

MATERIAL ON DRUGS - FY92 TO DATE

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TITLE: Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland

ACCESSION NUMBER: 148643

RPTNO: HRD-93-55FS

BNUMBER: B-251918

DOCUMENT DATE: 03/18/93

DOCUMENT TYPE: Fact Sheet

DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Medicaid programs, Health care cost control, State-administered programs, Drugs, Hospitals, Nursing homes, Health care costs, Overhead costs, Pharmaceutical industry, Patient care services

IDENTIFIERS:

Medicaid Program

Illinois

Maryland

ORGANIZATION CONCERNED:

Illinois

Maryland

Health Care Financing Administration

CONGRESSIONAL RELEVANCE:

Sen. Daniel P. Moynihan

Senate Committee on Finance

Sen. Bob Packwood

Senate Committee on Finance

Sen. David H. Pryor

Senate Special Committee on Aging

Sen. William S. Cohen

Senate Special Committee on Aging

Rep. John D. Dingell

House Committee on Energy and Commerce

Rep. Carlos J. Moorhead

House Committee on Energy and Commerce

LAW AUTHORITY:

Omnibus Budget Reconciliation Act of 1990

BACKGROUND:

Pursuant to a legislative requirement, GAO reviewed drug purchasing costs and Medicaid reimbursements in Illinois and Maryland, focusing on whether state pharmacies reimbursed Medicaid programs for the discounts on outpatient drugs they received from drug manufacturers.

FINDINGS:

GAO found that: (1) Medicaid reimbursed the state pharmacies about 17 percent more than they paid for outpatient drugs; (2) hospital and nursing home pharmacies' average reimbursements were 23 and 13 percent more than their purchase costs; (3) all of the pharmacies purchased drugs at prices below the average wholesale price; (4) the Health Care Financing Administration (HCFA) and the states have not established an appropriate profit margin on outpatient drugs for pharmacies; (5) the states' dispensing fees did not completely cover their dispensing costs; (6) HCFA and state Medicaid officials did not have current data on dispensing costs, so they could not determine what dispensing fees should be; and (7) data on pharmacies' actual dispensing costs are needed to determine whether Medicaid drug reimbursements are a potential source for savings.

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TITLE: Drug Control: Increased Interdiction and Its Contribution to the War on Drugs

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ACCESSION NUMBER: 148735
DOCUMENT DATE: 02/25/93
DOCUMENT CLASS: P,U

RPTNO: T-NSIAD-93-4
DOCUMENT TYPE: Testimony

GAO DIVISION/OFFICE:

National Security and International Affairs Division

SUBJECT TERMS:

Law enforcement, Interagency relations, Drug trafficking, Controlled substances, Narcotics, Intelligence gathering operations, Defense operations, Contraband, Search and seizure

IDENTIFIERS:

Caribbean
Central America
Mexico
National Drug Control Strategy

ORGANIZATION CONCERNED:

Department of Defense
United States Coast Guard
United States Customs Service

CONGRESSIONAL RELEVANCE:

Senate Committee on Appropriations: Treasury, Postal Service, and General Government Subcommittee

LAW AUTHORITY:

National Defense Authorization Act for Fiscal Year 1989

BACKGROUND:

GAO discussed the effectiveness of drug interdiction and its impact on the supply of cocaine entering the United States. GAO noted that: (1) interdiction efforts have not reduced the flow of cocaine into the United States; (2) the Department of Defense (DOD) is generally restricted to drug smuggling detection and monitoring efforts, and lacks authority over arrests and seizures; (3) although DOD interdiction resources have increased, from \$212 million in 1989 to over \$900 million in 1993, cocaine remains readily available and affordable; (4) continued lucrative drug profits make interdiction losses relatively inconsequential; (5) the government's interdiction efforts are unable to counter successful or new smuggling methods; (6) continued interdiction is important to the national resolve against drugs and should be linked with other efforts in the National Drug Control Strategy and the level of interdiction funding linked to its relative contribution to the national war on drugs; and (7) additional investments in air and maritime surveillance will not substantially improve the ability to interdict drugs.

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TITLE: Prescription Drugs: Companies Typically Charge More in the United States Than in Canada

ACCESSION NUMBER: 148543
DOCUMENT DATE: 02/22/93
DOCUMENT CLASS: P,U

RPTNO: T-HRD-93-5
DOCUMENT TYPE: Testimony

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Price regulation, Pharmaceutical industry, Drugs, Pharmacological research, Comparative analysis, Cost analysis, Federal regulations, Health care cost control, Price fixing, Foreign governments

IDENTIFIERS:

Canada

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CONGRESSIONAL RELEVANCE:

House Committee on Energy and Commerce: Health and the Environment
Subcommittee

BACKGROUND:

GAO discussed prescription drug prices in the United States and Canada, focusing on: (1) the different prices manufacturers charge for the same drugs in the two countries; and (2) the factors associated with those differences. GAO noted that: (1) in general, manufacturers charged U.S. wholesalers more than Canadian wholesalers for identical drugs; (2) U.S. drug prices ranged from 44 percent lower to 967 percent higher than Canadian prices; (3) research, production, distribution, and marketing costs in the two countries did not substantially affect price differences; (4) prices were generally lower in Canada because Canadian regulations tended to restrain prices on patented drugs, and provincial benefit plans paid for drugs for large population segments at negotiated prices; and (5) the impact of federal drug price regulation to reduce or restrain drug prices in the United States may be significantly different from Canada's experience, since the U.S. market is ten times the size of the Canadian market.

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TITLE: Prescription Drug Prices: Analysis of Canada's Patented Medicine
Prices Review Board
ACCESSION NUMBER: 148527 RPTNO: HRD-93-51
BNUMBER: B-247942 DOCUMENT DATE: 02/17/93
DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Price regulation, Price fixing, Pharmaceutical industry, Pharmacological
research, Comparative analysis, Cost analysis, Health care cost control,
Foreign governments, Drugs, Research and development costs

IDENTIFIERS:

Canada

ORGANIZATION CONCERNED:

Canada: Patented Medicine Prices Review Board

CONGRESSIONAL RELEVANCE:

Sen. David H. Pryor
Senate Special Committee on Aging

BACKGROUND:

Pursuant to a congressional request, GAO: (1) described the purpose and structure of Canada's Patented Medicine Prices Review Board as well as its guidelines and procedures, especially those used to determine if a drug price is excessive; and (2) summarized the evidence about the effects of the Board's actions on the prices of new drugs, on price increases for existing drugs, and on pharmaceutical research and development.

FINDINGS:

GAO found that: (1) the Board is the federal body responsible for restraining prescription drug prices in Canada; (2) the Board periodically publishes guidelines that it uses to determine whether a manufacturer's introductory price on a new drug or price increase on an older patented drug is excessive; (3) the Board has the power to order the removal of market exclusivity or a price reduction if it finds a price to be excessive; (4) Canadian experience shows that a drug price review board can restrain prescription drug prices; (5) statistical analyses suggest that Canadian prices of new patented drugs subject to Board review were, on average, one-third lower than had there been no Board; and (6) restraint of

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drug prices reduces the incentive for manufacturers to undertake innovative pharmaceutical research and development.

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TITLE: Drug Control: Status Report on Counterdrug Technology Development
ACCESSION NUMBER: 148486 RPTNO: NSAD-73-104
BNUMBER: B-242554 DOCUMENT DATE: 01/20/93
DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

National Security and International Affairs Division

SUBJECT TERMS:

Drug trafficking, Contraband, Search and seizure, Drugs, Law enforcement,
Federal aid for criminal justice, Research and development, Inspection,
Freight transportation operations, Technology transfer

IDENTIFIERS:

National Counterdrug Enforcement Research and Development Program
National Drug Control Strategy
ONDCP National Drug Control Program

ORGANIZATION CONCERNED:

Department of Defense
Office of National Drug Control Policy

CONGRESSIONAL RELEVANCE:

Sen. Sam Nunn
Senate Committee on Armed Services
Sen. Strom Thurmond
Senate Committee on Armed Services
Sen. John W. Warner
Senate Committee on Armed Services

LAW AUTHORITY:

Department of Defense Authorization Act, 1991
Anti-Drug Abuse Amendments Act of 1988
Department of Defense Appropriation Act, 1991

BACKGROUND:

Pursuant to a congressional request, GAO provided information on counterdrug technology development, focusing on the Department of Defense's (DOD) and the Office of National Drug Control Policy's (ONDCP) efforts to develop and demonstrate cargo container inspection technology.

FINDINGS:

GAO found that: (1) in 1990, the Counterdrug Technology Assessment Center was established within ONDCP; (2) in 1992, ONDCP published a counterdrug enforcement research and development blueprint which provided agencies with guidelines for developing the technology necessary to implement the National Counterdrug Enforcement Research and Development Program; (3) the Center allows the counterdrug community to discuss and develop research and development requirements, reviews ongoing and proposed counterdrug research and development plans and budget requests, and identifies unnecessary and duplicative research and development efforts; (4) three main counterdrug technology areas of demand reduction included wide area surveillance, non-intrusive inspection, and tactical operation technologies; (5) 1992 funding for counterdrug research and development projects totalled \$104 million and 1993 estimated funding is projected at \$131 million; (6) most of the counterdrug technology developed and fielded to date by the law enforcement community resulted from the adaptation of off-the-shelf technologies; (7) cargo container inspection technology is designed to facilitate inspection of cargo containers, personal luggage, vehicles, and bulk cargo using neutron, X-ray, and chemical techniques; and (8) concerns over the new technology included funding requirements, impact on shipping,

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and the safety of new detection systems.

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TITLE: Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since
Enactment of Rebat- Provisions

ACCESSION NUMBER: 148334

RPTNO: HRD-93-43

BNUMBER: B-245873

DOCUMENT DATE: 01/15/93

DOCUMENT TYPE: Letter Report

DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Medicaid programs, Drugs, Price adjustments, Hospitals, Health care cost
control, Health care costs, Health maintenance organizations, Price
regulation, Pharmaceutical industry

IDENTIFIERS:

Medicaid Program

CONGRESSIONAL RELEVANCE:

Sen. Lloyd Bentsen

Senate Committee on Finance

Sen. Bob Packwood

Senate Committee on Finance

Rep. John D. Dingell

House Committee on Energy and Commerce

Rep. Carlos J. Moorhead

House Committee on Energy and Commerce

Sen. David H. Pryor

Senate Special Committee on Aging

Sen. William S. Cohen

Senate Special Committee on Aging

LAW AUTHORITY:

Omnibus Budget Reconciliation Act of 1990

BACKGROUND:

GAO reported on changes in drug prices charged to health maintenance
organizations (HMO) and hospital group purchasing organizations (GPO) under
rebate provisions of the Omnibus Budget Reconciliation Act of 1990, which
required that drug manufacturers give state Medicaid programs rebates for
outpatient drugs.

FINDINGS:

GAO found that: (1) prices for HMO outpatient drugs increased significantly
the year after passage of the rebate provision, while GPO inpatient drug
prices dropped slightly and GPO outpatient drug prices rose slightly; (2)
the range of price changes varied widely before and after passage of the
rebate provision; (3) the effect of price changes on HMO and GPO drug costs
depended on the drugs' original costs and utilization; (4) HMO tended to
have greater overall drug expenditure increases because they did not have
inpatient drug costs to offset outpatient expenditures, and most of their
drugs were not available in a generic form; (5) the average percentage
discount both groups received rose slightly the year after the rebate
provisions took effect, although the variance was wide; and (6) many
manufacturers changed the duration of their contracts from 1 to 5 years to
1 year or less, and no longer offered fixed prices for the duration of the
contract.

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TITLE: Women's Health: FDA Needs To Ensure More Study of Gender Differences
in Prescription Drugs Testing

ACCESSION NUMBER: 147861

RPTNO: HRD-93-17

BNUMBER: B-243898

DOCUMENT DATE: 10/27/92

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DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U
GAO DIVISION/OFFICE:
 Human Resources Division
SUBJECT TERMS:
 Pharmaceutical industry, Pharmacological research, Womens rights,
 Testing, Information analysis operations, Medical research, Health
 surveys, Data collection operations, Statistical methods
ORGANIZATION CONCERNED:
 Food and Drug Administration
CONGRESSIONAL RELEVANCE:
 Rep. Henry A. Waxman
 House Committee on Energy and Commerce: Health and the Environment
 Subcommittee
 Rep. Patricia Schroeder
 Congressional Caucus for Women's Issues
 Rep. Olympia J. Snowe
 Congressional Caucus for Women's Issues
LAW AUTHORITY:
 Federal Food, Drug and Cosmetic Act
 21 U.S.C. 301 et seq.

BACKGROUND:

Pursuant to a congressional request, GAO examined the Food and Drug Administration's (FDA) policies and the pharmaceutical industry's practices regarding research on women in prescription drug testing, focusing on: (1) the representation of women in drug testing; (2) the sufficiency of female participation in drug trials to assess significant gender-related differences; (3) the extent to which FDA analyzes trial data for differences in response related to gender; and (4) whether studies were conducted to examine drug interaction with the varying hormonal status of women and oral contraceptive use.

FINDINGS:

GAO found that: (1) a quarter of the drug manufacturers in an industry survey reported that they did not deliberately recruit representative numbers of women as participants in drug trials; (2) half of the companies surveyed said that FDA asked them to include women in drug trials, but the remainder said they had not been asked; (3) women were included in clinical trials for all the drugs in the survey, but were generally underrepresented; (4) for more than 60 of the drugs, the representation of women in the test population was less than the representation of women in the population with the corresponding disease; (5) there were enough women represented to detect gender-related differences in response for most drugs in the survey; (6) FDA often does not analyze trial data to determine whether women's responses to a drug differ from men's; and (7) many drug manufacturers do not study whether their drugs specifically interact with the hormones present in women.

RECOMMENDATIONS TO AGENCIES

To ensure that women are adequately studied in drug trials and that data derived from testing are used to determine whether gender influences drug response, the Commissioner of Food and Drugs should issue more explicit policy guidance on the inclusion of women in clinical drug trials. This guidance should tell drug manufacturers how to determine when enough women are included in drug trials to assess potential differences in safety and effectiveness by gender.

The Commissioner of Food and Drugs should require that drug manufacturers analyze trial data by gender.

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TITLE: Prescription Drugs: Companies Typically Charge More in the United States Than in Canada
ACCESSION NUMBER: 147823 RPTNO: HRD-92-110
BNUMBER: B-249553 DOCUMENT DATE: 09/30/92
DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
Human Resources Division

SUBJECT TERMS:
Price regulation, Pharmaceutical industry, Drugs, Pharmacological research, Comparative analysis, Cost analysis, Federal regulations, Health care cost control, Price fixing, Foreign governments

IDENTIFIERS:
Canada

CONGRESSIONAL RELEVANCE:
Rep. Henry A. Waxman
House Committee on Energy and Commerce: Health and the Environment Subcommittee

BACKGROUND:

Pursuant to a congressional request, GAO provided information on the cost of prescription drug products, focusing on: (1) domestic and foreign price comparisons of identical prescription drugs; and (2) causes for documented price differentials.

FINDINGS:

GAO found that: (1) manufacturers' prices for identical prescription drugs are generally higher in the United States than in Canada; (2) differences in U.S. and Canadian drug prices can be attributed to Canadian price regulations, reimbursement practices, and price controls; (3) manufacturers' research, development, marketing, production, and distribution costs are the same for identical drugs, but manufacturers charge U.S. wholesalers substantially more for the same drugs; (4) 81 percent of the drugs reviewed were more expensive in the United States and prices averaged 32 percent more; (5) Canadian regulations force manufacturers to accept cost reviews for new drugs and restrain prices for existing drugs; (6) Canadian provincial governments' containment of manufacturers' price setting discretion, liberal reimbursement policy, and power over adding or removing drugs from the reimbursable list results in concentrated buying power and low prices; and (7) there is some dispute over whether similar U.S. regulation and price controls would effectively control drug prices while sufficiently encouraging research and development of new and innovative drug products.

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TITLE: Cancer Treatment: Actions Taken to More Fully Utilize the Bark of Pacific Yews on Federal Land
ACCESSION NUMBER: 147523 RPTNO: RCED-92-231
BNUMBER: B-247750 DOCUMENT DATE: 08/31/92
DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
Resources, Community, and Economic Development Division

SUBJECT TERMS:
Cooperative agreements, National forests, Forest management, Forest products, Pharmaceutical industry, Public lands, Drugs, Pharmacological research, Cancer research, Interagency relations

IDENTIFIERS:
Taxol
Pacific Yew

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ORGANIZATION CONCERNED:

Forest Service
Bureau of Land Management
Bristol-Myers Squibb, Co.
Hauser Northwest, Inc.

CONGRESSIONAL RELEVANCE:

Rep. ; Ron Wyden
House Committee on Small Business: Regulation, Business Opportunities
and Energy Subcommittee

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the utilization of Pacific yew bark, the source of the anticancer drug taxol, focusing on: (1) the collection of Pacific yew bark from federal lands in fiscal year (FY) 1991; and (2) the steps taken by the Bureau of Land Management (BLM) and the Forest Service to ensure greater utilization of Pacific yew bark in FY 1992.

FINDINGS:

GAO found that: (1) neither BLM nor the Service collected usable Pacific yew bark in FY 1991 primarily because of sawmill timber harvesting, failure to collect usable bark from branches and stems of smaller diameter, trees scattered throughout wide geographical areas, and taxol content deterioration; (2) both BLM and the Forest Service have revised their Pacific yew program plans and associated operations procedures for FY 1992 to ensure more complete utilization of yew bark; and (3) to increase utilization of yew bark, BLM and the Forest Service have required bark collectors to return to previously harvested sites to recover bark that was left, established collection priorities requiring the collection of yew bark before timber harvesting activities, and required agency field managers to review bark collectors' compliance with the utilization standards.

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TITLE:	Prescription Drugs: Changes in Prices for Selected Drugs		
ACCESSION NUMBER:	147429	RPTNO:	HRD-92-128
BNUMBER:	B-249510	DOCUMENT DATE:	08/24/92
DOCUMENT TYPE:	Letter Report	DOCUMENT CLASS:	P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Pharmaceutical industry, Price adjustments, Controlled substances,
Proprietary data, Medicaid programs, Health care costs, Consumer Price
Index, Drugs

IDENTIFIERS:

Medicaid Program
Federal Supply Schedule

ORGANIZATION CONCERNED:

Department of Veterans Affairs

CONGRESSIONAL RELEVANCE:

Rep. ; Byron L. Dorgan
Rep. Fortney H. Stark

LAW AUTHORITY:

Omnibus Budget Reconciliation Act of 1990

BACKGROUND:

Pursuant to a congressional request, GAO examined price increases for drugs purchased by pharmacies and the Department of Veterans Affairs, and the reasons companies raised the prices.

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FINDINGS:

GAO found that: (1) the prices for most of the drugs increased more than the consumer price indexes for the 6-year period ending December 31, 1991; (2) the maximum price increases were generally greater than 100 percent; and (3) companies gave various general and undetailed reasons for the price increases because they considered pricing information confidential and proprietary.

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TITLE: Food Safety and Quality: FDA Strategy Needed to Address Animal Drug Residues in Milk
ACCESSION NUMBER: 147243 RPTNO: T-RCED-92-89
DOCUMENT DATE: 08/05/92 DOCUMENT TYPE: testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Resources, Community, and Economic Development Division

SUBJECT TERMS:

Dairy industry, Dairy products, Drugs, Pharmacological research, Contaminated foods, Food inspection, Safety standards, Consumer protection, Safety regulation, Food supply

IDENTIFIERS:

FDA National Drug Residue Milk Monitoring Program

ORGANIZATION CONCERNED:

Food and Drug Administration

CONGRESSIONAL RELEVANCE:

House Committee on Government Operations: Human Resources and Intergovernmental Relations Subcommittee

LAW AUTHORITY:

Food, Drug and Cosmetic Act

BACKGROUND:

GAO discussed the Food and Drug Administration's (FDA) efforts to address animal drug residues in milk and on the agency's extra-label policy allowing veterinarians to treat dairy cows with higher-than-approved drug dosages. GAO noted that: (1) FDA efforts are ineffective and lack a comprehensive strategy to monitor animal drug residues in milk; (2) FDA has made limited progress in implementing program revisions; (3) states are only testing for 4 of 84 known drug residues; (4) FDA has not approved additional screening tests to test for additional drugs; (5) development of a national data base is behind schedule; (6) a new FDA program tests for 12 additional animal drug residues, at an estimated annual cost of \$500,000; (7) limited FDA enforcement of the extra-label policy undermines the federal drug approval process and discourages animal drug companies from seeking FDA extra-label approval; (8) FDA lacks effective enforcement and monitoring of veterinarians' extra-label policy use, and cannot detect residues of extra-label drugs used on cows; and (9) FDA cannot control animal drug usage or ensure that illegal or unsafe drugs do not contaminate the food supply.

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TITLE: Food Safety and Quality: FDA Strategy Needed to Address Animal Drug Residues in Milk
ACCESSION NUMBER: 147221 RPTNO: RCED-92-207
BNUMBER: B-246269 DOCUMENT DATE: 08/05/92
DOCUMENT TYPE: Chapter Report DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Resources, Community, and Economic Development Division

SUBJECT TERMS:

Drugs, Dairy products, Dairy industry, Safety regulation, Pharmacological

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research, Safety standards, Food inspection, Contaminated foods, Food supply, Consumer protection

IDENTIFIERS:

FDA National Drug Residue Milk Monitoring Program

ORGANIZATION CONCERNED:

Food and Drug Administration
National Academy of Sciences

CONGRESSIONAL RELEVANCE:

Rep. Ted G. Weiss
House Committee on Government Operations: Human Resources and Intergovernmental Relations Subcommittee
House Committee on Energy and Commerce
Senate Committee on Labor and Human Resources
Senate Committee on Appropriations: Labor, Health and Human Services, and Education Subcommittee
House Committee on Appropriations: Labor, Health and Human Services, and Education Subcommittee
Senate Committee on Governmental Affairs
Senate Committee on Agriculture, Nutrition, and Forestry
House Committee on Agriculture

LAW AUTHORITY:

Food, Drug and Cosmetic Act
Public Health Service Act
S. 2667 (102nd Cong.)
H.R. 5277 (102nd Cong.)

BACKGROUND:

Pursuant to a congressional request, GAO reviewed: (1) states' and the Food and Drug Administration's (FDA) control of animal drug residues in milk; and (2) the FDA extra-label drug use policy.

FINDINGS:

GAO found that: (1) FDA is responsible for approving new animal drugs, monitoring the distribution of drugs, and determining the safety of food products from treated animals; (2) by law, use of an animal drug in a manner inconsistent with its approved labelling is illegal; (3) under the FDA extra-label use policy, only veterinarians are allowed to use drugs in an unapproved manner, and only in emergencies; (4) states do most required monitoring, enforcement, and other regulation, while FDA ensures that states comply with all rules and regulations; (5) although reliable data are unavailable, approved and unapproved use of drugs on dairy cows is thought to be widespread; (6) states routinely test for only 4 of 82 drugs that could leave residues; and (7) states and the dairy industry were to expand their testing for drug residues, but FDA did not meet deadlines for recommending additional tests, and additional screening methods will not be available before 1993. GAO also found that: (1) limited enforcement of the extra-label use policy undermines FDA control of animal drugs; (2) veterinarians must rely on available information and their best judgment and experience in extra-label use cases, but may lack adequate information; (3) FDA cannot ensure that extra-label use conditions are followed by veterinarians because it does not routinely monitor compliance or have the ability to detect all residues; (4) drug manufacturers may have little incentive to obtain approval for new drugs and uses due to veterinarians' indiscriminate use and FDA inability to enforce its policies; and (5) proposed legislation to legalize extra-label use may provide a further disincentive to manufacturers.

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RECOMMENDATIONS TO AGENCIES

To better ensure the safety of the nation's milk supply, the Commissioner, FDA, should develop a comprehensive strategy to monitor milk for animal drugs that optimizes state and industry testing under the Milk Ordinance, outlines FDA offices' roles and responsibilities, and integrates the various efforts to improve milk monitoring. The strategy should, at a minimum, include: (1) developing an action plan to implement the 1971 revisions to the Milk Ordinance, focusing on those drugs that pose the greatest threat to the safety of the nation's milk supply; (2) resolving which types of test methods and what level of precision are necessary for the states and industry to use under the Milk Ordinance; (3) conducting a cost-benefit analysis of FDA updating older regulatory methods rather than trying to compel drug manufacturers to update their older methods; and (4) reexamining the objectives and mission of the FDA monitoring program to determine its relationship to state and industry testing under the Milk Ordinance and the costs and benefits of this program versus increased funding for other efforts needed to implement the revisions to the Milk Ordinance.

Because insufficient data are available to fully address some of the difficult public policy and animal welfare issues related to extra-label use of approved drugs on food-producing animals, the Commissioner, FDA, should request that the new National Academy of Sciences' panel on animal health and veterinary medicine give priority to evaluating the need for extra-label uses and whether veterinarians have sufficient information to make informed decisions on the efficacy and safety of extra-label uses. The Academy could also explore alternatives for FDA to take enforcement actions when drugs are used in an illegal manner on food-producing animals.

The Commissioner, FDA, should revise the extra-label use policy to further restrict its use, such as to specifically preclude the use of drugs not approved for use in at least one food-producing animal species.

The Commissioner, FDA, should obtain data on veterinarians' extra-label use and prescriptions of drugs to determine: (1) whether, and to what degree, the conditions of the policy are followed; and (2) whether to withdraw approval of a drug because its labelled directions are not being followed in practice--that is, the drug is used extensively in an extra-label manner. FDA could consider several of the options discussed in this report for collecting the data.

The Commissioner, FDA, should consider options, such as professional labelling, to develop an expedited approval process that would encourage animal drug manufacturers to seek approval of new dosage claims and proper withdrawal periods.

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TITLE: Medicaid Prescription Drug Diversion: A Major Problem, but State Approaches Offer Some Promise

ACCESSION NUMBER: 147230

RPTNO: T-HRD-92-48

DOCUMENT DATE: 07/29/92

DOCUMENT TYPE: testimony

DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Drugs, Drug abuse, Pharmaceutical industry, Health care programs, Crimes or offenses, Physicians, Medicaid programs, Law enforcement, Health care cost control, Program abuses

IDENTIFIERS:

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Medicaid Program

Medicaid Electronic Eligibility Verification System

CONGRESSIONAL RELEVANCE:

House Select Committee on Narcotics Abuse and Control

LAW AUTHORITY:

Omnibus Budget Reconciliation Act of 1990

P.L. 101-508

H.R. 4930 (102nd Cong.)

False Claims Amendments Act of 1986

BACKGROUND:

GAO discussed Medicaid prescription drug diversion, focusing on: (1) the extent of the problem; and (2) New York's initiatives against drug diversion. GAO noted that: (1) prescription drug diversion is a prevalent type of Medicaid fraud; (2) providers and recipients of diverted drugs can be identified, but Medicaid losses are seldom recovered, and punishing offenders is difficult; (3) provider enrollment procedures and ownership data are not sufficient to prevent fraudulent providers from continuing to bill Medicaid; and (4) New York's efforts to reduce drug diversion include timely information gathering on services to recipients, identification of suspicious activity, stricter provider enrollment procedures, and stronger financial recovery and prosecution measures.

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TITLE: Prescription Drug Monitoring: States Can Readily Identify Illegal Sales and Use of Controlled Substances

ACCESSION NUMBER: 147189

RPTNO: HRD-92-115

BNUMBER: B-248618

DOCUMENT DATE: 07/21/92

DOCUMENT TYPE: Letter Report

DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Drugs, Food and drug law, Controlled substances, Medicaid programs, Alcohol or drug abuse problems, State programs, Physicians, Computerized information systems, Law enforcement, Program abuses

IDENTIFIERS:

Medicaid Program

Massachusetts

New York

Michigan

ORGANIZATION CONCERNED:

Drug Enforcement Administration

CONGRESSIONAL RELEVANCE:

Rep. : Fortney H. Stark

House Committee on Ways and Means: Health Subcommittee

LAW AUTHORITY:

Controlled Substances Act

Social Security Act

BACKGROUND:

Pursuant to a congressional request, GAO provided information on state prescription drug monitoring programs, focusing on: (1) program benefits to investigations and their effectiveness in detecting and reducing drug diversion; (2) whether savings have resulted from reductions in Medicaid prescription drug claims; and (3) adverse effects on medical practice and patient care.

FINDINGS:

GAO found that: (1) prescription drug monitoring programs save investigators time, improve productivity, and allow identification of

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potential cases of drug diversion; (2) 5 of 10 states showed a reduction in the number of prescriptions due to reduced diversion or changes in physician prescribing practices; (3) states claim that prescription drug monitoring programs increase the efficiency of law enforcement operations and result in greater disciplinary action; (4) New York and Michigan estimated Medicaid cost savings at \$27 million and \$440,000, respectively, but a lack of complete data hampers Medicaid savings estimates and program tracking; (5) opponents believe that programs result in less effective drug prescription, compromise patient confidentiality, and change physicians' prescribing practices; and (6) three states utilize electronic transmission systems, which are viewed as less burdensome and less intrusive than multi-copy prescription form programs.

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TITLE: VA Health Care: Efforts To Improve Pharmacies' Controls Over Addictive Drugs
ACCESSION NUMBER: 146875 RPTNO: T-HRD-92-38
DOCUMENT DATE: 06/10/92 DOCUMENT TYPE: Testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
Human Resources Division

SUBJECT TERMS:
Controlled substances, Drug trafficking, Drug abuse, Internal audits, Facility security, Inventory control, Veterans hospitals, Larceny, Hospital administration, Property losses

ORGANIZATION CONCERNED:
Department of Veterans Affairs
Drug Enforcement Administration

CONGRESSIONAL RELEVANCE:
House Committee on Veterans' Affairs: Oversight Investigations Subcommittee

LAW AUTHORITY:
Controlled Substances Act
Federal Managers' Financial Integrity Act of 1982

BACKGROUND:

GAO discussed the Department of Veterans Affairs' (VA) efforts to improve controls over addictive prescription drugs. GAO noted that: (1) VA has greatly improved controls over bulk supplies of addictive drugs stored in its pharmacies; (2) VA has developed a plan to modify its perpetual inventory system by December 1992, and new security procedures should make it difficult to divert drugs from bulk supplies without detection; (3) until the perpetual inventory software becomes available, VA will require pharmacy managers to reconcile pharmacy receipt and dispensing records with inventory balances of selected drugs each month; (4) while they have improved controls over addictive drugs, some pharmacies are still struggling to implement risk management systems because computer software inadequacies force them to rely on estimates of dispensed quantities; (5) VA has less effectively implemented its efforts to strengthen controls over addictive drugs in dispensing areas, since pharmacy managers had varying interpretations of new VA policies and were reluctant to spend resources to improve drug security practices; and (6) it will take many months for VA to improve controls over dispensing supplies in all pharmacies, but its inclusion of controls over lower scheduled drugs as a material weakness in its Federal Managers' Financial Integrity Act Report should help to ensure that VA corrective actions are accomplished and should help to eliminate weaknesses in those controls.

MATERIAL ON DRUGS - FY92 TO DATE

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TITLE: War on Drugs: Heroin Price, Purity, and Quantities Seized Over the
Past 10 Years

ACCESSION NUMBER: 147113 RPTNO: GGD-92-95FS
BNUMBER: B-248687 DOCUMENT DATE: 05/27/92
DOCUMENT TYPE: Fact Sheet DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
General Government Division

SUBJECT TERMS:
Drugs, Narcotics, Drug abuse, Drug trafficking, Search and seizure,
Controlled substances, Law enforcement agencies, Interagency relations

IDENTIFIERS:
Federal-Wide Drug Seizure Statistics System
New York (NY)
DEA Domestic Monitor Program

ORGANIZATION CONCERNED:
Drug Enforcement Administration

CONGRESSIONAL RELEVANCE:
Rep. : John Conyers, Jr.
House Committee on Government Operations
Rep. Frank Horton
House Committee on Government Operations

BACKGROUND:

Pursuant to a congressional request, GAO provided information on the fluctuations in heroin's street price and purity levels, which are indicators of heroin availability, over the past 10 years, as well as data on heroin seizures, concentrating on seizures in New York City. GAO also provided information on the progress of the reduction in double-counting of drug seizures caused by multiple agencies reporting the same seizure.

FINDINGS:

GAO found that (1) the average price of heroin decreased slightly from 1982 to 1991; (2) the purity level of seized heroin increased from 1982 to 1991; (3) heroin seizures by all federal agencies increased; (4) heroin seizures in New York City decreased; and (5) progress on the reduction of double-counting has fluctuated, but double-counting has been a long-standing problem.

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TITLE: Over the Counter Drugs: Gaps and Potential Vulnerabilities in the
Regulatory System

ACCESSION NUMBER: 146484 RPTNO: T-PEMD-92-8
DOCUMENT DATE: 04/28/92 DOCUMENT TYPE: Testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Program Evaluation and Methodology Division

SUBJECT TERMS:

Pharmaceutical industry, Drugs, Pharmacological research, Food and drug law, Safety regulation, Product safety, Safety standards, Quality assurance

ORGANIZATION CONCERNED:

Food and Drug Administration

CONGRESSIONAL RELEVANCE:

House Committee on Small Business: Regulation, Business Opportunities and Energy Subcommittee

BACKGROUND:

GAO discussed the Food and Drug Administration's (FDA) system for approving and monitoring nonprescription drugs. GAO noted that: (1) the majority of

MATERIAL ON DRUGS - FY92 TO DATE

nonprescription drugs reach the market through a drug review monograph, which specifies the therapeutic categories of ingredients that are generally recognized as safe and effective and thus permissible in a given drug product, as well as dosage, labelling, and mode of administration; (2) FDA has been slow to develop monographs for nonprescription drugs, resulting in an undetermined number of products that have not been measured against generally accepted standards of safety and effectiveness; (3) FDA does not know the number of nonprescription products currently being marketed in the United States; and (4) since FDA does not have statutory authority to inspect nonprescription drug manufacturer's records, it is largely dependent on voluntary reports on monograph-controlled products from manufacturers, health providers, and consumers for post-marketing information.

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TITLE: Nonprescription Drugs: Over the Counter and Underemphasized
ACCESSION NUMBER: 146354 RPTNO: T-PEMD-92-5
DOCUMENT DATE: 04/08/92 DOCUMENT TYPE: Testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Program Evaluation and Methodology Division

SUBJECT TERMS:

Pharmaceutical industry, Drugs, Monitoring, Pharmacological research, Food and drug law, Consumer protection, Product safety, Safety standards, Safety regulation, Quality assurance

ORGANIZATION CONCERNED:

Food and Drug Administration

CONGRESSIONAL RELEVANCE:

House Committee on Government Operations: Human Resources and Intergovernmental Relations Subcommittee

LAW AUTHORITY:

Food, Drug and Cosmetic Act
P.L. 87-781

BACKGROUND:

GAO discussed the Food and Drug Administration's (FDA) procedures for approving and monitoring over-the-counter (OTC) drugs sold in the United States. GAO noted that: (1) many OTC drug products, unlike prescription drugs, are not required to be demonstrably safe and effective before being made available to the public; (2) although the current good manufacturing practices regulation requires manufacturers of both OTC and prescription drugs to maintain customer complaint files, equipment maintenance logs, and other manufacturing records, FDA does not have the statutory authority to inspect the records of OTC drug manufacturers as it does those of prescription drug manufacturers; (3) FDA obtains less postmarketing surveillance information and conducts less product performance analysis for OTC drugs than for prescription drugs; (4) FDA has been slow to develop monographs for OTC drugs and has only moved 36 of the 88 drug categories under consideration into final rules, as of April 1992; (5) FDA does not require manufacturers of OTC monograph drugs to report adverse reactions experienced by their customers; and (6) FDA does not know and is unable to determine the number of OTC products currently being marketed in the U.S. GAO believes that, since FDA may not know of adverse reactions to OTC drugs and is unable to determine the magnitude of problems it is made aware of, it is difficult to be sure that the FDA can fulfill its mission to protect the public health.

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TITLE: FDA Premarket Approval: Process of Approving Ansaid as a Drug
ACCESSION NUMBER: 146386 RPTNO: HRD-92-85
BNUMBER: B-248171 DOCUMENT DATE: 04/07/92
DOCUMENT TYPE: Letter Report DOCUMENT CLASS: P,U

GAD DIVISION/OFFICE:
Human Resources Division

SUBJECT TERMS:
Patents, Pharmacological research, Consumer protection, Safety
regulation, Regulatory agencies, Drugs, Data collection operations,
Marketing, Food and drug law

IDENTIFIERS:
Ansaid

ORGANIZATION CONCERNED:
Food and Drug Administration
Upjohn Co.
Boots Co.

CONGRESSIONAL RELEVANCE:
Rep. William J. Hughes
House Committee on the Judiciary: Intellectual Property and Judicial
Administration Subcommittee
Sen. Dennis DeConcini
Senate Committee on the Judiciary: Patents, Trademarks and Copyrights
Subcommittee

LAW AUTHORITY:
Drug Price Competition and Patent Term Restoration Act of 1984

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the Food and Drug Administration's (FDA) process for granting premarket approval for a nonsteroidal, anti-inflammatory drug primarily sold to treat arthritis symptoms, focusing on: (1) whether the manufacturing company delayed preparing and submitting its new drug application; and (2) the company's allegations that the FDA approval process period was excessive.

FINDINGS:

GAO found that the manufacturer requested a 53-month extension of the drug's patent term, based on its allegations that FDA: (1) took 79 months to grant premarket approval, 53 months longer than its average period for similar drugs; (2) needlessly requested different data displays and formats that had no scientific basis; (3) had limited contact with the company for the first 4 years after it submitted the new drug application; (4) lost some of the files regarding the drug; (5) unnecessarily attempted to reconcile its drug with a similar drug; and (6) focused its resources on responding to congressional and public concerns about the safety of similar drugs. GAO also found that: (1) the manufacturer took about 8 years, almost half of the drug's patent term, to prepare and submit its new drug application in March 1982; (2) other companies took about 7 years to submit their applications for similar drugs; (3) FDA characterized the application as problematic, and issued a 13-page deficiency list within 9 months; (4) the manufacturer submitted a revised application in May 1983, although it believed that all the necessary data were in its original application; (5) between May 1983 and May 1984, FDA concentrated on the company's application for an over-the-counter drug, citing its staffing constraints; and (6) due to reports of adverse responses to similar drugs, FDA concentrated on safety issues regarding the anti-inflammatory drug, but there was no evidence that it unnecessarily requested data, improperly delayed the approval process, or inappropriately compared the drug data

MATERIAL ON DRUGS - FY92 TO DATE

with other data before issuing premarket approval in October 1988.

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TITLE: Board and Care Homes: Medication Mishandling Places Elderly at Risk
ACCESSION NUMBER: 146175 RPTNO: T-HRD-92-16
DOCUMENT DATE: 03/13/92 DOCUMENT TYPE: testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
Human Resources Division

SUBJECT TERMS:
Health care services, Elderly persons, Nursing homes, Compliance, Federal/
state relations, Documentation, Medical records, Drugs, Education or
training, State programs

ORGANIZATION CONCERNED:
Department of Health and Human Services

CONGRESSIONAL RELEVANCE:
House Select Committee on Aging: Health and Long-Term Care
Subcommittee

LAW AUTHORITY:
Omnibus Budget Reconciliation Act of 1990

BACKGROUND:

GAO discussed the misuse and mismanagement of residents' medication in board and care homes for the elderly, focusing on whether: (1) board and care staff were knowledgeable about the proper handling of medication; (2) staff followed proper procedures for storing, supervising and assisting residents with taking medications; and (3) residents received appropriate medications. GAO noted that: (1) staff received little medication training, and frequently violated medication handling requirements; (2) state inspection procedures may not identify medication violations; (3) board and care home staff do not always maintain adequate medication records; and (4) in the homes visited, resident records included sufficient medical information to indicate that medications were appropriately prescribed for 20 of the 35 residents in its sample. GAO also noted that: (1) residents in homes that were in states that more strictly regulated board and care facilities were at less risk of medication errors than residents in states with less regulation; and (2) the Department of Health and Human Services should help states address medication handling issues and develop medication training programs.

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TITLE: Cancer Treatment: Efforts to More Fully Utilize the Pacific Yew's Bark
ACCESSION NUMBER: 146070 RPTNO: T-RCED-92-36
DOCUMENT DATE: 03/04/92 DOCUMENT TYPE: testimony
DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:
Resources, Community, and Economic Development Division

SUBJECT TERMS:
Cancer research, Pharmacological research, Drugs, Cooperative agreements,
Public lands, National forests, Pharmaceutical industry, Proposed
legislation, Forest management, Forest products

ORGANIZATION CONCERNED:
National Institutes of Health: National Cancer Institute
Bristol-Myers Squibb, Co.
Hauser Chemical Research, Inc.
Hauser Northwest, Inc.
Bureau of Land Management
Forest Service

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CONGRESSIONAL RELEVANCE:

House Committee on Merchant Marine and Fisheries: Fisheries, Wildlife Conservation and the Environment Subcommittee
House Committee on Interior and Insular Affairs: National Parks and Public Lands Subcommittee
House Committee on Agriculture: Forests, Family Farms and Energy Subcommittee
Congress
House Committee on Agriculture: Forests, Family Farms and Energy Subcommittee
Senate Committee on Agriculture, Nutrition, and Forestry: Conservation and Forestry Subcommittee
House Committee on Appropriations: Interior Subcommittee
Senate Committee on Appropriations: Interior and Related Agencies Subcommittee

LAW AUTHORITY:

H. R. 3836 (102nd Cong.)

BACKGROUND:

GAO discussed whether the Pacific yew's bark is being fully utilized. GAO noted that: (1) the Pacific yew's bark is the only approved source of the anticancer drug taxol; (2) the Forest Service and the Bureau of Land Management (BLM) entered into cooperative agreements with a major pharmaceutical company to provide it with Pacific yew bark; (3) neither cooperative agreement established full utilization as a program goal or requirement; and (4) all of the usable bark which could have been collected on federal lands in 1991 was not collected. GAO also noted that usable yew bark was not collected: (1) prior to sawmill harvesting; (2) from branches and stems with smaller diameters; (3) from trees which were scattered throughout wide geographical areas; or (4) before the taxol content had deteriorated or the bark was burned. GAO also noted that the: (1) Service and BLM are working with the pharmaceutical company to include provisions in their fiscal year 1992 Pacific yew program plans which would require the agencies to assign responsibilities for ensuring increased utilization, establish utilization standards, and monitor compliance with utilization provisions; (2) Service and BLM have established policies to monitor salvage operations to ensure that usable bark buried by logging debris is not overlooked and burned along with other debris; (3) Service has instructed its field personnel to ensure that bark from smaller yew branches and stems is utilized; and (4) pharmaceutical companies' contractor instructed collectors to collect bark from smaller branches.

RECOMMENDATIONS TO CONGRESS

Because existing and future demand clearly exceed the current supply of taxol, Congress should enact the full-utilization provisions of H. R. 3836 to provide both a clear legislative requirement to more fully utilize the tree's bark as well as a statutory basis for promulgating implementing regulations.

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TITLE:	Board and Care Homes: Elderly at Risk From Mishandled Medications
ACCESSION NUMBER:	446111
BNUMBER:	B-246481
DOCUMENT TYPE:	Letter Report
RPTNO:	HRD-92-45
DOCUMENT DATE:	02/07/92
DOCUMENT CLASS:	P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Health care services, Elderly persons, Nursing homes, Compliance, Federal/state relations, Documentation, Medical records, Drugs, Education or

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training, State programs

IDENTIFIERS:

California

Missouri

Washington

ORGANIZATION CONCERNED:

Department of Health and Human Services

CONGRESSIONAL RELEVANCE:

Rep. Edward R. Roybal

House Select Committee on Aging: Health and Long-Term Care
Subcommittee

House Select Committee on Aging: Health and Long-Term Care
Subcommittee

LAW AUTHORITY:

Omnibus Budget Reconciliation Act of 1990

Unemployment Compensation Amendments of 1976

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the misuse and mismanagement of residents' medications in board and care homes for the elderly, focusing on whether: (1) staff who work in licensed board and care homes are knowledgeable about the proper handling of medications; (2) staff follow proper procedures for storing, supervising, and administering medications; and (3) residents receive the appropriate medications.

FINDINGS:

GAO found that: (1) because staff may not be properly trained or do not always follow state regulations, residents in board and care homes are at risk of being harmed by medication errors; (2) over one-third of the homes reviewed employed staff who did not meet state medication training requirements; (3) half of the homes reviewed violated medication-handling regulations for storing medications, supervising and assisting with residents' self-medication, and disposing of medications; and (4) the records for 20 of the 35 residents reviewed had sufficient medical information to indicate that medications were appropriately prescribed.

RECOMMENDATIONS TO AGENCIES

To minimize the risk of improper medication assistance to residents, the Secretary of Health and Human Services should direct the Department of Health and Human Services (HHS) to develop and disseminate to states guidelines for assisting with self-medication, storing and disposing of medications, and recordkeeping.

To minimize the risk of improper medication assistance to residents, the Secretary of Health and Human Services should direct HHS to develop and disseminate to states model classroom training programs for board and care home administrators, operators, staff, and state inspectors on such topics as medication types, proper storage, supervision and assistance, and adverse effects of medications.

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TITLE: VA Health Care: Modernizing VA's Mail-Service Pharmacies Should Save Millions of Dollars

ACCESSION NUMBER: 145672

BNUMBER: B-247064

DOCUMENT TYPE: Letter Report

RPTNO: HRD-92-30

DOCUMENT DATE: 01/22/92

DOCUMENT CLASS: P,U

GAO DIVISION/OFFICE:

Human Resources Division

SUBJECT TERMS:

Pharmaceutical industry, Mail transportation operations, Drugs, Health care cost control, Comparative analysis, Cost effectiveness analysis,

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Health care services, Productivity, Veterans benefits

ORGANIZATION CONCERNED:

Department of Veterans Affairs

Department of Veterans Affairs: Veterans Health Services and Research
Administration: Office of the Chief Medical Director

CONGRESSIONAL RELEVANCE:

Sen. ; Frank H. Murkowski

Senate Committee on Veterans' Affairs

Senate Committee on Appropriations: VA, HUD, and Independent Agencies
Subcommittee

House Committee on Appropriations: VA, HUD, and Independent Agencies
Subcommittee

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the Department of Veterans Affairs' (VA) mail-service pharmacies, focusing on: (1) whether VA pharmacies efficiently and economically fill veterans' prescriptions; and (2) ways that VA could improve its mail pharmaceutical services.

FINDINGS:

GAO found that: (1) although VA mail-service pharmacies are capable of filling prescriptions in 90-day quantities, most routinely dispense drugs in 30-day quantities; (2) dispensing drugs in 30-day quantities causes VA to incur unnecessary mail-handling costs, since mailing drugs generally costs more than the drugs themselves; (3) VA could save as much as \$34 million annually by reducing the number of mail-service pharmacies and modernizing them to increase productivity; (4) in a February 1989 circular, VA informed its pharmacies that they could submit consolidation and automation plans to regional directors, but only a few of the 226 pharmacies developed plans to change their operating practices; and (5) in 1991, VA headquarters pharmacy officials developed a pilot test study to test equipment and assess the operational requirements of consolidated, automated mail service pharmacies.

RECOMMENDATIONS TO AGENCIES

The Secretary of Veterans Affairs should direct the Chief Medical Director to require pharmacies to maximize the use of 90-day supplies when dispensing maintenance drugs, which are prescribed at a stabilized dose.

The Secretary of Veterans Affairs should require the Chief Medical Director to ensure that VA plans for consolidating and automating mail-service pharmacies determine the optimal work load for the pharmacies by using work-load data that assume maximum use of 90-day supplies.

The Secretary of Veterans Affairs should require the Chief Medical Director to ensure that VA plans for consolidating and automating mail-service pharmacies include steps for selecting the most cost-efficient locations for the facilities, considering such factors as available transportation and personnel.

The Secretary of Veterans Affairs should require the Chief Medical Director to ensure that VA plans for consolidating and automating mail-service pharmacies ensure compatibility of prescription handling and automatic data processing equipment throughout VA facilities to maximize efficiency.

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TITLE:	Food Safety and Quality: FDA Needs Stronger Controls Over the Approval Process for New Animal Drugs			
ACCESSION NUMBER:	145807	RPTNO:	RCED-92-63	
BNUMBER:	B-246269	DOCUMENT DATE:	01/17/92	
DOCUMENT TYPE:	Letter Report		DOCUMENT CLASS:	P,U

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GAO DIVISION/OFFICE:

Resources, Community, and Economic Development Division

SUBJECT TERMS:

Human resources training, Animal husbandry, Data collection operations, Management information systems, Internal controls, Inspection, Food and drug law, Pharmaceutical industry, Pharmacological research, Reporting requirements

IDENTIFIERS:

FDA Bioresearch Monitoring Program
FDA Good Laboratory Practice Program
FDA Clinical Investigator Program
FDA Sponsor/Monitor Program

ORGANIZATION CONCERNED:

Food and Drug Administration
Department of Health and Human Services
Food and Drug Administration: Center for Veterinary Medicine
Executive Office of the President

CONGRESSIONAL RELEVANCE:

Rep. ; Ted S. Weiss
House Committee on Government Operations: Human Resources and Intergovernmental Relations Subcommittee
Congress
House Committee on Appropriations: Rural Development, Agriculture, and Related Agencies Subcommittee

LAW AUTHORITY:

Food, Drug and Cosmetic Act
Federal Managers' Financial Integrity Act of 1982

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the Food and Drug Administration's (FDA) efforts to ensure the accuracy and integrity of new animal drug data that animal drug manufacturers provide as part of the approval process for new animal drugs.

FINDINGS:

GAO found that: (1) FDA cannot ensure that animal drug manufacturers provide accurate data, because its data reviewers lack adequate training on the new review process and because its Bioresearch Monitoring Program (BMP), which it uses to detect fraudulent data, lacks adequate regulations, does not provide for timely or sufficient inspections, and has an inadequate management information system; (2) although FDA established BMP to inspect at least one study for each new animal drug approval, between fiscal years 1985 and 1990, FDA did not conduct any inspections to verify the accuracy and integrity of data supporting 54 percent of new approved drugs for food-producing animals; (3) although FDA can improve the BMP program, it may be unable to conduct a sufficient number of inspections due to competing priorities for inspection resources; (4) FDA inability to approve new animal drugs for food-producing animals on the basis of valid, accurate data, as required by the Federal Managers' Financial Integrity Act (FMFIA), constitutes a material internal control weakness and hinders FDA ability to fulfill its mission to protect the health and safety of animals and people; and (5) the Department of Health and Human Services also has not complied with FMFIA because it has not fully assessed FDA internal controls for approving new animal drugs, and, as a result, has failed to identify or report any material weaknesses in this program.

RECOMMENDATIONS TO CONGRESS

Congress should consider the larger policy issue of whether the existing approval process for new animal drugs should be supported by user

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fees, regardless of the need to expand the number of bioresearch monitoring inspections. Furthermore, if Congress authorizes user fees for approving new animal drugs, it should consider earmarking those funds for FDA to conduct this program.

RECOMMENDATIONS TO AGENCIES

- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director of the Center for Veterinary Medicine (CVM) to follow through with CVM plans to provide training and guidance to new data reviewers on the scientific review of new animal drug applications.
- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director, CVM, to propose regulations detailing the responsibilities of sponsor/monitor and clinical investigators.
- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director, CVM, to establish criteria for the number of pivotal studies that should be inspected as part of the new animal drug approval process.
- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director, CVM, to require drug sponsors to provide adequate advance notification before shipping drugs for clinical trials in order to allow FDA to conduct inspections while trials are ongoing.
- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director, CVM, to improve the CVM management information system by developing: (1) a system that can track all inspections and sponsor-submitted studies performed throughout the drug approval process; and (2) system standards, procedures, and documentation, for ensuring uniform, accurate, and complete data in the bioresearch monitoring data base.
- To improve FDA controls over the accuracy and integrity of new animal drug data, the Commissioner, FDA, should direct the Director, CVM, to use the improved CVM management information system to identify critical inspection needs and direct limited inspection resources to those needs.
- If, after taking actions to improve controls over new animal drug data, FDA can document that it needs additional resources to expand its inspection activities for approving new animal drugs, the Secretary of Health and Human Services should consider asking Congress for additional funding or specific authority to charge user fees earmarked to pay for the expenses of approving new animal drugs, including the costs of conducting bioresearch monitoring inspections.
- The Secretary of Health and Human Services should include the FDA lack of sufficient controls to ensure the accuracy and integrity of sponsor-submitted animal drug data as a material weakness in his next internal report to the President, as required by the Federal Managers' Financial Integrity Act.

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TITLE:	Nonprescription Drugs: Over the Counter and Underemphasized		
ACCESSION NUMBER:	145958	RPTNO:	PEMD-92-9
BNUMBER:	B-246187	DOCUMENT DATE:	01/10/92
DOCUMENT TYPE:	Letter Report	DOCUMENT CLASS:	P,U

GAO DIVISION/OFFICE:

Program Evaluation and Methodology Division

SUBJECT TERMS:

Pharmaceutical industry, Drugs, Monitoring, Pharmacological research, Food

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and drug law, Safety regulation, Comparative analysis, Product safety,
Safety standards, Quality assurance

ORGANIZATION CONCERNED:

Food and Drug Administration

CONGRESSIONAL RELEVANCE:

Rep. : Ron Wyden

House Committee on Small Business: Regulation, Business Opportunities
and Energy Subcommittee

LAW AUTHORITY:

Food, Drug and Cosmetic Act
P.L. 87-781

BACKGROUND:

Pursuant to a congressional request, GAO reviewed the Food and Drug Administration's (FDA) procedures for approving and monitoring over-the-counter (OTC) drugs, focusing on: (1) procedural vulnerabilities that could result in the approval and marketing of unsafe and ineffective drugs; and (2) procedures for approving prescription drugs compared to OTC drug procedures.

FINDINGS:

GAO found that: (1) unlike prescription drugs, FDA does not require some OTC drugs to demonstrate their safety and effectiveness; (2) during FDA inspections for compliance with current good manufacturing practices, FDA has statutory authority to inspect prescription drug manufacturers' records and documents, but not OTC drug manufacturers' documents; (3) FDA collects less post-marketing surveillance information and conducts fewer product performance analyses for OTC drugs than for prescription drugs; and (4) post-marketing responses collected for prescription drugs include patterns of usage, the magnitude of any identified problems and the appropriate level of response, and trends in adverse reactions.