (Rx) 15 cc bottles have been erroneously packaged in Prefrin-Z (OTC) unit cartons	Vol.	I	OTC
D-127-5	Potassium Phosphate Inj.	1	Travenol Labs., Inc. Hays, Kan. (MFR) Travenol Labs., Inc. Deerfield, Ill. (RECALLER)	Vials of potassium phosphate in individual vial cartons labeled potassium chloride	Vol.	II	Rx
D-131-5	Nesacaine - CE 2% 30 ml. single dose vials - Inj.	3	Taylor Pharmacal Co. Decatur, Ill. (MFR) Pennwalt Corp. Pharmaceutical Div. Rochester, N.Y. (RECALLER)	Discoloration	Vol.	II	Rx
D-132-5	Digoxin Tablets 0.25 mg.	1	American Pharmaceutical Co. Bronx, N.Y. (MFR) The Reyman Drug Co. Baltimore, Md. (RECALLER)	Product failed USP Dissolution tests and requirements set forth in the FR 1/22/74	FDA Init.	II	RX
D-133-5	Promethazine HCl 25 mg/ml in 10 ml multiple dose vials injection. Also packaged under private labels: "Anergan 25"; "Prorex 25"; "Phenerject 25"	3	The Central Pharmacal Co. Seymour, Ind.	Crystallization	Vol.	II	Rx
D-134-5	Chlorpheniramine Compound 1000 tablet bottles	1	J. W. S. Delavau Co., Inc. Philadelphia, Pa.	Misbranded - contains undeclared antacids	Vol.	II	OTC

** The labels on the bottles of the two products are correct and the products themselves were not recalled. Corrective action involved a check of the cardboard carrier to assure that it is consistent with the bottle labels.

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-014-5	Promapar Tablets 50 mg. (Chlorpromazine HCl)	1	Bulk Tablets - Cord Labs. Detroit, Mich. Blister Packaging - Sauter/ Sparks, Inc. Harleysville, Pa. Parke Davis & Co. Detroit, Mich. (RECALLER & DIST.)	Label mix-up. 100 mg. tablets labeled as 50 mg. tablets	Vol.	II	Rx
D-017-5	Reserpine Tablets 0.1 mg.	1	McKesson Labs. Div. Foremost - McKesson, Inc. Fairfield, Conn.	Subpotent	Vol.	II	Rx
D-018-5	Digitoxin Tablets 0.2 mg.	2	Westerfield Labs. (MFR. & RECALLER) O'Neal, Jones, & Feldman, Inc. Cincinnati, Ohio (NEW OWNERS)	Product failed Content Uniformity requirements	FDA Init.	II	Rx
D-022-5	Apresoline HCl (Hydralazine HCl) 1 ml Ampules 20 mg/ml.	all	Ciba Pharmaceutical Co. Div. Ciba-Geigy Co. Summit, N.J.	Particulate matter	Vol.	II	Rx
D-023-5	D-Alpha-E Jelly 30 I.U. per gram Topical Ointment	1	Wilson & Wolfer Prescription Center Detroit, Mich.	Bacterial Contamination	Vol.	II	OTC
D-028-5	Otalgine Drops 8cc	1	Bard Pharmaceutical Inc. Yonkers, N.Y. (MFR.) Purdue Frederick Co. Norwich, Conn. (RECALLER)	Subpotent (81% of declared Neomycin)	FDA Init.	II	Rx
D-052/102-5	Various suture products sterilized under two autoclave lots.	2	Deknatel, Inc. Queens Village, N.Y.	Lack of assurance of sterility	Vol.	II	Rx

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RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC 3/ or Rx 4/
D-002-5	Meperidine HCl Inj. 25 mg/ml	1	Knoll Pharmaceutical Co. Whippany, N.J.	Cartons labeled Meperidine HCl 100 mg/ml which contained ampules correctly labeled as Meperidine HCl 25 mg/ml.	Vol. 1/	II	Rx
D-004-5	Digoxin Tablets 0.25 mg.	1	The Lannett Co., Inc. Philadelphia, Pa.	Product failed USP Dissolution test and requirements set forth in the FR Announcement 1/22/74	FDA Init. 2/	II	Rx
D-008-5	Deknatel 18" Sutures USP - Code 6-915	1	Deknatel Inc. Queens Village, N.Y.	Non-sterile	Vol.	II	Rx
D-010-5	Lidocaine HCl Inj. USP 1/2%, 30 ml.	1	Invenex Pharmaceuticals Div. of Mogul Corp. Grand Island, N.Y.	Glass particles found in product	Vol.	II	Rx
D-011-5	Gentamycin 10 mcg. No. 822E 100 Sensitivity Disks	1	Pfizer Diagnostic Div. Maywood, N.J. (MFR) Pfizer Diagnostic Div. New York, N.Y. (RECALLER)	Mislabeled - Gentamycin susceptibility Disks - contain some disks which are labeled as streptomycin	Vol.	II	Rx
D-012-5	Vitamin B-12 (Cyanobalamin USP) 50 mcgms Tablets	1	Banner Gelatin Products Corp. Chatsworth, Ca. (MFR) Indianapolis Pharmacal Co. Indianapolis, Ind. (RECALLER)	Mislabeled - two bottles containing Vitamin E, lot 37406 were mislabeled as Vitamin B-12 tablets 50 mcgm.	Vol.	II	OTC
D-013-5	Promapar Tablets 100 mg (Chlorpromazine HCl)	1	Bulk Tablets - Cord Labs. Detroit, Mich. Blister Packaging - Sauter/ Sparks, Inc. Harleysville, Pa. Parke Davis & Co. Detroit, Mich. (RECALLER & DIST.)	Label mix-up - 100 mg. tablets labeled as 50 mg. tablets	Vol.	II	Rx

1/ Voluntary
2/ FDA Initiated
3/ Over-the-Counter Drug
4/ Prescription Drug

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-472-4	Erythromycin Stearate Tablets 500 mgs.	4	Mylan Pharmaceutical Inc. Morgantown, W. Va. Raw materail from Pierrel Sud S.P.A. Capua, Italy	Penicillin Contamination of raw material	Vol.	II	Rx
D-474-4	Barbium Tablets Urinary Analgesic	3	Barry Martin Pharmaceuticals Inc. Miami, Fla.	Tablets failed the NF test for disintegration	Vol.	II	OTC
D-475-4	Sodium Salicylate Tablets	7	ICN Pharmacueticals Inc. Cincinnati, Ohio	Product fails disintegration tests	Vol.	II	OTC
D-477-4	Ammonium Chloride Tablets	4	ICN Pharmaceuticals Inc. Cincinnati, Ohio	Product fails dis-integration tests	Vol.	II	OTC
D-482-4	"Ethril 500" Erythromycin Stearate Tablets USP 500 mg packaged in two's blister pack. Physician samples	1	Recaller: E. R. Squibb & Sons Inc. Princeton, N.J. Mfr: Mylan Pharmaceuticals Inc. Morgantown, W. Va. Raw materail from Pierrel Sud S.P.A. Capua, Italy	Penicillin contamination of raw material	Vol.	II	Rx
D-484-4	Digoxin Tablets 0.25 mg.	All	Barr Labs Inc. Northvale, N.J.	Product failed USP Dis-solution test and require-ments set forth in the Federal Register of 1-22-74	FDA Init.	II	Rx
D-486-4	Unitensen Aqueous Solution (Cryptenamine Acetates) Inj.	4	Mallinckrodt Chemical Works St. Louis, Mo.	Loss in Volume	Vol.	II	Rx
D-488-4	Sopor (Methaqualone) 300 mg. tablets	1	Arnar-Stone Labs Mt. Prospect, Ill.	Unit Dose strips labeled as 150 mg.	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-457-4	Valium Tablets 10 mg. in Tel-E-Dose packaging	1	Roche Labs. Div. of Hoffman LaRoche Inc. Nutley, N.J.	Carton label declares 5 mg.	Vol.	II	Rx
D-458-4	Furacin Topical Solution	5	Eaton Labs Div. of Morton-Norwich Products Inc. Norwich, N.Y. mfr: Greenville, S.C.	Precipitate	Vol.	II	Rx
D-461-4	Calcium Gluconate 10% injectable	All	International Medication Systems Limited South El Monte, Calif.	Precipitation	Vol.	II	Rx
D-465-4	Potassium Phenoxymethyl penicillin for oral solution 125 mg/5 cc in bottle of 100 cc & 200 cc.	3	Biocraft Labs. Inc. Elmwood Park, N.J. Mfr. of bulk: Pfizer Inc. Groton, Conn.	Contamination of bulk potassium phenoxymethyl penicillin with monosodium Carbenicillin	Vol.	II	Rx
D-467-4	Potassium Phenoxymethyl Penicillin tablets 250 mg.	2	Same as above	Same as above	Vol.	II	Rx
D-466-4	Potassium Phenoxymethyl penicillin for oral solution 250 mg/5 cc in bottle of 100 cc & 200 cc.	2	Same as above	Same as Above	Vol.	II	Rx
D-468-4	Erythromycin Stearate 250 mg. tablets	2	Mylan Pharmaceutical Inc. Morgantown, W. Va. Raw material from Pierrel SUD S.P.A. Capua, Italy	Penicillin contamination of raw material	FDA Init.	II	Rx
D-469-4	Potassium Phenoxymethyl Penicillin (Bulk powder)	7	Pfizer Inc. CHemicals Div. Groton, Conn.	Contaminated with monosoidum carbencillin	Vol.	II	Rx
D-471-4	Erythromycin Stearate USP Tablets 500 mg.	1	Milan Pharmacuetical Inc. Morgantown, W. Va. recaller: Wyeth Labs. Radnor, Pa. Raw material from Pierrel SUD S.P.A. Capua, Italy	Penicillin Contamination of raw material	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-431-4	H.A.F. Ointment	9	Harold Pharmacal Inc. Bedford, Va.	Microbiological contamination	Vol.	II	OTC
D-434-4	Erythromycin Stearate Tablets 250 mg.	1	Mylan Pharmaceuticals Inc. Morgantown, W. Va. bulk powder Pierrel Sud S.P.A. Capua, Italy	Penicillin contamination of raw materials	Vol.	II	Rx
D-437-4	5% Dextrose & 0.45% Na Cl Inj. Viaflex Container	1	Travenol Labs Inc. North Cove, N.C. recaller: Travenol Labs Inc. Deerfield, Ill.	Solution leaking from inner bag.	Vol.	II	Rx
D-438-4	Digoxin 0.25 mg. ICN Also uses list numbers for product identification #239 - 100s #240 - 1000s #5230 - bulk 50,000 #928 or 929 - unit dose Blister pack of 100s.	9	ICN Pharmaceutical Inc. Cincinnati, Ohio	Product failed USP Dissolution test and requirement set forth in the FR 1-22-74	FDA Init.	II	Rx
D-439-4	Erythromycin Tablets 250 mg. 100 & physician samples	2	Reid-Provident Labs Inc. Atlanta, Ga. - raw material from Cipan (Lisbon, Portugal)	Penicillin Contamination of raw material	Vol.	II	Rx
D-440-4	Unipen (Sodium Nafcillin) Injection 1 gm., 2 gm & 500 mg.	5	Wyeth Labs Radnor, Pa.	Glass particles	Vol.	II	Rx
D-445-4	Calcium Gluconate Inj. Inj. 10% 10 cc	1	Torigian Labs. Inc. Queens Village, N.Y.	Carton labeling error	Vol.	II	OTC
D-453-4	Pilocar SMP (pilocarpine HCl) 3% ophthalmic	1	SMP Division Cooper Labs. San German, P.R.	Carton error in strength declaration	Vol.	II	Rx
D-454-4	CU-7 IUD	All	Searle Labs Skokie, I..	Defective seal on sterile container	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-399-4	Digoxin 0.25 mg. Tablet	1	Heather Drug Co. Inc. Cherry Hill, N.J.	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init	II	Rx
D-401-4	Digoxin 0.25 mg. Tablets	9	Heather Drug Co. Cherry Hill, N.J.	Product fails USP Dissolution test & requirements set forth in the FR dated 1-22-74	FDA Init.	II	Rx
D-402-4	Sodium Phenobarbital Inj. USP 130 mg (2 gr) per cc.	1	Wyeth Labs Inc. Marietta, Pa. recaller: Wyeth Labs Inc. Radnor, Pa.	Mislabeled product. one or more units of Sodium Phenobarbital Inj. labeled as Sparine 50 mg. per cc.	Vol.	II	Rx
D-410-4	Haemolyte Dialysis Concentrate #7 (Special Formula)	1	Nutrilite Products Inc. Buena Park, Ca. recalling through its subsidiary Tera Pharmaceuticals Inc. Buena Park, Ca.	Distributed without analysis after reworking.	Vol.	II	Rx
D-414-4	Alcohol Absolute	1	Recalled: Abbott Labs. N. Chicago, Ill.	Product Exceeds the USP limit for non-volatile substances in ethyl alcohol.	Vol.	II	Rx
D-418-4	Kelfin (Sodium cephalothin)	1	Eli Lilly & Co. Indianapolis, Ind.	Mislabeling - a bulk package labeled as Loridine actually contained Keflin.	Vol.	II	Rx
D-419-4	Loridine (Cephaloridine)	1	Eli Lilly & Co. Indianapolis, Ind.	Mislabeling. A bulk package labeled as Keflin actually contained Loridine.	Vol.	II	Rx
D-429-4	Digoxin Tablets USP 0.25 mg.	1	Cord Labs. Inc. Detroit, Michigan	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-430-4	Radiocaps - 131. Sodium Iodide I-131 Capsules packed 20/ caps/carton	1	Abbott Labs. N. Chicago, Ill.	Erroneous labeling re: expiration date	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-386-4	Nesacaine - CE 3% Inj.	1	Pennwalt Corp. Pharmaceutical Div. Rochester, N.Y.	Label carton mix up - Nesacaine CE 3% in cartons labeled Nesacaine CE 2%.	Vol.	II	Rx
D-387-4	Solu-Medrol Injectable 40 mg.	2	Upjohn Co. Kalamazoo, Mich.	Vials of Solu-Medrol 40 mg. were packaged in cartons labeled as Solu-Cortef 100 mg. per 2 ml. The Vials of Solu-Medrol are properly labeled.	Vol.	II	Rx
D-388-4	Neut. Sodium Bicarbonate 4% Additive Solution	1	Abbott Labs. N. Chicago, Ill.	An in-process control failure that does not provide assurance of the products' sterility.	Vol.	II	Rx
D-390-4	Digoxin 0.25 mg. Tablets	2	Heather Drug Co., Inc. Cherry Hills, N.J.	Product failed USP Dissolution tests and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-393-4	Digoxin 0.25 mg. Tablets	1	Davies Rose Hoyt Pharmaceutical Div. of The Kendall Co. Needham, Mass.	Product failed USP Dissolution tests and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-394-4	Panalgesic Aerosol in 6 oz. can.	1	Wm. P. Poythress & Co. Inc. Richmond, Va.	Reports of leaking containers and 4 reports of exploding cans	Vol.	II	OTC
D-395-4	Bronkephrine HCl. Injection 10 ml vials	All	Winthrop Labs. Rensselaer, N.Y. dist. & recaller: Breon Labs Inc. Subsidiary of Sterling Drug Inc. New York, New York	Precipitation	Vol.	II	Rx
D-396-4	Diethylstilbestrol Tablets, Enteric Coated 1 mg. & 5 mg.	3	ICN Pharmaceutical Inc. Cincinnati, Ohio	Product fails USP Dis - integration tests	Vol.	II	Rx
D-397-4	Sodium Salicylate Tablets USP 600 mg.	12	ICN Pharmaceutical Inc. Cincinnati, Ohio	Product fails USP Disintegration test.	Vol.	II	OTC

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-358-4	Milk of Magnesia Tablets, Bottles of 100 & 250	2	L. Perrigo Co. Allegan, Michigan	Aspirin Tablets in bottles labeled as Milk of Magnesia Tablets	Vol.	II	OTC
D-359-4	OTC Decongestant Nasal Spray in ½ oz. plastic squeeze Spray bottles	2	L. Perrigo Co. Allegan, Michigan	Excess Sodium Bisulfite	Vol.	II	OTC
D-365-4	Digoxin 0.25 mg. tablets 100's & 1000's	2	Towne Paulsen & Co. Monrovia, Ca.	Product failed USP Dissolution test and requirement set forth in the FR dated 1-22-74	FDA Init.	II	Rx
D-366-4	Promethazine Hydrochloride USP 12.5 mg. Tablets	1	Danbury Pharmacal Danbury, Conn. dist: Spencer Mead Valley Stream, N.Y.	Promethazine HCl. 50 mg. lot 6516 mislabeled as 12.5 mg. Promethazine HCl.	Vol.	I	Rx
D-367-4	Digoxin Tablets USP 0.25 mg.	1	Barr Labs Northvale, N.J.	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-368-4	Digoxin Tablets 0.25 mg.	1	Heather Drug Co. Cherry Hill, N.J.	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-372-4	Pitocin (oxytocin Inj.) Synehtic 10 units per ml in packages of ten 1 ml Steri-Dose Syringes	2	Parke Davis & Co. Detroit, Michigan	One or more unit dose syringes labeled as Fluogen	Vol.	I	Rx
D-374-4	Aminophylline 1½ gr. E.C. Tablets 1000's	1	Manhattan Drug Co., Inc. Hillside, N.J.	Failed disintegration requirements	Vol.	II	Rx
D-383-4	Hemodialysis Concentrate	3	Mallinckrodt Chemical Works St. Louis, Mo.	Misprint in labeling re Chloride and sodium Content	Vol.	II	Rx
D-384-4	Digoxin Tablets 0.25 mg.	2	Philips Roxane Labs. Inc. Columbus, Ohio	Product failed USP Dissolution tests and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-348-4	Ampicillin Trihydrate 250 mg/5 ml	1	International Labs Inc. Mayaguez, P.R.	Label mix up - shipping containers & inner containers were labeled QID Ampicillin 125 mg/5 ml instead of QID Ampicillin 250 mg/5 ml.	Vol.	II	Rx
D-349-4	Neo-Hytone Cream ½% (Neomycin-Hydro Cortisone)	1	Dermik Labs. Inc. Syosset, N.Y.	Label error - The product is Neo-Hytone Cream labeled Hytone Cream. The immediate tube label only is mislabeled. The Unit carton tube is properly labeled, as is the insert information printed on the inside of the unit carton.	Vol.	II	Rx
D-350-4	Digoxin Tablets 0.25 mg.	1	Blue Line Chemical Co. St. Louis, Mo.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-351-4	Digoxin Tablets	All	Kasco Efco Labs. Inc. Hicksville, N.Y. recaller: E. Fougera & Co. Inc. Hicksville, N.Y.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-352-4	Lidocaine HCl. Injection 2% 100 mg in 5 ml (20.0 mg. per ml) in automated disposable syringe System units	1	Bristol Labs., Div. Bristol-Myers Co. Syracuse, N.Y.	Label error - two or more sealed unit dose packages contain an inner label insert for "Sodium Bicarbonate Injection USP 7.5%"	Vol.	I	Rx
D-353-4	Digoxin 0.25 mg. tablets	1	Rexall Drug Co. St. Louis, Mo.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-356-4	Digoxin Tablets 0.25 mg.	1	Parke Davis & Co. Detroit, Michigan	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-357-4	Cortisone Acetate Tablets 25 mg, 100's, 500s & 1000s. Also in bulk cartons 15,000s and 25,000	1	Panray Div., Ormont Drug & Chemical Co. Englewood, N.J.	Cortisone Acetate tablets mixed w/an OTC antiasthmatic drug.	Vol.	I	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or RX
D-333-4	Lidocaine HCl. Injection USP 1% 30 ml	4	Invenex Pharmaceuticals Div. of Mogul Corp. Grand Island, N.Y.	Glass particles found in product	Vol.	II	Rx
D-334-4	Lidocaine HCl. Injection USP 2% 30 ml.	2	Same as above	Glass particles found in product	Vol.	II	Rx
D-335-4	Procaine HCl Injection USP 2% 30 ml.	1	Same as above	Glass particles found in product	Vol.	II	Rx
D-336-4	Digoxin Tablets USP .25 mg.	1	Premo Pharmaceuticals South Hachensack, N.J.	Product failed USP dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-338-4	Pitocin (oxytocin Injection U.S.P.) Synthetic 10 units per ml steri-dose Syringes	1	Parke Davis & Co. Detroit, Mich.	Some inserts for tetanus Toxid were in error placed in packages labeled as and containing pitocin disposable syringes.	Vol.	II	Rx
D-339-4	Digoxin Tablets	1	Heather Drug Co. Cherry Hill, N.J.	Product failed USP Dissolution Test FR 1-22-74	FDA Init.	II	Rx
D-345-4	Digoxin Tablets USP 0.25 mg	1	Barr Labs. Northvale, N.J.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-347-4	Digoxin Tablets USP 0.25 mg.	2	Stanlabs Inc. Portland, Ore.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-346-4	Digoxin Tablets USP 0.25 mg.	1	Marshall Pharmcal Corp. South Hachesack, N.J.	Product failed USP dissolution test and FR 1-22-74	FDA INIT.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or RX
D-313-4	Lido-caine HCl. Inj. USP 2% (100 mg in 5.0 Ml) 2.0 mg per Ml	1	Bristol Labs. Div. of Bristol-Myers Co. Syracuse, N.Y.	Physical malfunctioning of units	Vol.	II	Rx
D-318-4	Aminophylline 1½ gr. with Phenobarbital ¼ gr. E.C. tablets	1	Manhattan Drug Co. Hillside, N.J.	Failed USP XVIII Test for disintegration	Vol.	II	Rx
D-320-4	Levo-Dromoran 2 mg Brand of Levophanol Tartrate	4	Roche Labs., Div. of Hoffman La Roche Inc. Nutley, N.J.	Label error - boxes of 10 Ampuls Levo-Dromoran 2 mg. containing back panel ingredient, Dosage and storage information which is actually meant for "Prostigmin Injection." Other panels, labels and inserts are correct.	Vol.	II	Rx
D-323-4	Nitrofurantoin Tablets 50 mg	1	Rochelle Labs. Inc. Long Beach, Ca.	Product exceeds the USP limit for dissolution	Vol.	II	Rx
D-328-4	Vaponefrin Metermatic Aerosol Mist (Racemic epinephrine HCl) 15 cc Complete Units and refills	All	USV Pharmaceutical Corp. Tuckahoe, N.Y.	Delivers super potent dosage	Vol.	II	OTC
D-329-4	Aathmanefrin Aerosol Mist (Racemic epinephrine HCl 15 & 30 cc complete Units & 15 cc refills)	All	Mitchum Thayer Inc. Tuckahoe, N.Y.	Delivers super potent dosage	Vol.	II	OTC
D-331-4	Potassium Chloride 30 mg. Injection	2	Invenex Pharmaceuticals Div. of Mogul Corp. Grand Island, N.Y.	Glass particles found in product	Vol.	II	Rx
D-332-4	Potassium Chloride 60 mg. Injection	2	Invenex Pharmaceuticals Grand Island, N.Y.	Glass particles found in product	Vol	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-309-4	Aminophylline 3 gr. w Phenobarbital 1/4 gr.	1	Mfr & Recaller: Manhattan Drug Co.Inc. Hillside, N.J.	Product fails disintegration test.	Vol.	II	R_X
D-310-4	Promethazine HCl Injection 25 mg/ml	all	Mfr & recalling firm: Myers Carter Labs Inc. Glendale, Arizona	Crystalline material	Vol.	II	R_X

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-290-4	Procaine HCl 2% Vials	1	Elkins-Sinn Inc. Cherry Hill, N.J.	Carton label mixup-vials are correctly labeled Procaine HCl and outer individual cartons labeled bacteriastatic Nacl Injections	Vol	I	R_X
D-293-4	Isoproterenol Sterile Sol. 10 ml size	1	International Medication Systems Inc., S.El Monte,Calif.	Subpotent	Vol.	II	R_X
D-294-4	Demerol Hydrochloride 2.5%, 5%, 7.5% & 10% Inj.	22	Winthrop Labs Rennselaer, N.Y.	Particulate matter discoloration & leaking containers	Vol	II	R_X
D-301-4	Vapo-N-Iso	all	Mfr: USV Pharmaceuticals Corp., Tuckahoe,N.Y.	Superpotent dose delivered	Vol.	I	R_X
D-302-4	Isoniazid 100 mg tablets	1	Recaller: Bolar Pharmaceuticals Co.Inc. Copiague, N.Y.	Subpotency - 92.8% and failure of content uniformity requirements	Vol.	II	R_X
D-303-4	Sodium Bicarbonate 5% 500 ml LVP	all(G) lots prefixes	Travenol Labs Deerfield, Ill.	Excessive carbon dioxide	Vol	II	R_X
D-304-4	Surital 1 gm Sterivial W Diluent	3	Parke Davis & Co. Detroit, Mich.	Particulate matter in the water for injection (rubber)	Vol.	II	R_X
D-305-4	Furachel/1000 tablets - Nitrofurantoin 100 mg.	1	Rachelle Labs Inc. Subsidiary of International Rectifier Corp.,Long Beach,Cal.	Active Ingredients contaminated with nitrofurazone	Vol.	II	R_X

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-278-4	Mercuhydrin Injection 10cc multiple dose vials or I.M. & S.C. use and 1cc & 2 cc ampules for IM, IV & S.C. use	all	Mfr & Recaller: Lakeside Labs Div. Colgate Palmolive Milwaukee, Wisc.	Unidentified precipitate	Vol	II	R_X
D-280-4	H.P.Acthar Gel (ACTH Repository Cortitropin 40 USP units per ml)	1	Armour Pharmecuticals Co., Kankakee, Ill.	Subpotency	Vol.	II	R_X
D-282-4	Magnesium Sulfate Injection	1	Mfr: Abbott Labs Rocky Mount,N.C. Recaller: Abbott Labs N.Chicago, Ill.	labeling incorrect - front panel label on boxes of 25 ampules incorrectly stated ...4mEq. This should have read 8 mEq... All other labeling correct.	Vol.	II	R_X
D-284-4	Surgical Simplex P. Radiopaque Bone Cement	1	Mfr: North Hill Plastic Ltd.,London, England Recaller: Howmedica Inc. Medical Division Rutherford, N.J.	Product contains foreign particulate matter	Vol.	II	R_X
D-287-4	Quinidine Sulfate 0.2 gm. tablets	1	Mfr & Recaller: Cenci Labs Inc. Fresno, Calif.	Subpotency	Vol.	II	R_X
D-288-4	Labtubes (A10450 Defect Report)	4	Abbott Scientific Products Div. Abbott Labs, Inc. South Pasadena, Calif.	Calcium contamination which would result in errors in clinical determinations if the tubes were used for blood analyses	Vol.	II	R_X

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-249-4	PETN 10 mg. (Pentaerythritol Tetranitrate) tablets	1	Cord Labs Inc. Detroit, Michigan	Mislabeling (Bottles labeled as 10mg but actually contained 20 mg)	Vol	II	Rx
D-251-4	Digitalis 1 1/2gr. E.C. Green		C.M. Bundy Co. Cincinnati, Ohio	Subpotent	Vol.	II	Rx
D-262-4	Sodium Hypochlorite Solution 5%	1	Mfr: Mathison, Coleman and Bell, Rutherford, N.J. Recaller: LaMar Labs Oceanside, N.Y.	Misbranded - the product which contains 5% Na Hypochlorite was incorrectly labeled as "Dakins"	Vol.	II	OTC
D-265-4	Sodium Methicillin for injection Buffered 6 gram for I.M. or I.V. use.	2	Mfr & Recaller: Beecham-Massengill Pharmaceuticals Inc Piscataway, N.J.	Pyrogenic type reactions	Vol.	II	Rx
D-270-4	Harlecola Carbonated Glucose Cola Beverage for Glucose Tolerance testing	15	Mfr: Boulevard Beverage Co., Phila., Pa. Recaller: Harleco Phila., Pa.	Leaking Cans	Vol.	II	OTC
D-273-4	5% Dextrose Solution USP Code 2B0064 Sterile 1000 ml	1	Mfr: Travenol Labs Inc., Kingstree, S.C. Recaller: Travenol Labs. Inc. Deerfield, Ill.	Pyrogen reactions	Vol.	II	Rx
D-277-4	Digitoxin 0.2mg.	1	The Zemmer Co. Oakmont, Pa.	Product failed to meet USP XVIII requirements for content uniformity	Vol.	II	Rx

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-242-4	Reserpine Tablets	1	Mfr & Recaller: Vita Fore Products Ozone Park, N.Y.	Tablets failed content uniformity and other alkaloids requirements (USP XVIII)	Vol	II	R_X
D-243-4	Furacin Gauze Pads 3 x 9 in List No. 70431 (12 pads)	All lots	Norwich Pharmacal Norwich, N.Y.	Contaminated with mold	Vol.	II	R_X
D-244-4	Furacin Gauze Pads 3 x 9 in. List No. 70493 (50 pads)	Same	Same	Same	Vol.	II	R_X
D-245-4	Furacin Batiste Pads List No. 70481 3 x 9 in. (12 pads)	Same	Same	Same	Vol	II	R_X
D-246-4	Furacin Batiste Pads 3 x 9 in. List No. 70494 (50 pads)	Same	Same	Same	Vol.	II	R_X
D-247-4	Furacin Rayon Pads 3 x 9 in. List No. 70433 (12 pads)	Same	Same	Same	Vol.	II	R_X
D-248-4	Solubase Batiste Pads 3 x 9 inch List No. 70435	Same	Same	Same	Vol.	II	R_X

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-158-4	Enteric Coated Aspirin 5 gr. Tablets	2	Mfr: K-V Pharmaceuticals Co., St. Louis, Mo. Recaller: Hudson Pharmaceutical Corp., New York, N.Y.	Tablets failed USP disintegration test.	Vol.	II	OTC
D-165-4	Hydrocortone Phosphate Inj. 50 mg/ml 10 ml vials (some unit cartons labeled) Elavil 10 mg/ml)	1	Merck Sharp and Dohme West Point, N.Y.	Some unit cartons labeled "Elavil 10 mg/ml lot #0444R "	Vol	II	R_X
D-193-4	Spirits of Camphor	1	Rush and Hebble Co.Inc. Indianapolis, Ind.	Superpotent in Camphor - Subpotent in alcohol	Vol	II	OTC
D-200-4/ 219-4	Various gauze bandage and cotton products	20	Recaller & Mfr: Acme Cotton Products Co. Inc., Valley Stream,N.Y. Products returned to: Acme Cotton Products Co. Inc., East Killingly,Conn.	Questionable sterility	Vol.	II	OTC

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RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-080-4	Lipiodol 28% (iodized oil)	1	Mfr: Kasco-Efco Labs Hicksville,N.Y. Recaller: Savage Labs Inc. Houston, Texas	Label error contains the incorrect phrase "intramuscular only" instead of the correct phrases "not for parenteral use" for lipiodol 28% and "not for intravenous use" for lipiodol 40%	Vol.	II	Rx
D-081-4	Lipiodol 40% (iodized oil)	1	Mfr: Same Recaller: Same	Same	Vol	II	Rx
D-082-4	Spirit of Ammonia in flint glass labeled Tincture Asafoetida (only 1/2 oz bottles recalled)	1	Mfr & recaller: R.G. Dunwody & Sons, Inc. Atlanta, Ga.	Label mixup. Bottles containing aromatic spirit Amonia NF labeled Tincture Asafoetida	Vol	II	OTC
D-100-4	Digitalis 1 1/2 gr	1	Mfr & recaller: Delavau,J.W.S. Co.Inc. Philadelphia, Pa. Own label dist/recaller: (1) United Research Labs Phila, Pa.	Subpotent - (77.6% & 84.9%)	FDA Init.	II	Rx
D-153-4	Activated Cephaloplastin 2 ml	2	Dade Division American Hospital Supply Miami, Florida	Clotting time was approximately 5 seconds below the mean of 31.4 seconds	Vol	II	OTC
D-155-4	Ammonium chloride 7 1/2 gr. or 500 mg.	1	Mfr & recaller: Tablicaps Inc. Franklinville,N.J.	Product failed USP XVIII disintegration requirements	Vol.	II	OTC
D-156-4	Crestline Calamine Lotion USP with Bentonite	all	Mfr & recaller: American Drug Co. Chicago, Ill.	Pseudomonas sp. contamination and without adequate directions for use.	Vol	II	OTC

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RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC 3/ OR Rx 4/
D-001-4	Ammonium Chloride Tablets 7 1/2 gr.	1	Carroll Chemical Baltimore, Md.	Product fails disintegration requirements	Vol.1/	II	OTC
D-003-4	Triavil 2-25 perphenazine 2ml amitriptyline HCl 25 mg	1	Merck Sharp & Dohme West Point,Pa.	Subpotent: 65% of declared label of perphenazine	Vol	II	Rx
D-046-4	Travenol 20% Osmitrol(Mannitol) in Water	4	Recaller: Travenol Labs.,Morton Grove,Ill. Mfr: Travenol Labs Carolina, P.R.	Mannitol solutions prepared from raw material found to be pyrogenic	FDA Init.2/	II	Rx
D-047-4	Travenol 15% Osmitrol (Mannitol) in water	1	Recaller: Travenol Labs,Morton Grove,Ill. Mfr: Travenol Labs Carolina, P.R.	Same	FDA Init.	II	Rx
D-048-4	Travenol 10% Osmitrol (mannitol) in water	1	Recaller: Same Mfr: Same	Same	FDA Init.	II	Rx
D-049-4	Travenol 5% Osmitrol (mannitol) in water	1	Recaller: Same Mfr: Same	Same	FDA Init.	II	Rx
D-050-4	Fenural 15% Mannitol in 0.45% Sodium Chloride Solution 500 mg	1	Recaller: Same Mfr: Same	Same	FDA Init.	II	Rx
D-076-4	Abbject disposable syringes epinephrine 1:10,000	7	Abbott Labs North Chicago,Ill.	Subpotent (82%, 85.7%, 88.9%)	Vol.	II	Rx
D--79-4	Quantisorb T-4N Diagnostic Kit	all	Mfr & recaller: Abbott Labs N.Chicago, Ill.	Product is not stable. Test values obtained by Clinician for normal patient would be autoergized hypothyroid using kit	Vol.	II	OTC

1/ Voluntary
2/ FDA Initiated
3/ Over-the-Counter Drug
4/ Prescription Drug

This program is workable, as proven in the States I have mentioned, and it is long overdue as a national policy. We have had constructive comment and we are paying the closest attention to it. We shall do our part to make the program equitable and workable. But to be sure that it is workable we need the understanding, acceptance, and support of the entire health and pharmaceutical community.

One other point might be made in closing, Mr. Chairman. Some complaints about the MAC program characterize it as totally unjustifiable Federal intrusion into matters which are none of the government's business. No one is more unsympathetic to unwarranted Federal intrusion than I am. Yet I must point out that our health programs spend a large number of Federal tax dollars on drugs. We have no choice except to see that these Federal funds are spent prudently. I believe that our MAC policy fulfills our plain public responsibility while avoiding an unjustifiable interference in medical choice and patient care.

Thank you, Mr. Chairman. My colleagues and I would be pleased to answer any questions you may have.

There are many other issues--over 200 thus far--that need to be addressed before further action can be taken to implement the MAC policy. Until we have fully analyzed and addressed these issues I cannot predict the substance of a final regulation, but this much I can say:

-- The policy will not restrict or encumber the ability of physicians to prescribe as they see fit in the interests of all their patients;

-- It will not discourage or prevent pharmacists from processing Medicaid prescriptions nor deny them equitable reimbursement for their essential professional services;

-- It will not create a second or lower class of care for any beneficiary in a Federally funded program; and

-- It will not discourage new efforts at drug development by the pharmaceutical industry. On the contrary, establishing a workable national policy on drug cost reimbursement could pave the way for a drug benefit under national health insurance, and this would in turn almost certainly lead to increased resources for drug development.

We do not need, nor do we plan to assemble, a large staff to carry out the MAC program. The Social Security Administration has for several years maintained a small but effective staff working in the drug price field. While implementation of the MAC program would probably require a modest expansion of this staff, that surely would not begin to offset the potential savings. The principal administrative machinery is already in place and functioning at the State level.

As to the cost of monitoring to assure compliance with the regulations, we are convinced that the vast majority of those affected by the program would be in voluntary compliance. What additional auditing we might have to undertake would merely represent an extension of our present auditing activities under Medicare and Medicaid.

All told, we estimate that the administrative costs would not exceed 5 to 7 percent of projected savings or between $4 and $6 million. In short, the suggestion that administrative costs would consume all the money saved under the MAC program, or even a significant portion of it, is, in our view, grossly and improperly exaggerated.

Interestingly, relatively few adverse comments about the quality of care and questions of liability came from States such as California, Colorado, and Tennessee where MAC-like programs are currently in effect.

A major concern of industry is that the annual reduction in Federal and State reimbursement for drug costs that we project--$49 million--will result in a lowering of investment in research and new drug development.

Frankly, Mr. Chairman, that argument is hard to accept when applied to an industry that spends nearly a billion dollars in such research and a near equal amount in marketing and promotional efforts.

Some critics of the MAC proposal assert that the administrative costs of the program will exceed the savings it might realize. This argument was raised when I first announced our plans some 15 months ago, and it is rather strongly reiterated in the public comments we have received on the proposed regulations.

Let me say that those who make this argument I think misunderstand what we are trying to do.

A number of physicians felt that the regulations would interfere in the practice of medicine and would create a second and lower class of medicine for beneficiaries of public programs. We disagree on both points. First, the proposed regulations make clear that any physician will be able to order a drug priced above the MAC limit simply by certifying its medical necessity. The present language requires the prescriber to certify that the requested brand "is the only brand which can be tolerated or will be effective" for a given patient. Many physicians have indicated this is impossible to do without testing all other brands. We believe this objection has merit and we are considering alternative language.

The argument that lower costs imply second class care runs directly counter to the well defined trend toward increased generic prescribing by physicians, to the increased participation in the generic drug market by major brand name firms, and to the broad substitution authorities granted by hospital staffs to hospital pharmacists. A recent study published in the American Journal of Hospital Pharmacy revealed that over two thirds of the brands dispensed in surveyed hospitals were selected by pharmacists, not physicians.

A number of pharmacists and physicians expressed concern about the quality of lower cost alternatives and about the possibility they could be held legally liable for an adverse result of therapy with a lower cost drug.

It is difficult for me to understand how a physician could be held liable for prescribing according to official terminology instead of trade names or that a pharmacist could be held liable for dispensing an officially named drug entity in accordance with the prescriber's valid instructions.

The primary responsibility for maintaining quality in the production of drugs necessarily lies with the manufacturers. It is the mission of the Food and Drug Administration to see that manufacturers are fulfilling that responsibility. I hope my earlier remarks are sufficient to assure you that both the manufacturers and the Food and Drug Administration are meeting their respective responsibilities.