



UNITED STATES GENERAL ACCOUNTING OFFICE  
WASHINGTON, D.C. 20548

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MANPOWER AND WELFARE  
DIVISION

B-164031 (2)

Feb 15 '74

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The Honorable  
The Secretary of Health,  
Education, and Welfare

RE

Dear Mr. Secretary:

During our survey of the administration of the Medicaid drug program, we found that the three States included in the survey (California, Ohio, and Texas) were expending significant amounts of funds (portions of which are reimbursed by the Federal Government) for prescription drugs that have been declared ineffective or possibly effective by the Food and Drug Administration (FDA). The Department of Health, Education, and Welfare (HEW) has not issued regulations prohibiting the use of Federal funds for the purchase of ineffective and possibly effective drugs under the Medicaid program. We believe that HEW should expedite the issuance of such regulations.

BACKGROUND

The 1962 Amendments (P.L. 87-781) to the Federal Food, Drug and Cosmetic Act required that drugs be effective before they can be approved for marketing. Under these amendments, FDA began evaluating the effectiveness of all drugs that it had approved for marketing under a safety criteria in force before the amendments. After analysis by the National Academy of Sciences/National Research Council of the available data relating to the effectiveness of a drug, FDA publishes in the Federal Register a notice of its initial classification of the drug as being effective, probably effective, possibly effective, or ineffective.

If a drug is not classified as effective, a notice of an opportunity for a hearing is also published. If interested parties justify, on the basis of new evidence, the need for a hearing, one is held. After the hearings FDA publishes its final determination of the effectiveness of the drug and declares it to be either effective or ineffective.

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STATES STILL PAYING FOR INEFFECTIVE  
AND POSSIBLY EFFECTIVE DRUGS

We found that the three States in our current survey were expending significant amounts for ineffective and possibly effective drugs. The costs and number of prescriptions of ineffective and possibly effective drugs purchased under each of the three States' Medicaid programs are presented in the table below. The data for California and Texas is for September 1973. Because data was not available for Ohio for September 1973, the data presented is the average monthly figures for the period September 1972 through August 1973.

	<u>California</u>	<u>Ohio</u>	<u>Texas</u>
Ineffective:			
Cost	\$104,754	\$25,700	\$ 81,264
Number of prescriptions	(note a)	6,700	15,816
Number of drugs	27	80	93
Possibly Effective			
Cost	169,767	45,500	264,921
Number of prescriptions	(note a)	8,300	36,863
Number of drugs	77	174	211
Total cost:	<u>\$274,521</u>	<u>\$71,200</u>	<u>\$346,185</u>
Percent of Total Medicaid Drug Costs	4.4%	6.6%	11.9%

Note a: Data not obtained

Expenditures at these monthly levels represent annual costs of about \$8.3 million for ineffective and possibly effective drugs in the three States.

Neither Ohio nor Texas have procedures for removing drugs classified as ineffective or possibly effective from their Medicaid drug formularies. California has a procedure for removing drugs which have been finally determined by FDA to be ineffective--a State employee reads the Federal Register to determine which drugs have been finally classified as ineffective and provides this information to the California Medical and Therapeutics Committee which has them removed from California's Medicaid

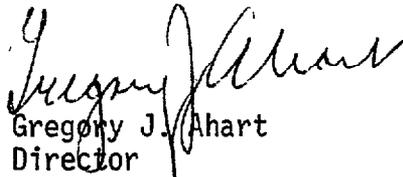
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We recommend also that you direct the Administrator of SRS, in conjunction with the Commissioner of FDA, to establish procedures for providing to States and drug providers, lists of drugs declared to be ineffective or possibly effective, and lists of all identical, related, and similar drugs.

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We are sending copies of this report to the Chairmen, House and Senate Committees on Appropriations; the Chairmen, House and Senate Committees on Government Operations, the Chairman, House Committee on Ways and Means; and the Chairman, Senate Committee on Finance. Copies are also being sent to the Director, Office of Management and Budget. 50300  
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Sincerely yours,

  
Gregory J. Ahart  
Director